UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the quarterly period ended September 30, 2021

or

☐ **TRANSITION REPORTS PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the transition period from to

Commission File Number: 001-35068

ACELRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**41-2193603**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**

25821 Industrial Boulevard, Suite 400
Hayward, CA 94545
(650) 216-3500
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	**Trading symbol(s)**	**Name of Each Exchange on Which registered:**
Common Stock, $0.001 par value	**ACRX**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2) Yes ☐ No ☒

As of November 10, 2021, the number of outstanding shares of the registrant's common stock was 119,318,584.

ACELRX PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED SEPTMEBER 30, 2021

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Unless the context indicates otherwise, the terms "AcelRx," "AcelRx Pharmaceuticals," "we," "us" and "our" refer to AcelRx Pharmaceuticals, Inc., and its consolidated subsidiaries. "DZUVEO" is a trademark, and "ACELRX", "DSUVIA" and "Zalviso" are registered trademarks, all owned by AcelRx Pharmaceuticals, Inc. This report also contains trademarks and trade names that are the property of their respective owners.

Forward-Looking Statements

This Quarterly Report on Form 10-Q, or Form 10-Q, contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by that section. The forward-looking statements in this Form 10-Q are contained principally under "Part I. Financial Information - Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Part II. Other Information - Item 1A. Risk Factors". In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Form 10-Q, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Many important factors affect our ability to achieve our objectives, including:

- the accuracy of our estimates regarding the sufficiency of our cash resources, future revenues, expenses, capital requirements and needs for additional financing, and our ability to obtain additional financing;
- the uncertainties and impact arising from the worldwide COVID-19 pandemic, including restrictions on the ability of our sales force to contact and communicate with target customers and resulting delays and challenges to our commercial sales of DSUVIA® (sufentanil sublingual tablet, 30 mcg);
- our success in commercializing DSUVIA in the United States, including the marketing, sales, and distribution of the product, whether alone or with contract sales organizations and other collaborators;
- our ability to satisfactorily comply with FDA regulations concerning the advertising and promotion of DSUVIA, including receiving a close out letter resolving the concerns raised by FDA in the warning letter delivered to us on February 11, 2021;
- the size and growth potential of the markets for DSUVIA, and, if approved, Zalviso® (sufentanil sublingual tablet system) and our other product candidates in the United States, and our ability to serve those markets;
- our ability to maintain regulatory approval of DSUVIA in the United States, including effective management of and compliance with the DSUVIA Risk Evaluation and Mitigation Strategies, or REMS, program;
- acceptance of DSUVIA by physicians, patients and the healthcare community, including the acceptance of pricing and placement of DSUVIA on payers' formularies;
- our ability to satisfy the required conditions and otherwise complete our planned acquisition of Lowell Therapeutics, Inc., or Lowell, pursuant to the Agreement and Plan of Merger, or Merger Agreement, on a timely basis or at all;
- the expected benefits and potential value created by the proposed Merger Agreement with Lowell for our stockholders;
- potential legal proceedings relating to the proposed acquisition of Lowell and the outcome of any such legal proceedings;
- our ability to achieve all or any of the anticipated benefits of the proposed acquisition of Lowell on a timely basis or at all;
- the integration and performance of any assets or businesses we acquire;
- our ability to develop and commercialize products and product candidates that we in-license;
- our ability to develop sales and marketing capabilities in a timely fashion, whether alone through recruiting qualified employees, by engaging a contract sales organization, or with potential future collaborators;
- successfully establishing and maintaining commercial manufacturing with third parties;
- our ability to manage effectively, and the impact of any costs associated with, potential governmental investigations, inquiries, regulatory actions or lawsuits that may be, or have been, brought against us;
- continued demonstration of an acceptable safety profile of DSUVIA;
- effectively competing with other medications for the treatment of moderate-to-severe acute pain in medically supervised settings, including IV-opioids and any subsequently approved products;
- our ability to manufacture and supply DZUVEO® to Laboratoire Aguettant, or Aguettant, in accordance with their forecasts and the License and Commercialization Agreement, or DZUVEO Agreement, with Aguettant;
- the status of the DZUVEO Agreement or any other future potential collaborations, including potential milestones and revenue share payments under the DZUVEO Agreement;
- our, or Aguettant's, ability to maintain regulatory approval of DZUVEO in the European Union, or EU;
- our ability to timely and efficiently close-out our relationship with Grünenthal GmbH, or Grünenthal, following the termination of our Collaboration and License Agreement and the Manufacture and Supply Agreement;
- our ability to fulfill our obligations under the Purchase and Sale Agreement with SWK Funding, LLC, or SWK, (assignee of PDL BioPharma, Inc., or PDL) including our obligation to use commercially reasonable efforts to negotiate a replacement license agreement for Zalviso with a third party;

- our ability to successfully execute the pathway towards a resubmission of the Zalviso New Drug Application, or NDA, and subsequently obtain and maintain regulatory approval of Zalviso in the United States and comply with any related restrictions, limitations, and/or warnings in the label of Zalviso, if approved;
- the outcome of any potential FDA Advisory Committee meeting held for Zalviso;
- our ability to successfully commercialize Zalviso, if approved in the United States;
- the rate and degree of market acceptance of Zalviso, if approved in the United States;
- our ability to obtain adequate government or third-party payer reimbursement;
- our ability to attract additional collaborators with development, regulatory and commercialization expertise;
- our ability to successfully retain our key commercial, scientific, engineering, medical or management personnel and hire new personnel as needed;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers, including any supply chain impacts or work limitations resulting from shelter-in-place orders related to COVID-19;
- the success of competing therapies that are or become available;
- our liquidity and capital resources; and
- our ability to obtain and maintain intellectual property protection for DSUVIA/DZUVEO and Zalviso.

In addition, you should refer to “Part II. Other Information - Item 1A. Risk Factors” in this Form 10-Q for a discussion of these and other important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Form 10-Q will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Also, forward-looking statements represent our estimates and assumptions only as of the date of this Form 10-Q. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Balance Sheets
(In thousands, except share data)

	September 30, 2021 (unaudited)	December 31, 2020[1]
Assets		
Current Assets:		
Cash and cash equivalents	$ 13,271	$ 27,274
Short-term investments	35,428	15,612
Accounts receivable, net	153	635
Inventories, net	1,556	1,626
Prepaid expenses and other current assets	1,345	1,683
Total current assets	51,753	46,830
Operating lease right-of-use assets	4,454	3,150
Property and equipment, net	15,775	15,659
Other assets	281	656
Total Assets	$ 72,263	$ 66,295
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	$ 2,228	$ 2,737
Accrued and other liabilities	5,333	5,045
Long-term debt, current portion	8,780	8,735
Operating lease liabilities, current portion	729	1,118
Total current liabilities	17,070	17,635
Long-term debt, net of current portion	6,952	13,140
Deferred revenue	1,237	—
Operating lease liabilities, net of current portion	3,935	2,606
Liability related to the sale of future royalties, net of current portion	85,981	88,365
Other long-term liabilities	109	299
Total liabilities	115,284	122,045
Commitments and Contingencies		
Stockholders' Deficit:		
Common stock, $0.001 par value—200,000,000 shares authorized as of September 30, 2021 and December 31, 2020; 119,317,335 and 98,812,008 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	119	98
Additional paid-in capital	422,527	382,637
Accumulated deficit	(465,667)	(438,485)
Total stockholders' deficit	(43,021)	(55,750)
Total Liabilities and Stockholders' Deficit	$ 72,263	$ 66,295

(1) The condensed consolidated balance sheet as of December 31, 2020 has been derived from the audited financial statements as of that date included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Product sales	$ 160	$ 1,287	$ 1,003	$ 1,864
Contract and other collaboration	1,702	81	1,813	2,814
Total revenue	1,862	1,368	2,816	4,678
Operating costs and expenses:				
Cost of goods sold	439	1,851	2,519	4,732
Research and development	1,416	956	3,109	3,181
Selling, general and administrative	8,640	7,598	24,978	28,484
Total operating costs and expenses	10,495	10,405	30,606	36,397
Loss from operations	(8,633)	(9,037)	(27,790)	(31,719)
Other income:				
Interest expense	(538)	(824)	(1,824)	(2,551)
Interest income and other income, net	32	106	92	311
Non-cash interest income on liability related to future sale of royalties	764	825	2,345	2,502
Total other income	258	107	613	262
Net loss before income taxes	(8,375)	(8,930)	(27,177)	(31,457)
Provision for income taxes	—	—	(5)	(4)
Net loss	$ (8,375)	$ (8,930)	$ (27,182)	$ (31,461)
Comprehensive loss	$ (8,375)	$ (8,930)	$ (27,182)	$ (31,461)
Net loss per share of common stock, basic and diluted	$ (0.07)	$ (0.10)	$ (0.23)	$ (0.38)
Shares used in computing net loss per share of common stock, basic and diluted – See Note 11	119,224,484	87,912,505	117,222,219	82,895,664

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Statements of Stockholders' Deficit
(Unaudited)
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance as of December 31, 2020	98,812,008	$ 98	$ 382,637	$ (438,485)	$ (55,750)
Stock-based compensation	—	—	1,089	—	1,089
Restricted stock units vested	404,172	—	—	—	—
Tax payments related to shares withheld for restricted stock units vested	—	—	(249)	—	(249)
Net proceeds from issuance of common stock in connection with equity financings	19,701,562	20	36,340	—	36,360
Issuance of common stock upon ESPP purchase	183,132	—	192	—	192
Issuance of common stock upon exercise of stock options	2,125	—	2	—	2
Net loss	—	—	—	(8,956)	(8,956)
Balance as of March 31, 2021 (unaudited)	119,102,999	118	420,011	(447,441)	(27,312)
Stock-based compensation	—	—	1,172	—	1,172
Restricted stock units vested	74,438	—	—	—	—
Issuance of common stock upon exercise of stock options	2,369	1	1	—	2
Net loss	—	—	—	(9,851)	(9,851)
Balance as of June 30, 2021 (unaudited)	119,179,806	119	421,184	(457,292)	(35,989)
Stock-based compensation	—	—	1,221	—	1,221
Restricted stock units vested	7,793	—	—	—	—
Issuance of common stock upon exercise of stock options	14,909	—	13	—	13
Issuance of common stock upon ESPP purchase	114,827	—	109	—	109
Net loss	—	—	—	(8,375)	(8,375)
Balance as of September 30, 2021 (unaudited)	119,317,335	$ 119	$ 422,527	$ (465,667)	$ (43,021)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance as of December 31, 2019	79,573,101	$ 79	$ 356,609	$ (398,106)	$ (41,418)
Stock-based compensation	—	—	1,146	—	1,146
Restricted stock units vested	216,399	—	—	—	—
Tax payments related to shares withheld for restricted stock units vested	—	—	(86)	—	(86)
Net proceeds from issuance of common stock in connection with equity financings	431,800	1	783	—	784
Issuance of common stock upon ESPP purchase	194,451	—	218	—	218
Net loss	—	—	—	(15,925)	(15,925)
Balance as of March 31, 2020 (unaudited)	80,415,751	80	358,670	(414,031)	(55,281)
Stock-based compensation	—	—	1,090	—	1,090
Restricted stock units vested	29,434	—	—	—	—
Net proceeds from issuance of common stock in connection with equity financings	445,000	—	665	—	665
Net loss	—	—	—	(6,606)	(6,606)
Balance as of June 30, 2020 (unaudited)	80,890,185	80	360,425	(420,637)	(60,132)
Stock-based compensation	—	—	1,104	—	1,104
Restricted stock units vested	7,789	—	—	—	—
Net proceeds from issuance of common stock in connection with equity financings	9,433,962	10	9,941	—	9,951
Issuance of common stock upon ESPP purchase	145,677	—	154	—	154
Net loss	—	—	—	(8,930)	(8,930)
Balance as of September 30, 2020 (unaudited)	90,477,613	$ 90	$ 371,624	$ (429,567)	$ (57,853)

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (27,182)	$ (31,461)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash royalty revenue related to royalty monetization	(83)	(181)
Non-cash interest income on liability related to future sale of royalties	(2,345)	(2,502)
Depreciation and amortization	1,512	1,471
Non-cash interest expense related to debt financing	607	823
Stock-based compensation	3,482	3,340
Other	89	463
Changes in operating assets and liabilities:		
Accounts receivable	482	(696)
Inventories	(180)	734
Prepaid expenses and other assets	320	616
Accounts payable	281	174
Accrued liabilities	390	(1,238)
Operating lease liabilities	(559)	(673)
Deferred revenue	1,188	(3,048)
Net cash used in operating activities	(21,998)	(32,178)
Cash flows from investing activities:		
Purchase of property and equipment	(1,799)	(224)
Purchase of investments	(53,869)	(38,817)
Proceeds from sales and maturities of investments	33,984	67,405
Net cash (used in) provided by investing activities	(21,684)	28,364
Cash flows from financing activities:		
Payment of long-term debt	(6,750)	(2,583)
Net proceeds from issuance of common stock in connection with equity financings	36,360	11,400
Net proceeds from issuance of common stock through equity plans	318	372
Payment of employee tax obligations related to vesting of restricted stock units	(249)	(86)
Net cash provided by financing activities	29,679	9,103
Net (decrease) increase in cash and cash equivalents	(14,003)	5,289
Cash and cash equivalents—Beginning of period	27,274	14,684
Cash and cash equivalents—End of period	$ 13,271	$ 19,973

See notes to condensed consolidated financial statements.

1. Organization and Summary of Significant Accounting Policies

The Company

AcelRx Pharmaceuticals, Inc., or the Company or AcelRx, was incorporated in Delaware on July 13, 2005 as SuRx, Inc., and in January 2006, the Company changed its name to AcelRx Pharmaceuticals, Inc. The Company's operations are based in Hayward, California.

AcelRx is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings. DSUVIA® (known as DZUVEO® in Europe) and Zalviso® are both focused on the treatment of acute pain, and each utilize sufentanil, delivered via a non-invasive route of sublingual administration, exclusively for use in medically supervised settings. On November 2, 2018, the U.S. Food and Drug Administration, or FDA, approved DSUVIA for use in adults in a certified medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. The commercial launch of DSUVIA in the United States occurred in the first quarter of 2019. In June 2018, the European Commission, or EC, granted marketing approval of DZUVEO for the management of acute moderate to severe pain in adults in medically monitored settings. AcelRx is further developing a distribution capability and commercial organization to continue to market and sell DSUVIA in the United States. In geographies where AcelRx decides not to commercialize products by itself, the Company may seek to out-license commercialization rights. The Company currently intends to commercialize and promote DSUVIA/DZUVEO outside the United States with one or more strategic partners, and, in July 2021, entered into a License and Commercialization Agreement with Laboratoire Aguettant, or Aguettant, for Aguettant to commercialize DZUVEO in the European Union, Norway, Iceland, Liechtenstein, Andorra, Vatican City, Monaco, Switzerland and the United Kingdom (see *Out-License Agreement (DZUVEO)* below). The timing of the resubmission of the Zalviso new drug application, or NDA, is in part dependent upon the finalization of the FDA's new opioid approval guidelines and process. AcelRx intends to seek regulatory approval for Zalviso in the United States and, if successful, potentially promote Zalviso either by itself or with strategic partners. Zalviso is approved in Europe and was commercialized by Grünenthal GmbH, or Grünenthal, through May 12, 2021 (see *Termination of Grünenthal Agreements* below). In July 2021, the Company also entered into a separate License and Commercialization Agreement with Aguettant pursuant to which the Company obtained the exclusive right to develop and, subject to FDA approval, commercialize in the United States (i) an ephedrine pre-filled syringe containing 10 ml of a solution of 3 mg/ml ephedrine hydrochloride for injection, and (ii) a phenylephrine pre-filled syringe containing 10 ml of a solution of 50 mcg/ml phenylephrine hydrochloride for injection (see *In-License Agreement* below). On November 14, 2021, the Company executed a definitive merger agreement, or the Merger Agreement, to acquire Lowell Therapeutics, Inc., or Lowell, a privately held company (see *Acquisition* below).

The Company has incurred recurring operating losses and negative cash flows from operating activities since inception. As of September 30, 2021 and December 31, 2020, the Company had cash, cash equivalents and short-term investments of $48.7 million and $42.9 million, respectively. Based on the Company's current operating plans and projections, the Company expects that its existing cash, cash equivalents and short-term investments will be sufficient to fund operations for at least one year from the date this Quarterly Report on Form 10-Q is filed with the United States Securities and Exchange Commission, or SEC. Although Zalviso was approved for sale in Europe on September 18, 2015, the Company sold the majority of the royalty rights and certain commercial sales milestones it was entitled to receive under the Amended License Agreement (defined below) with Grünenthal to PDL BioPharma, Inc., or PDL, in a transaction referred to as the Royalty Monetization. On August 31, 2020, PDL announced it sold its royalty interest for Zalviso to SWK Funding, LLC, or SWK. In consideration of the termination of the Amended License Agreement, under the Royalty Monetization, the Company must use commercially reasonable efforts to negotiate a replacement license agreement, or New Arrangement, with a third party. The Company expects to continue to incur operating losses and negative cash flows until such time as DSUVIA has gained market acceptance and generated significant revenues.

DSUVIA/DZUVEO

DSUVIA, known as DZUVEO in Europe, approved by the FDA in November 2018 and granted marketing approval by the EC in June 2018, is indicated for use in adults in a certified medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. DSUVIA was designed to provide rapid analgesia via a non-invasive route and to eliminate dosing errors associated with IV administration. DSUVIA is a single-strength solid dosage form administered sublingually via a single-dose applicator, or SDA, by healthcare professionals. Sufentanil is an opioid analgesic currently marketed for intravenous, or IV, and epidural anesthesia and analgesia. The sufentanil pharmacokinetic profile when delivered sublingually avoids the high peak plasma levels and short duration of action observed with IV administration.

DSUVIA was approved with a Risk Evaluation and Mitigation Strategy, or REMS, program which restricts distribution to certified medically supervised healthcare settings in order to prevent respiratory depression resulting from accidental exposure. DSUVIA is only distributed to facilities certified under the DSUVIA REMS program following attestation by an authorized representative to comply with appropriate dispensing and use restrictions of DSUVIA. To become certified, a healthcare setting is required to train their healthcare professionals on the proper use of DSUVIA and have the ability to manage respiratory depression. DSUVIA is not available in retail pharmacies or for outpatient use. As part of the REMS program, the Company monitors distribution and audits wholesalers' data, evaluates proper usage within the healthcare settings and monitors for any diversion and abuse. AcelRx will de-certify healthcare settings that are non-compliant with the REMS program.

Zalviso

Zalviso delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia, or PCA, system. Zalviso is approved in Europe and is in late-stage development in the United States. The Company had initially submitted to the FDA an NDA seeking approval for Zalviso in September 2013 but received a complete response letter, or CRL, on July 25, 2014. Subsequently, the FDA requested an additional clinical study, IAP312, designed to evaluate the effectiveness of changes made to the functionality and usability of the Zalviso device and to take into account comments from the FDA on the study protocol. In the IAP312 study, for which top-line results were announced in August 2017, Zalviso met safety, satisfaction and device usability expectations. These results will supplement the three Phase 3 trials already completed in the Zalviso NDA resubmission.

Termination of Grünenthal Agreements

On December 16, 2013, AcelRx and Grünenthal entered into a Collaboration and License Agreement, or the License Agreement, which was amended effective July 17, 2015 and September 20, 2016, or the Amended License Agreement, which granted Grünenthal rights to commercialize the Zalviso PCA system, or the Product, in the 28 European Union, or EU, member states, at the time of the agreement, plus Switzerland, Liechtenstein, Iceland, Norway and Australia (collectively, the Zalviso Territory) for human use in pain treatment within, or dispensed by, hospitals, hospices, nursing homes and other medically supervised settings, (collectively, the Field). In September 2015, the EC granted marketing approval for the marketing authorization application, or MAA, previously submitted to the EMA, for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients. On December 16, 2013, AcelRx and Grünenthal entered into a Manufacture and Supply Agreement, or the MSA, and together with the License Agreement, the Agreements. Under the MSA, the Company exclusively manufactured and supplied the Product to Grünenthal for the Field in the Zalviso Territory. On July 22, 2015, the Company and Grünenthal amended the MSA, or the Amended MSA, effective as of July 17, 2015. The Amended MSA and the Amended License Agreement are referred to as the Grünenthal Agreements.

On May 18, 2020, the Company received a notice from Grünenthal that it had exercised its right to terminate the Grünenthal Agreements, effective November 13, 2020. The terms of the Grünenthal Agreements were extended to May 12, 2021 to enable Grünenthal to sell down its Zalviso inventory, a right it had under the Grünenthal Agreements. The rights to market and sell Zalviso in the Zalviso Territory reverted back to the Company on May 12, 2021.

Out-License Agreement (DZUVEO)

On July 14, 2021, the Company entered into a License and Commercialization Agreement, or the DZUVEO Agreement, with Aguettant, pursuant to which Aguettant obtained the exclusive right to develop and commercialize DZUVEO in the European Union, Norway, Iceland, Liechtenstein, Andorra, Vatican City, Monaco, Switzerland and the United Kingdom, or the DZUVEO Territory, for the management of acute moderate to severe pain in adults in medically monitored settings. The Company will supply Aguettant with product.

The DZUVEO Agreement has an initial term of ten (10) marketing years, with the first marketing year ending on December 31 of the calendar year after the launch of DZUVEO (or December 31, 2022, if the launch occurs between January 1, 2022 and April 30, 2022). The term will automatically renew for successive five marketing year periods unless a party notifies the other party of its intention not to renew at least six (6) months prior to the expiration of the then-current term. The DZUVEO Agreement may be terminated for cause by either party based on uncured material breach by the other party, insolvency of the other party, or force majeure event. Upon early termination, all ongoing activities under the agreement and all rights and commercialization licenses and sublicenses with respect to DZUVEO will terminate. Additionally, if terminated early by either party, any accrued liability at the time of such termination will not be released.

The Company is entitled to receive up to €47.0 million in a combination of up-front and sales-based milestone payments, of which the Company received €2.5 million, or approximately $2.9 million, in the third quarter of 2021, for which it recognized revenue of $1.7 million in the third quarter of 2021. Aguettant will purchase product from the Company at an agreed price, or the DZUVEO Purchase Price, subject to adjustment. Aguettant will also make revenue share payments that, combined with the DZUVEO Purchase Price, range from 35% to 45% of net sales in the DZUVEO Territory.

Beginning in the third marketing year, the parties will establish binding annual minimums for purchase orders to be submitted by Aguettant. Aguettant has the right to grant sublicenses to its affiliates or, with the prior approval of the Company, third parties, subject to certain limitations.

The DZUVEO Agreement also provides Aguettant with a right of first negotiation for eighteen (18) months before the Company can enter into a collaboration regarding Zalviso in Europe.

In-License Agreement

On July 14, 2021, the Company entered into a License and Commercialization Agreement, or the PFS Agreement, with Aguettant pursuant to which the Company obtained the exclusive right to develop and, subject to FDA approval, commercialize in the United States (i) an ephedrine pre-filled syringe containing 10 ml of a solution of 3 mg/ml ephedrine hydrochloride for injection, and (ii) a phenylephrine pre-filled syringe containing 10 ml of a solution of 50 mcg/ml phenylephrine hydrochloride for injection. Aguettant will supply the Company with the products for use in commercialization, if they are approved in the U.S.

The PFS Agreement has an initial term of ten (10) marketing years, with the first marketing year ending on December 31 of the calendar year after the first launch of a product (or December 31 of the same calendar year if the first launch of a product occurs between January 1 and April 30 of a calendar year). The term will automatically renew for successive five marketing year periods unless a party notifies the other party of its intention not to renew at least six (6) months prior to the expiration of the then-current term.

Aguettant is entitled to receive up to $24.0 million in sales-based milestone payments. The Company will purchase each product from Aguettant at an agreed price, or the PFS Purchase Price, subject to adjustment. The Company will also make revenue share payments that, combined with the PFS Purchase Price, will range from 40% to 45% of net sales in the United States.

The Company and Aguettant will agree on minimum sales obligations twelve (12) months prior to the launch of each product. The Company has the right to grant sublicenses to its affiliates or, with the prior approval of Aguettant, third parties, subject to certain limitations.

As of September 30, 2021, there have been no payments by the Company to Aguettant under the PFS Agreement.

Acquisition

On November 14, 2021, the Company and two of its direct wholly owned subsidiaries, Lowell Therapeutics, Inc., or Lowell, and the stockholder representative, entered into the Agreement and Plan of Merger, or the Merger Agreement, pursuant to which the Company will acquire Lowell in a transaction valued at approximately $32.5 million plus net cash acquired, and subject to certain other adjustments, which is expected in the fourth quarter of 2021 subject to certain closing conditions. For additional information regarding the Merger Agreement, see Note 12 “Subsequent Events” and “Part II. Other Information - Item 5. Other Information” in this Form 10-Q.

Principles of Consolidation

The Condensed Consolidated Financial Statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. Refer to Note 7 “Liability Related to Sale of Future Royalties” for additional information.

Reclassifications

Certain prior period amounts in the Condensed Consolidated Financial Statements have been reclassified to conform to the current period's presentation.

Basis of Presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP, for interim financial information and the rules and regulations of the SEC. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included.

Operating results for the three and nine months ended September 30, 2021, are not necessarily indicative of the results that may be expected for the year ending December 31, 2021 or any future period. The Condensed Consolidated Balance Sheet as of December 31, 2020, was derived from the Company’s audited financial statements as of December 31, 2020, included in the Company’s Annual Report on Form 10-K filed with the SEC. These Condensed Consolidated Financial Statements should be read in conjunction with the Company’s Annual Report on Form 10-K for the year ended December 31, 2020, which includes a broader discussion of the Company’s business and the risks inherent therein.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the Condensed Consolidated Financial Statements and accompanying notes. Management evaluates its estimates on an ongoing basis including critical accounting policies. Estimates are based on historical experience and on various other market-specific and other relevant assumptions that the Company believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Significant Accounting Policies

The Company's significant accounting policies are detailed in its Annual Report on Form 10-K for the year ended December 31, 2020. There have been no significant changes to the Company's significant accounting policies during the three and nine months ended September 30, 2021, from those previously disclosed in its 2020 Annual Report on Form 10-K, except to reflect that the Company applies the graded-vesting attribution method to awards with market conditions that include graded-vesting features. Additionally, the Company uses the Monte Carlo Simulation model to evaluate the derived service period and fair value of awards with market conditions, including assumptions of historical volatility and risk-free interest rate commensurate with the vesting term.

Recently Issued Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2016-13, "*Financial Instruments – Credit Losses: Measurement of Credit Losses on Financial Instruments*," or ASU 2016-13. ASU 2016-13 replaces the incurred loss impairment model in current GAAP with a model that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to determine credit loss estimates. ASU 2016-13 is effective for the Company beginning January 1, 2023, with early adoption allowed beginning January 1, 2020. In May 2019, the FASB issued ASU 2019-05, "*Financial Instruments – Credit Losses*," or ASU 2019-05, to allow entities to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost upon adoption of the new credit losses standard. The new effective dates and transition align with those of ASU 2016-13. Management is currently assessing the date of adoption and the impact ASU 2016-13 and ASU 2019-05 will have on the Company, but it does not anticipate adoption of these new standards to have a material impact on the Company's financial position, results of operations or cash flows.

In March 2020, the FASB issued ASU 2020-04, "*Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*." The amendments provide optional guidance for a limited time to ease the potential burden in accounting for reference rate reform. The new guidance provides optional expedients and exceptions for applying U.S. GAAP to contracts, hedging relationships and other transactions affected by reference rate reform if certain criteria are met. The amendments apply only to contracts and hedging relationships that reference LIBOR or another reference rate expected to be discontinued due to reference rate reform. These amendments are effective immediately and may be applied prospectively to contract modifications made and hedging relationships entered into or evaluated on or before December 31, 2022. The Company is currently evaluating its contracts and the optional expedients provided by the new standard, but it does not anticipate its adoption to have a material impact on the Company's financial position, results of operations or cash flows.

2. Investments and Fair Value Measurement

Investments

The Company classifies its marketable securities as available-for-sale and records its investments at fair value. Available-for-sale securities are carried at estimated fair value based on quoted market prices or observable market inputs of almost identical assets, with the unrealized holding gains and losses included in accumulated other comprehensive income (loss). Marketable securities which have maturities beyond one year as of the end of the reporting period are classified as non-current.

The table below summarizes the Company's cash, cash equivalents and short-term investments (in thousands):

	As of September 30, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 2,984	$ —	$ —	$ 2,984
Money market funds	10,287	—	—	10,287
Total cash and cash equivalents	13,271	—	—	13,271
Short-term investments:				
Commercial paper	25,913	—	—	25,913
Corporate debt securities	9,515	—	—	9,515
Total short-term investments	35,428	—	—	35,428
Total cash, cash equivalents and short-term investments	$ 48,699	$ —	$ —	$ 48,699

	As of December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 5,181	$ —	$ —	$ 5,181
Money market funds	3,996	—	—	3,996
Commercial paper	18,097	—	—	18,097
Total cash and cash equivalents	27,274	—	—	27,274
Short-term investments:				
U.S. government agency securities	5,818	—	—	5,818
Commercial paper	9,794	—	—	9,794
Total short-term investments	15,612	—	—	15,612
Total cash, cash equivalents and short-term investments	$ 42,886	$ —	$ —	$ 42,886

There were no other-than-temporary impairments for these securities at September 30, 2021 or December 31, 2020. No gross realized gains or losses were recognized on the available-for-sale securities and, accordingly, there were no amounts reclassified out of accumulated other comprehensive income (loss) to earnings during the three and nine months ended September 30, 2021 and 2020.

As of September 30, 2021, and December 31, 2020, the contractual maturity of all investments held was less than one year.

Fair Value Measurement

The Company's financial instruments consist of Level I and II assets and Level III liabilities. Money market funds and U.S. treasury securities are highly liquid investments and are actively traded. The pricing information on these investment instruments are readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy. For Level II instruments, the Company estimates fair value by utilizing third party pricing services in developing fair value measurements where fair value is based on valuation methodologies such as models using observable market inputs, including benchmark yields, reported trades, broker/dealer quotes, bids, offers and other reference data. Such Level II instruments typically include U.S. government agency securities, corporate debt securities and commercial paper. As of September 30, 2021, and December 31, 2020, the Company held, in addition to Level II assets, a contingent put option associated with the Loan Agreement with Oxford. See Note 5 "Long-Term Debt" for further description. The Company's estimate of fair value of the contingent put option liability was determined using a risk-neutral valuation model, wherein the fair value of the underlying debt facility is estimated both with and without the presence of the default provisions, holding all other assumptions constant. The resulting difference between the two estimated fair values is the estimated fair value of the default provisions, or the contingent put option, which is included under other long-term liabilities on the Condensed Consolidated Balance Sheets. Changes to the estimated fair value of this liability is recorded in interest income and other income (expense), net in the Condensed Consolidated Statements of Comprehensive Loss. The fair value of the underlying debt facility is estimated by calculating the expected cash flows in consideration of an estimated probability of default and expected recovery rate in default and discounting such cash flows back to the reporting date using a risk-free rate.

The following table sets forth the fair value of the Company's financial assets and liabilities by level within the fair value hierarchy (in thousands):

	As of September 30, 2021			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 10,287	$ 10,287	$ —	$ —
Commercial paper	25,913	—	25,913	—
Corporate debt securities	9,515	—	9,515	—
Total assets measured at fair value	$ 45,715	$ 10,287	$ 35,428	$ —
Liabilities				
Contingent put option liability	$ 109	$ —	$ —	$ 109
Total liabilities measured at fair value	$ 109	$ —	$ —	$ 109

	As of December 31, 2020			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 3,996	$ 3,996	$ —	$ —
U.S. government agency securities	5,818	—	5,818	—
Commercial paper	27,891	—	27,891	—
Total assets measured at fair value	$ 37,705	$ 3,996	$ 33,709	$ —
Liabilities				
Contingent put option liability	$ 246	$ —	$ —	$ 246
Total liabilities measured at fair value	$ 246	$ —	$ —	$ 246

The following tables set forth a summary of the changes in the fair value of the Company's Level III financial liabilities for the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2021
Fair value—beginning of period	$ 128	$ 246
Change in fair value of contingent put option associated with the Loan Agreement	(19)	(137)
Fair value—end of period	$ 109	$ 109

	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2020
Fair value—beginning of period	$ 591	$ 437
Change in fair value of contingent put option associated with the Loan Agreement	(85)	69
Fair value—end of period	$ 506	$ 506

3. Inventories, net

Inventories consist of raw materials, work in process and finished goods and are stated at the lower of cost or net realizable value and consist of the following (in thousands):

	Balance as of	
	September 30, 2021	December 31, 2020
Raw materials	$ 579	$ 257
Work-in-process	68	30
Finished goods	909	1,339
Total	$ 1,556	$ 1,626

The Company recorded inventory impairment charges of $0.1 and $0.2 million for the three and nine months ended September 30, 2021, respectively, primarily related to DSUVIA and Zalviso component parts inventory. For the three and nine months ended September 30, 2020, the Company recorded inventory impairment charges of $0.2 million and $0.6 million, respectively. In the nine months ended September 30, 2020, $0.3 million of these charges related to the termination of the Grünenthal Agreements, while $0.3 million related to DSUVIA inventory, primarily inventory that may expire before being sold.

4. Revenue from Contracts with Customers

The following table summarizes revenue from contracts with customers for the three and nine months ended September 30, 2021 and 2020 into categories that depict how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors (in thousands):

	Three months ended September 30, 2021	Nine months ended September 30, 2021
Product sales:		
DSUVIA	$ 160	$ 733
Zalviso	—	270
Total product sales	160	1,003
Contract and collaboration revenue:		
License revenue	1,696	1,696
Non-cash royalty revenue related to Royalty Monetization (Note 7)	—	83
Royalty revenue	—	28
Other revenue	6	6
Total revenues from contract and other collaboration	1,702	1,813
Total revenue	$ 1,862	$ 2,816

	Three months ended September 30, 2020	Nine months ended September 30, 2020
Product sales:		
DSUVIA	$ 935	$ 1,092
Zalviso	352	772
Total product sales	1,287	1,864
Contract and collaboration revenue:		
Non-cash royalty revenue related to Royalty Monetization (Note 7)	60	181
Royalty revenue	21	61
Other revenue	—	2,572
Total revenues from contract and other collaboration	81	2,814
Total revenue	$ 1,368	$ 4,678

For additional details on the Company's accounting policy regarding revenue recognition, refer to Note 1 "Organization and Summary of Significant Accounting Policies - Revenue from Contracts with Customers" in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

Product Sales

The Company's commercial launch of DSUVIA in the United States occurred in the first quarter of 2019. Zalviso was sold in Europe by the Company's collaboration partner, Grünenthal, through May 12, 2021. DZUVEO sales in Europe by the Company's new partner, Aguettant, have not commenced as of September 30, 2021.

Contract and Other Collaboration

Contract and other collaboration revenue includes revenue under the Grünenthal Agreements related to research and development services, non-cash royalty revenue related to the Royalty Monetization and royalty revenue for sales of Zalviso in Europe.

The Company concluded that Aguettant is a customer and therefore revenue recognition for the DZUVEO Agreement in Europe should be accounted for in accordance with FASB Accounting Standards Codification, or ASC, Topic 606, "*Revenue from Contracts with Customers*", because the Company granted to Aguettant licenses and will provide the supply of product, as defined below, all of which are outputs of the Company's ongoing activities, in exchange for consideration.

The Company identified the following promises under the DZUVEO Agreement at inception, namely: (a) granting of the licenses, (b) manufacturing services inclusive of quality control testing and stability testing which are options in the initial arrangement, and (c) a material right associated with the discounted price for future optional orders of DZUVEO commercial product supply.

The licenses are considered to be functional intellectual property. The Company determined that the licenses are capable of being distinct because Aguettant can benefit from the license on its own by commercializing the underlying product using its own resources. The Company manufacturing services are not highly specialized in nature and can be performed by third party contract manufacturing organizations. There are no binding commitments for manufacturing purchase orders at inception of the arrangement. Therefore, the manufacturing services are considered to be an option and not a performance obligation in the initial arrangement. However, the Company has determined that the discounted price per unit on future optional product orders constitutes a material right and is a performance obligation. The right to purchase at a discount is capable of being used by the customer on a standalone basis, because this relates to future product purchases and occur after the licenses' performance obligations are transferred.

The Company evaluated if there is an interdependence between the performance obligations and determined that the licenses are a combined solution and the predominant performance obligation. The material right is separately identifiable in the context of the contract and is not modified by, and does not modify, the license performance obligation and is not highly interdependent or interrelated with the material right performance obligations in the contract.

The transaction price at the inception of the DZUVEO Agreement consisted of the upfront fee of €2.5 million, or approximately $2.9 million. The variable consideration related to product supply and reimbursables has been constrained as of September 30, 2021 as there has been no forecast provided by Aguettant. The Company will re-evaluate the transaction price each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The Company determined that the $52.2 million sales-based milestone payments and revenue share payments were probable of significant revenue reversal, as their achievement was highly dependent on factors outside the Company's control. As a result, these payments were fully constrained and were not included in the transaction price. Any variable consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur, as they were determined to relate predominantly to the licenses granted to Aguettant and the optional manufacturing services provided by the Company.

The transaction price is allocated to the performance obligations based on relative standalone selling price which were determined for the licenses using the adjusted market approach, and for the manufacturing services and the material right associated with discounted DZUVEO product supply using the cost-plus reasonable margin approach. Variable consideration is allocated to the specific performance obligations to which it relates.

For revenue recognition purposes, the Company determined that the duration of the contract began on the effective date in July 2021 and ends after an initial term of 10 marketing years, unless it automatically renews for a successive five marketing years. The Company also analyzed the impact if Aguettant terminated the agreement prior to the end of the term and determined, considering both quantitative and qualitative factors, that there were substantive non-monetary penalties to Aguettant for doing so.

Revenue for the granting of the licenses was recognized on the effective date of the DZUVEO Agreement at the point in time that the licenses are effective. The manufacturing services inclusive of quality control testing and stability testing will be recognized at a point in time when, or as, the Company transfers the associated promised goods and services to Aguettant. The material right for the discounted price per unit on future optional orders will be recognized over time with the measure of progress being straight-line over the period in which the Company stands ready to provide the discounted price per unit on the manufacturing services.

For the three months ended September 30, 2021, the Company recorded $1.7 million in Contract and other collaboration revenue as a result of satisfying its licenses performance obligation by transferring the license rights to Aguettant. A contract liability of $1.2 million was recorded on the Condensed Consolidated Balance Sheets as deferred revenue as of September 30, 2021, for the portion of the upfront fee received under the DZUVEO Agreement allocated to the material right for discounted price on future optional product supply which has not yet been satisfied. The material right contract liability will be recognized over the period the discount on future product supply is made available. There was no contract asset as of September 30, 2021 associated with the DZUVEO Agreement.

As of September 30, 2021, deferred contract acquisition costs were negligible and deferred contract acquisition costs amortized during the three and nine months ended September 30, 2021 were $0.3 million.

Contract Liabilities

The following table presents changes in the Company's contract liabilities for the nine months ended September 30, 2021 (in thousands):

	Balance at Beginning of the Period	Additions	Deductions	Balance at the end of the Period
Contract liabilities:				
Deferred revenue – DZUVEO Agreement	$ —	$ 1,237	$ —	$ 1,237
Deferred revenue – Grünenthal Agreements	49	—	(49)	—
Deferred revenue	$ 49	$ 1,237	$ (49)	$ 1,237

For the three and nine months ended September 30, 2021 and 2020, the Company recognized the following revenue from performance obligations satisfied or eliminated related to its contract liabilities (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Amounts included in contract liabilities at the beginning of the period:				
Performance obligations satisfied	$ —	$ 147	$ 49	$ 380
Performance obligations eliminated upon termination	—	—	—	2,572
New activities in the period from performance obligations satisfied:				
Performance obligations satisfied at a point in time	1,696	205	1,917	392
Total revenue from performance obligations satisfied or eliminated	$ 1,696	$ 352	$ 1,966	$ 3,344

5. Long-Term Debt

Loan Agreement with Oxford

On May 30, 2019, the Company entered into the Loan Agreement with Oxford Finance LLC, or Oxford, as the Lender. Under the Loan Agreement, the Lender made a term loan to the Company in an aggregate principal amount of $25.0 million, or the Loan, which was funded on May 30, 2019.

In connection with the Loan Agreement, on May 30, 2019, the Company issued warrants to the Lender and its affiliates, or the Warrants, which are exercisable for an aggregate of 176,679 shares of the Company's common stock with a per share exercise price of $2.83. The Warrants have been classified within stockholders' deficit and accounted for as a discount to the loan by allocating the gross proceeds on a relative fair value basis.

As of September 30, 2021 and December 31, 2020, the accrued balance due under the Loan Agreement with Oxford was $15.3 million and $21.0 million, respectively. Interest expense related to the Loan Agreement was $0.5 million, $0.1 million of which represented amortization of the debt discount, and $1.7 million, $0.5 million of which represented amortization of the debt discount for the three and nine months ended September 30, 2021, respectively, and was $0.7 million, $0.2 million of which represented amortization of the debt discount, and $2.4 million, $0.7 million of which represented amortization of the debt discount, for the three and nine months ended September 30, 2020, respectively.

Non-Interest Bearing Payments for the Construction of Leasehold Improvements

In August 2019, the Company entered into a Site Readiness Agreement, or SRA, with Catalent Pharma Solutions, LLC, or Catalent, in contemplation of entering into a commercial supply agreement for its product DSUVIA at a future date. Under the SRA, the Company is building out a suite within Catalent's production facility in Kansas City. If additional equipment and facility modifications are required to meet the Company's product needs, the Company may be required to contribute to the cost of such additional equipment and facility modifications. The Company has determined that it is the owner of the leasehold improvements related to the build-out which will be paid for in four installments of $0.5 million through July 2022. As of September 30, 2021 and December 31, 2020, the accrued balance under the SRA was $0.4 million and $0.8 million, respectively, and $1.7 million of these leasehold improvements had been capitalized. The effective interest rate at September 30, 2021 and December 31, 2020 was 14.35%. The leasehold improvements are recorded as property and equipment, net, in the Condensed Consolidated Balance Sheets.

6. Leases

Office Leases

The Company leased office and laboratory space for its former corporate headquarters, located at 301 – 351 Galveston Drive, Redwood City, California, and entered into an agreement to sublease approximately 12,106 square feet of this office and laboratory space.

On March 26, 2021, the Company entered into a Lease Termination Agreement with its landlord and a Sublease Termination Agreement with its sublessee, to terminate the lease and sublease agreements at its former corporate headquarters. The termination of both the lease and sublease was effective on April 30, 2021. As of the date of the Lease Termination Agreement, the Company remeasured its lease liability and recorded a gain of $0.5 million upon derecognition of the lease liability and right of use asset for the master lease, which was included in operating expenses for the nine months ended September 30, 2021. In connection with the Sublease Termination, the remaining deferred costs of $0.3 million were fully amortized through April 30, 2021, the effective date of the Sublease Termination, and included in operating expenses for the nine months ended September 30, 2021.

On March 26, 2021, the Company entered into a Sublease Agreement to sublet space for its new corporate headquarters, located at 25821 Industrial Boulevard, Hayward, California. The Sublease Agreement commencement date was April 1, 2021. The Sublease Agreement is for a period of two years and three months with monthly rental payments of $17,000, including one month of abated rent. On the lease commencement date, the Company recognized an operating lease right-of-use asset in the amount of $0.4 million.

Contract Manufacturing Leases

On April 21, 2021, the Company entered into a Commercial Supply Agreement, or the CSA, with Catalent Pharma Solutions, LLC, or Catalent, effective March 31, 2021, under which Catalent provides certain services to the Company in connection with the processing and packaging of a packaged single dose applicator containing the sublingual tablet 30 mcg sufentanil dosage form contained in the pharmaceutical product, DSUVIA (sufentanil), intended for commercialization.

The term of the CSA is for a period of five years from the first date upon which the FDA approves Catalent as a manufacturer of DSUVIA in the United States, or the Commencement Date. The term shall automatically be extended for successive two-year periods, unless and until one party gives the other party at least 24 months' prior written notice of its desire to terminate as of the end of the then-current term.

The Company will pay Catalent an annual fee of $1.0 million beginning January 1, 2022. Pursuant to the CSA, the Company will purchase each 10-pack carton of DSUVIA from Catalent at an agreed price through December 31, 2022, and pay other fees set forth in the CSA. All pricing and fees, with the exception of raw materials, may be adjusted on an annual basis, effective on January 1 of each calendar year, beginning with January 1, 2023, subject to certain limitations. Price increases for raw materials will be passed through to the Company.

The Company has determined that the fixed fees in the CSA are in-substance lease payments. The Company concluded that this agreement contains an embedded lease as the clean rooms have been built specifically for production of the Company's product and their use is effectively controlled by the Company as it has sole use over the space during the term of the agreement. The Company accounts for the agreement as an operating lease and has evaluated the non-cancelable lease term to be through the binding commitment date of May 15, 2027.

In addition, the Company has entered into an agreement for commercial supply manufacturing services related to the Company's Zalviso drug product with a contract manufacturing organization, which it accounts for as an operating lease.

The components of lease expense are presented in the following table (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating lease costs	$ 343	$ 305	$ 1,123	$ 914
Gain on derecognition of operating lease	—	—	(522)	—
Sublease income	—	(150)	(199)	(449)
Loss on termination of sublease	—	—	331	—
Net lease costs	$ 343	$ 155	$ 733	$ 465

The weighted average remaining lease term and discount rate related to the operating leases are presented in the following table:

	September 30, 2021
Weighted-average remaining term – operating lease (years)	5.21
Weighted-average discount rate – operating lease	12.80%

Future minimum lease payments as of September 30, 2021 are presented in the following table (in thousands):

Year:		
2021 (remaining three months)	$	237
2022		1,483
2023		1,194
2024		1,040
2025		1,040
2026		1,040
Thereafter		415
Total future minimum lease payments		6,449
Less imputed interest		(1,785)
Total	$	4,664

Reported as:

Operating lease liabilities	$	4,664
Operating lease liabilities, current portion		(729)
Operating lease liabilities, net of current portion	$	3,935

7. Liability Related to Sale of Future Royalties

On September 18, 2015, the Company entered into the Royalty Monetization with PDL for which it received gross proceeds of $65.0 million. Under the Royalty Monetization, PDL was to receive 75% of the European royalties under the Amended License Agreement with Grünenthal, as well as 80% of the first four commercial milestones worth $35.6 million (or 80% of $44.5 million), up to a capped amount of $195.0 million over the life of the arrangement.

The Company periodically assesses the expected royalty and milestone payments using a combination of historical results, internal projections and forecasts from external sources. To the extent such payments are greater or less than the Company's initial estimates or the timing of such payments is materially different than its original estimates, the Company will prospectively adjust the amortization of the liability and the effective interest rate. During the three months ended June 30, 2020, Grünenthal notified the Company that it was terminating the Amended License Agreement, effective November 13, 2020. The terms of the Grünenthal Agreements were extended to May 12, 2021 to enable Grünenthal to sell down its Zalviso inventory. The rights to market and sell Zalviso in the Zalviso Territory reverted back to the Company on May 12, 2021. There is a continuing obligation on the Company's part, through the term of the Royalty Monetization with SWK (assignee of PDL), to use commercially reasonable efforts to negotiate a replacement license agreement, or New Arrangement. If the Company is unable to find a New Arrangement, a contingent gain of up to approximately $64 million may be recognized when it is realized upon expiration of the liability at the end of the Royalty Monetization term. Due to the significant judgments and factors related to the estimates of future payments under the Royalty Monetization, there are significant uncertainties surrounding the amount and timing of future payments and the probability of realization of the estimated contingent gain.

The effective interest rate over the life of the liability will be 0% as the Company records interest income over the remaining term of the arrangement as an offset to the interest expense that was recognized in prior periods. The effective interest income rate for each of the three and nine months ended September 30, 2021 and 2020, was approximately 3.5% and 3.6%, respectively.

The following table shows the activity within the liability account for the nine months ended and the period from inception on September 18, 2015 to September 30, 2021 (in thousands):

	Nine months ended September 30, 2021	Period from inception to September 30, 2021
Liability related to sale of future royalties — beginning balance	$ 88,471	$ —
Proceeds from sale of future royalties	—	61,184
Non-cash royalty revenue	(145)	(1,083)
Non-cash interest (income) expense recognized	(2,345)	25,880
Liability related to sale of future royalties as of September 30, 2021	$ 85,981	$ 85,981

As royalties are remitted to SWK from ARPI LLC, as described in Note 1 “Organization and Summary of Significant Accounting Policies - Non-Cash Interest Income (Expense) on Liability Related to Sale of Future Royalties” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2020, the balance of the liability will be effectively repaid over the life of the agreement. The Company will record non-cash royalty revenues and non-cash interest (income) expense within its Condensed Consolidated Statements of Comprehensive Loss over the term of the Royalty Monetization. The liability related to the sale of future royalties, current portion, is recorded as accrued liabilities in the Company’s Condensed Consolidated Balance Sheets.

8. Legal Proceedings

On June 8, 2021, a securities class action complaint was filed in the U.S. District Court for the Northern District of California against the Company and two of its officers. The plaintiff is a purported stockholder of the Company. The complaint alleges that defendants violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by making false and misleading statements and omissions of material fact about the Company’s disclosure controls and procedures with respect to its marketing of DSUVIA. The complaint seeks unspecified damages, interest, attorneys’ fees, and other costs. Motions for appointment of lead plaintiff under the Private Securities Litigation Reform Act were filed on August 9, 2021 and a hearing on the motions has been noticed for December 16, 2021.

On July 6, 2021, a purported shareholder derivative complaint was filed in the U.S. District Court for the Northern District of California. The complaint names ten of the Company’s officers and directors and asserts state and federal claims based on the same alleged misstatements as the shareholder class action complaint. On September 30, 2021 and October 26, 2021, two additional purported shareholder derivative complaints were filed in the U.S. District Court for the Northern District of California. The complaints name nine of the Company’s officers and directors and also assert state and federal claims based on the same alleged misstatements as the shareholder class action complaint. All three complaints seek unspecified damages, attorneys’ fees, and other costs. The plaintiffs in the first two derivative actions have agreed to consolidate the cases and stay the action pending the outcome of any motion to dismiss the securities class actions. The Company and individual defendants have not yet been served in the third derivative action. Please see “*Item 1A. Risk Factors—Risks of a General Nature—Litigation may substantially increase our costs and harm our business.*”

The Company believes that these lawsuits are without merit and intends to vigorously defend against them. Given the uncertainty of litigation, the preliminary stage of the cases, and the legal standards that must be met for, among other things, class certification and success on the merits, the Company cannot estimate the reasonably possible loss or range of loss that may result from these actions.

9. Stockholders’ Equity

Common Stock

Underwritten Public Offering

On January 22, 2021, the Company completed an underwritten public offering in which the Company issued and sold 14,500,000 shares of its common stock to the underwriter at a price of $1.7625 per share. On January 27, 2021, the underwriters exercised their option in full and purchased an additional 2,175,000 shares at a price of $1.7625 per share. The total net proceeds from this offering of an aggregate 16,675,000 shares were approximately $28.9 million.

ATM Agreement

The Company has entered into a Controlled Equity Offering℠ Sales Agreement, or the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, as agent, pursuant to which the Company may offer and sell, from time to time through Cantor, shares of the Company’s common stock having an aggregate offering price of up to $80.0 million.

There were no shares of common stock sold pursuant to the ATM Agreement during the three months ended September 30, 2021. During the nine months ended September 30, 2021, the Company issued and sold approximately 3.0 million shares of common stock pursuant to the ATM Agreement, and received net proceeds of approximately $7.5 million, after deducting fees and expenses. There were no shares of common stock sold pursuant to the ATM Agreement during the three months ended September 30, 2020. During the nine months ended September 30, 2020, the Company issued and sold 876,800 shares of common stock pursuant to the ATM Agreement, respectively, for which the Company received net proceeds of approximately $1.5 million. As of September 30, 2021, the Company may offer and sell shares of the Company’s common stock having an aggregate offering price of up to $36.1 million under the ATM Agreement.

Amended Stock Plan

Amended 2020 Plan

On June 17, 2021, at the 2021 Annual Meeting of Stockholders of the Company, upon the recommendation of the Company's Board of Directors, the Company's stockholders approved an amendment and restatement of the Company's 2020 Equity Incentive Plan, or 2020 Plan, or as amended and restated, the Amended 2020 Plan, to increase the number of authorized shares reserved for issuance thereunder by 4,300,000 shares, subject to adjustment for certain changes in the Company's capitalization. The aggregate number of shares of the Company's common stock that may be issued under the Amended 2020 Plan will not exceed the sum of: (i) 4,300,000 shares approved in connection with the adoption of the Amended 2020 Plan, (ii) 5,500,000 shares approved in connection with the original adoption of the 2020 Plan, and (iii) certain shares subject to outstanding awards granted under the 2011 Equity Incentive Plan that may become available for issuance under the 2020 Plan and Amended 2020 Plan, as such shares become available from time to time.

10. Stock-Based Compensation

The Company recorded total stock-based compensation expense for stock options, stock awards and awards made under the Amended 2011 ESPP as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cost of goods sold	$ 24	$ 25	$ 67	$ 98
Research and development	216	188	597	572
Selling, general and administrative	981	891	2,818	2,670
Total	$ 1,221	$ 1,104	$ 3,482	$ 3,340

As of September 30, 2021, there were, in the aggregate, 12,170,713 shares available for grant, 14,376,874 options outstanding and 1,828,448 restricted stock units outstanding under the Company's equity incentive plans.

11. Net Loss per Share of Common Stock

The Company's basic net loss per share of common stock is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding for the period. The diluted net loss per share of common stock is computed by giving effect to all potential common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, options to purchase common stock, RSUs, and warrants to purchase common stock were considered to be common stock equivalents. In periods with a reported net loss, common stock equivalents are excluded from the calculation of diluted net loss per share of common stock as their effect is antidilutive.

The following outstanding shares of common stock equivalents were excluded from the computation of diluted net loss per share of common stock for the periods presented because including them would have been antidilutive:

	September 30,	
	2021	2020
ESPP, RSUs and stock options to purchase common stock	16,475,322	14,669,512
Common stock warrants	176,679	176,679

12. Subsequent Events

Acquisition

On November 14, 2021, the Company and two of its direct wholly owned subsidiaries, AcelRx Intermediate Sub, Inc., or Merger Sub 1, and AcelRx Consolidation Sub, LLC, or Merger Sub 2, Lowell, and the stockholder representative, entered into the Merger Agreement, pursuant to which, among other things, (a) Merger Sub 1 will merge with and into Lowell and Lowell will continue as the initial surviving company and the Company's direct wholly owned subsidiary, or the First Merger, and (b) the initial surviving company will merge with and into Merger Sub 2 and Merger Sub 2 will continue as the surviving company and the Company's direct wholly owned subsidiary, or the Second Merger and, together with the First Mergers, the Mergers.

Pursuant to the Merger Agreement, the Company will acquire Lowell in a transaction valued at approximately $32.5 million plus net cash acquired, and subject to certain other adjustments. The transaction value includes approximately $26.0 million of contingent consideration payable upon the achievement of regulatory and sales-based milestones. If the acquisition of Lowell is completed, an amount of shares of AcelRx common stock valued at approximately $6.5 million will be issued to Lowell securityholders at the closing, subject to the condition to closing that Lowell has at least $3.5 million in cash at the closing and assuming certain stockholders of Lowell elect to receive merger consideration up to $3.5 million payable in cash. If those stockholders do not elect to receive cash, the amount of shares of common stock issued by the Company will be greater. The merger consideration is payable upon the closing of the First Merger in shares of AcelRx's common stock, and, at the option of certain Lowell stockholders, in cash to such stockholder. The Merger Agreement has been approved by the board of directors of the Company and Lowell. The closing of the Mergers is expected in the fourth quarter of 2021, subject to certain closing conditions. For additional information regarding the Merger Agreement, see "Part II. Other Information - Item 5. Other Information" in this Form 10-Q.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with the unaudited financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q, or Form 10-Q, and with the audited Consolidated Financial Statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2020, or Annual Report.

About AcelRx Pharmaceuticals, Inc.

We are a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings.

Our Portfolio

The following table summarizes our portfolio of products and product candidates.

Product/Product Candidate	Description	Target Use	Status
DSUVIA®	Sufentanil sublingual tablet, 30 mcg	Moderate-to-severe acute pain in a medically supervised setting, administered by a healthcare professional	Received U.S. Food and Drug Administration, or FDA, approval in November 2018; commercial launch began first quarter of 2019.
DZUVEO®	Sufentanil sublingual tablet, 30 mcg	Moderate-to-severe acute pain in a medically monitored setting, administered by a healthcare professional	Granted European Commission, or EC, marketing approval in June 2018. Sunset date extended to December 31, 2022 by EC. To be commercialized in Europe by Laboratoire Aguettant, or Aguettant.
Zalviso®	Sufentanil sublingual tablet system, 15 mcg	Moderate-to-severe acute pain in the hospital setting, administered by the patient as needed	In the U.S., positive results from Phase 3 trial, IAP312, announced in August 2017. Currently evaluating the timing of the resubmission of the New Drug Application, or NDA, which is in part dependent on the finalization of the FDA's new opioid approval guidelines and process. Approved in the European Union, where it was marketed commercially by Grünenthal GmbH, or Grünenthal, through May 12, 2021.
Ephedrine	Ephedrine pre-filled syringe, containing 10 ml of a solution of 3 mg/ml ephedrine hydrochloride for injection	Clinically important hypotension occurring in the setting of anesthesia	Product candidate licensed from Laboratoire Aguettant, or Aguettant, preparing a New Drug Application, or NDA, for submission to FDA. Approved in the European Union, owned and marketed by Aguettant.
Phenylephrine	Phenylephrine pre-filled syringe containing 10 ml of a solution of 50 mcg/ml phenylephrine hydrochloride for injection	Clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia.	Product candidate licensed from Aguettant, preparing NDA for submission to FDA. Approved in the European Union, marketed by Aguettant.
ARX-02	Higher Strength Sufentanil Sublingual Tablet	Cancer breakthrough pain in opioid-tolerant patients	Phase 2 clinical trial and End of Phase 2 meeting completed. Investigational New Drug, or IND, application was inactivated. Future development contingent upon identification of corporate partnership resources.
ARX-03	Combination Sufentanil/Triazolam Sublingual Tablet	Mild sedation and pain relief during painful procedures in a physician's office	Phase 2 clinical trial and End of Phase 2 meeting completed. IND application was inactivated. Future development contingent upon identification of corporate partnership resources.

Acquisition

On November 14, 2021, we and two of our direct wholly owned subsidiaries, AcelRx Intermediate Sub, Inc., or Merger Sub 1, and AcelRx Consolidation Sub, LLC, or Merger Sub 2, Lowell Therapeutics, Inc., or Lowell, and the stockholder representative, entered into the Agreement and Plan of Merger, or the Merger Agreement, pursuant to which, (a) Merger Sub 1 will merge with and into Lowell and Lowell will continue as the initial surviving company and our direct wholly owned subsidiary, or the First Merger, and (b) the initial surviving company will merge with and into Merger Sub 2 and Merger Sub 2 will continue as the surviving company and our direct wholly owned subsidiary, or the Second Merger and, together with the First Merger, the Mergers.

Pursuant to the Merger Agreement, we will acquire Lowell in a transaction valued at approximately $32.5 million plus net cash acquired, and subject to certain other adjustments. The transaction value includes approximately $26.0 million of contingent consideration payable upon the achievement of regulatory and sales-based milestones. If the acquisition of Lowell is completed, an amount of shares of AcelRx common stock valued at approximately $6.5 million will be issued to Lowell securityholders at the closing, subject to the condition to closing that Lowell has at least $3.5 million in cash at the closing and assuming certain stockholders of Lowell elect to receive merger consideration up to $3.5 million payable in cash. If those stockholders do not elect to receive cash, the amount of shares of common stock issued by AcelRx will be greater. The merger consideration is payable upon the closing of the First Merger in shares of AcelRx's common stock, and, at the option of certain Lowell stockholders, in cash to such stockholder. The Merger Agreement has been approved by the board of directors of AcelRx and Lowell. The closing of the Mergers is expected in the fourth quarter of 2021, subject to certain closing conditions. For additional information regarding the Merger Agreement, see "Part II. Other Information - Item 5. Other Information" in this Form 10-Q.

Out-License Agreement (DZUVEO)

On July 14, 2021, we entered into a License and Commercialization Agreement, or the DZUVEO Agreement, with Aguettant pursuant to which Aguettant obtained the exclusive right to develop and commercialize DZUVEO in the European Union, Norway, Iceland, Liechtenstein, Andorra, Vatican City, Monaco, Switzerland and the United Kingdom, or the DZUVEO Territory, for the management of acute moderate to severe pain in adults in medically monitored settings. We will supply Aguettant with primary packaged product and Aguettant will then complete secondary packaging of the finished product. We are entitled to receive up to €47.0 million in a combination of up-front and sales-based milestone payments, of which we received €2.5 million, or approximately $2.9 million, in the third quarter of 2021. Refer to Note 1 "Organization and Summary of Significant Accounting Policies" in the accompanying notes to the Condensed Consolidated Financial Statements for additional information.

In-License Agreement

On July 14, 2021, we entered into a License and Commercialization Agreement, or the PFS Agreement, with Aguettant pursuant to which we obtained the exclusive right to develop and, subject to FDA approval, commercialize in the United States (i) an ephedrine pre-filled syringe containing 10 ml of a solution of 3 mg/ml ephedrine hydrochloride for injection, and (ii) a phenylephrine pre-filled syringe containing 10 ml of a solution of 50 mcg/ml phenylephrine hydrochloride for injection. Aguettant will supply the Company with the products for use in commercialization, if they are approved in the U.S. Aguettant is entitled to receive up to $24 million in sales-based milestone payments. Refer to Note 1 "Organization and Summary of Significant Accounting Policies" in the accompanying notes to the Condensed Consolidated Financial Statements for additional information.

General Trends and Outlook

COVID-19-related

Government-mandated orders and related safety policies on account of the COVID-19 pandemic continue to prevent us from operating our business in the normal course. Beginning in early 2020, state and local officials issued orders in response to the pandemic which included, among other things, requirements for residents to shelter in place and for non-essential businesses to cease activities at facilities within certain cities, counties, and states. State and local officials have taken different approaches to these orders, and some have not issued any such orders. Once issued, the orders have been relaxed and then tightened, depending on the rate of COVID-19 cases. As a result of these orders, we implemented a work from home policy for our California-based employees and we continue to adhere to the various and diverse orders issued by government officials in the jurisdictions in which we operate. In addition, some hospitals, ambulatory surgery centers and other healthcare facilities have barred visitors that are not caregivers or mission-critical and otherwise restricted access to such facilities. As a result, the educational and promotional efforts of our commercial and medical affairs personnel have been substantially reduced, and in some cases, stopped. Cancellation or delays of formulary committee meetings and delays of elective surgeries have also affected the pace of formulary approvals and, consequently, the rate of adoption and use of DSUVIA. We expect our near-term sales volumes to continue to be adversely impacted as long as access to healthcare facilities by our commercial and medical affairs personnel continues to be limited, especially in light of the rise in COVID-19 cases associated with the Delta variant. We will continue to evaluate the impact on our revenues and related metrics and operating expenses during this period and assess the need to adjust our expenses and expectations.

As a result of COVID-19 and related international travel restrictions, the timing for testing and acceptance of our DSUVIA fully automated packaging line, and subsequent FDA approval, has been delayed. Based on our best estimate, now that the line has been installed, we expect FDA approval in 2022.

We will continue to engage with various elements of our supply chain and distribution channel, including our customers, contract manufacturers, and logistics and transportation providers, to meet demand for products and to remain informed of any challenges within our supply chain. We continue to monitor demand and intend to adapt our plans as needed to continue to drive our business and meet our obligations during the evolving COVID-19 pandemic. However, if the COVID-19 pandemic continues and persists for an extended period of time, we may face disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our products. Such supply disruptions may adversely impact our ability to generate sales of and revenues from our products and our business, financial condition, results of operations and growth prospects could be adversely affected.

As the global pandemic of COVID-19 continues to rapidly evolve, it could result in a significant long-term disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. The extent to which the COVID-19 pandemic impacts our business, our ability to generate sales of and revenues from our approved products, and our future clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions, quarantines and social distancing requirements in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the virus.

Financial Overview

We have incurred net losses and generated negative cash flows from operations since inception and expect to incur losses in the future as we continue commercialization activities to support the U.S. launch of DSUVIA, support European sales of DZUVEO by Aguettant, and of Zalviso by any replacement partner, and fund any future research and development activities needed to support the FDA regulatory review of our product candidates. As a result, we expect to continue to incur operating losses and negative cash flows until such time as DSUVIA has gained market acceptance and generated significant revenues.

We will incur capital expenditures related to our fully automated packaging line for DSUVIA, which has now been installed, and for which we expect FDA approval in 2022. We anticipate that the fully automated line for DSUVIA will contribute to a significant decrease in costs of goods sold in 2022 and beyond.

Our net loss for the three and nine months ended September 30, 2021 was $8.4 million and $27.2 million, respectively, compared to net losses of $8.9 million and $31.5 million for the three and nine months ended September 30, 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $465.7 million. As of September 30, 2021, we had cash, cash equivalents and short-term investments totaling $48.7 million compared to $42.9 million as of December 31, 2020.

Critical Accounting Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our unaudited Condensed Consolidated Financial Statements and the related disclosures, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected. Our critical accounting policies and estimates are detailed in our Annual Report.

There have been no significant changes to our critical accounting policies or significant judgements and estimates for the three and nine months ended September 30, 2021, from those previously disclosed in our Annual Report, except to reflect that we apply the graded-vesting attribution method to awards with market conditions that include graded-vesting features. Additionally, we use the Monte Carlo Simulation model to evaluate the derived service period and fair value of awards with market conditions, including assumptions of historical volatility and risk-free interest rate commensurate with the vesting term.

Results of Operations

Our results of operations have fluctuated from period to period and may continue to fluctuate in the future, based upon the progress of our commercial launch of DSUVIA, our research and development efforts, variations in the level of expenditures related to commercial launch, development efforts and debt service obligations during any given period, and the uncertainty as to the extent and magnitude of the impact from the COVID-19 pandemic. Results of operations for any period may be unrelated to results of operations for any other period. In addition, historical results should not be viewed as indicative of future operating results. In particular, to the extent our commercial and medical affairs personnel continue to be subject to varying levels of restriction on accessing hospitals and ambulatory surgical centers due to COVID-19, and to the extent government authorities and certain healthcare providers are continuing to limit elective surgeries, we expect our sales volume to be adversely affected.

Three and Nine Months Ended September 30, 2021 and 2020

Revenue

Product Sales Revenue

Product sales revenue consists of sales of DSUVIA in the U.S. and, prior to May 13, 2021, Zalviso in Europe.

Product sales revenue by product for the three and nine months ended September 30, 2021 and 2020, was as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020
	(In thousands, except percentages)							
DSUVIA	$ 160	$ 935	$ (775)	(83)%	$ 733	$ 1,092	$ (359)	(33)%
Zalviso	—	352	(352)	(100)%	270	772	(502)	(65)%
Total product sales revenue	$ 160	$ 1,287	$ (1,127)	(88)%	$ 1,003	$ 1,864	$ (861)	(46)%

The decrease in product sales revenue for the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020, was primarily the result of a significant purchase from the Department of Defense in the third quarter of 2020 and the termination of the Collaboration and License Agreement and the Manufacture and Supply Agreement, or the Grünenthal Agreements, pursuant to which Grünenthal sold Zalviso in the European Union through May 12, 2021.

Contract and Other Collaboration Revenue

Contract and other collaboration revenue included revenue under the DZUVEO Agreement related to the upfront payment received in the third quarter of 2021, and prior to May 13, 2021, under the Grünenthal Agreements related to research and development services, non-cash royalty revenue related to the sale of the majority of our royalty rights and certain commercial sales milestones under the Grünenthal Agreements to SWK Funding, LLC, or SWK, (assignee of PDL BioPharma, Inc., or PDL), in a transaction referred to as the Royalty Monetization, and royalty revenue for sales of Zalviso in Europe.

Contract and other collaboration revenue for the three and nine months ended September 30, 2021 and 2020, was as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020
	(In thousands, except percentages)							
License revenue	$ 1,696	$ —	$ 1,696	100%	$ 1,696	$ —	$ 1,696	100%
Non-cash royalty revenue related to Royalty Monetization	—	61	(61)	(100)%	83	181	(98)	(54)%
Royalty revenue	—	20	(20)	(100)%	28	61	(33)	(54)%
Other revenue	6	—	6	100%	6	2,572	(2,566)	(100)%
Total contract and other collaboration revenue	$ 1,702	$ 81	$ 1,621	2,001%	$ 1,813	$ 2,814	$ (1,001)	(36)%

As of September 30, 2021, we granted Aguettant the license rights to DZUVEO in the European Union. Accordingly, for the three and nine months ended September 30, 2021, we recognized $1.7 million of the $2.9 million upfront fee as license revenue under the DZUVEO Agreement. In May 2020, Grünenthal terminated the Grünenthal Agreements, accordingly the rights to market and sell Zalviso in Europe reverted back to us on May 12, 2021. Upon notification of early termination by Grünenthal, we recognized approximately $2.6 million of deferred revenue for the discount on Zalviso manufacturing services which were no longer a performance obligation.

Cost of Goods Sold

We commenced commercial sales of DSUVIA in the first quarter of 2019.

Total cost of goods sold for the three and nine months ended September 30, 2021 and 2020, was as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020
	(In thousands, except percentages)							
Direct costs	$ 134	$ 771	$ (637)	(83)%	$ 569	$ 1,396	$ (827)	(59)%
Indirect costs	305	1,080	(775)	(72)%	1,950	3,336	(1,386)	(42)%
Total costs of goods sold	$ 439	$ 1,851	$ (1,412)	(76)%	$ 2,519	$ 4,732	$ (2,213)	(47)%

Direct costs from contract manufacturers for DSUVIA and Zalviso totaled $0.1 million and $0.6 million, respectively, in the three and nine months ended September 30, 2021, and included inventory impairment charges of $0.1 and $0.2 million, respectively, primarily related to DSUVIA and Zalviso component parts inventory. Direct costs from contract manufacturers for DSUVIA and Zalviso in the three and nine months ended September 30, 2020 totaled $0.8 million and $1.4 million, respectively, and included inventory impairment charges of $0.2 million and $0.6 million, respectively. In the nine months ended September 30, 2020, $0.3 million of these charges related to the termination of the Grünenthal Agreements, while $0.3 million related to DSUVIA inventory, primarily inventory that may expire before being sold. Direct cost of goods sold for DSUVIA and Zalviso includes the inventory costs of the active pharmaceutical ingredient, or API, third-party contract manufacturing costs, estimated warranty costs, packaging and distribution costs, shipping, handling and storage costs.

The indirect costs to manufacture DSUVIA and Zalviso totaled $0.3 million and $2.0 million in the three and nine months ended September 30, 2021, respectively, while the indirect costs to manufacture DSUVIA and Zalviso totaled $1.1 million and $3.3 million for the three and nine months ended September 30, 2020, respectively. Indirect costs include internal personnel and related costs for purchasing, supply chain, quality assurance, depreciation and related expenses.

Research and Development Expenses

The majority of our operating expenses to date have been for research and development activities related to Zalviso and DSUVIA. Research and development expenses included the following:

- expenses incurred under agreements with contract research organizations and clinical trial sites;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- payments to third party pharmaceutical and engineering development contractors;
- payments to third party manufacturers;
- depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, and equipment and laboratory and other supply costs; and
- costs for equipment and laboratory and other supplies.

We expect to incur future research and development expenditures to support the FDA regulatory review of our product candidates. The timing of the resubmission of the Zalviso NDA is in part dependent on the finalization of the FDA's new opioid approval guidelines and process.

We track external development expenses on a program-by-program basis. Our development resources are shared among all our programs. Compensation and benefits, facilities, depreciation, stock-based compensation, and development support services are not allocated specifically to projects and are considered research and development overhead.

Below is a summary of our research and development expenses for the three and nine months ended September 30, 2021 and 2020:

Drug Indication/Description	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020
	(In thousands, except percentages)							
DSUVIA	$ 646	$ 187	$ 459	245%	$ 990	$ 667	$ 323	48%
Zalviso	20	43	(23)	(53)%	32	75	(43)	(57)%
Overhead	750	726	24	3%	2,087	2,439	(352)	(14)%
Total research and development expenses	$ 1,416	$ 956	$ 460	48%	$ 3,109	$ 3,181	$ (72)	(2)%

Research and development expenses for the three months ended September 30, 2021 increased by $0.5 million as compared to the three months ended September 30, 2020, primarily due to increased Catalent manufacturing-related DSUVIA development expenses. Research and development expenses for the nine months ended September 30, 2021 decreased as compared to the nine months ended September 30, 2020, primarily due to decreases in personnel-related overhead expenses and Zalviso-related spending, partially offset by increased Catalent manufacturing-related DSUVIA development expenses.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consisted primarily of salaries, benefits and stock-based compensation for personnel engaged in commercialization, administration, finance and business development activities. Other significant expenses included allocated facility costs and professional fees for general legal, audit and consulting services.

Total selling, general and administrative expenses for the three and nine months ended September 30, 2021 and 2020, were as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020
	(In thousands, except percentages)							
Selling, general and administrative expenses	$ 8,640	$ 7,598	$ 1,042	14%	$ 24,978	$ 28,484	$ (3,506)	(12)%

Selling, general and administrative expenses increased by $1.0 million and decreased by $3.5 million during the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020, respectively. The increase for the three months ended September 30, 2021, as compared to the three months ended September 30, 2020 was primarily due to a $0.5 million increase in business development expenses, a $0.3 million increase in legal fees, primarily related to the DZUVEO and PFS Agreements, and net increases of $0.2 million in other selling, general and administrative expenses. The decrease for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, is primarily due to a $2.2 million reduction in personnel-related costs, a decrease in business development expenses of $0.8 million, a $0.6 million reduction in DSUVIA commercialization-related expenses, such as travel, offset by net increases in other selling, general and administrative expenses of $0.1 million.

In March 2020, we eliminated 30 positions, mainly within the commercial organization. For additional information regarding the Restructuring Costs see Note 1 “Organization and Summary of Significant Accounting Policies” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2020.

Other Income (Expense)

Total other income (expense) for the three and nine months ended September 30, 2021 and 2020, was as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020	2021	2020	$ Change 2021 vs. 2020	% Change 2021 vs. 2020
	(In thousands, except percentages)							
Interest expense	$ (538)	$ (824)	$ 286	(35)%	$ (1,824)	$ (2,551)	$ 727	(28)%
Interest income and other income, net	32	106	(74)	(70)%	92	311	(219)	(70)%
Non-cash interest income (expense) on liability related to sale of future royalties	764	825	(61)	(7)%	2,345	2,502	(157)	(6)%
Total other income (expense)	$ 258	$ 107	$ 151	141%	$ 613	$ 262	$ 351	134%

Interest expense consisted primarily of interest accrued or paid on our debt obligation agreements and amortization of debt discounts. Interest expense decreased for the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020, primarily as a result of a lower outstanding loan balance. As of September 30, 2021, the accrued balance due under the Loan Agreement with Oxford was $15.3 million. Refer to Note 5 “Long-Term Debt” in the accompanying notes to the Condensed Consolidated Financial Statements for additional information.

Interest income and other income (expense), net, for the three and nine months ended September 30, 2021 and 2020, primarily consisted of the change in the fair value of our contingent put option and interest earned on our investments. Interest income decreased in the three and nine months ended September 30, 2021 as compared to the three and nine months ended September 30, 2020, primarily due to the change in the fair value of our contingent put option and lower yields on our investments.

The non-cash interest income on the liability related to the sale of future royalties is attributable to the Royalty Monetization that we completed in September 2015. As described in Note 7 “Liability Related to Sale of Future Royalties”, the Royalty Monetization has been recorded as debt under the applicable accounting guidance. We periodically assess the expected royalty and milestone payments using a combination of historical results, internal projections and forecasts from external sources. To the extent such payments are greater or less than our initial estimates or the timing of such payments is materially different than our original estimates, we will prospectively adjust the amortization of the liability and the interest rate.

The effective interest income rate for each of the three and nine months ended September 30, 2021 and 2020, was approximately 3.5% and 3.6%, respectively. We anticipate that we will record approximately $3 million in non-cash interest income related to the Royalty Monetization for the year ending December 31, 2021.

Liquidity and Capital Resources

Liquidity

We have incurred losses and generated negative cash flows from operations since inception. We expect to continue to incur significant losses in 2021 and may incur significant losses and negative cash flows from operations in the future. We have funded our operations primarily through issuance of equity securities, borrowings, payments from Grünenthal, the monetization of certain future royalties and commercial sales milestones from the European sales of Zalviso by Grünenthal, funding of approximately $22.6 million from the DoD, and more recently with revenues from sales of DSUVIA since the commercial launch in the first quarter of 2019 and the upfront payment under the DZUVEO Agreement with Aguettant.

As of September 30, 2021, we had cash, cash equivalents and investments totaling $48.7 million compared to $42.9 million as of December 31, 2020. The increase was primarily due to net proceeds received from the issuance of common stock in connection with equity offerings in the first quarter of 2021, partially offset by cash required to fund our continuing operations, including debt service, as we continued our commercialization activities for DSUVIA, including installation of our fully automated packaging line for DSUVIA, and business development activities. We anticipate that our existing capital resources will permit us to meet our capital and operational requirements for at least the next twelve months; however, our expectations may change depending on a number of factors including the extent and magnitude of the impact from the COVID-19 pandemic, in particular the negative impact on sales volumes as our sales force is limited in its access to potential customers, our expenditures related to the United States commercial launch of DSUVIA and the timing of business development activities. Our existing capital resources will not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to sustain our operations.

On January 22, 2021, we completed an underwritten public offering in which we issued and sold 14,500,000 shares of our common stock to the underwriter at a price of $1.7625 per share. On January 27, 2021, the underwriters exercised their option in full and purchased an additional 2,175,000 shares at a price of $1.7625 per share. The total net proceeds from this offering of an aggregate 16,675,000 shares were approximately $28.9 million.

We entered into a Controlled Equity Offering℠ Sales Agreement, or the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, as agent, pursuant to which we may offer and sell, from time to time through Cantor, shares of our common stock. As of September 30, 2021, we had issued and sold an aggregate of approximately 14.2 million shares of common stock pursuant to the ATM Agreement, for which we had received net proceeds of approximately $42.6 million, after deducting commissions, fees and expenses of approximately $1.2 million. As of September 30, 2021, we have the ability to sell approximately $36.1 million of our common stock under the ATM Agreement.

On May 30, 2019, we entered into the Loan Agreement with Oxford. Under the Loan Agreement, we borrowed an aggregate principal amount of $25.0 million under a term loan. After deducting all loan initiation costs and outstanding interest on the prior loan agreement with Hercules, we received $15.9 million in net proceeds. As of September 30, 2021, the accrued balance under the Loan Agreement was $15.3 million. For more information, see Note 5 “Long-Term Debt” in the accompanying notes to the Condensed Consolidated Financial Statements.

Our cash and investment balances are held in a variety of interest-bearing instruments, including obligations of commercial paper, corporate debt securities, U.S. government sponsored enterprise debt securities and money market funds. Cash in excess of immediate requirements is invested with a view toward capital preservation and liquidity. We do not expect COVID-19 to have a material impact on our high quality, short-dated investments.

Cash Flows

The following is a summary of our cash flows for the periods indicated and has been derived from our Condensed Consolidated Financial Statements which are included elsewhere in this Form 10-Q (in thousands):

	Nine Months Ended September 30,	
	2021	**2020**
Net cash used in operating activities	$ (21,998)	$ (32,178)
Net cash (used in) provided by investing activities	(21,684)	28,364
Net cash provided by financing activities	29,679	9,103

Cash Flows from Operating Activities

The primary use of cash for our operating activities during these periods was to fund commercial activities for our approved product, DSUVIA. Our cash used in operating activities also reflected changes in our working capital, net of adjustments for non-cash charges, such as depreciation and amortization of our fixed assets, stock-based compensation, non-cash interest income (expense) related to the sale of future royalties and interest expense related to our debt financings.

Cash used in operating activities of $22.0 million during the nine months ended September 30, 2021, reflected a net loss of $27.2 million, partially offset by aggregate non-cash charges of $3.3 million and included an approximate $1.9 million net change in our operating assets and liabilities. Non-cash charges included $3.5 million for stock-based compensation expense, $2.3 million in non-cash interest income on the liability related to the Royalty Monetization, and $1.5 million in depreciation and amortization expense. The net change in our operating assets and liabilities included a $1.2 million increase in deferred revenue.

Cash used in operating activities of $32.2 million during the nine months ended September 30, 2020, reflected a net loss of $31.5 million, partially offset by aggregate non-cash charges of $3.4 million and included an approximate $4.1 million net change in our operating assets and liabilities. Non-cash charges included $3.3 million for stock-based compensation expense, $2.5 million in non-cash interest income on the liability related to the Royalty Monetization and $1.5 million in depreciation expense. The net change in our operating assets and liabilities included a $1.2 million decrease in accrued liabilities and a $3.0 million decrease in deferred revenue.

Cash Flows from Investing Activities

Our investing activities have consisted primarily of our capital expenditures and purchases and sales and maturities of our available-for-sale investments.

During the nine months ended September 30, 2021, cash used in investing activities of $21.7 million was primarily the net result of $53.8 million for purchases of investments and $1.8 million for purchases of property and equipment, partially offset by $34.0 million in proceeds from the sale and maturity of investments. During the nine months ended September 30, 2020, cash provided by investing activities of $28.4 million was the net result of $67.4 million in proceeds from maturity of investments, offset by $38.8 million for purchases of investments and purchases of property and equipment of $0.2 million.

Cash Flows from Financing Activities

Cash flows from financing activities primarily reflect proceeds from the sale of our securities and payments made on debt financings.

During the nine months ended September 30, 2021, cash provided by financing activities of $29.7 million was primarily due to $36.4 million in net proceeds received in connection with equity financings, partially offset by $6.7 million used for payment of long-term debt. During the nine months ended September 30, 2020, cash provided by financing activities was primarily due to $11.4 million in net proceeds received in connection with equity financings, and $0.4 million in net proceeds received through our equity plans, partially offset by $2.6 million used for payment of long-term debt.

Operating Capital and Capital Expenditure Requirements

Our current operating plan includes expenditures related to the continued launch of DSUVIA in the United States. This plan includes an assumption that COVID-19 related restrictions will not increase considerably, and includes anticipated activities required to resubmit the Zalviso NDA and anticipated activities required for preparation and submission of the NDAs for our two in-licensed product candidates from Aguettant. These assumptions may change as a result of many factors. We will continue to evaluate the work necessary to successfully launch DSUVIA and gain approval of our product candidates in the United States and intend to update our cash forecasts accordingly. Our forecast that our existing capital resources will permit us to meet our capital and operational requirements through at least the next twelve months is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

Our future capital requirements may vary materially from our expectations based on numerous factors, including, but not limited to, the following:

- the impact and timing of COVID-19 on our operations, our sales representatives' access to hospitals or other healthcare facilities, and our level of sales;
- expenditures related to the launch of DSUVIA and potential commercialization of our product candidates, if approved;
- future manufacturing, selling and marketing costs related to DSUVIA and our product candidates, if approved, including our contractual obligations to Aguettant under the DZUVEO Agreement;
- costs associated with business development activities and licensing transactions;
- the outcome, timing and cost of the regulatory submissions for our product candidates and any approvals for our product candidates;
- the initiation, progress, timing and completion of any post-approval clinical trials for DSUVIA, or our product candidates, if approved;
- changes in the focus and direction of our business strategy and/or research and development programs;
- milestone and royalty revenue we receive under our collaborative development and commercialization arrangements, including the DZUVEO Agreement;
- delays that may be caused by changing regulatory requirements;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the timing and terms of future in-licensing and out-licensing transactions;
- the cost and timing of establishing sales, marketing, manufacturing and distribution capabilities;
- the cost of procuring clinical and commercial supplies of DSUVIA and our product candidates, if approved;
- the extent to which we acquire or invest in businesses, products and product candidates or technologies; and
- the expenses associated with litigation.

In the long-term, our existing capital resources will not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to sustain our operations. We will have to raise additional funds through the sale of our equity securities, monetization of current and future assets, issuance of debt or debt-like securities or from development and licensing arrangements to sustain our operations and continue our development programs.

Please see “Part II., Item 1A. Risk Factors—Risks Related to Our Financial Condition and Need for Additional Capital.”

Off-Balance Sheet Arrangements

Through September 30, 2021, we have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide the information specified under this item.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures (as defined in Exchange Act Rule 13a–15(e) and 15d-15(e)) that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Evaluation of disclosure controls and procedures. As required by Rule 13a-15(b) under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal control over financial reporting. There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time we may be involved in legal proceedings relating to intellectual property, commercial, employment and other matters arising in the ordinary course of business. Such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on our business, results of operations, financial position or cash flows. Please see the matters under the caption “Part I. Financial Information —Item 1. Financial Statements—Note 8, Legal Proceedings.”

Item 1A. Risk Factors

This Quarterly Report on Form 10-Q contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements made by or on behalf of us, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our revenues, expenses, net loss and loss per share. You should carefully consider these risk factors, together with all of the other information included in this Quarterly Report on Form 10-Q as well as our other publicly available filings with the U.S. Securities and Exchange Commission, or SEC.

Summary Risk Factors

Our business is subject to numerous risks, as more fully described in this section below this summary. You should read these risks before you invest in our common stock. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy. In particular, our risks include:

- Our business is being adversely impacted by the COVID-19 pandemic.
- We have incurred significant losses since our inception, anticipate that we will continue to incur significant losses in 2021 and may continue to incur losses in the future.
- We have not yet generated significant product revenue and may never be profitable.
- We will require additional capital and may be unable to raise capital, which would force us to delay, reduce or eliminate our commercialization efforts and product development programs and could cause us to cease operations.
- Positive clinical results obtained to date for Zalviso may be disputed in FDA review, do not guarantee regulatory approval and may not be obtained from future clinical trials.
- Existing and future legislation may increase the difficulty and cost for us to commercialize our products and affect the prices we may obtain.
- Guidelines and recommendations published by government agencies, as well as non-governmental organizations, and existing laws and regulations can reduce the use of DSUVIA, and Zalviso, if approved in the United States.
- Zalviso may cause adverse effects or have other properties that could delay or prevent regulatory approval or limit the scope of any approved label or market acceptance. DSUVIA may cause adverse effects or have other properties that could limit market acceptance.
- Although we have obtained regulatory approval for DSUVIA, and even if we obtain regulatory approval for Zalviso in the United States, we and our collaborators face extensive regulatory requirements, and our products may face future development and regulatory difficulties.
- The commercial success of DSUVIA and, if approved, Zalviso and our other product candidates in the United States, as well as DZUVEO and Zalviso in Europe, will depend upon the acceptance of these products by the medical community, including physicians, nurses, patients, and pharmacy and therapeutics committees.
- If we are unable to maintain or grow our sales and marketing capabilities or enter into agreements with third parties to market and sell our products, we may be unable to generate sufficient product revenue.
- The success of our Merger Agreement with Lowell Therapeutics, Inc, or Lowell, including our ability to satisfy the required closing conditions, and realize the expected benefits and potential value creation related to the proposed acquisition;
- A key part of our business strategy is to establish collaborative relationships to commercialize and fund development and approval of our products, particularly outside of the United States. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our products successfully, if at all.
- If we cannot defend our issued patents from third party claims or if our pending patent applications fail to issue, our business could be adversely affected.
- The market price of our common stock may be highly volatile.
- Litigation may substantially increase our costs and harm our business.
- Our involvement in securities-related class action litigation could divert our resources and management's attention and harm our business.

We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2020.

Risks Related to COVID-19 Pandemic

Our business is being adversely impacted by the COVID-19 pandemic.

Our business has been adversely affected by the COVID-19 outbreak. Federal, state, local and foreign government orders on account of the COVID-19 pandemic are preventing us from conducting certain activities. Following local and state government orders in California, where our corporate office is located and many of our employees live, we implemented work from home policies, which are limiting certain of our operations. If the COVID-19 outbreak continues, we may need to limit operations further and implement additional limitations, such as extending our work from home policies.

In response to the COVID-19 pandemic, some hospitals, ambulatory surgery centers and other healthcare facilities have barred visitors that are not caregivers or mission-critical and we have no visibility as to when these restrictions on access will be lifted for all of our customers. As a result, our commercial and medical affairs teams' educational and promotional efforts have been reduced, and in some cases, stopped. Furthermore, some governments, hospitals and doctors, as a measure to combat the further spread of COVID-19, reduced the number of procedures in which DSUVIA is administered as part of the pain treatment program, and temporarily halted performing elective surgeries, which adversely impacted the level of our sales relating to such procedures. We expect our near-term sales volumes to be adversely impacted for as long as access to healthcare facilities by our commercial and medical affairs personnel and the number of procedures in which DSUVIA is administered continues to be limited. The ultimate impact of the COVID-19 outbreak remains highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

Risks Related to Commercialization

Our success is highly dependent on our ability to successfully commercialize DSUVIA.*

We invested a significant portion of our efforts and financial resources to develop and gain regulatory approval for DSUVIA and expect to continue making significant investments to commercialize DSUVIA. We believe our success is highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully commercialize DSUVIA in the United States. The commercial success of DSUVIA depends heavily on numerous factors, including:

- our ability to market, sell, and distribute DSUVIA;
- our ability to establish and maintain commercial manufacturing with third parties;
- acceptance by the medical community, including physicians, nurses, patients and pharmacy and therapeutics committees;
- acceptance of pricing and placement on payers' formularies;
- our ability to effectively compete with other medications for the treatment of moderate-to-severe acute pain in medically supervised settings, including IV-opioids and any subsequently approved products;
- effective management of, and compliance with, the DSUVIA Risk Evaluation and Mitigation Strategy, or REMS, program;
- continued demonstration of an acceptable safety profile of DSUVIA; and
- our ability to obtain, maintain, enforce, and defend our intellectual property rights and claims.

If we are unable to successfully commercialize DSUVIA, our business, financial condition, and results of operations will be materially harmed.

The commercial success of DSUVIA and, if approved, Zalviso and our other product candidates in the United States, as well as DZUVEO and Zalviso in Europe, will depend upon the acceptance of these products by the medical community, including physicians, nurses, patients, and pharmacy and therapeutics committees.*

The degree of market acceptance of DSUVIA and, if approved, Zalviso and our other product candidates in the United States, as well as DZUVEO and Zalviso in Europe, by the medical community will depend on a number of factors, including:

- demonstration of clinical safety and efficacy compared to other products;
- the relative convenience, ease of administration and acceptance by physicians, patients and health care payers;
- the use of our approved products by a healthcare professional for patient types that were not specifically studied in clinical trials;
- the prevalence and severity of any adverse events, or AEs, or serious adverse events, or SAEs;
- overcoming any perceptions of sufentanil as a potentially unsafe drug due to its high potency opioid status;
- limitations or warnings contained in the U.S. Food and Drug Administration, or FDA, -approved label for DSUVIA and, if approved, our other product candidates, or the European Medicines Agency, or EMA,-approved label for DZUVEO or Zalviso;
- restrictions or limitations placed on DSUVIA due to the REMS program or, if approved, on our product candidates;
- availability of alternative treatments;
- existing capital investment by hospitals in IV PCA technology;

- pricing and cost-effectiveness;
- the effectiveness of our current or any future collaborators' sales and marketing strategies;
- our ability to obtain formulary approvals; and
- our ability to obtain and maintain sufficient third-party coverage and reimbursement.

If our approved products do not achieve an adequate level of acceptance by the medical community, including physicians, nurses, patients and pharmacy and therapeutics committees, we may not generate sufficient revenue and become or remain profitable.

If we are unable to maintain or grow our sales and marketing capabilities or enter into agreements with third parties to market and sell our products and, if approved, our product candidates***, we may be unable to generate sufficient product revenue.****

In order to commercialize DSUVIA and, if approved, our product candidates in the United States, we must maintain or grow internal sales, marketing, distribution, managerial and other capabilities or make arrangements with third parties to perform these services. We have entered into agreements with third parties for the distribution of DSUVIA and may enter into such agreements for our product candidates, if approved, in the United States, including the product candidates we in-licensed from Laboratoire Aguettant, or Aguettant, in July 2021 pursuant to a License and Commercialization Agreement, or the PFS Agreement; however, if these third parties do not perform as expected or there are delays in establishing such relationships, our ability to effectively distribute products would suffer.

We have entered into strategic partnerships with third parties to commercialize our products outside of the United States. For example, in 2013 we entered into a collaboration with Grünenthal GmbH, or Grünenthal, for the commercialization of Zalviso in Europe and Australia, and in July 2021, we entered a License and Commercialization Agreement, or the DZUVEO Agreement, with Aguettant for the commercialization of DZUVEO in the European Union, Norway, Iceland, Liechtenstein, Andorra, Vatican City, Monaco, Switzerland and the United Kingdom, or the DZUVEO Territory. Grünenthal ceased commercializing Zalviso on May 12, 2021 and the rights to market and sell Zalviso reverted back to us. We intend to enter into additional strategic partnerships with third parties to commercialize our products outside of the United States, including a replacement license agreement for Zalviso in Europe. Per the terms of the royalty monetization arrangement with SWK Funding, LLC, or SWK (assignee of PDL BioPharma, Inc., or PDL), or the Royalty Monetization, we are obligated to use commercially reasonable efforts to negotiate a replacement license agreement, or New Arrangement. Accordingly, even if we are able to enter into a New Arrangement, and that licensee is successful in commercializing Zalviso in Europe, we will receive only a portion of any royalties until the capped amount owing to SWK is reached.

We face significant competition in seeking appropriate strategic partners, and these strategic partnerships can be intricate and time consuming to negotiate and document. We may not be able to negotiate future strategic partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any new strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships. Our current or future collaboration partners, if any, may not dedicate sufficient resources to the commercialization of our products and product candidates, if approved, or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective collaborations to enable the sale of our products to healthcare professionals and in geographical regions that will not be covered by our own marketing and sales force, or if our potential future collaboration partners do not successfully commercialize our products, our ability to generate revenues from product sales will be adversely affected.

If we are unable to maintain or grow adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and become profitable. We compete with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

A key part of our business strategy is to establish collaborative relationships to commercialize and fund development and approval of our products, particularly outside of the United States. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our products successfully, if at all.*

We will need to establish and maintain successful collaborative relationships to obtain international sales, marketing and distribution capabilities for our products. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty. For example:

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical or regulatory results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- our contracts for collaborative arrangements are or may be terminable at will on written notice and may otherwise expire or terminate, and we may not have alternatives available to achieve the potential for our products in those territories or markets;
- our partners may choose to pursue alternative technologies, including those of our competitors;

- we may have disputes with a partner that could lead to litigation or arbitration, including in connection with any contractual force majeure notices tied to the COVID-19 pandemic;
- we have limited control over the decisions of our partners, and they may change the priority of our programs in a manner that would result in termination of the agreement or add significant delays to the partnered program;
- our ability to generate future payments and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of our drugs, maintain regulatory approvals and our ability to successfully manufacture and achieve market acceptance of our products;
- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may use our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;
- our partners may not devote sufficient capital or resources towards our products; and
- our partners may not comply with applicable government regulatory requirements necessary to successfully market and sell our products.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, any research, clinical development, manufacturing or commercialization efforts pursuant to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. For example, we have a continuing obligation, through the term of the Royalty Monetization with SWK, to use commercially reasonable efforts to negotiate a New Arrangement following Grünenthal's termination of our collaboration agreement for the commercialization of Zalviso in Europe. More generally, if we are unable to establish and maintain collaborative relationships on acceptable terms we may have to undertake development and commercialization activities at our own expense.

We may experience difficulties in retaining our existing employees and managing our operations, including our continued commercialization of DSUVIA.*

We need to retain and maintain our existing sales, managerial, operational, finance and other personnel and resources in order to continue the commercialization of DSUVIA and manage our operations. Our current infrastructure may be inadequate to support our strategy and any future workforce reduction, such as the reduction that eliminated approximately 33% of our workforce in March 2020 in connection with a strategic transaction, may be disruptive to our operations, may negatively affect our productivity, and may constrain our commercialization activities. For example, a workforce reduction could yield unanticipated consequences, such as attrition beyond planned staff reductions, negatively impacting employee morale and our corporate culture, or increased difficulties in our day-to-day operations, and prevent us from successfully commercializing DSUVIA as rapidly as planned. If we encounter such unanticipated consequences, we may have difficulty retaining and attracting personnel. In addition, the implementation of any additional workforce or expense reduction programs may divert the efforts of our management team and other key employees, which could adversely affect our business. Furthermore, we may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our cost reduction plan, due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the cost reduction plan, our operating results and financial condition would be adversely affected.

Guidelines and recommendations published by government agencies, as well as non-governmental organizations, and existing laws and regulations can reduce the use of DSUVIA, and Zalviso, if approved in the United States.

Government agencies and non-governmental organizations promulgate regulations and guidelines applicable to certain drug classes that may include DSUVIA and Zalviso, if approved in the United States. Recommendations of government agencies or non-governmental organizations may relate to such matters as maximum quantities dispensed to patients, dosage, route of administration, and use of concomitant therapies. Government agencies and non-governmental organizations have offered commentary and guidelines on the use of opioid-containing products. We are uncertain how these activities and guidelines may impact DSUVIA and our ability to gain marketing approval of Zalviso in the United States. Regulations or guidelines suggesting the reduced use of certain drug classes that may include DSUVIA or Zalviso, or the use of competitive or alternative products as the standard-of-care to be followed by patients and healthcare providers, could result in decreased use of DSUVIA or Zalviso, if approved, or negatively impact our ability to gain market acceptance and market share. The U.S. government and state legislatures have prioritized combatting the growing misuse and addiction to opioids and opioid overdose deaths and have enacted legislation and regulations as well as other measures intended to fight the opioid epidemic. Addressing opioid drug abuse is a priority for the current U.S. administration and the FDA and is part of a broader initiative led by the U.S. Department of Health and Human Services, or HHS. Overall, there is greater scrutiny of entities involved in the manufacture, sale and distribution of opioids. These initiatives, existing laws and regulations, and any negative publicity related to opioids may have a material impact on our business and our ability to manufacture opioid products.

Governmental investigations, inquiries, and regulatory actions and lawsuits brought against us by government agencies and private parties with respect to our commercialization of opioids could adversely affect our business, financial condition, results of operations and cash flows.

As a result of greater public awareness of the public health issue of opioid abuse, there has been increased scrutiny of, and investigation into, the commercial practices of opioid manufacturers by state and federal agencies. As a result of our manufacturing and commercial sale of DSUVIA in the United States and Zalviso in Europe, we could become the subject of federal, state and foreign government investigations and enforcement actions, focused on the misuse and abuse of opioid medications.

In addition, a significant number of lawsuits have been filed against opioid manufacturers, distributors, and others in the supply chain by cities, counties, state Attorney's General and private persons seeking to hold them accountable for opioid misuse and abuse. The lawsuits assert a variety of claims, including, but not limited to, public nuisance, negligence, civil conspiracy, fraud, violations of the Racketeer Influenced and Corrupt Organizations Act, or RICO, or similar state laws, violations of state Controlled Substance Acts or state False Claims Acts, product liability, consumer fraud, unfair or deceptive trade practices, false advertising, insurance fraud, unjust enrichment and other common law and statutory claims arising from defendants' manufacturing, distribution, marketing and promotion of opioids and seek restitution, damages, injunctive and other relief and attorneys' fees and costs. The claims generally are based on alleged misrepresentations and/or omissions in connection with the sale and marketing of prescription opioid medications and/or an alleged failure to take adequate steps to prevent abuse and diversion. While DSUVIA is designed for use solely in certified medically supervised healthcare settings and administered only by a healthcare professional in these settings, and is not distributed or available at retail pharmacies to patients by prescription, we can provide no assurance that parties will not file lawsuits of this type against us in the future. In addition, current public perceptions of the public health issue of opioid abuse may present challenges to favorable resolution of any potential claims. Accordingly, we cannot predict whether we may become subject to these kinds of investigations and lawsuits in the future, and if we were to be named as a defendant in such actions, we cannot predict the ultimate outcome. Any allegations against us may negatively affect our business in various ways, including through harm to our reputation.

If we were required to defend ourselves in these matters, we would likely incur significant legal costs and could in the future be required to pay significant amounts as a result of fines, penalties, settlements or judgments. It is unlikely that our current product liability insurance would fully cover these potential liabilities, if at all. Moreover, we may be unable to maintain insurance in the future on acceptable terms or with adequate coverage against potential liabilities or other losses. For more information about our product liability insurance and exclusions therefrom, please see the risk factor entitled "We face potential product liability claims, and, if such claims are successful, we may incur substantial liability" elsewhere in this section. The resolution of one or more of these matters could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Furthermore, in the current climate, stories regarding prescription drug abuse and the diversion of opioids and other controlled substances are frequently in the media or advocated by public interest groups. Unfavorable publicity regarding the use or misuse of opioid drugs, the limitations of abuse-deterrent formulations, the ability of drug abusers to discover previously unknown ways to abuse opioid products, public inquiries and investigations into prescription drug abuse, litigation, or regulatory activity regarding sales, marketing, distribution or storage of opioids could have a material adverse effect on our reputation and impact on the results of litigation.

Finally, various government entities, including Congress, state legislatures or other policy-making bodies, or public interest groups have in the past and may in the future hold hearings, conduct investigations and/or issue reports calling attention to the opioid crisis, and may mention or criticize the perceived role of manufacturers, including us, in the opioid crisis. Similarly, press organizations have and likely will continue to report on these issues, and such reporting may result in adverse publicity for us, resulting in reputational harm.

Approval of Zalviso and DZUVEO in Europe has resulted in a variety of risks associated with international operations that could materially adversely affect our business.*

Our collaborations with international partners, including Grünenthal and Aguettant, have required, and will require, us to supply product to support the commercialization of our products in Europe and it is likely that any New Arrangement would also include such a requirement. Entering into international business relationships subjects us to additional risks including:

- multiple, conflicting, and changing laws and regulations such as privacy and data regulations, transparency regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, including for drug approvals, and other governmental approvals, permits, and licenses;
- EMA "sunset clause" requirements, which apply to DZUVEO, providing that the marketing authorization of a medicine will cease to be valid if it is not placed on the market within three years of the authorization being granted or if it is removed from the market for three consecutive years; however, the European Commission has extended this date to December 31, 2022 for DZUVEO;

- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different payer reimbursement regimes, governmental payers, patient self-pay systems and price controls;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from pandemics, geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Any of these factors could have a material adverse effect on our business.

If we, or current and potential partners, are unable to compete effectively, our products may not reach their commercial potential.

The U.S. biotechnology and pharmaceutical industries are characterized by intense competition and cost pressure. DSUVIA competes, and our product candidates, if approved in the U.S., will compete, with a number of existing and future pharmaceuticals and drug delivery devices developed, manufactured and marketed by others. In particular, DSUVIA may compete with a wide variety of products and product candidates including (i) injectable opioid products, such as morphine, fentanyl, hydromorphone and meperidine; (ii) oral opioids such as oxycodone and hydrocodone; (iii) generic injectable local anesthetics, such as bupivacaine or branded formulations thereof; (iv) non-steroidal anti-inflammatory drugs, or NSAIDS, including ketorolac in intranasal or generic IV form, and IV meloxicam; and (v) transmucosal fentanyl products. Zalviso, if approved in the U.S., may compete with a number of opioid-based treatment options, including IV PCA pumps, oral PCA devices, and transdermal opioid PCAs. The PFS product candidates, if approved in the U.S., may compete with other ready-to-use formulations of ephedrine and phenylephrine.

Key competitive factors affecting the commercial success of our approved products are likely to be efficacy, safety profile, reliability, convenience of dosing, price and reimbursement. Many of our competitors and potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drug candidates, obtaining FDA and other regulatory approval of products, and the commercialization of those products. Accordingly, our competitors may be more successful than we are in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors' drugs or drug delivery systems may be more effective, have fewer adverse effects, be less expensive to develop and manufacture, or be more effectively marketed and sold than any product we may seek to commercialize. This may render our products obsolete or non-competitive. We anticipate that we will face intense and increasing competition as new drugs enter the market, additional technologies become available, and competitors establish collaborative or licensing relationships, which may adversely affect our competitive position. These and other competitive risks may materially adversely affect our ability to attain or sustain profitable operations.

Hospital or other health care facility formulary approvals for DSUVIA or our product candidates, if approved, in the United States may not be achieved, or could be subject to certain restrictions, which could make it difficult for us to sell our products.

Obtaining hospital or other health care facility formulary approvals can be an expensive and time-consuming process. We cannot be certain if and when we will obtain formulary approvals to allow us to sell our products into our target markets. In particular, the COVID-19-related restrictions on our commercial and medical affairs teams' access to hospitals and other health care facilities has adversely impacted the number of formulary approvals we achieved to date, and for as long as these restrictions remain in place, or new restrictions are implemented, we may have limited visibility or difficulties in obtaining these formulary approvals. Failure to obtain timely formulary approvals will limit our commercial success. In order to obtain formulary approvals, we often are required to complete evaluation programs whereby DSUVIA, or our product candidates, if approved, are used on a limited basis for certain patient types. The evaluation period may last several months and there can be no assurance that use during the evaluation period will lead to formulary approvals of DSUVIA, or our product candidates, if approved. Further, even successful formulary approvals are subject to certain restrictions based on patient type or hospital protocol. Failure to obtain timely formulary approvals for DSUVIA, or our product candidates, if approved, would materially adversely affect our ability to attain or sustain profitable operations.

Coverage and adequate reimbursement may not be available for DSUVIA or our product candidates, if approved, in the United States, or DZUVEO or Zalviso in Europe, which could make it difficult for us, or our partners, to sell our products profitably.

Our ability to commercialize DSUVIA or our product candidates, if approved, in the United States, and any collaboration partner's ability to commercialize DZUVEO or Zalviso in Europe successfully will depend, in part, on the extent to which coverage and adequate reimbursement will be available from government payer programs at the federal and state levels, authorities, including Medicare and Medicaid, private health insurers, managed care plans and other third-party payers.

No uniform policy requirement for coverage and reimbursement for drug products exists among third-party payers in the United States or Europe. Therefore, coverage and reimbursement can differ significantly from payer to payer. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our inability to promptly obtain and sufficiently maintain coverage and adequate reimbursement rates from third party payers could significantly harm our operating results, our ability to raise capital needed to commercialize our approved drugs and our overall financial condition.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. There have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell our products profitably. These legislative and/or regulatory changes may negatively impact the reimbursement for our products, following approval. The availability of numerous generic pain medications may also substantially reduce the likelihood of reimbursement for DSUVIA or Zalviso, if approved, in the United States, and DSUVIA/DZUVEO and Zalviso in Europe and elsewhere. The application of user fees to generic drug products may expedite the approval of additional pain medication generic drugs. We expect to experience pricing pressures in connection with our sales of DSUVIA and Zalviso, if approved, in the United States, and future product sales of Zalviso and DZUVEO in Europe, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

Furthermore, market acceptance and sales of our products will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payers, such as private health insurers, hospitals and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that reimbursement will be available for DSUVIA or our product candidates, if approved, in the United States, or DZUVEO or Zalviso in Europe. Also, reimbursement amounts may reduce the demand for, or the price of, our products. For example, studies of DZUVEO in Europe may be needed to ensure premium reimbursement in certain countries. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize DSUVIA or our product candidates, if approved, in the United States, or DZUVEO or Zalviso in Europe.

Additionally, the regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues able to be generated from the sale of the product in that country. For example, separate pricing and reimbursement approvals may impact any future collaboration partners' ability to market and successfully commercialize our products in the 27 member states of the European Union. Adverse pricing limitations may hinder our ability to recoup our investment in DSUVIA in the United States, or Zalviso, even after obtaining FDA marketing approval.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If we are found to have improperly promoted off-label uses of our products, including DSUVIA or our product candidates, if approved, in the United States, we may become subject to significant liability. Such enforcement has become more common in the industry. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription drug products. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. While we have received marketing approval for DSUVIA for our proposed indication, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment it could be used in such manner. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties and a requirement for corrective advertising, including Dear Doctor letters. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, increased losses and diminished profits and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. The FDA or other enforcement authorities could also request that we enter into a consent decree or a corporate integrity agreement or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of DSUVIA or our product candidates, if approved, in the United States, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

If we are unable to establish and maintain relationships with group purchasing organizations any future revenues or future profitability could be jeopardized.

Many end-users of pharmaceutical products have relationships with group purchasing organizations, or GPOs, whereby such GPOs provide such end-users access to a broad range of pharmaceutical products from multiple suppliers at competitive prices and, in certain cases, exercise considerable influence over the drug purchasing decisions of such end-users. Hospitals and other end-users contract with the GPO of their choice for their purchasing needs. We expect to derive revenue from end-user customers that are members of GPOs for DSUVIA and our product candidates, if approved. Establishing and maintaining strong relationships with these GPOs will require us to be a reliable supplier, remain price competitive and comply with FDA regulations. The GPOs with whom we have relationships may have relationships with manufacturers that sell competing products, and such GPOs may earn higher margins from these products or combinations of competing products or may prefer products other than ours for other reasons. If we are unable to establish or maintain our GPO relationships, sales of DSUVIA and our product candidates, if approved, and related revenues could be negatively impacted.

We intend to rely on a limited number of distributors and pharmaceutical wholesalers to distribute DSUVIA and our product candidates, if approved, in the United States.

We intend to rely primarily upon distributors and pharmaceutical wholesalers in connection with the distribution of DSUVIA and our product candidates, if approved, in the United States. As part of the DSUVIA REMS program, we monitor distribution and audit wholesalers' data and will monitor such data from other distributors. If our distributors and wholesalers do not comply with the DSUVIA REMS requirements, or if we are unable to establish or maintain our business relationships with these distributors and pharmaceutical wholesalers on commercially acceptable terms, or if our distributors and wholesalers are unable to distribute our drugs for regulatory, compliance or any other reason, it could have a material adverse effect on our sales and may prevent us from achieving profitability.

Risks Related to Our Planned Acquisition of Lowell Therapeutics, Inc.

The failure to complete our planned acquisition of Lowell Therapeutics, Inc. in a timely manner or at all, may adversely affect our business and our stock price.

Our and Lowell Therapeutics, Inc.'s, or Lowell's, obligations to consummate our planned acquisition of Lowell are subject to the satisfaction or waiver of certain customary conditions, including, among others, (i) the adoption of the Agreement and Plan of Merger and the transactions contemplated therein by the stockholders of Lowell; (ii) the absence of any law or governmental order enacted, issued, promulgated, enforced, threatened or entered by a governmental entity restraining, enjoining or prohibiting the consummation of the Mergers or any of the other transactions contemplated by the Merger Agreement; (iii) compliance in all material respects with certain agreements and covenants; (iv) certain document delivery requirements; (v) subject to certain qualifications, the accuracy of the representations and warranties of the parties and compliance by the parties with their respective obligations under the Merger Agreement; and (vi) any regulatory approvals that are required by law shall have been obtained or shall have occurred or the applicable waiting period shall have expired. In addition, our obligation to consummate our planned acquisition of Lowell are subject to the satisfaction or waiver of certain other conditions, including, among others, (i) the absence of certain legal proceedings wherein an unfavorable result could reasonably be expected to prevent consummation of the transactions contemplated by the Merger Agreement, cause such transactions to be rescinded following consummation, or be material to us or Lowell; (ii) stockholders of Lowell representing on hundred percent (100%) of the issued and outstanding shares of the Lowell and all Lowell option holders shall have executed and delivered joinders to the Merger Agreement; (iii) Lowell shall have no less than $3.5 million in immediately available funds; (iv) stockholders representing not more than ten percent (10%) of issued and outstanding shares of Lowell shall have indicated they are seeking appraisal rights; and (v) the absence of any material adverse effect on Lowell since the date of the Merger Agreement. We cannot provide assurance that these or the other conditions to the completion of the planned acquisition of Lowell will be satisfied in a timely manner or at all. In addition, other factors may affect when and whether the acquisition will occur. If our planned acquisition of Lowell is not completed, our share price could fall to the extent that our current price reflects an assumption that we will complete the planned acquisition. Furthermore, if the planned acquisition of Lowell is not completed and the Merger Agreement is terminated, we may suffer other consequences that could adversely affect our business, results of operations and share price, including the following:

- we have incurred and will continue to incur costs relating to the planned acquisition (including significant legal fees) and these costs are payable by us whether or not the planned acquisition is completed;
- matters relating to the planned acquisition may require substantial commitments of time and resources by our management team, which could otherwise have been devoted to other opportunities that may have been beneficial to us;
- we may be subject to legal proceedings related to the acquisition or the failure to complete the acquisition;
- the failure to consummate the acquisition may result in negative publicity and a negative impression of us in the investment community; and
- any disruptions to our business resulting from the announcement and pendency of the acquisition, including any adverse changes in our relationships with our customers, suppliers, collaboration partners and employees, may continue or intensify in the event the Mergers are not consummated.

Uncertainty about our planned acquisition of Lowell may adversely affect our business and stock price, whether or not the planned acquisition is completed.

We are subject to risks in connection with the announcement and pendency of our planned acquisition of Lowell, including the pendency and outcome of any legal proceedings against us, our directors and others relating to the planned acquisition and the risks from possibly foregoing opportunities we might otherwise pursue absent the planned acquisition of Lowell. Furthermore, uncertainties about the planned acquisition may cause our current and prospective employees to experience uncertainty about their future with us. These uncertainties may impair our ability to retain, recruit or motivate key management and other personnel.

In addition, in response to the announcement of our planned acquisition of Lowell, our existing or prospective customers, suppliers or collaboration partners may:

- delay, defer or cease purchasing our products or providing goods or services to us;
- delay or defer other decisions concerning us, or refuse to extend credit terms to us;
- cease further joint development activities; or
- otherwise seek to change the terms on which they do business with us.

While we are attempting to address these potential risks with our existing and prospective customers, suppliers or collaboration partners, they may be reluctant to purchase our products, supply us with goods and service or continue collaborations due to the potential uncertainty about the direction of our product offerings and the support and service of our products after we complete the planned acquisition of Lowell.

We may fail to realize the benefits expected from our planned acquisition of Lowell, which could adversely affect our stock price.

Our planned acquisition of Lowell, if completed, will be our largest acquisition to date. The anticipated benefits we expect from the planned acquisition are, necessarily, based on projections and assumptions about the combined businesses of our company and Lowell, which may not materialize as expected or which may prove to be inaccurate. The value of our common stock following the completion of the planned acquisition could be adversely affected if we are unable to realize the anticipated benefits from the acquisition on a timely basis or at all. Achieving the benefits of the planned acquisition of Lowell will depend, in part, on our ability to integrate the business, operations and products of Lowell successfully and efficiently with our business. The challenges involved in this integration include, but are not limited to, (i) difficulties entering new markets and integrating new product candidates with which we have no or limited direct prior experience; and (ii) successfully managing relationships with our combined supplier base.

The financial results of the combined company may be adversely affected by cash expenses and non-cash accounting charges incurred in connection with our integration of the business and operations of Lowell. The amount and timing of these possible charges are not yet known. Further, our failure to identify or accurately assess the magnitude of certain liabilities we are assuming in the acquisition could result in unexpected litigation or regulatory exposure, unfavorable accounting charges, unexpected increases in taxes due, a loss of anticipated tax benefits or other adverse effects on our business, operating results or financial condition. The price of our common stock following the acquisition could decline to the extent the combined company's financial results are materially affected by any of these events.

The issuance of shares of our common stock in connection with the planned acquisition of Lowell will dilute our stockholders' ownership interest in us.

Pursuant to the Merger Agreement, we will acquire Lowell in a transaction valued at approximately $32.5 million plus net cash acquired, and subject to certain other adjustments. The transaction value includes approximately $26.0 million of contingent consideration payable upon the achievement of regulatory and sales-based milestones. If the acquisition of Lowell is completed, up to an amount of common stock valued at approximately $6.5 million will be issued to Lowell securityholders at the closing, subject to the condition to closing that Lowell has at least $3.5 million in cash at the closing and assuming that certain stockholders of Lowell elect to receive merger consideration up to $3.5 million payable in cash. If those stockholders do not elect to receive cash, the amount of shares of common stock issued by the Company will be greater. This issuance of shares of our common stock will dilute your ownership interest in us, and you will have a reduced ownership and voting interest in us following the completion of this transaction. In addition, if we elect to settle any contingent value rights through the issuance of additional shares of common stock, you will experience further dilution.

Risks Related to Clinical Development and Regulatory Approval

Our expectations for FDA approvability of the Aguettant pre-filled syringe products may be inaccurate, and we may be required to conduct additional manufacturing, nonclinical or clinical development work in order to obtain FDA approval for these products, which would add to our expenses and delay any associated revenue.*

On July 14, 2021, we entered into the PFS Agreement with Aguettant pursuant to which we obtained the exclusive right to develop and, subject to FDA approval, commercialize in the United States (i) an ephedrine pre-filled syringe containing 10 ml of a solution of 3 mg/ml ephedrine hydrochloride for injection, and (ii) a phenylephrine pre-filled syringe containing 10 ml of a solution of 50 mcg/ml phenylephrine hydrochloride for injection. Aguettant will supply us with the products for use in commercialization, if they are approved in the U.S. Our current expectation is that the PFS products will be approvable by the FDA without additional manufacturing, nonclinical or clinical development, but we have not met with FDA yet to obtain their feedback on the available data to support the PFS products. If, after meeting with the FDA, we determine that additional development work will be needed for U.S. approval, we would incur additional expense and be delayed in obtaining any revenue from the PFS products.

Existing and future legislation may increase the difficulty and cost for us to commercialize our products and affect the prices we may obtain.*

In the United States and some foreign jurisdictions, the legislative landscape continues to evolve, including changes to the regulation of opioid-containing products. There have been a number of legislative and regulatory changes and proposed changes regarding healthcare systems that could prevent or delay marketing approval of Zalviso outside of Europe. These changes will restrict or regulate post-approval activities for DSUVIA, DZUVEO and Zalviso, and affect our ability to profitably sell any products for which we obtain marketing approval. For example, in February 2016, the FDA announced a comprehensive action plan to take concrete steps towards reducing the impact of opioid abuse on American families and communities. As part of this plan, the FDA announced that it intended to review product and labeling decisions and re-examine the risk-benefit paradigm for opioids. In June 2019, the FDA issued draft guidance related to a new benefit/risk framework for new opioid analgesic products, which proposes that the new product candidate show some benefit over an existing product. In September 2019, the FDA held a public hearing to receive stakeholder input on the approval process for new opioids. In January 2020, FDA's Anesthetic and Analgesic Drug Products Advisory Committee recommended against the approval of a new opioid analgesic, oxycodegol, the NDA for which was subsequently withdrawn by its sponsor. The timing of the resubmission of the Zalviso NDA is dependent upon the finalization of the FDA's new opioid approval guidelines and process.

In the European Union, or EU, the pricing of prescription drugs is subject to government control. The EU also provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. In addition, the EMA has a "sunset clause" which provides that the marketing authorization of a medicine will cease to be valid if it is not placed on the market within three years of the authorization being granted or if it is removed from the market for three consecutive years; however, the European Commission has extended this date to December 31, 2022 for DZUVEO.

In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, was enacted in an effort to, among other things, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, impose new taxes and fees on the health industry and impose additional health policy reforms. Aspects of the Affordable Care Act that may impact our business include:

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- expansion of eligibility criteria for Medicaid programs, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance; and
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The Affordable Care Act continues to substantially change health care financing and delivery by both governmental and private insurers, which may increase our regulatory burdens and operating costs.

There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. Moreover, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is also unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act. We expect that the Affordable Care Act and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to successfully commercialize our products. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our products may lose regulatory approval and we may not achieve or sustain profitability, which would adversely affect our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. Aggregate reductions of Medicare payments to providers of 2% per fiscal year went into effect on April 1, 2013 and due to subsequent legislative amendments to the statute will stay in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic, unless Congressional action is taken. The American Taxpayer Relief Act further reduced Medicare payments to several providers, including hospitals.

Moreover, the Drug Supply Chain Security Act of 2013 imposes additional obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product.

In the United States, there has been increasing legislative and enforcement interest with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, President Trump announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which has also been delayed until January 1, 2023. Further, on November 20, 2020, the Centers for Medicare & Medicaid Services, or CMS, issued an interim final rule implementing President Trump's Most Favored Nation, or MFN, executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the MFN model, on August 10, 2021, CMS published a proposed rule that seeks to rescind the MFN Model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. Furthermore, even after initial price and reimbursement approvals, reductions in prices and changes in reimbursement levels can be triggered by multiple factors, including reference pricing systems and publication of discounts by third party payers or authorities in other countries. In Europe, prices can be reduced further by parallel distribution and parallel trade (i.e., arbitrage between low-priced and high-priced countries). If any of these events occur, revenue from sales of Zalviso and DZUVEO in Europe would be negatively affected.

Legislative and regulatory proposals have been made to expand post-approval requirements and further restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our products, if any, may be.

We expect that additional healthcare reform measures will be adopted within and outside the United States in the future, any of which could negatively impact our business. For instance, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect the demand for any drug products for which we have obtained or may obtain regulatory approval, our ability to set a price that we believe is fair for our products, our ability to obtain coverage and reimbursement approval for a product, our ability to generate revenues and achieve or maintain profitability, and the level of taxes that we are required to pay.

We may experience market resistance, delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy regarding opioids generally, and sufentanil specifically.

In February 2016, the FDA announced a comprehensive action plan to take concrete steps towards reducing the impact of opioid abuse on American families and communities. As part of this plan, the FDA announced that it intended to review product and labeling decisions and re-examine the risk-benefit paradigm for opioids. In June 2019, the FDA issued draft guidance related to a new benefit/risk framework for new opioid analgesic products, which proposes that the new product candidate show some benefit over an existing product. In September 2019, the FDA held a public hearing to receive stakeholder input on the approval process for new opioids. The timing of the resubmission of the Zalviso NDA is dependent upon the finalization of the FDA's new opioid approval guidelines and process.

In May 2017, an Opioid Policy Steering Committee was established to address and advise regulators on opioid use. The Committee was charged with three initial questions: (i) should the FDA require mandatory education for healthcare professionals, or HCPs, who prescribe opioids; (ii) should the FDA take steps to ensure the number of prescribed opioid doses is more closely tailored to the medical indication; and (iii) is the FDA properly considering the risk of abuse and misuse of opioids during its drug review process. Zalviso has not been designed with an abuse-deterrent formulation and is not tamper-resistant. As a result, Zalviso has not undergone testing for tamper-resistance or abuse deterrence.

The FDA can delay, limit or deny marketing approval for many reasons, including:

- a product candidate may not be considered safe or effective;
- the manufacturing processes or facilities we have selected may not meet the applicable requirements; and
- changes in their approval policies or adoption of new regulations may require additional work on our part.

Part of the regulatory approval process includes compliance inspections of manufacturing facilities to ensure adherence to applicable regulations and guidelines. The regulatory agency may delay, limit or deny marketing approval of our product candidate, Zalviso, as a result of such inspections. We, our contract manufacturers, and their vendors, are all subject to preapproval and post-approval inspections at any time. The results of these inspections could impact our ability to obtain FDA approval for Zalviso and, if approved, our ability to launch and successfully commercialize Zalviso in the United States. In addition, results of FDA inspections could impact our ability to maintain FDA approval of DSUVIA, and our ability to expand and sustain commercial sales of DSUVIA in the United States.

Any delay in, or failure to receive or maintain, approval for Zalviso in the United States could prevent us from generating meaningful revenues or achieving profitability. Zalviso may not be approved even if we believe it has achieved its endpoints in clinical trials. Regulatory agencies, including the FDA, or their advisors, may disagree with our trial design and our interpretations of data from preclinical studies and clinical trials. Regulatory agencies may change requirements for approval even after a clinical trial design has been approved. The FDA exercises significant discretion over the regulation of combination products, including the discretion to require separate marketing applications for the drug and device components in a combination product. Zalviso is being regulated as a drug product under the NDA process administered by the FDA. The FDA could in the future require additional regulation of Zalviso, or DSUVIA, under the medical device provisions of the Federal Food, Drug and Cosmetic Act, or FDCA. We must comply with the Quality Systems Regulation, or QSR, which sets forth the FDA's current good manufacturing practice, or cGMP, requirements for medical devices, and other applicable government regulations and corresponding foreign standards for drug cGMPs. If we fail to comply with these regulations, it could have a material adverse effect on our business and financial condition.

Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing trials. For example, DSUVIA is subject to a deferred post-marketing requirement for study in the pediatric population ages 6-17 years. As required in the DSUVIA FDA approval letter, a final protocol for this trial was submitted to the FDA in August 2020, in conjunction with a request to defer initiation of pediatric studies until additional post-market safety data is obtained in adult patients using DSUVIA. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. For example, we intend to seek approval of Zalviso for the management of moderate-to-severe acute pain in adult patients in the hospital setting; however, our clinical trial data was generated exclusively from the post-operative segment of this population, and the FDA may restrict any approval to post-operative patients only, which would reduce the size of the commercial opportunity.

The success of Zalviso relies, in part, on obtaining regulatory approval in the United States.

The success of Zalviso relies, in part, upon our ability to develop and receive regulatory approval of this product candidate in the United States for the management of moderate-to-severe acute pain in adult patients in the hospital setting. Our Phase 3 program for Zalviso initially consisted of three Phase 3 clinical trials. We reported positive top-line data from each of these trials and submitted an NDA for Zalviso to the FDA in September 2013, which the FDA then accepted for filing in December 2013. In July 2014, the FDA issued a Complete Response Letter, or CRL, for our NDA for Zalviso, or the Zalviso CRL. The Zalviso CRL contained requests for additional information on the Zalviso System to ensure proper use of the device. The requests include submission of data demonstrating a reduction in the incidence of device errors, changes to address inadvertent dosing, among other items, and submission of additional data to support the shelf life of the product. Furthermore, in March 2015, we received correspondence from the FDA stating that in addition to the bench testing and two Human Factors studies we had performed in response to the issues identified in the Zalviso CRL, a clinical trial was needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures. Based on the results of our Type C meeting with the FDA in September 2015, we completed the protocol review with the FDA and initiated this study, IAP312, in September 2016.

IAP312 was a Phase 3 study in post-operative patients designed to evaluate the effectiveness of changes made to the functionality and usability of the Zalviso device and to take into account comments from the FDA on the study protocol. The IAP312 study was designed to rule out a 5% device failure rate. The study design required a minimum of 315 patients. In the IAP312 study, sites proactively looked for tablets that were dispensed by the patient but failed to be placed under the tongue, known as dropped tablets. The FDA refers to dropped tablets as inadvertent dispensing. Correspondence from the FDA suggests that they may include the rate of inadvertent dispensing along with the device failures to calculate a total error rate. The IAP312 study evaluated all incidents of misplaced tablets; however, per the protocol, the error rate calculation does not include the rate of inadvertent dispensing. If the FDA includes the rate of inadvertent dispensing along with the device failures to calculate a total error rate, the resulting error rate may be unacceptable to the FDA. Further, the correspondence from the FDA suggests that we may need to modify the REMS program for Zalviso to address dropped tablets. The IAP312 results will supplement the three Phase 3 trials already completed in the Zalviso NDA resubmission. The timing of the resubmission of the Zalviso NDA is dependent upon the finalization of the FDA's new opioid approval guidelines and process.

There is no guarantee that the additional work we performed related to Zalviso, including the IAP312 trial, will result in our successfully obtaining FDA approval of Zalviso in a timely fashion, if at all. Although we believe the IAP312 study met safety, satisfaction and device usability expectations, there is no guarantee the IAP312 trial results will address the issues raised by the FDA. For example, the FDA may include the rate of inadvertent dispensing along with the device failures to calculate a total error rate and the resulting error rate may be unacceptable to the FDA, or the FDA may still have concerns regarding the performance of the device, inadvertent dosing (dropped tablets), or other issues. At any future point in time, the FDA could require us to complete further clinical, Human Factors, pharmaceutical, reprocessing or other studies, which could delay or preclude any NDA resubmission or approval of the NDA and could require us to obtain significant additional funding. We may not be able to identify appropriate remediations to issues that the FDA may raise, and we may not have sufficient time or financial resources to conduct future activities to remediate issues raised by the FDA. We intend to seek a label indication for Zalviso for the management of moderate-to-severe acute pain in adult patients in the hospital setting. However, our clinical trial data was generated exclusively from the post-operative segment of this population, and the FDA may restrict any approval to post-operative patients only, which would reduce our commercial opportunity.

Upon resubmission of the Zalviso NDA, the FDA may hold an advisory committee meeting to obtain committee input on the safety and efficacy of Zalviso. Typically, advisory committees will provide responses to specific questions asked by the FDA, including the committee's view on the approvability of the drug under review. Advisory committee decisions are not binding, but an adverse decision at the advisory committee may have a negative impact on the regulatory review of Zalviso. Additionally, we may choose to engage in the dispute resolution process with the FDA.

Our proposed trade name of Zalviso has been approved by the EMA and is currently being used in Europe. It has also been conditionally approved by the FDA, which must approve all drug trade names to avoid medication errors and misbranding. However, the FDA may withdraw this approval in which case any brand recognition or goodwill that we establish with the name Zalviso prior to commercialization may be worthless.

Any delay in approval by the FDA of the Zalviso NDA, once it is resubmitted, may negatively impact our stock price and harm our business operations. Any delay in obtaining, or inability to obtain, regulatory approval would prevent us from commercializing Zalviso in the United States, generating revenues and potentially achieving profitability. If any of these events occur, we may be forced to delay or abandon our development efforts for Zalviso, which would have a material adverse effect on our business.

Positive clinical results obtained to date for Zalviso may be disputed in FDA review, do not guarantee regulatory approval and may not be obtained from future clinical trials.

We have reported positive top-line data from each of our four Zalviso Phase 3 clinical trials completed to date, as well as our Phase 2 clinical trials for Zalviso. However, even if we believe that the data obtained from clinical trials is positive, the FDA has, and in the future could, determine that the data from our trials was negative or inconclusive or could reach a different conclusion than we did on that same data. Negative or inconclusive results of a clinical trial or difference of opinion could cause the FDA to require us to repeat the trial or conduct additional clinical trials prior to obtaining approval for commercialization, and there is no guarantee that additional trials would achieve positive results or that the FDA will agree with our interpretation of the results. If the FDA were to require any additional clinical trials for Zalviso, our development efforts would be further delayed, which would have a material adverse effect on our business. Any such determination by the FDA would delay the timing of our commercialization plan for Zalviso and adversely affect our business operations.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We have experienced and may in the future experience delays in clinical trials of our product candidates. While we have completed four Phase 3 clinical trials and several Phase 2 clinical trials for Zalviso, future clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. For example, we postponed the start of IAP312, originally planned for the first quarter of 2016, to September 2016. The postponement was due to a delay in the receipt and testing of final clinical supplies for this trial. As a result, the development timeline for Zalviso was further extended.

Our post-approval clinical trials for DSUVIA, or any future FDA-required clinical trials for Zalviso, could be delayed for a variety of reasons, including:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;

- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold by the FDA, Institutional Review Board, or IRB, or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required IRB approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in the testing, validation, manufacture and delivery of the tablets and device components of DSUVIA or Zalviso;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment or being delayed in entering data to allow for clinical trial database closure;
- time required to add new clinical sites; or
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

If any future FDA-required clinical trials are delayed for any reason, our development costs may increase, our approval process for Zalviso could be delayed, our ability to commercialize and commence sales of Zalviso could be materially harmed, and our ability to maintain FDA approval of DSUVIA could be jeopardized, which could have a material adverse effect on our business.

Zalviso may cause adverse effects or have other properties that could delay or prevent regulatory approval or limit the scope of any approved label or market acceptance. DSUVIA may cause adverse effects or have other properties that could limit market acceptance.

Adverse events, or AEs, caused by Zalviso could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt any future FDA-required clinical trials and could result in the denial of regulatory approval. Phase 2 clinical trials we conducted with Zalviso did generate some AEs, but no significant adverse events, or SAEs, related to the trial drug. In our Phase 3 active-comparator clinical trial (IAP309), 8% of Zalviso-treated patients dropped out of the trial prematurely due to an AE (11% in the IV patient-controlled morphine group), and we observed three SAEs that were assessed as possibly or probably related to study drug (one- respiratory depression in the Zalviso group and two- abdominal distension and ileus in the IV patient-controlled morphine group). In our Phase 3, double-blind, placebo-controlled, abdominal surgery trial (IAP310), 6% of Zalviso-treated patients dropped out of the trial prematurely due to an AE (9% in placebo group). There were no SAEs determined to be related to study drug. In our Phase 3, double-blind, placebo-controlled, orthopedic surgery trial (IAP311), 7% of Zalviso-treated patients dropped out of the trial prematurely due to an AE (7% in placebo group). Four patients (three in the Zalviso group and one in the placebo group) experienced an SAE considered possibly or probably related to the trial drug by the investigator. The SAEs possibly or probably attributed to Zalviso were severe oxygen saturation decrease, sinus tachycardia and confusional state. In our Phase 3 multicenter, open-label study of Zalviso (IAP312), 3% of patients dropped out prematurely due to an AE. Five patients experienced SAEs in the IAP312 study and none of these were considered possibly or probably related to the study drug by the investigator.

In our Phase 2 DSUVIA placebo-controlled bunionectomy study (SAP202), two patients in the DSUVIA 30 mcg group (5%) discontinued treatment due to an AE, one unrelated to study drug and the other probably related to study drug. There were no SAEs deemed related to study drug. In our Phase 3 placebo-controlled abdominal surgery study (SAP301), one DSUVIA-treated patient (1%) dropped out of the trial prematurely due to an AE (4% in placebo group). There were two SAEs determined to be related to study drug in the placebo-treated group and no related SAEs in the DSUVIA group. In our Phase 3 open-label, single-arm emergency room study (SAP302), no DSUVIA-treated patients dropped out of the trial prematurely due to an AE. One patient had an SAE - angina pectoris - possibly related to study drug. In our post-operative study in patients aged 40 years or older (SAP303), 3% of DSUVIA-treated patients dropped out of the trial prematurely due to an AE. There were no SAEs deemed related to study drug.

If DSUVIA or, if approved, Zalviso cause serious or unexpected side effects after receiving marketing approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in the form of a modified REMS program;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of DSUVIA or, if approved, Zalviso, and could substantially increase the costs of commercializing our products.

Additional time may be required to obtain U.S. regulatory approval for Zalviso because it is a drug/device combination product candidate.

DSUVIA and Zalviso are combination products with both drug and device components. The FDA requires both the drug and device components of combination product candidates to be reviewed as part of an NDA submission. There are very few examples of the FDA approval process for drug/device combination products such as DSUVIA and Zalviso. As a result, we experienced delays in the development and commercialization of DSUVIA, and may experience future delays in the development and commercialization of Zalviso, due to regulatory uncertainties in the product development and approval process, in particular as it relates to a drug/device combination product approval under an NDA.

The process for obtaining approval of an NDA is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources.

If the FDA determines that any of the clinical work submitted, including the clinical trials, Human Factors studies and bench testing submitted for a product candidate in support of an NDA were not conducted in full compliance with the applicable protocols for these trials, studies and testing as well as with applicable regulations and standards, or if the FDA does not agree with our interpretation of the results of such trials, studies and testing, the FDA may reject the data and results. The FDA may audit some or all of our clinical trial sites to determine the integrity of our clinical data. The FDA may audit some or all of our Human Factors study sites to determine the integrity of our data and may audit the data and results of bench testing. Any rejection of any of our data would negatively impact our ability to obtain marketing authorization for our product candidate, Zalviso, and would have a material adverse effect on our business and financial condition. In addition, an NDA may not be approved, or approval may be delayed, as a result of changes in FDA policies for drug approval during the review period. For example, although many products have been approved by the FDA in recent years under Section 505(b)(2) of the FDCA, objections have been raised to the FDA's interpretation of Section 505(b)(2). If challenges to the FDA's interpretation of Section 505(b) (2) are successful, the FDA may be required to change its interpretation, which could delay or prevent the approval of such an NDA. More generally, the FDA's comprehensive action plan to take concrete steps towards reducing the impact of opioid abuse on American families and communities may result in delays and challenges in obtaining NDA approval. Any significant delay in the acceptance, review or approval of an NDA that we have submitted would have a material adverse effect on our business and financial condition and would require us to obtain significant additional funding.

Although we have obtained regulatory approval for DSUVIA, and even if we obtain regulatory approval for Zalviso in the United States, we and our collaborators face extensive regulatory requirements, and our products may face future development and regulatory difficulties.*

Although we have obtained regulatory approval for DSUVIA, and even if we obtain regulatory approval for Zalviso in the United States, the FDA may impose significant restrictions on the indicated uses or marketing of our products or impose ongoing requirements for potentially costly post-approval trials or post-market surveillance. For example, DSUVIA is subject to a deferred post-marketing requirement for study in the pediatric population ages 6-17 years. A final protocol for this trial was submitted to the FDA in August 2020, in conjunction with a request to defer initiation of pediatric studies until additional post-market safety data is obtained in adult patients using DSUVIA. Additionally, the labeling approved for DSUVIA includes restrictions on use due to the opioid nature of sufentanil. If approved, the labeling for Zalviso will likely include similar restrictions on use.

DSUVIA in the United States is also subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process.

Advertising and promotional materials must comply with FDA rules concerning the advertising and promotion of DSUVIA and are subject to FDA review, in addition to other potentially applicable federal and state laws. Failure to comply with these regulations can result in the receipt of warning letters and further liability if off-label promotion is involved. For example, on February 11, 2021, we received a warning letter from the Office of Prescription Drug Promotion, or OPDP, of the FDA relating to a banner advertisement we submitted to the OPDP on December 6, 2019, and a tabletop display we submitted on February 28, 2020, and resubmitted to the OPDP at its request on September 23, 2020. We submitted the materials to the OPDP pursuant to the FDA requirement that sponsors submit all promotional materials to the FDA at the time of their initial dissemination or publication. The FDA's concerns identified in the letter include its view that the promotional material makes misleading claims and representations about the risks and efficacy of DSUVIA because the material does not reveal facts that are material in light of the representations made. As a result, we conducted a review of our marketing materials to identify any potential revisions in light of the letter. We responded to the FDA within the timeframe requested in the letter and, on March 23, 2021, held a teleconference with OPDP to seek guidance and clarification on the concerns raised in the letter. Following our meeting with OPDP, we conducted a further review of our marketing materials to identify any potential revisions in light of the letter and OPDP's guidance. We submitted a second response to FDA on April 7, 2021, and on June 17, 2021 we announced that the FDA agreed with our proposed plan to update certain promotional materials, including providing a letter to healthcare professionals, or the DHCP letter, explaining the corrections to the discontinued promotional materials. We will also include this DHCP letter on the DSUVIA.com website for a period of eight months. Although we believe we have updated all promotional materials currently in use by our commercial team to address the FDA's concerns and we expect to receive a close-out letter from the FDA after the DHCP letters have been sent to the identified healthcare professionals and the letter has been posted on the website for eight months, we cannot give any assurances that we will receive such close-out letter or that we will not receive additional FDA warning letters in the future. If approved, Zalviso will be subject to these same requirements.

We must also register and obtain various state prescription drug distribution licenses and controlled substance permits, and any delay or failure to obtain or maintain these licenses or permits may limit our market and materially impact our business. In certain states we cannot apply for a license until a drug is approved by the FDA. The state licensing process may take several months which would delay commercialization in those states. In addition, manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs and adherence to commitments made in the NDA. If we, or a regulatory agency, discover previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facilities, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of our products, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize DSUVIA, or, if approved, Zalviso, and generate revenues.

Except for Zalviso and DZUVEO, which are both approved in Europe, we may never obtain additional regulatory approvals for our products and product candidates outside of the United States, which would limit our ability to realize their full market potential.*

In order to market any products outside of the United States, we or our commercial partners, must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. On September 22, 2015, we announced that the EC had granted marketing approval for Grünenthal's MAA for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients. In April 2016, Grünenthal completed the first commercial sale of Zalviso. Grünenthal terminated the collaboration, effective November 13, 2020. The terms of the Grünenthal Agreements were extended to May 12, 2021 to enable Grünenthal to sell down its Zalviso inventory, a right it had under the Grünenthal Agreements. Grünenthal's rights to market and sell Zalviso reverted back to us on May 12, 2021. We have not yet negotiated a New Arrangement and there can be no assurance that we will successfully enter into a New Arrangement. In June 2018, we announced that the EC had granted marketing approval of DZUVEO for the treatment of patients with moderate-to-severe acute pain in medically monitored settings. In July 2021, we entered into the DZUVEO Agreement with Aguettant.

Part of the foreign regulatory approval process includes compliance inspections of manufacturing facilities to ensure adherence to applicable regulations and guidelines. The foreign regulatory agency may delay, limit or deny marketing approval as a result of such inspections. We, our contract manufacturers, and their vendors, are all subject to preapproval and post-approval inspections at any time. The results of these inspections could impact our ability to obtain regulatory approval of DSUVIA and Zalviso in countries outside of the United States and Europe, or our ability to launch and successfully commercialize these products, once approved. In addition, results of EMA inspections could impact our ability to maintain EC approval of Zalviso and DZUVEO, and any future collaboration partner's ability to expand and sustain commercial sales of Zalviso or DZUVEO in Europe.

Outside of Europe, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical trials or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country-to-country and could delay or prevent the introduction of our products in those countries. Our current clinical trial data may not be sufficient to support marketing approval or premium reimbursement in all territories. For example, we anticipate we may need comparator studies for DZUVEO in Europe to ensure premium reimbursement in certain countries. While we have obtained approval of DZUVEO in Europe, we will be substantially dependent on Aguettant to comply with regulatory requirements. If we, or our commercial partners, fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

DSUVIA requires, and, if approved, Zalviso will require, a REMS program.

DSUVIA was approved in the United States with a REMS program. If Zalviso is approved in the United States, it will also require a REMS program. The DSUVIA REMS program includes restrictions on product distribution and use only in certified medically supervised settings. Before DSUVIA is distributed, an authorized representative from each medically supervised setting must sign an attestation that they have the ability to manage acute opioid overdose and will train all relevant staff on administration of DSUVIA, including the importance of only dispensing the product in a medically supervised setting. Therefore, REMS-certification is a key gating item to generating product revenues for DSUVIA. In addition, the REMS program for DSUVIA may significantly increase our costs to commercialize this product. While we have received pre-clearance from the FDA regarding certain aspects of the proposed required REMS program for Zalviso, we cannot predict the final REMS program to be required as part of any FDA approval of Zalviso. Depending on the extent of the REMS requirements, any U.S. launch may be delayed, the costs to commercialize Zalviso may increase substantially and the potential commercial market could be restricted. Furthermore, risks of sufentanil that are not adequately addressed through the proposed REMS program for Zalviso may also prevent or delay its approval for commercialization.

Risks Related to Our Financial Condition and Need for Additional Capital

We have incurred significant losses since our inception, anticipate that we will continue to incur significant losses in 2021 and may continue to incur losses in the future.*

We have incurred significant net losses in each year since our inception in July 2005, and as of September 30, 2021, we had an accumulated deficit of $465.7 million.

We have devoted most of our financial resources to research and development, including our non-clinical development activities and clinical trials. To date, we have financed our operations primarily through the issuance of equity securities, borrowings, payments from Grünenthal, the monetization of certain future royalties and commercial sales milestones from the European sales of Zalviso by Grünenthal, funding from the Department of Defense, or DoD, and more recently with revenues from sales of DSUVIA since the commercial launch in the first quarter of 2019 and the upfront payment under the DZUVEO Agreement with Aguettant. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenues. We expect to continue to incur substantial expenses as we support commercialization activities for DSUVIA, manufacturing and supply activities for DZUVEO, and research and development activities for Zalviso and the PFS Products, including the FDA regulatory review of the Zalviso NDA, once resubmitted. If DSUVIA is not successfully commercialized in the U.S., if our product candidates are not successfully developed or commercialized in the U.S., or if revenues are insufficient following marketing approval, we will not achieve profitability and our business may fail. Our success is also dependent on current and future collaborations to market our products outside of the United States, which may not materialize or prove to be successful.

We have not yet generated significant product revenue and may never be profitable.

Our ability to generate revenue from commercial sales and achieve profitability depends on our ability, alone and with collaborators, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize our products. Although we received FDA approval of DSUVIA and began the commercial launch of DSUVIA in the United States, we may never generate enough revenues from sales of DSUVIA, or our product candidates, if approved, in the United States to become profitable. Although the EC granted marketing approval of DZUVEO in June 2018, we only recently entered into the DZUVEO Agreement with Aguettant to commercialize DZUVEO in Europe and there can be no assurance that Aguettant will successfully commercialize DZUVEO. Although we had a collaboration agreement with Grünenthal for commercialization of Zalviso in Europe and Australia, Grünenthal was unable to achieve a level of commercial sales of Zalviso to trigger sales milestone payments that would have been payable to us. The Grünenthal Agreements have been terminated and Grünenthal’s rights to market and sell Zalviso reverted back to us on May 12, 2021.

In September 2015, we consummated a monetization transaction with PDL pursuant to which we sold to PDL for $65.0 million 75% of the European royalties from sales of Zalviso and 80% of the first four commercial milestones under the Amended License Agreement, subject to a capped amount. PDL sold its royalty interest for Zalviso to SWK in 2020. As mentioned above, Grünenthal has terminated the Grünenthal Agreements and the rights reverted back to us on May 12, 2021. Per the terms of the Royalty Monetization, we are obligated to use commercially reasonable efforts to negotiate a New Arrangement. Accordingly, even if we are able to enter into a New Arrangement, and that licensee is successful in commercializing Zalviso in Europe, we will receive only a portion of any royalties until the capped amount owing under the Royalty Monetization is reached. We do not anticipate generating significant near-term revenues from DSUVIA or our product candidates, if approved, in the United States. Our ability to generate future revenues from product sales depends heavily on our success in:

- maintaining regulatory approval for DSUVIA and obtaining and maintaining regulatory approval for our product candidates in the United States; and
- launching and commercializing DSUVIA and our product candidates, if approved, in the United States by building, internally or through collaborations, an institutionally focused sales force, and launching and commercializing DZUVEO and Zalviso internationally through collaborations, which may require additional funding.

Because of the numerous risks and uncertainties associated with launching a commercial pharmaceutical product, pharmaceutical product development and the regulatory environment, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are delayed in receiving regulatory approval for our product candidates in the United States, or if we are required by the FDA to complete activities in addition to those we currently anticipate or have already completed.

We anticipate continuing to incur significant costs associated with commercializing DSUVIA in the United States. Even if we are able to generate revenues from the sale of DSUVIA or our product candidates, if approved, in the United States, we may not become profitable and may need to obtain additional funding to continue operations.

Future sales of DSUVIA to the DoD are not predictable, may occur on an irregular basis and may not meet our expectations due to various U.S. government-related factors that are beyond our control and into which we have little to no visibility, including the timing and extent of future U.S. military deployments. If DoD spending on DSUVIA does not meet our expectations, it could adversely affect our expected results of operations, financial condition and liquidity.

In April 2020, DSUVIA achieved Milestone C approval by the DoD, a decision that clears the path for the DoD to begin placing orders for DSUVIA. In September 2020, we announced that DSUVIA was added to the DoD Joint Deployment Formulary, a core list of pharmaceutical products that are designated for deploying military units across all service branches. Future sales of DSUVIA to the DoD are not predictable, may occur on an irregular basis, and may not meet our expectations due to various U.S. government-related factors that are beyond our control and into which we have little to no visibility, including the timing and extent of future U.S. military deployments. Even if we do generate revenue from such sales, we may never generate revenue that is significant or predictable, which could impair our value and our ability to raise capital, expand our business or continue our operations. The placement of new orders by the DoD is, among other things, contingent upon overall U.S. government policies, budget and appropriation decisions and processes which are driven by numerous factors, including geo-political events, deployment of military units, macroeconomic conditions, and the ability of the U.S. government to enact relevant legislation, such as appropriations bills and accords on the debt ceiling. Our expectations about the timing and size of initial stocking orders for U.S. Army sets, kits and outfits, or SKOs, and other orders by the DoD are based on our understanding of troop deployment schedules. If DoD spending on DSUVIA does not meet our expectations, it could have a material adverse effect on our expected results of operations, financial condition and liquidity.

We have been substantially dependent on Grünenthal to successfully commercialize Zalviso in Europe and they have terminated their collaboration agreement with us.

Under our agreements with Grünenthal, we granted Grünenthal rights to commercialize Zalviso in Europe for human use in pain treatment within, or dispensed by, hospitals, hospices, nursing homes and other medically supervised settings. In September 2015, the EC granted marketing approval for Grünenthal's MAA for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients, and Grünenthal began its European launch of Zalviso with the first commercial sale occurring in April 2016. Grünenthal terminated the collaboration, effective November 13, 2020. The terms of the Grünenthal Agreements were extended to May 12, 2021 to enable Grünenthal to sell down its Zalviso inventory, a right it had under the Grünenthal Agreements. Grünenthal's rights to market and sell Zalviso reverted back to us on May 12, 2021.

During the pilot and launch phases in the various European countries, Grünenthal reported certain issues from HCPs with the initial set up of the Zalviso controllers before being given to patients for use. To address the issues, we assisted Grünenthal with implementing additional training for HCPs and revised the controller software. Controllers with the revised software, which were delivered in December 2016, underwent extensive bench testing and we believe we successfully addressed the issues presented. Additional devices were delivered beginning in early 2017. Controllers with the U.S. version of the revised software were also used in the IAP312 clinical study that was initiated in September 2016. There can be no assurance that the issues identified in the initial pilot and launch phases by Grünenthal will not have a material adverse impact on future sales of Zalviso in Europe under a New Arrangement. Further, if new issues occur, there may be a material adverse impact on the future sales of Zalviso in Europe under a New Arrangement which may have a negative impact on future revenues received and recognized by us.

We did not realize the expected benefits from our collaboration with Grünenthal, and may not realize the expected benefits from any New Arrangement, due to a number of important factors, including:

- The timing and amount of any payments we may receive under our agreements will depend on, among other things, the efforts, allocation of resources, and successful commercialization of Zalviso by any future collaboration partner in Europe;
- Grünenthal changed the focus of its commercialization efforts to pursue higher-priority programs and any future collaboration partner may do the same;
- Grünenthal stopped its commercialization efforts in countries where it had the sole right to commercialize Zalviso, requiring us to find another collaboration partner for Zalviso in Europe; and
- Grünenthal terminated its agreements with us, and any future collaboration partner may also terminate any future agreement with us, adversely affecting our potential revenue from Zalviso;

Any failures in commercialization of Zalviso outside the United States could have a material adverse impact on our business, including an adverse impact on the commercialization of DSUVIA or the development of Zalviso in the United States, if related to issues underlying the sufentanil sublingual tablet technology, safety or efficacy. Additionally, we agreed to certain representations and covenants relating to the Grünenthal Agreements under our agreements with PDL, and, if we breach those representations or covenants, we may become subject to indemnification claims by SWK (assignee of PDL) and liable to SWK for its indemnifiable losses relating to such breaches. The amount of such losses could be material and could have a material adverse impact on our business.

We will be substantially dependent on Aguettant to successfully commercialize DZUVEO in Europe.*

In June 2018, the EC granted marketing approval for DZUVEO and in July 2021 we entered into the DZUVEO Agreement with Aguettant to commercialize DZUVEO in Europe. We will be substantially dependent on Aguettant to successfully commercialize DZUVEO in Europe. Any failures in the commercialization of DZUVEO in Europe could have a significant adverse impact on our revenues and operating results.

The DZUVEO Agreement requires us to support the manufacturing and supply of DZUVEO for Aguettant. In addition, we anticipate we may need comparator studies in Europe to ensure premium reimbursement in certain countries. Our inability to profitably manufacture and supply DZUVEO to Aguettant, or to successfully complete these additional comparator studies and obtain premium reimbursement in certain countries, may prevent, limit or delay commercialization and any associated future revenues from DZUVEO in Europe.

We have limited experience commercializing DSUVIA, which may make it difficult to predict our future performance or evaluate our business and prospects.

Since inception, our operations have been primarily focused on developing our technology and undertaking pharmaceutical development and clinical trials for DSUVIA and Zalviso, understanding the market potential for DSUVIA and Zalviso, and preparing for the commercialization of DSUVIA and the potential commercialization of Zalviso in the United States. We launched commercialization efforts for DSUVIA in February 2019. As a result of our limited commercialization experience, any predictions that are made about our future performance, or viability, or evaluation of our business and prospects, may not be accurate.

We will require additional capital and may be unable to raise capital, which would force us to delay, reduce or eliminate our commercialization efforts and product development programs and could cause us to cease operations.

Launch of a commercial pharmaceutical product and pharmaceutical development activities can be time consuming and costly. We expect to incur significant expenditures in connection with supporting our ongoing commercialization activities for DSUVIA, manufacturing and supply activities for DZUVEO, and research and development activities for Zalviso and the PFS Products, including the FDA regulatory review of the Zalviso NDA, once resubmitted. While we believe we have sufficient capital resources to continue planned operations for at least the next twelve months, we will need additional capital to pursue full commercialization of DSUVIA and our product candidates, if approved.

Clinical trials, regulatory reviews, and the launch of commercial product are expensive activities. In addition, commercialization costs for DSUVIA and our product candidates, if approved, in the United States may be significantly higher than estimated as a result of technical difficulties or otherwise. Revenues may be lower than expected and costs to produce such revenues may exceed those revenues. We will need to seek additional capital to continue operations. Such capital demands could be substantial. In the future, we may seek to sell additional equity securities, including under the Sales Agreement with Cantor, and debt securities, monetize or securitize certain assets including future royalty streams and milestones, refinance our loan agreement, obtain a revolving credit facility, enter into product development, license or distribution agreements with third parties, or divest DSUVIA, DZUVEO or Zalviso. Such arrangements may not be available on favorable terms, if at all.

Future events and circumstances, including those beyond our control, may cause us to consume capital more rapidly than we currently anticipate. Furthermore, any product development, licensing, distribution or sale agreements that we enter into may require us to relinquish valuable rights. We may not be able to obtain sufficient additional funding or enter into a strategic transaction in a timely manner. If adequate funds are not available, we would be required to reduce our workforce, reduce the scope of, or cease, the commercial launch of DSUVIA, or the development of our product candidates in advance of the date on which we exhaust our cash resources to ensure that we have sufficient capital to meet our obligations and continue on a path designed to preserve stockholder value.

Securing additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to commercialize DSUVIA or develop our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly scale back or discontinue the commercialization of DSUVIA, or the development of our product candidates;
- seek additional corporate partners for Zalviso on terms that might be less favorable than might otherwise be available;
- seek corporate partners for DSUVIA/DZUVEO on terms that might be less favorable than might otherwise be available; or
- relinquish, or license on unfavorable terms, our rights to technologies or products that we otherwise would seek to develop or commercialize ourselves.

To fund our operations, we may sell additional equity securities, which may result in dilution to our stockholders, or debt securities, which may impose restrictions on our business.

We expect that significant additional capital will be needed in the future to continue our planned operations. In order to raise additional funds to support our operations, we may sell additional equity securities, including under the Controlled Equity Offering℠ Sales Agreement, or the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, as agent. We may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. Selling additional equity securities may result in dilution to our existing stockholders and new investors may be materially diluted by subsequent sales. Incurring additional indebtedness, including through the sale of debt securities, would result in increased fixed payment obligations and could also result in additional restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions, such as minimum cash balances, that could adversely impact our ability to conduct our business. Sales of equity or debt securities may also provide new investors with rights superior to our existing stockholders. If we are unable to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected, and we may not be able to meet our debt service obligations.

In addition, worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic may negatively affect the market price of our stock, regardless of our actual operating performance. The market price for our common stock is likely to continue to be volatile, particularly due to the ongoing COVID-19 pandemic, and subject to significant price and volume fluctuations in response to market, industry and other factors. If additional funding is not available on favorable terms, if at all, due to these factors, we may not be able to obtain sufficient additional funding to support our operations.

The terms of our loan agreement with Oxford may restrict our current and future operations, particularly our ability to respond to changes in business or to take certain actions, including to pay dividends to our stockholders.

On May 30, 2019, we entered into the Loan Agreement with Oxford Finance LLC, or Oxford, a Delaware limited liability company, as the Lender. The Loan Agreement contains, and any future indebtedness we incur will likely contain, a number of restrictive covenants that impose operating restrictions, including restrictions on our ability to engage in acts that may be in our best long-term interests. The Loan Agreement includes covenants that, among other things, restrict our ability to (i) declare dividends or redeem or repurchase equity interests; (ii) incur additional liens; (iii) make loans and investments; (iv) incur additional indebtedness; (v) engage in mergers, acquisitions, and asset sales; (vi) transact with affiliates; (vii) undergo a change in control; (viii) add or change business locations; and (ix) engage in businesses that are not related to our existing business. The Loan Agreement also requires that we at all times maintain unrestricted cash of not less than $5.0 million.

A breach of any of these covenants could result in an event of default under the Loan Agreement. Upon the occurrence of such an event of default, a default interest rate of an additional 5% may be applied to the outstanding loan balances and all outstanding obligations under the Loan Agreement can be declared to be immediately due and payable If our indebtedness is accelerated, we cannot assure you that we will have sufficient assets to repay the indebtedness. The restrictions and covenants in the Loan Agreement and any future financing agreements may adversely affect our ability to finance future operations or capital needs or to engage in other business activities.

We might be unable to service our existing debt due to a lack of cash flow and might be subject to default.

As of September 30, 2021, we had approximately $15.3 million of accrued debt under the Loan Agreement. The Loan Agreement has a scheduled maturity date of June 1, 2023 and is secured by a first priority security interest in substantially all of our assets, with the exception of our intellectual property and those assets sold under the Royalty Monetization, where the security interest is limited to proceeds of intellectual property if it is licensed or sold.

If we do not make the required payments when due, either at maturity, or at applicable installment payment dates, or if we breach the agreement or become insolvent, the Lender could elect to declare all amounts outstanding, together with accrued and unpaid interest, and other payments, to be immediately due and payable. Additional capital may not be available on terms acceptable to us, or at all. Even if we were able to repay the full amount in cash, any such repayment could leave us with little or no working capital for our business. If we are unable to repay those amounts, the Lender will have a first claim on our assets pledged under the Loan Agreement. If the lender should attempt to foreclose on the collateral, it is unlikely that there would be any assets remaining after repayment in full of such secured indebtedness. Any default under the Loan Agreement and resulting foreclosure would have a material adverse effect on our financial condition and our ability to continue our operations.

Risks Related to Our Reliance on Third Parties

We rely on third party manufacturers to produce commercial supplies of DSUVIA in the United States, commercial supplies of Zalviso in Europe, and clinical supplies of Zalviso in the United States, and will rely on third party manufacturers to produce DZUVEO for Aguettant and on Aguettant to produce commercial supplies of the PFS Products, if approved, in the United States. The failure of third-party manufacturers to provide us with adequate commercial and clinical supplies could result in a material adverse effect on our business.*

Third party manufacturers produce commercial and clinical supplies of our products and product candidates. Reliance on third party manufacturers entails many risks including:

- the inability to meet our product specifications and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- a failure to maintain in good order our production and manufacturing equipment for our products;
- a failure to comply with cGMP and similar foreign standards;
- the inability to negotiate manufacturing or supply agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing or supply agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our products in a timely fashion, in sufficient quantities or under acceptable terms;
- the lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, or government orders related to the COVID-19 pandemic;
- carrier disruptions or increased costs that are beyond our control; and
- the failure to deliver our products under specified storage conditions and in a timely manner.

Any of these events could lead to stock outs, inability to successfully commercialize our products, clinical trial delays, or failure to obtain regulatory approval. Some of these events could be the basis for FDA action, including injunction, recall, seizure, or total or partial suspension of production.

In addition, the DZUVEO Agreement requires us to manufacture and supply DZUVEO to Aguettant. As mentioned above, we were obligated to manufacture and supply Zalviso under the Grünenthal Agreements for use in Europe and their other licensed territories and will likely be required to do so under any New Arrangement. If we are unable to establish a reliable commercial supply of DZUVEO for Aguettant, and, if a New Arrangement is entered into, Zalviso for Europe, we may be unable to satisfy our obligations under the DZUVEO Agreement or any New Arrangement in a timely manner or at all, and we may, as a result, be in breach of such agreements. If any such breach, or other breach, were to be material and remain uncured, it could result in termination of the agreement, which in turn could, in the case of a New Arrangement, result in us being responsible for indemnification of losses suffered by SWK (assignee of PDL) under the Royalty Monetization. If any of these events were to occur, our business would be materially adversely affected.

We rely on limited sources of supply for the active pharmaceutical ingredient, or API, of DSUVIA and Zalviso and any disruption in the chain of supply may cause a delay in supplying DSUVIA and Zalviso.

Currently we only have one supplier qualified as a vendor for the manufacture of DSUVIA, known as DZUVEO in Europe, and Zalviso with the FDA and EMA, respectively. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply. For example, our API provider for DSUVIA is changing its process for manufacturing our drug, which could impact our commercial supply of API for DSUVIA. This change in process requires a regulatory submission to the FDA. The European Health Authority has approved the change in process for both DZUVEO and Zalviso in the EU. In the U.S., a regulatory submission has been submitted to support the use of the API made with the new manufacturing process, but there is no guarantee that the FDA will approve the submission. For example, in July 2019, we received notice from the FDA that a deficiency in the API manufacturer's drug master file, or DMF, will need to be addressed before the submission can be approved. The API manufacturer responded to the FDA's DMF deficiency notice for the new manufacturing process, and we resubmitted the Supplemental NDA seeking approval of use of the new manufacturing process API. Any alternate vendor would need to be qualified through an NDA supplement and/or an MAA variation which could result in delays. The FDA or other regulatory agencies outside of the United States may also require additional trials if a new sufentanil supplier is relied upon for commercial production.

Manufacture of sufentanil sublingual tablets requires specialized equipment and expertise.

Ethanol, which is used in the manufacturing process for our sufentanil sublingual tablets, is flammable, and sufentanil is a highly potent, Schedule II controlled substance. These factors necessitate the use of specialized equipment and facilities for manufacture of sufentanil sublingual tablets. There are a limited number of facilities that can accommodate our manufacturing process and we or our partners need to use dedicated equipment throughout development and commercial manufacturing to avoid the possibility of cross-contamination. If our or our partners' equipment breaks down or needs to be repaired or replaced, it may cause significant disruption in clinical or commercial supply, which could result in delay in the process of obtaining approval for or sale of our products. Furthermore, we are using one manufacturer to produce our sufentanil sublingual tablets. Any problems with our or our partners' facilities or equipment may impair our ability to successfully commercialize DSUVIA or Zalviso, if approved, and to complete our clinical trials, and increase our cost.

Manufacturing issues may arise that could delay or increase costs related to commercialization, product development and regulatory approval.*

We have relied, and will continue to rely, on contract manufacturers, component fabricators and third-party service providers to produce the necessary DSUVIA single-dose applicator, or SDA, and Zalviso devices for the commercial marketplace. We currently outsource manufacturing and packaging of the DSUVIA SDA and the controller, dispenser and cartridge components of the Zalviso device to third parties and intend to continue to do so. Some of these component purchases were made and will continue to be made utilizing short-term purchase agreements and we may not be able to enter into long-term agreements for commercial supply of DSUVIA, DZUVEO or Zalviso devices with each of the third-party manufacturers or may be unable to do so on acceptable terms. In addition, we have encountered and may continue to encounter production issues with our current or future contract manufacturers and other third party service providers, including the reliability of the production equipment, quality of the components produced, their inability to meet demand or other unanticipated delays including scale-up and automating processes, which could adversely impact our ability to supply our customers with DSUVIA, Zalviso and DZUVEO in Europe, and, if approved, Zalviso in the U.S. and any other foreign territories.

As we scale up manufacturing of DSUVIA and Zalviso, if approved, and conduct required stability testing, product, packaging, equipment and process-related issues may require refinement or resolution. For example, as we scale up, we may identify significant issues which could result in failure to maintain regulatory approval of DSUVIA, increased scrutiny by regulatory agencies, delays in clinical program and regulatory approval, increases in our operating expenses, or failure to obtain approval for our product candidates in the United States.

We have built out a suite within our CMO's production facility in Cincinnati, Ohio that serves as a manufacturing facility for clinical and commercial supplies of sufentanil sublingual tablets. Late-stage development and manufacture of registration stability lots, which were utilized in clinical trials, were manufactured at this location. While we produced a number of commercial lots to support Grünenthal's launch in Europe, our experience is limited, which impacted our ability to deliver commercial supplies to Grünenthal on a timely basis, and may in the future impact our ability to deliver commercial supplies under any New Arrangement, if required, on a timely basis.

In January 2013, we entered into an agreement with a CMO to manufacture, supply, and provide certain validation and stability services with respect to Zalviso for potential sales in the United States, Canada, Mexico and other countries, subject to agreement by the parties to any additional fees for such other countries. On August 22, 2017, we entered into an amendment to this agreement to manufacture, supply, and provide certain validation and stability services with respect to DSUVIA for sales in the United States, and potential sales in Canada and Mexico, and other countries. There is no guarantee that our CMO's services will be satisfactory or that they will continue to meet the strict regulatory guidelines of the FDA or other foreign regulatory agencies. If our CMO cannot provide us with an adequate supply of sufentanil sublingual tablets, we may be required to pursue alternative sources of manufacturing capacity. Switching or adding commercial manufacturing capability can involve substantial cost and require extensive management time and focus, as well as additional regulatory filings which may result in significant delays. In addition, there is a natural transition period when a new manufacturing facility commences work. As a result, delays may occur, which can materially impact our ability to meet our desired commercial timelines, thereby increasing our costs and reducing our ability to generate revenue.

The facilities of any of our future manufacturers of sufentanil-containing sublingual tablets must be approved by the FDA or the relevant foreign regulatory agency, such as the EMA, before commercial distribution from such manufacturers occurs. We do not fully control the manufacturing process of sufentanil sublingual tablets and are completely dependent on these third-party manufacturing partners for compliance with the FDA or other foreign regulatory agency's requirements for manufacture. In addition, although our third-party manufacturers are well-established commercial manufacturers, we are dependent on their continued adherence to cGMP manufacturing and acceptable changes to their process. If our manufacturers do not meet the FDA or other foreign regulatory agency's strict regulatory requirements, they will not be able to secure FDA or other foreign regulatory agency approval for their manufacturing facilities. Although European inspectors have approved our tablet manufacturing site, our third-party manufacturing partner is responsible for maintaining compliance with the relevant foreign regulatory agency's requirements. If the FDA or the relevant foreign regulatory agency does not approve these facilities for the commercial manufacture of sufentanil sublingual tablets, we will need to find alternative suppliers, which would result in significant delays in obtaining FDA approval for Zalviso, and other foreign regulatory agency approval of DSUVIA/DZUVEO and Zalviso outside Europe. These challenges may have a material adverse impact on our business, results of operations, financial condition and prospects.

We may not be able to establish additional sources of supply for sufentanil-containing sublingual tablets or device manufacture. Such suppliers are subject to FDA and other foreign regulatory agency's regulations requiring that materials be produced under cGMPs or Quality System Regulations, or QSR, or in ISO 13485 accredited manufacturers, and subject to ongoing inspections by regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in delays and interruptions to our product supply while we seek to secure another supplier that meets all regulatory requirements. In addition, if we are unable to establish a reliable commercial supply of Zalviso for Europe, we may be unable to satisfy our obligations under any New Arrangement, if required, in a timely manner or at all, and we may, as a result, be in breach of any New Arrangement.

For DSUVIA, we currently package the finished goods under a manual process and would package DZUVEO in the same manner. The capacity and cost to package the goods under this manual process are not optimal to support successful future sales of DSUVIA and DZUVEO. We have purchased and installed an automated filling and packaging line to support increased capacity packaging for DSUVIA and DZUVEO. Despite the delays we experienced due to the impact of COVID-19, we have now completed the acquisition and installation of this line; however, there can be no assurance that we will be able to successfully complete the qualification and validation of this line and obtain the necessary regulatory approvals to manufacture product on this line.

We rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We utilized contract research organizations, or CROs, for the conduct of the Phase 2 and 3 clinical trials of DSUVIA, as well as our Phase 3 clinical program for Zalviso. We rely on CROs, as well as clinical trial sites, to ensure the proper and timely conduct of our clinical trials and document preparation. While we have agreements governing their activities, we have limited influence over their actual performance. We have relied and plan to continue to rely upon CROs to monitor and manage data for our post-approval clinical programs for DSUVIA and any FDA-required clinical programs for Zalviso, as well as the execution of nonclinical and clinical trials. We control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We, and our CROs, are required to comply with the FDA's current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA for all product candidates in clinical development. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. Upon inspection, the FDA may determine that our clinical trials do not comply with cGCPs. Accordingly, if our CROs or clinical trial sites fail to comply with these regulations, we may be required to repeat clinical trials, which would delay the regulatory process.

Our CROs are not our employees, and we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may allow our potential competitors to access our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize Zalviso. As a result, our financial results and the commercial prospects for Zalviso, if approved, would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Risks Related to Our Business Operations and Industry

Failure to receive required quotas of controlled substances or comply with the Drug Enforcement Agency regulations, or the cost of compliance with these regulations, may adversely affect our business.

Our sufentanil-based products are subject to extensive regulation by the DEA, due to their status as scheduled drugs. Sufentanil is classified as a Schedule II controlled substance, considered to present a high risk of abuse. The manufacture, shipment, storage, sale and use of controlled substances are subject to a high degree of regulation, including security, record-keeping and reporting obligations enforced by the DEA and also by comparable state agencies. In addition, our contract manufacturers are required to maintain relevant licenses and registrations. This high degree of regulation can result in significant compliance costs, which may have an adverse effect on the commercialization of DSUVIA and the development and commercialization of Zalviso, if approved.

The DEA limits the availability and production of all Schedule II controlled substances, including sufentanil, through a quota system. The DEA requires substantial evidence and documentation of expected legitimate medical and scientific needs before assigning quotas to manufacturers. Our contract manufacturers apply for quotas on our behalf. We will need significantly greater amounts of sufentanil to successfully commercialize DSUVIA, to support European commercialization of DZUVEO and Zalviso, and to commercialize Zalviso, if approved in the United States. Any delay by the DEA in establishing the procurement quota, reduction in our quota for sufentanil, failure to increase our quota over time to meet anticipated increases in demand, or refusal by the DEA to establish the procurement quota could delay or stop the commercial sale of our approved products or the clinical development of Zalviso in the United States. This, in turn, could have a material adverse effect on our business, results of operations, financial condition and prospects.

Our relationships with clinical investigators, health care professionals, consultants, commercial partners, third-party payers, hospitals, and other customers are subject to applicable anti-kickback, fraud and abuse and other healthcare laws, which could expose us to significant penalties.

Healthcare providers, including physicians, and others play a primary role in the recommendation and prescribing of any products for which we may obtain marketing approval. Our business operations and arrangements with investigators, healthcare professionals, consultants, commercial partners, hospitals, third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws. These laws may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute the products for which we obtain marketing approval. Applicable federal and state healthcare laws include, but are not limited to, the following:

- the federal healthcare Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private) and knowingly or willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which impose certain obligations, including mandatory contractual terms, on covered healthcare providers, health plans and clearinghouses, and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, as well as their covered subcontractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- foreign laws, regulations, standards and regulatory guidance which govern the collection, use, disclosure, retention, security and transfer of personal data, including the European Union General Data Privacy Regulation, or GDPR, which introduces strict requirements for processing personal data of individuals within the European Union;
- the federal transparency law, enacted as part of the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies to report annually to the CMS information related to payments and other transfers of value provided to physicians, (defined to include, doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and other transfers of value made to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year;
- analogous state laws that may apply to our business practices, including but not limited to, state laws that require pharmaceutical companies to implement compliance programs and/or comply with the pharmaceutical industry's voluntary compliance guidelines; state laws that impose restrictions on pharmaceutical companies' marketing practices and require manufacturers to track and file reports relating to pricing and marketing information, which requires tracking and reporting gifts, compensation and other remuneration and items of value provided to healthcare professionals and entities, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects; and
- the federal Foreign Corrupt Practices Act of 1977, United Kingdom Bribery Act 2010 and other similar anti-bribery laws in other jurisdictions which generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage.

Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice and the SEC. A determination that our operations or activities are not, or were not, in compliance with United States or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these or any other healthcare regulatory laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, increased losses and diminished profits, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations any of which could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses or divert our management's attention from the operation of our business.

In order to supply the Zalviso device to any future collaborator for commercial sales in Europe, we must maintain conformity of our quality system to applicable ISO standards and must comply with applicable European laws and directives.

We underwent a Conformité Européenne approval process for the Zalviso device, more commonly known as a CE Mark approval process. We received CE Mark approval in December 2014, which permits the commercial sale of the Zalviso device in Europe. In connection with the CE Mark approval, we were also granted International Standards Organization, or ISO, 13485:2003 certification of our quality management system in November 2014. This is an internationally recognized quality standard for medical devices. The CE Mark was originally issued by the British Standards Institution, or BSI, a Notified Body, or NB, located in the United Kingdom, or U.K., or BSI-U.K. The CE Mark file and certification has been transferred to the Netherlands NB of BSI, or BSI-NL, to mitigate the uncertainty with regards to Brexit. The ISO certification issued through BSI-U.K. was recently upgraded to the latest version of the standard, ISO 13485:2016 through BSI-U.K. and remains in effect. BSI ISO 13485:2016 certification recognizes that consistent quality policies and procedures are in place for the development, design and manufacturing of medical devices. The certification indicates that we have successfully implemented a quality system that conforms to ISO 13485 standards for medical devices. Certification to this standard is one of the key regulatory requirements for a CE Mark in the EU and European Economic Area (which includes the 27 EU member states as well as Norway, Iceland and Liechtenstein), or EEA, as well as to meet equivalent requirements in other international markets. The certification applies to the Redwood City, California location which designs, manufactures and distributes finished medical devices, and includes critical suppliers. If we fail to remain in compliance with applicable European laws and directives, we would be unable to continue to affix the CE Mark to our Zalviso device, which would prevent any future collaboration partner from selling these devices within the EU and EEA.

Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we manage a number of third-party vendors who may or could have access to our computer networks or our confidential information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious internal and external attacks on our technology environment. Potential vulnerabilities can be exploited from inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

Significant disruptions of our third-party vendors' and/or business partners' information technology systems or other similar data security incidents could adversely affect our business operations and result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in financial, legal, regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war and telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

There is no way of knowing with certainty whether we have experienced any data security incidents that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that they have been attacked. Any event that leads to unauthorized access, use or disclosure of personal information, including but not limited to personal information regarding our patients or employees, could disrupt our business, harm our reputation, compel us to comply with applicable federal and state breach notification laws and foreign law equivalents, subject us to time consuming, distracting and expensive litigation, regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under laws, regulations and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to us, and result in significant legal and financial exposure and/or reputational harm. In addition, any failure or perceived failure by us or our vendors or business partners to comply with our privacy, confidentiality or data security-related legal or other obligations to third parties, or any further security incidents or other inappropriate access events that result in the unauthorized access, release or transfer of sensitive information, which could include personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including clinical sites, regulators or current and potential partners, to lose trust in us or we could be subject to claims by third parties that we have breached our privacy- or confidentiality-related obligations, which could materially and adversely affect our business and prospects. Moreover, data security incidents and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or security incidents.

Business interruptions could delay our operations and sales efforts.

Our headquarters is located in the San Francisco Bay Area, near known earthquake fault zones and is vulnerable to significant damage from earthquakes. Our contract manufacturers, suppliers, clinical trial sites and local and national transportation vendors are all subject to business interruptions due to weather, outbreaks of pandemic diseases, natural disasters, or man-made incidents. We are also vulnerable to other types of natural disasters and other events that could disrupt our operations. If any of these events occurred and prevented us or third parties on which we rely from using all or a significant portion of our or their facilities, it may be difficult or, in certain cases, impossible for us to continue our business and operations for a substantial period of time.

We do not carry insurance for earthquakes or other natural disasters, and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on principal members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into offer letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are "at will" employees. Recruiting and retaining qualified scientific, manufacturing, and commercial personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. In addition, failure to succeed in clinical trials, or delays in the regulatory approval process, may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive or key employee might impede the progress of our research, development and commercialization objectives.

We may acquire companies, product candidates or products or engage in strategic transactions, which could divert our management's attention and cause us to incur various costs and expenses.

We may acquire or invest in companies, product candidates or products that we believe could complement or expand our business or otherwise offer growth opportunities. The pursuit of potential acquisitions or investments may divert the attention of management and has caused, and in the future may cause, us to incur various costs and expenses in identifying, investigating, and pursuing them, whether or not they are consummated. We may not be able to identify desirable acquisitions or investments or be successful in completing or realizing anticipated benefits from such transactions. In addition, the acquisition of product candidates and products is a highly competitive area, and many other companies are pursuing the same or similar product candidates to those that we may consider attractive. Larger companies with more well-established and diverse revenue streams may have a competitive advantage over us due to their size, financial resources and more extensive clinical development and commercialization capabilities.

In addition, we receive inquiries relating to potential strategic transactions, including collaborations, licenses, and acquisitions. Such potential transactions may divert the attention of management and may cause us to incur various costs and expenses in investigating and evaluating such transactions, whether or not they are consummated.

We face potential product liability claims, and, if such claims are successful, we may incur substantial liability.

Commercial sales of DSUVIA and Zalviso expose us to the risk of product liability claims. Product liability claims might be brought against us by patients, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our products; and
- decreased demand for our products.

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. In addition, our current product liability insurance contains an exclusion related to any claims related to our products from a governmental body, or payer, or those claims arising from a multi-plaintiff action for bodily injury or property damage. Multi-plaintiff claims caused by product defects are covered. This exclusion does not apply to any bodily injury claim related to our products made by an individual. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim, or series of claims, brought against us could cause our stock price to decline and, if judgments are excluded from our insurance coverage or exceed our insurance coverage, could adversely affect our results of operations and business. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability.

Our insurance coverage included the sale of Zalviso to our former commercial partner, Grünenthal, and will likely include the sale of Zalviso by any future commercial partner. We intend to commercialize and promote DZUVEO in Europe with a strategic partner which may result in further expansion of our insurance coverage to include sales of DZUVEO in Europe. There can be no assurance that such coverage will be adequate to protect us against any future losses due to liability.

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, investigators, consultants, commercial partners and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates (1) regulations implemented by the FDA and similar foreign regulatory bodies; (2) laws requiring the reporting of true, complete and accurate information to such regulatory bodies; (3) healthcare fraud and abuse laws of the United States and similar foreign fraudulent misconduct laws; and (4) laws requiring the reporting of financial information or data accurately. The promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry are subject to extensive laws designed to prevent misconduct, including fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. It is not always possible to identify and deter employee and other third-party misconduct. The precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws. If any such actions are instituted against us, and we are not successful in defending ourselves, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar agreements to resolve allegations of non-compliance with these laws, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Our Intellectual Property

If we cannot defend our issued patents from third party claims or if our pending patent applications fail to issue, our business could be adversely affected.

To protect our proprietary technology, we rely on patents as well as other intellectual property protections including trade secrets, nondisclosure agreements, and confidentiality provisions. As of September 30, 2021, we are the owner of record of 93 issued patents worldwide. These issued patents cover AcelRx's sufentanil sublingual tablet, medication delivery devices and other platform technology. These issued patents include patents we have listed in the FDA's Orange Book for DSUVIA, and patents expected to provide coverage until 2031. These issued patents also include a European patent covering the DZUVEO device that is expected to provide coverage until at least 2036.

Because sufentanil is not a new chemical entity, its regulatory exclusivity period in the United States is limited to three years under the Hatch-Waxman Act. While the FDA may not approve a 505(b)(2) NDA or abbreviated new drug application, or ANDA, using DSUVIA as its reference listed drug prior to November 2, 2021, we may be subject to certification based on the patents we have listed in the FDA's Orange Book for DSUVIA and engage in litigation against such a 505(b)(2) or ANDA applicant at any time.

In addition, we are pursuing a number of U.S. non-provisional patent applications and foreign national applications directed to DSUVIA and Zalviso. The patent applications that we have filed and have not yet been granted may fail to result in issued patents in the United States or in foreign countries. Even if the patents do successfully issue, third parties may challenge the patents.

Our commercial success will depend in part on successfully defending our current patents against third party challenges and expanding our existing patent portfolio to provide additional layers of patent protection, as well as extending patent protection. There can be no assurance that we will be successful in defending our existing and future patents against third party challenges, or that our pending patent applications will result in additional issued patents.

The patent positions of pharmaceutical companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States. Legal developments may preclude or limit the scope of available patent protection.

There is also no assurance that any patents issued to us will not become the subject of adversarial proceedings such as opposition, inter partes review, post-grant review, reissue, supplemental examination, re-examination or other post-issuance proceedings. In addition, there is no assurance that the respective court or agency in such adversarial proceedings would not make unfavorable decisions, such as reducing the scope of a patent of ours or determining that a patent of ours is invalid or unenforceable. There is also no assurance that any patents issued to us will provide us with competitive advantages, will not be challenged by any third parties, or that the patents of others will not prevent the commercialization of products incorporating our technology. Furthermore, there can be no guarantee that others will not independently develop similar products, duplicate any of our products, or design around our patents.

Litigation involving patents, patent applications and other proprietary rights is expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing our products to market and interfere with our business.

Our commercial success depends in part on not infringing patents and proprietary rights of third parties. Although we are not currently aware of litigation or other proceedings or third-party claims of intellectual property infringement related to DSUVIA or Zalviso, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights.

As we enter our target markets, it is possible that competitors or other third parties will claim that our products and/or processes infringe on their intellectual property rights. These third parties may have obtained and may in the future obtain patents covering products or processes that are similar to, or may include compositions or methods that encompass our technology, allowing them to claim that the use of our technologies infringes on these patents.

In a patent infringement claim against us, we may assert, as a defense, that we do not infringe the relevant patent claims, that the patent is invalid or both. The strength of our defenses will depend on the patents asserted, the interpretation of these patents, and our ability to invalidate the asserted patents. However, we could be unsuccessful in advancing non-infringement and invalidity arguments in our defense. In the United States, issued patents enjoy a presumption of validity, and the party challenging the validity of a patent claim must present clear and convincing evidence of invalidity, which is a high burden of proof. Conversely, the patent owner need only prove infringement by a preponderance of the evidence, which is a lower burden of proof.

If we were found by a court to have infringed a valid patent claim, we could be prevented from using the patented technology and be required to pay the owner of the patent for damages for past sales and for the right to license the patented technology for future sales. If we decide to pursue a license to one or more of these patents, we may not be able to obtain a license on commercially reasonable terms, if at all, or the license we obtain may require us to pay substantial royalties or grant cross licenses to our patent rights. For example, if the relevant patent is owned by a competitor, that competitor may choose not to license patent rights to us. If we decide to develop alternative technology, we may not be able to do so in a timely or cost-effective manner, if at all.

In addition, because patent applications can take years to issue and are often afforded confidentiality for some period of time there may currently be pending applications, unknown to us, that later result in issued patents that could cover one or more of our products.

It is possible that we may in the future receive communications from competitors and other companies alleging that we may be infringing their patents, trade secrets or other intellectual property rights, offering licenses to such intellectual property or threatening litigation. In addition to patent infringement claims, third parties may assert copyright, trademark or other proprietary rights against us. We may need to expend considerable resources to counter such claims and may not be successful in our defense. Our business may suffer if a finding of infringement is established.

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States. The pharmaceutical patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property.

We cannot predict the breadth of claims that may be allowed or enforced in the patents that may be issued from the applications we currently, or may in the future, own or license from third parties. Claims could be brought regarding the validity of our patents by third parties and regulatory agencies. Further, if any patent license we obtain is deemed invalid and/or unenforceable, it could impact our ability to commercialize or partner our technology.

Competitors or third parties may infringe our patents. We may decide it is necessary to file patent infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or that the third party's technology does not in fact infringe upon our patents. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our related pending patent applications at risk of not issuing. Litigation may fail and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able to prevent misappropriation of our proprietary rights, particularly in countries outside the United States where patent rights may be more difficult to enforce. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. In addition, during the course of litigation there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we were the first to make the inventions covered by each of our pending patent applications or issued patents;
- our patent applications were filed before the inventions covered by each patent or patent application was published by a third party;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents issued to us or our collaborators will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties; or
- the patents of others will not have an adverse effect on our business.

If we do not adequately protect our proprietary rights, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize DSUVIA and Zalviso, if approved, and delay or render impossible our achievement of profitability.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be paid to the United States Patent and Trademark Office and various foreign governmental patent agencies in several stages over the lifetime of the patents and/or applications.

We have systems in place, including use of third-party vendors, to manage payment of periodic maintenance fees, renewal fees, annuity fees and various other patent and application fees. The United States Patent and Trademark Office, or the USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. There are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. Additionally, claims may be brought regarding the validity of our patents by third parties and regulatory agencies in the United States and foreign countries. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

We have not yet registered our trademarks in all our potential markets, and failure to secure those registrations could adversely affect our business.

We have registered our ACELRX mark in the United States, Canada, the EU and India. In early 2014, the FDA accepted the Zalviso mark and, in November 2018, the FDA accepted the DSUVIA mark. Although we are not currently aware of any oppositions to or cancellations of our registered trademarks or pending applications, it is possible that one or more of the applications could be subject to opposition or cancellation after the marks are registered. The registrations will be subject to use and maintenance requirements. It is also possible that we have not yet registered all of our trademarks in all of our potential markets, such as securing the registration of DSUVIA in Canada, and that there are names or symbols other than "ACELRX" that may be protectable marks for which we have not sought registration, and failure to secure those registrations could adversely affect our business. Opposition or cancellation proceedings may be filed against our trademarks and our trademarks may not survive such proceedings.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile.*

The trading price of our common stock has experienced significant volatility and is likely to be volatile in the future. For example, the closing price of our common stock ranged between $0.93 and $2.77 during the first nine months of 2021, and between $0.76 and $2.07 during the year ended December 31, 2020. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- failure to successfully commercialize DSUVIA in the United States or to successfully develop and commercialize our product candidates in the United States;
- inability to obtain additional funding needed to conduct our planned business operations;
- inability to satisfactorily comply with FDA regulations concerning the advertising and promotion of DSUVIA, including receiving a close out letter resolving the concerns raised by FDA in the warning letter delivered to us on February 11, 2021;
- the integration and performance of any assets or businesses we acquire;
- our inability to develop and commercialize products and product candidates that we in-license;
- uncertainties regarding the magnitude and duration of impacts we are experiencing due to COVID-19;
- the perception of limited market sizes or pricing for our products;
- further delays in resubmitting the NDA for Zalviso, and any additional adverse developments or perceived adverse developments with respect to the FDA's review of the Zalviso NDA, upon resubmission;
- inability to enter into, or unfavorable terms associated with, a New Arrangement for the commercialization of Zalviso in Europe;
- safety issues;
- adverse results or delays in future clinical trials;
- changes in laws or regulations applicable to our products;
- inability to obtain adequate product supply for our products, or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- changes in the structure of the healthcare payment systems;
- inability to maintain regulatory approvals for DZUVEO and Zalviso in the European Union, including ISO 13485 certification and CE Mark approval for Zalviso;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;

- decisions by our collaboration partners regarding market access, pricing, and commercialization efforts in countries where they have the right to commercialize our products;
- failure to maintain our existing collaborations or enter into new collaborations;
- the perception of the pharmaceutical industry generally, and of opioid manufacturers more specifically, by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or other significant transactions, including disposition transactions, or capital commitments by us or our competitors;
- disputes or other developments relating to employment matters, business development efforts, proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key management or scientific personnel;
- costs associated with potential governmental investigations, inquiries, regulatory actions or lawsuits that may be brought against us as a result of us being an opioid manufacturer;
- other types of significant lawsuits, including patent, stockholder, securities class action and derivative litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

In addition, the stock market in general, and The Nasdaq Global Market, or Nasdaq, in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Sales of a substantial number of shares of our common stock in the public market by our stockholders could cause our stock price to fall.

Because we will continue to need additional capital in the future to continue to expand our business and our research and development activities, among other things, we may conduct additional equity offerings. For example, under the universal shelf registration statement filed by us in June 2020 and declared effective by the SEC in July 2020, we may offer and sell any combination of common stock, preferred stock, debt securities and warrants in one or more offerings, up to a cumulative value of $150 million. To date, we have approximately $54.5 million remaining under such universal shelf registration statement. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants under our equity incentive plans. Grants under our equity incentive plans may also cause our stockholders to experience additional dilution, which could cause our stock price to fall. We may also issue shares of our common stock as consideration in mergers, acquisitions and other business development transactions. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. All of our shares of common stock outstanding are eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements of Rule 144 under the Securities Act. Sales of stock by our stockholders could have a material adverse effect on the trading price of our common stock.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our capital stock, and we are prohibited from doing so under the terms of the Loan Agreement. Regardless of the restrictions in the Loan Agreement or the terms of any potential future indebtedness, we anticipate that we will retain all available funds and any future earnings to support our operations and finance the growth and development of our business and, therefore, we do not expect to pay cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our Board of Directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our Board of Directors may deem relevant.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- a staggered Board of Directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our Board of Directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Risks of a General Nature

Litigation may substantially increase our costs and harm our business.*

We have been, are, and may in the future become, party to lawsuits including, without limitation, actions and proceedings in the ordinary course of business relating to our directors, officers, stockholders, intellectual property rights, employment matters and the safety or efficacy of our products, which will cause us to incur legal fees and other costs related thereto, including potential expenses for the reimbursement of legal fees of officers and directors under indemnification obligations. The expense of defending against such litigation may be significant and there can be no assurance that we will be successful in any defense. Further, the amount of time that may be required to resolve such lawsuits is unpredictable, and these actions may divert management's attention from the day-to-day operations of our business, which could adversely affect our business, results of operations, and cash flows. Our insurance carriers may deny coverage, may be inadequately capitalized to pay on valid claims, or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our consolidated operations, cash flows and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. Litigation is subject to inherent uncertainties, and an adverse result in such matters that may arise from time to time could have a material adverse effect on our business, results of operations, and financial condition. Please see "Part II. Other Information—Item 1. Legal Proceedings" for additional information about pending legal proceedings.

Our involvement in securities-related class action litigation could divert our resources and management's attention and harm our business.*

The stock markets have from time-to-time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In addition, the market price of our common stock may vary significantly based on AcelRx-specific events, such as receipt of complete response letters, warnings letters, such as the warning letter we received from the FDA on February 11, 2021, negative clinical results, a negative vote or decision by an FDA advisory committee, or other negative feedback from the FDA, EMA, or other regulatory agencies. In the past, securities-related class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies often experience significant stock price volatility in connection with their investigational drug candidate development programs and the FDA's review of their NDAs. Following receipt of the FDA's warning letter, a securities class action complaint was filed against us and two of our officers on June 8, 2021 in the United States District Court for the Northern District of California. On June 30, 2021 and September 30, 2021, two purported shareholder derivative complaints were filed in the United States District Court for the Northern District of California asserting state and federal claims based on the same alleged misstatements as the securities class action complaint. Please see "Part II. Other Information—Item 1. Legal Proceedings" for additional information about this pending legal proceeding. Securities-related class action litigation often is expensive and diverts management's attention and our financial resources, which could harm our business. Additional lawsuits related to the pending litigation may follow. Moreover, if AcelRx experiences a decline in its stock price, we could face additional securities class action lawsuits.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2020, we had federal net operating loss carryforwards of $264.4 million, of which $114.9 million federal net operating losses generated before January 1, 2018 will begin to expire in 2029. Federal net operating losses of $149.5 million generated after January 1, 2018 will carryforward indefinitely but are subject to the 80% taxable income limitation. As of December 31, 2020, we had state net operating loss carryforwards of $141.5 million, which begin to expire in 2028.

Our ability to use our federal and state net operating losses to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the net operating losses, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our net operating losses. Federal net operating losses generated prior to 2018 will continue to be governed by the net operating loss tax rules as they existed prior to the adoption of the Tax Cuts and Jobs Act of 2017, or Tax Act, which means that generally they will expire 20 years after they were generated if not used prior thereto. Many states have similar laws. Accordingly, our federal and state net operating losses could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted Tax Act as modified by CARES Act, federal net operating losses incurred in tax years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five tax years preceding such loss, and federal net operating losses arising in tax years beginning after December 31, 2020 may not be carried back. Moreover, federal net operating losses generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to 80% of current year taxable income for tax years beginning after December 31, 2020.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. The completion of the July 2013 public equity offering, together with our public equity offering in December 2012, our initial public offering, private placements and other transactions that have occurred, have triggered such an ownership change. In addition, since we will need to raise substantial additional funding to finance our operations, we may undergo further ownership changes in the future. In the future, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in numerous U.S. states and territories. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal income tax law, changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Merger Agreement

On November 14, 2021, we and two of our direct wholly owned subsidiaries, AcelRx Intermediate Sub, Inc., or Merger Sub 1, and AcelRx Consolidation Sub, LLC, or Merger Sub 2, Lowell Therapeutics, Inc., or Lowell, and the stockholder representative, entered into an Agreement and Plan of Merger, or Merger Agreement, pursuant to which, among other things, (a) Merger Sub 1 will merge with and into Lowell and Lowell will continue as the initial surviving company and our direct wholly owned subsidiary, or the First Merger, and (b) the initial surviving company will merge with and into Merger Sub 2 and Merger Sub 2 will continue as the surviving company and our direct wholly owned subsidiary, or the Second Merger and, together with the First Merger, the Mergers.

Pursuant to the Merger Agreement, we will acquire Lowell in a transaction valued at approximately $32.5 million plus net cash acquired, and subject to certain other adjustments. The transaction value includes approximately $26.0 million of contingent consideration payable upon the achievement of regulatory and sales-based milestones. If the acquisition of Lowell is completed, an amount of shares of AcelRx common stock valued at approximately $6.5 million will be issued to Lowell securityholders at the closing, subject to the condition to closing that Lowell has at least $3.5 million in cash at the closing and assuming that certain stockholders of Lowell elect to receive merger consideration up to $3.5 million payable in cash. If those stockholders do not elect to receive cash, the amount of shares of common stock issued by the Company will be greater. The merger consideration is payable at closing of the First Merger in shares of our common stock, and, at the option of certain Lowell stockholders, in cash to such stockholders, as discussed below. Our board of directors (i) determined that the terms of the Mergers are fair to, advisable and in the best interest of AcelRx and its stockholders, and (ii) authorized and approved the execution, delivery and performance of the Merger Agreement and approved the Mergers and the other transactions contemplated thereby.

Subject to the terms and conditions set forth in the Merger Agreement, at the effective time of the First Merger, or the First Effective Time:

- each share of Series B preferred stock, par value $0.0001 per share, of Lowell issued and outstanding immediately prior to the First Effective Time (other than shares owned by AcelRx, its affiliates, Lowell or by stockholders of Lowell who have properly demanded appraisal rights in accordance with Delaware law and not withdrawn or lost such rights, or Cancelled and Dissenting Shares) will be automatically converted into the right to receive (a) a number of shares of AcelRx common stock equal to $2.60 divided by the average of the daily volume-weighted average price per share of our common stock on Nasdaq during the five consecutive trading days ending on and including the last full trading day immediately preceding the date of closing, or the Closing Parent Share Value, (b) a number of shares of AcelRx common stock equal to the Exchange Ratio (as defined in the Merger Agreement), (c) one contractual contingent value right, or CVR, to receive the consideration set forth in the CVR Agreement (as defined in the Merger Agreement), and (d) the right to receive a pro rata portion of any holdback shares released pursuant to the Merger Agreement;

- each share of Series B-1 preferred stock, par value $0.0001 per share, of Lowell issued and outstanding immediately prior to the First Effective Time (other than Cancelled and Dissenting Shares) will be automatically converted into the right to receive (a) a number of shares of AcelRx common stock equal to $2.08 divided by the Closing Parent Share Value, (b) a number of shares of AcelRx common stock equal to equal to Exchange Ratio, (c) one CVR, and (d) the right to receive a pro rata portion of any holdback shares released pursuant to the Merger Agreement;

- each share of Series A preferred stock, par value $0.0001 per share, of Lowell issued and outstanding immediately prior to the First Effective Time (other than Cancelled and Dissenting Shares) will be automatically converted into the right to receive (a) a number of shares of AcelRx common stock equal to $2.50 divided by the Closing Parent Share Value, (b) a number of shares of AcelRx common stock equal to equal to Exchange Ratio, (c) one CVR, and (d) the right to receive a pro rata portion of any holdback shares released pursuant to the Merger Agreement; and

- each share of common stock, par value $0.0001 per share, of Lowell issued and outstanding immediately prior to the First Effective Time (other than Cancelled and Dissenting Shares) will be automatically converted into the right to receive (a) a number of shares of AcelRx common stock equal to the Exchange Ratio, (b) one CVR, and (c) the right to receive a pro rata portion of any holdback shares released pursuant to the Merger Agreement.

Holders of Series B preferred stock and Series B-1 preferred stock have the option to elect to receive cash in lieu of a portion of the shares of AcelRx common stock otherwise payable to such holder, subject to proration; provided that the aggregate amount of cash payable at the closing shall not exceed $3.5 million. Stockholders and option holders of Lowell that are not accredited investors may, at the option of AcelRx, be paid in cash in lieu of AcelRx common stock.

The Merger Agreement also provides that:

- each option to purchase Lowell common stock, whether vested or unvested, will be cancelled and converted into the right to receive (a) a number of shares of AcelRx common stock equal to (i) the amount, if any, by which the per share merger consideration exceeds the exercise price of the option, multiplied by the number of shares of Lowell common stock into which the option is exercisable, if fully vested and exercised, divided by the Closing Parent Share Value, (b) one CVR, and (c) the right to receive a pro rata portion of any holdback shares released pursuant to the Merger Agreement; and

- each warrant to purchase shares of Lowell common stock shall be treated in accordance with its terms.

The total consideration payable under the Merger Agreement is an amount equal to (i) $6,500,000, less (ii) $800,000 (representing the value of the holdback shares to be used to satisfy any indemnification obligations of Lowell or its security holders (calculated at the Closing Parent Share Value)), less (iii) the amount, if any, of any closing indebtedness of Lowell in excess of $175,000, plus (iv) the amount of any closing cash of Lowell (currently expected to be approximately $3.5 million), less (v) any third-party expenses that are incurred by Lowell prior to or as of the closing and that are unpaid as of immediately prior to the First Effective Time, less (vi) the cost of a tail director and officers insurance policy, less (vii) $75,000. To the extent not used to satisfy indemnification obligations, the holdback shares will be released to the former stockholders and optionholders of Lowell. In addition, pursuant to the Merger Agreement, addition consideration may be payable pursuant to the CVR Agreement, as described below.

We intend to issue the shares of our common stock pursuant to the Merger Agreement in reliance upon the exemptions from registration afforded by Section 4(a)(2) and/or Rule 506 promulgated under the Securities Act.

The consummation of the Mergers is subject to the satisfaction or waiver of certain customary conditions, including, among others, the adoption of the Merger Agreement and the transactions contemplated therein by the stockholders of Lowell and the absence of any material adverse effect on Lowell since the date of the Merger Agreement. We expect the Mergers to close during the fourth quarter of 2021.

The number of shares of our common stock to be issued in connection with the Mergers will be calculated based on a value per share to be equal to the average of the daily volume-weighted average price per share of our common stock on Nasdaq during the five consecutive trading days ending on and including the last full trading day immediately preceding the date of determination of value.

The Merger Agreement includes representations, warranties and covenants of the parties customary for a transaction of this nature. From the date of the Merger Agreement until the earlier of the First Effective Time and the termination of the Merger Agreement, Lowell has agreed to operate its business subject to operating covenants, as set forth more fully in the Merger Agreement. Lowell has also agreed (i) not to solicit, initiate, consider, encourage, promote, recommend, approve, agree to, accept or support any inquiry or proposal that could reasonably be expected to lead to a transaction that is an alternative transaction to the Mergers, (ii) to call and hold a meeting of its stockholders and, (iii) subject to certain exceptions, to require the board of directors of Lowell to recommend to Lowell's stockholders that they vote in favor of the adoption of the Merger Agreement. Lowell may, under certain circumstances, change its recommendation of the transaction, and/or terminate the Merger Agreement in the event it receives an unsolicited superior offer.

The Merger Agreement includes customary termination provisions for both AcelRx and Lowell and provides that, in connection with the termination of the Merger Agreement under specified circumstances, including termination by Lowell to accept and enter into a definitive agreement with respect to an unsolicited superior offer, Lowell will be required to pay AcelRx a termination fee of an amount in cash equal to $500,000. Any such termination of the Merger Agreement by Lowell in connection with an unsolicited superior offer to enter into a definitive agreement with respect to an unsolicited superior offer is subject to certain conditions, including its compliance with certain procedures set forth in the Merger Agreement and a determination by its board of directors that the failure to take such action could reasonably be expected to be inconsistent with the fiduciary duties of the Lowell board of directors to the Lowell stockholders under applicable law and the payment of the termination fee by Lowell. In addition, if the Merger Agreement is terminated by AcelRx or Lowell because the Merger Agreement is not adopted by the Lowell stockholders at the meeting for a final vote on the proposal to adopt the Merger Agreement, Lowell has agreed to reimburse AcelRx up to $400,000 in transaction expenses.

The foregoing description of the Merger Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Merger Agreement, which is filed as Exhibit 2.1 to this Form 10-Q and is incorporated herein by reference.

The Merger Agreement and the foregoing description of the Merger Agreement have been included to provide investors and stockholders with information regarding its terms. The assertions embodied in the representations and warranties contained in the Merger Agreement are qualified by information in confidential disclosure schedules that the parties have exchanged in connection with the signing of the Merger Agreement. Moreover, certain representations and warranties in the Merger Agreement were made as of a specified date solely for the benefit of the other parties to the Merger Agreement, may be subject to a contractual standard of materiality different from what might be viewed as material to stockholders, or may have been used for the purpose of allocating risk between the parties to the Merger Agreement. Accordingly, the representations and warranties in the Merger Agreement should not be relied on by any persons as characterizations of the actual state of facts and circumstances of AcelRx or Lowell, as applicable, at the time they were made and should only be read in conjunction with the entirety of the factual disclosure about AcelRx or Lowell, as applicable, in their respective public reports, statements and other documents filed with the SEC. Information concerning the subject matter of the representations and warranties may change after the date of the Merger Agreement, which subsequent information may or may not be fully reflected in AcelRx or Lowell's public disclosures, as applicable.

Contingent Value Rights Agreement

At or prior to the First Effective Time, AcelRx will enter into a contingent value rights agreement, or the CVR Agreement, with a rights agent and the stockholder representative governing the terms of the CVRs. The CVRs represent an aggregate right to receive up to approximately $26.0 million, without interest and less any applicable withholding taxes, in contingent consideration, conditioned upon the achievement of regulatory milestones and specified levels of annual net sales as follows:

- a one-time payment of $3.0 million upon the approval of NIYAD for the specified indication;
- a one-time payment of $2.0 million upon obtaining (i) the approval from the FDA, via a PMA or NDA, for NIYAD with a label indication for use for patients undergoing intermittent hemodialysis (IHD) in the outpatient setting and (ii) the receipt of approval from CMS of NIYAD to be included in the End-Stage Renal Dialysis (ESRD) Prospective Payment System (PPS), as a qualified device under the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES), if approved by the FDA as a device, or the Transitional Drug Add-on Payment Adjustment (TDAPA), if approved by the FDA as a drug;
- a one-time payment of $2.0 million upon the approval of LTX-608 for the specified indication;
- a one-time payment of $2.0 million upon obtaining the specified issued patent for LTX-608;
- a one-time payment of $3.5 million upon the achievement of specified annual revenues on or before December 31, 2026;
- a one-time payment of $3.5 million upon the achievement of specified annual revenues on or before December 31, 2027; and
- a one-time payment of $10.0 million upon the achievement of specified annual revenues on or before December 31, 2030.

The terms of the CVRs described above reflect the parties' agreement over the sharing of potential economic upside benefits from future net sales of product candidates and do not necessarily reflect anticipated net sales of such candidates. There can be no assurance that such levels of net sales will occur or that any or all of the payments in respect of the CVRs will be made.

AcelRx may elect to pay such contingent consideration in AcelRx common stock or cash, provided however that the total number of shares of AcelRx common stock issuable as Merger Consideration, including the CVRs, will not exceed 19.9% of the total number of shares of AcelRx common stock that are issued and outstanding immediately prior to the closing of the First Merger and certain other conditions described in the CVR Agreement. AcelRx will have the ability to pay cash payable in lieu of shares of AcelRx common stock for any shares exceeding the 19.9% percent threshold.

The right to such contingent consideration as evidenced by the CVR Agreement is a contractual right only and will not be transferable, except in the limited circumstances specified in the CVR Agreement. The foregoing description of the CVR Agreement does not purport to be complete and is qualified in its entirety by reference to the form of CVR Agreement, which is filed as Exhibit 10.3 to this Form 10-Q and is incorporated herein by reference.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
2.1§	Agreement and Plan of Merger, dated as of November 14, 2021, by and among the Registrant, Lowell, Merger Sub 1, Merger Sub 2 and the Stockholder Representative.				
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-35068	3.1	02/18/2011
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-35068	3.1	6/25/2019
3.3	Amended and Restated Bylaws of the Registrant.	S-1	333-170594	3.4	01/07/2011
10.1§#	License and Commercialization Agreement (DZUVEO), dated July 14, 2021, between Laboratoire Aguettant and the Registrant.				
10.2§#	License and Commercialization Agreement (PFS), dated July 14, 2021, between Laboratoire Aguettant and the Registrant.				
10.3	Form of CVR Agreement.				
10.4	First Amendment to Loan and Security Agreement, dated as of May 5, 2021, between Oxford Finance, LLC and the Registrant.				
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.				
31.2	Certification of Principal Financial and Accounting Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.				
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*				
101.INS	Inline XBRL Instance Document- the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Schema Document.				
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document.				
101.DEF	Inline XBRL Taxonomy Definition Linkbase Document.				
101.LAB	Inline XBRL Taxonomy Label Linkbase Document.				
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document.				
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.INS, 101.SCH, 101.CAL, 101.DEF, 101.LAB, and 101.PRE).				

§ Schedules omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of any omitted schedule upon request by the SEC.

Material in the exhibit marked with an "[***]" has been omitted because it is confidential, not material, and would be competitively harmful if publicly disclosed.

* The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 15, 2021

AcelRx Pharmaceuticals, Inc.
(Registrant)

/s/ Raffi Asadorian

Raffi Asadorian
Chief Financial Officer
(Duly Authorized and Principal Financial and Accounting Officer)

Exhibit 2.1

Execution Version

AGREEMENT AND PLAN OF MERGER

BY AND AMONG

ACELRX PHARMACEUTICALS, INC.,

ACELRX INTERMEDIATE SUB, INC.,

ACELRX CONSOLIDATION SUB, LLC,

LOWELL THERAPEUTICS, INC.,

AND

JAMES WILKIE, AS STOCKHOLDER REPRESENTATIVE

November 14, 2021

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INDEX OF ANNEXES, EXHIBITS AND SCHEDULES

AGREEMENT AND PLAN OF MERGER

THIS AGREEMENT AND PLAN OF MERGER (this "**Agreement**") is made and entered into as of November 14, 2021 by and among AcelRx Pharmaceuticals, Inc., a Delaware corporation ("**Parent**"), AcelRx Intermediate Sub, Inc., a Delaware corporation and a direct wholly owned subsidiary of Parent ("**Merger Sub 1**"), AcelRx Consolidation Sub, LLC, a Delaware limited liability company and a direct wholly owned subsidiary of Parent ("**Merger Sub 2**"), Lowell Therapeutics, Inc., a Delaware corporation (the "**Company**") and James Wilkie (the "**Stockholder Representative**"), solely in his capacity as the representative of the Stockholders and the Company Option Holders. All capitalized terms that are used but not defined herein shall have the respective meanings ascribed thereto in **Annex A**.

RECITALS

WHEREAS, upon the terms and subject to the conditions of this Agreement and in accordance with the DGCL, Parent and the Company will enter into a business combination transaction pursuant to which (a) Merger Sub 1 will merge with and into the Company and the Company will continue as the Initial Surviving Company (as defined herein) and a direct wholly owned subsidiary of Parent (the "**First Merger**") and (b) the Initial Surviving Company will merge with and into Merger Sub 2 and Merger Sub 2 will continue as the Surviving Company (as defined herein) and a direct wholly owned subsidiary of Parent (the "**Second Merger**", together with the First Merger, the "**Mergers**");

WHEREAS, the Company Board of Directors (the "**Company Board of Directors**") has unanimously (a) approved and declared advisable this Agreement and the Related Agreements and the transactions contemplated hereby, including the Mergers and the Charter Amendment, and thereby (the "**Transactions**"), upon the terms and subject to the conditions set forth in this Agreement, (b) determined that this Agreement and the Transactions, including the Mergers, are fair to, and in the best interests of, the Company and the Stockholders, (c) approved the execution, delivery and performance by the Company of this Agreement, and (d) recommended the adoption of this Agreement to the Stockholders, upon the terms and subject to the conditions set forth in this Agreement;

WHEREAS, the board of directors of each of Parent and Merger Sub 1 and the sole member of Merger Sub 2 have unanimously (a) approved and declared advisable this Agreement and the Transactions, including the Mergers, upon the terms and subject to the conditions set forth in this Agreement, and (b) determined that this Agreement and the Transactions, including the Mergers, are fair to, and in the best interests of, Parent, Merger Sub 1 and Merger Sub 2 and their respective stockholder(s).

WHEREAS, for U.S. federal income tax purposes, it is intended that (a) the Mergers are part of a single integrated plan undertaken by the parties to this Agreement, (b) the Mergers qualify as a reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended, and (c) this Agreement is intended to be and is adopted as a "plan of reorganization" within the meaning of Treasury Regulation Section 1.368-2(g) (the "**Intended Tax Treatment**");

WHEREAS, as an inducement and condition to Parent's willingness to enter into this Agreement, concurrently with the execution and delivery of this Agreement, the individuals set forth on **Schedule A** (the "**Key Holders**") are each entering into a non-competition and non-solicitation agreement that is in form and substance reasonably acceptable to Parent and each Key Holder (the "**Non-Competition and Non-Solicitation Agreement**") and the Key Holder set forth in paragraph (a) of **Schedule A** is entering into a consulting agreement that is in form and substance reasonably acceptable to Parent and such Key Holder (the "**Offer Letter**");

WHEREAS, as an inducement and condition to Parent's willingness to enter into this Agreement, concurrently with the execution and delivery of this Agreement the Stockholders and Company Option Holders set forth on paragraph (a) of **Schedule B** are entering into a joinder agreement with Parent substantially in the form attached hereto as **Exhibit B** ("**Joinders**") and each other Stockholder and Company Option Holder will enter into Joinders at or prior to Closing, pursuant to which, among other things, such Stockholder or Company Option Holder, as applicable, agrees to be bound by certain terms of this Agreement and submits an accredited investor questionnaire in the form attached thereto (an "**Accredited Investor Questionnaire**"). Notwithstanding the delivery of any Accredited Investor Questionnaire to Parent, any holder of Company Capital Stock, in the sole discretion of Parent, may be deemed an Unaccredited Investor for purposes of this Agreement;

WHEREAS, as an inducement and condition to Parent's willingness to enter into this Agreement, each Person set forth on **Schedule C**, constituting all Company Option Holders, will enter into, as applicable, an Option Cancellation Agreement (the "**Option Cancellation Agreement**") with the Company substantially in the form attached hereto as **Exhibit C-1;** and

WHEREAS, the parties hereto desire to make certain representations, warranties, covenants and agreements, as more fully set forth herein, in connection with the Mergers and the other Transactions.

NOW, THEREFORE, in consideration of the foregoing and the respective representations, warranties, agreements and covenants contained in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the parties hereto hereby agree as follows:

ARTICLE I
THE MERGERS

SECTION 1.1 The Mergers.

(a) Upon the terms and subject to the conditions set forth in this Agreement and the applicable provisions of the DGCL, at the First Effective Time, Merger Sub 1 shall merge with and into the Company, the separate corporate existence of Merger Sub 1 shall cease and the Company shall continue as the surviving company and shall become a wholly owned subsidiary of Parent. The Company, as the surviving company after the First Merger, is sometimes referred to herein as the "**Initial Surviving Company**."

(b) Upon the terms and subject to the conditions set forth in this Agreement and the applicable provisions of the DGCL and the Limited Liability Company Act of the State of Delaware (the "**LLCA**"), at the Second Effective Time, the Initial Surviving Company shall merge with and into Merger Sub 2, the separate corporate existence of the Initial Surviving Company shall cease and Merger Sub 2 shall continue as the surviving company and shall remain a wholly owned subsidiary of Parent. Merger Sub 2, as the surviving company after the Second Merger, is sometimes referred to herein as the "**Surviving Company**."

SECTION 1.2 Closing and Effective Times.

(a) Unless this Agreement is validly terminated pursuant to **Section 9.1**, the Mergers shall be consummated at a closing (the "**Closing**") on a date that is the second (2nd) Business Day following the satisfaction or waiver (if permissible hereunder) of the conditions set forth in **Article VI** (other than those conditions that, by their nature, are to be satisfied at the Closing, but subject to the satisfaction or waiver (if permissible hereunder) of those conditions) via the remote exchange of documents, unless another time or place is mutually agreed upon in writing by Parent and the Company. The date upon which the Closing actually occurs shall be referred to herein as the "**Closing Date**."

(b) On the Closing Date, the parties hereto shall cause the First Merger to be consummated by filing a duly executed certificate of merger in substantially the form attached hereto as **Exhibit A-1** (the "**First Certificate of Merger**") with the Secretary of State of the State of Delaware in accordance with the applicable provisions of the DGCL. The time of the filing and acceptance by the Secretary of State of the State of Delaware, or such other later time as may be agreed in writing by Parent and the Company and specified in the First Certificate of Merger, shall be referred to herein as the "**First Effective Time**."

(c) On the Closing Date, the parties hereto shall cause the Second Merger to be consummated by filing a duly executed certificate of merger in substantially the form attached hereto as **Exhibit A-2** (the "**Second Certificate of Merger**") with the Secretary of State of the State of Delaware in accordance with the applicable provisions of the DGCL and the LLCA. The time of the filing and acceptance by the Secretary of State of the State of Delaware, or such other later time as may be agreed in writing by Parent and the Company and specified in the Second Certificate of Merger, shall be referred to herein as the "**Second Effective Time**."

SECTION 1.3 Organizational Documents.

(a) The certificate of incorporation of the Initial Surviving Company shall be amended and restated as of the First Effective Time to be identical to the certificate of incorporation of Merger Sub 1 as in effect immediately prior to the First Effective Time as set forth on **Exhibit D-1**, until thereafter changed or amended as provided in such certificate of incorporation or by applicable Law; *provided*, *however*, that at the First Effective Time, Article I of the certificate of incorporation of the Initial Surviving Company shall be amended and restated in its entirety as follows: "The name of the company is Lowell Therapeutics, Inc".

(b) The bylaws of Merger Sub 1 as in effect immediately prior to the First Effective Time shall be the bylaws of the Initial Surviving Company as of the First Effective Time until thereafter changed or amended as provided in the certificate of incorporation of the Initial Surviving Company or such bylaws or by applicable Law.

(c) The certificate of formation of Merger Sub 2, as in effect immediately prior to the Second Effective Time, shall be the certificate of formation of the Surviving Company as set forth on **Exhibit D-2** as of the Second Effective Time, until thereafter amended in accordance with the LLCA and as provided in such certificate of formation; *provided, however*, that at the Second Effective Time, Article I of the certificate of formation of the Surviving Company shall be amended and restated in its entirety as follows: "The name of the limited liability company is Lowell Therapeutics, LLC". The limited liability company agreement of Merger Sub 2 as set forth on **Exhibit D-3**, as in effect immediately prior to the Second Effective Time, shall be the limited liability company agreement of the Surviving Company as of the Second Effective Time, until thereafter replaced, amended or modified in accordance with the LLCA and as provided in such limited liability company agreement.

SECTION 1.4 Directors and Officers.

(a) The directors of Merger Sub 1 immediately prior to the First Effective Time shall be the directors of the Initial Surviving Company immediately after the First Effective Time, each to hold the office of a director of the Initial Surviving Company in accordance with the provisions of the DGCL and the certificate of incorporation and the bylaws of the Initial Surviving Company until such director's successor is duly elected or appointed and qualified, or until the earlier of his or her death, resignation or removal.

(b) The officers of Merger Sub 1 immediately prior to the First Effective Time shall be the officers of the Initial Surviving Company immediately after the First Effective Time, each to hold office in accordance with the provisions of the certificate of incorporation and the bylaws of the Initial Surviving Company until such officer's successor is duly elected or appointed and qualified, or until the earlier of his or her death, resignation or removal.

(c) Parent shall be the Managing Member (as defined in the limited liability company agreement of the Surviving Company) of the Surviving Company, and the officers of Merger Sub 2 immediately prior to the Second Effective Time shall be the officers of the Surviving Company as of the Second Effective Time, each to hold office in accordance with the provisions of the limited liability company agreement of the Surviving Company.

SECTION 1.5 General Effects of the Mergers.

(a) *First Merger*. At the First Effective Time, the effects of the First Merger shall be as provided in the applicable provisions of the DGCL. Without limiting the generality of the foregoing, and subject thereto, at the First Effective Time, all the properties, rights, privileges, powers and franchises of the Company and Merger Sub 1 shall vest in the Initial Surviving Company, and all debts, liabilities and duties of the Company and Merger Sub 1 shall become the debts, liabilities and duties of the Initial Surviving Company.

(b) *Second Merger*. At the Second Effective Time, the effects of the Second Merger shall be as provided in the applicable provisions of the LLCA. Without limiting the generality of the foregoing, and subject thereto, at the Second Effective Time, all the properties, rights, privileges, powers and franchises of the Initial Surviving Company and Merger Sub 2 shall vest in the Surviving Company, and all debts, liabilities and duties of the Initial Surviving Company and Merger Sub 2 shall become the debts, liabilities and duties of the Surviving Company.

SECTION 1.6 Effect of Mergers on Capital Stock and Membership Interests of Constituent Corporations.

(a) ***Treatment of Capital Stock of Merger Sub 1 and Merger Sub 2***.

(i) At the First Effective Time, by virtue of the First Merger and without further action on the part of Parent, Merger Sub 1, the Company or holders of any securities of the Company, Merger Sub 1 or any other Person, each share of common stock, par value $0.01 per share, of Merger Sub 1 issued and outstanding immediately prior to the First Effective Time shall be automatically converted into and become one (1) fully paid and non-assessable share of common stock of the Initial Surviving Company.

(ii) At the Second Effective Time, by virtue of the Second Merger and without further action on the part of Parent, Merger Sub 2, the Initial Surviving Company or holders of any securities of the Initial Surviving Company, Merger Sub 2 or any other Person, each share of common stock, par value $0.01 per share, of Initial Surviving Company outstanding immediately prior to the Second Effective Time shall be cancelled, and no consideration shall be paid with respect thereto and each membership interest of Merger Sub 2 outstanding immediately prior to the Second Effective Time shall remain outstanding and shall constitute the only outstanding shares of capital stock of the Surviving Company.

(b) ***Treatment of Company Capital Stock***.

(i) ***Generally***. At the First Effective Time, by virtue of the First Merger, and without further action on the part of Parent, Merger Sub 1, the Company or holders of any securities of the Company, Merger Sub 1 or any other Person, the shares of Company Capital Stock (other than (x) Cancelled Shares, which shall be treated in the manner set forth in **Section 1.6(b)(iii)**, and (y) Dissenting Shares, which shall be treated in the manner set forth in **Section 1.6(b)(iv)**) shall cease to exist and shall automatically be cancelled and shall be converted into the right to receive, the following (subject to **Section 1.6(e)** and, with respect to any Cash Holders, to the receipt of cash in lieu of Parent Common Stock pursuant to **Section 1.6(f)** hereof):

(A) Each share of Senior Series B Preferred Stock issued and outstanding immediately prior to the First Effective Time (other than Dissenting Shares and Cancelled Shares) shall be converted into the right to receive (w) a number of shares of Parent Common Stock (rounded down to the nearest whole share) equal to $2.60 *divided by* the Closing Parent Share Value (the "**Senior Series B Liquidation Payment**") or, subject to compliance with the provisions of **Section 1.6(b)(i)(E)** and **Section 1.6(g)** below, and to the extent permitted by the terms thereof, cash in lieu of such shares of Parent Common Stock, *plus* (x) if, and only if, the Exchange Ratio is a positive number, a number of shares of Parent Common Stock (rounded down to the nearest whole share) equal to the Exchange Ratio or, subject to compliance with the provisions of **Section 1.6(b)(i)(E)** and **Section 1.6(g)** below, and to the extent permitted by the terms thereof, cash in lieu of such shares of Parent Common Stock, *plus* (y) one contingent value right representing the right to receive the consideration set forth in the CVR Agreement if, and if so, when and to the extent, payable pursuant to the CVR Agreement (a "**CVR**"), *plus* (z) the right to receive a Pro Rata Portion of any Holdback Shares (rounded down to the nearest whole share) released pursuant to this Agreement, if any. The Senior Series B Liquidation Payment shall be allocated among holders of the Senior Series B Preferred Stock in the manner set forth in the Allocation Schedule.

(B) Each share of Series B-1 Preferred Stock issued and outstanding immediately prior to the First Effective Time (other than Dissenting Shares and Cancelled Shares) shall be converted into the right to receive (w) a number of shares of Parent Common Stock (rounded down to the nearest whole share) equal to $2.08 *divided by* the Closing Parent Share Value (the "**Series B-1 Liquidation Payment**") or, subject to compliance with the provisions of **Section 1.6(b)(i)(E)** and **Section 1.6(g)** below, and to the extent permitted by the terms thereof, cash in lieu of such shares of Parent Common Stock, *plus* (x) if, and only if, the Exchange Ratio is a positive number, a number of shares of Parent Common Stock (rounded down to the nearest whole share) equal to the Exchange Ratio or, subject to compliance with the provisions of **Section 1.6(b)(i)(E)** and **Section 1.6(g)** below, and to the extent permitted by the terms thereof, cash in lieu of such shares of Parent Common Stock, *plus* (y) one CVR, *plus* (z) the right to receive a Pro Rata Portion of any Holdback Shares (rounded down to the nearest whole share) released pursuant to this Agreement, if any. The Series B-1 Liquidation Payment shall be allocated among holders of the Series B-1 Preferred Stock in the manner set forth in the Allocation Schedule.

(C) Each share of Series A Preferred Stock issued and outstanding immediately prior to the First Effective Time (other than Dissenting Shares and Cancelled Shares) shall be converted into the right to receive (w) a number of shares of Parent Common Stock (rounded down to the nearest whole share) equal to $2.50 *divided by* the Closing Parent Share Value (the "**Series A Liquidation Payment**"), *plus* (x) if, and only if, the Exchange Ratio is a positive number, a number of shares of Parent Common Stock (rounded down to the nearest whole share) equal to the Exchange Ratio, *plus* (y) one CVR, *plus* (z) the right to receive a Pro Rata Portion of any Holdback Shares (rounded down to the nearest whole share) released pursuant to this Agreement, if any. The Series A Liquidation Payment shall be allocated among holders of the Series A Preferred Stock in the manner set forth in the Allocation Schedule.

(D) Each share of Company Common Stock issued and outstanding immediately prior to the First Effective Time (other than Dissenting Shares and Cancelled Shares) shall be converted into the right to receive (x) if, and only if, the Exchange Ratio is a positive number, a number of shares of Parent Common Stock (rounded down to the nearest whole share) equal to the Exchange Ratio, *plus* (y) one CVR, *plus* (z) the right to receive a Pro Rata Portion of any Holdback Shares (rounded down to the nearest whole share) released pursuant to this Agreement, if any.

(E) Any holder of shares of Series B Preferred Stock shall have the option by the Election Deadline pursuant to an validly delivered Election Form that complies with **Section 1.6(g)** to elect to receive cash (a "**Cash Election**") in lieu of a portion of the shares of Parent Common Stock (based on the Closing Parent Share Value) otherwise payable to such holder of Series B Preferred Stock pursuant to **clauses (A)** or **(B)** of this **Section 1.6(b)(i)**; *provided* that the aggregate amount of cash payable pursuant to this **clause (E)** shall not exceed $3,500,000 (the "**Cash Amount**"). In the event that the holders of shares of Series B Preferred Stock elect to receive cash in excess of the Cash Amount (with Dissenting Shares of Series B Preferred Stock being deemed to have elected to have made a Cash Election for this purpose and for all purposes of this sentence), the Cash Amount shall be prorated among such electing holders by multiplying the Cash Amount by the quotient of (x) the number of shares of Series B Preferred Stock for which an electing holder has made a Cash Election *divided by* (y) the total number of shares of Senior B Preferred Stock that have made a Cash Election (the "**Cash Allocation**"), with the remaining consideration payable in shares of Parent Common Stock as set forth herein. Subject to the terms of this Agreement, the Cash Amount will be wired directly from the Company's bank account at the First Effective Time to the holders of Series B Preferred Stock making Cash Election consistent with the Cash Allocation.

(ii) From and after the First Effective Time, each holder of a certificate or certificates which immediately prior to the First Effective Time represented any shares of Company Capital Stock (including any Company Preferred Stock) (each, a "**Company Stock Certificate**") or evidenced by way of book-entry in the register of stockholders of the Company immediately prior to the First Effective Time (each, a "**Book-Entry Share**") shall cease to have any rights with respect to such Company Capital Stock (including any rights to receive any accrued but unpaid dividends or any liquidation preference on such shares of Company Capital Stock, if any) other than the right to receive, upon surrender of such Company Stock Certificates or Book-Entry Shares in accordance with **Section 1.7**, the applicable Merger Consideration including the right to receive the Releasable Shares, if any, to be delivered in accordance with this Agreement.

(A) The Holdback Shares shall not be issued to the Stockholders or Company Option Holders at the First Effective Time and shall be a source for effecting the satisfaction and discharge of any indemnification obligation owed to Parent under this Agreement or any obligation under any Related Agreement, and Parent shall have the right to recover any Losses for which it is entitled to indemnification from such Holdback Shares. Each Stockholder and Company Option Holder hereby assigns to Parent all rights, title and interest in and to the Holdback Shares, including the right to recover any payments, releases, disbursements or other distributions thereof.

(B) On the date that is sixteen (16) months after the Closing Date (the "**Holdback Period**"), Parent shall issue to each Stockholder and Company Option Holder from the Holdback Shares allocable to such Stockholder or Company Option Holder, the number of Releasable Shares (rounded down to the nearest whole share) allocable to such Stockholder or Company Option Holder and deliver evidence of an uncertificated book-entry position with respect to such Releasable Shares to such Stockholder or Company Option Holder. Upon the final resolution of all unresolved claims in accordance with **Section 8.5**, Parent shall promptly issue to each Stockholder and Company Option Holder the Holdback Shares (rounded down to the nearest whole share) remaining, if any, allocable to such Stockholder or Company Option Holder, *less* the amount of such Holdback Shares forfeited by such Stockholder or Company Option Holder in accordance with this Agreement.

(C) The right of the Stockholders and Company Option Holders to receive any Holdback Shares, if any: (i) does not give the Stockholder Representative, the Stockholders or the Company Option Holders dividend rights, voting rights, liquidation rights, preemptive rights or other economic rights of holders of capital stock of Parent; (ii) shall not be evidenced by a certificate or other instrument; (iii) shall not be assignable or otherwise transferable by the Stockholder Representative, Stockholders or Company Option Holders except by will, upon death or by operation of the Laws of descent and distribution, or to a trust formed by a Stockholder or Company Option Holder for the sole benefit of immediate family members; (iv) shall not accrue or pay interest on any portion thereof; and (v) does not represent any right other than the right to receive the consideration set forth in this Agreement. Any attempted transfer of the right to any Holdback Shares by any holder thereof (other than as specifically permitted by the immediately preceding sentence) shall be null and void.

(D) Notwithstanding this **Section 1.6(b)(ii)**, if during the Holdback Period there shall occur any reorganization, recapitalization, consolidation or merger involving Parent (including any combination thereof but excluding a merger solely for the purpose of changing the Parent's jurisdiction of incorporation) (a "**Change of Control**") in which Parent Common Stock becomes convertible or exchangeable for securities, cash or other property ("**Reference Property**"), then immediately prior to the closing of such Change of Control, the Holdback Period shall be deemed expired, and all Releasable Shares shall be released, such that the Holdback Shares shall be deemed issued and outstanding immediately prior to the closing of such Change of Control and eligible to receive the same kind and amount of Reference Property as a holder of Parent Common Stock in such Change of Control transaction.

(iii) ***Cancelled Shares***. At the First Effective Time, by virtue of the First Merger and without any action on the part of Parent, Merger Sub 1, the Company or holders of any securities of the Company, Merger Sub 1 or any other Person, each share of Company Capital Stock issued and outstanding as of immediately prior to the First Effective Time that is owned or held by Parent or any of its Affiliates and each share of Company Capital Stock that is owned by the Company shall automatically be cancelled and extinguished without any conversion thereof or payment of any cash or other property or consideration therefor and shall cease to exist (collectively, the "**Cancelled Shares**").

(iv) ***Treatment of Dissenting Shares***. Notwithstanding anything to the contrary in this Agreement, any shares of Company Capital Stock outstanding immediately prior to the First Effective Time and with respect to which the holder thereof has properly demanded appraisal rights in accordance with Section 262 of the DGCL, and who has not effectively withdrawn or lost such holder's appraisal rights under DGCL with respect to such shares (collectively, the "**Dissenting Shares**"), shall not be converted into or represent a right to receive the applicable Merger Consideration set forth in **Section 1.6(b)**, but the holder thereof shall only be entitled to such rights (and only such rights) as are provided by the DGCL. At the First Effective Time, all Dissenting Shares shall no longer be outstanding and shall automatically be cancelled and extinguished and shall cease to exist, and except as otherwise provided by applicable Law, each holder of Dissenting Shares shall cease to have any rights with respect thereto other than the rights granted pursuant to Section 262 of the DGCL. Notwithstanding the provisions of this **Section 1.6(b)(iv)**, if any holder of Dissenting Shares shall effectively withdraw, waive or lose (through failure to validly perfect or otherwise) such holder's appraisal rights under the DGCL or if a court of competent jurisdiction shall determine that such holder is not entitled to the relief provided by Section 262 of the DGCL, then as of the later of the First Effective Time and the occurrence of such event, such holder's shares shall automatically be converted into and represent only the right to receive, subject to the terms of this Agreement, including the terms set forth in this **Section 1.6**, **Section 1.7** and the indemnification provisions set forth in **Article VIII**, the applicable Merger Consideration, without interest thereon. The Company shall give Parent (A) prompt notice and a copy of any written demand for appraisal received by the Company pursuant to the applicable provisions of the DGCL and (B) the opportunity to participate in and direct all negotiations and proceedings with respect to such demands. The Company shall not, except with the prior written consent of Parent, make, propose, enter into or approve any payment with respect to any such demands or offer to settle or settle any such demands. Any communication to be made by the Company to any Stockholder with respect to such demands shall be submitted to Parent in advance and shall not be presented to any Stockholder prior to the Company receiving Parent's written consent.

(v) ***Fractional Interests***. For purposes of calculating the aggregate amount of shares of Parent Common Stock issuable to each Stockholder or Company Option Holder pursuant to this Agreement, the number of shares of Parent Common Stock to be issued to each Stockholder in exchange for each Company Stock Certificate or Book-Entry Share shall be rounded down to the nearest whole number of shares of Parent Common Stock. No fraction of a share of Parent Common Stock will be issued by virtue of the First Merger.

(c) ***Company Options***

(i) ***Treatment of Company Options***. Effective as of the First Effective Time, each Company Option (or portion thereof) that is outstanding as of immediately prior to the First Effective Time, whether or not then vested and exercisable and in accordance with the terms of the Plan and the stock option agreement evidencing such Company Option, in each case, as in effect immediately prior to the First Effective Time, shall be surrendered and cancelled and converted automatically into the right to receive from Parent (A) a number of shares of Parent Common Stock (rounded down to the nearest whole share) equal to (x) the amount, if any, by which the Per Share Merger Consideration exceeds the per share exercise price of such Company Option, *multiplied by* (y) the number of shares of Company Common Stock as to which such Company Option is exercisable as if such Company Option were fully vested and exercised, the product of which is *divided by* (z) the Closing Parent Share Value; (B) one CVR per share of Parent Common Stock into which the option is exercisable representing the right to receive the consideration set forth in the CVR Agreement; and (C) the right to receive a Pro Rata Portion of any Holdback Shares released pursuant to this Agreement (the "**Company Option Consideration**"), which shall be paid without interest and *less* all applicable withholding and other authorized deductions, rounded down to the nearest whole share of Parent Common Stock. The Company Option Consideration shall be paid to each eligible Company Option Holder in accordance with the provisions of **Section 1.7** and subject to withholding pursuant to **Section 1.8** and in a manner that will not trigger a Tax or penalty under Section 409A of the Code.

(ii) ***Necessary Actions***. Prior to the First Effective Time, and subject to the review and reasonable approval of Parent, the Company shall take all actions necessary to effect the transactions anticipated by this **Section 1.6(c)** under all Company Options, the Plan, any applicable Law and any other plan or arrangement of the Company (whether written or oral, formal or informal) governing the terms of any Company Options, including determination by the administrator of the Plan that the treatment of Company Options contemplated by this **Section 1.6(c)** is permissible under the terms of the Plan and the applicable equity award agreements, delivering all required notices, obtaining all necessary approvals and consents, and delivering evidence satisfactory to Parent that all necessary determinations by the Company's board of directors or applicable committee of the Company's board of directors to convert or terminate Company Options in accordance with this **Section 1.6(c)** have been made.

(iii) ***Notice***. Within ten (10) Business Days before the Closing Date, the Company shall deliver notice to the holders of Company Options, which notice shall be in compliance with the terms of the Plan and each such Company Option and in a form reasonably acceptable to Parent, that the Company Options will be treated as set forth in this **Section 1.6(c)**. Any materials to be submitted to the Company Option Holders in connection with the notice required under this **Section 1.6(c)(iii)** shall be subject to advance review and approval by Parent, which Parent shall not unreasonably withhold or delay, *provided* that the Company considers in good faith any comments or proposed revisions made by Parent thereto.

(d) ***Treatment of the Company Warrant***. In the event the Company Warrant is not exercised prior to the First Effective Time, the Company Warrant shall be cancelled immediately prior to the First Effective Time and substituted with a written instrument substantially similar in form and substance to the Company Warrant (the "**Replacement Warrant**") in accordance with the Company Warrant, and upon the consummation of the Mergers, the Company Warrant Holder shall have the right to receive the Replacement Warrant. Prior to the First Effective Time, the Company shall deliver to the Company Warrant Holder any notice required pursuant to the terms of the Company Warrant. In the event the Company Warrant is exercised prior to the First Effective Time, pursuant to the Company Warrant, as of the First Effective Time, the Company Warrant shall no longer be outstanding and shall automatically be cancelled and cease to exist and the Company Warrant Holder shall cease to have any rights with respect thereto except the rights to receive the shares of Company Common Stock set forth in the Company Warrant which shall be converted into the right to receive the Merger Consideration at the First Effective Time in accordance with **Section 1.6(b)**. The Company shall use its reasonable best efforts to have the Company Warrant Holder enter into the Warrant Cancellation Agreement (the "**Warrant Cancellation Agreement**") with the Company prior to the Closing substantially in the form attached hereto as **Exhibit C-2**. Notwithstanding the foregoing, to the extent the Company Warrant Holder does not execute the Warrant Cancellation Agreement or exercise the Company Warrant prior to the consummation of the First Merger, Parent shall assume, by the Replacement Warrant, the obligation to deliver to the Company Warrant Holder such shares of Parent Common Stock which, in accordance with the Company Warrant, the Company Warrant Holder shall be entitled to receive upon exercise of the Company Warrant immediately prior to the Closing.

(e) Notwithstanding anything to the contrary in this Agreement, but subject to this **Section 1.6(e)**, the aggregate number of shares of Parent Common Stock issuable pursuant to **Section 1.6** (including Holdback Shares) in exchange for issued and outstanding shares of Company Capital Stock plus any other shares of Parent Common Stock aggregable for purposes of determining whether the Nasdaq Stock Market would require a stockholder vote in connection with any such issuances shall not exceed 19.9% of the total number of shares of Parent Common Stock that are issued and outstanding immediately prior to the First Effective Time (the "**Parent Common Stock Consideration Cap**"); *provided* that there shall be excluded from the shares issued and outstanding immediately prior to the First Effective Time any shares that have been issued prior to the First Effective Time and which are aggregable with the issuance pursuant to **Section 1.6** to determine whether the 19.9% limit has been reached. In the event the aggregate number of shares of Parent Common Stock issued pursuant to **Section 1.6** in exchange for issued and outstanding shares of Company Capital Stock at Closing would result in the issuance or reservation of shares of Parent Common Stock in an amount in excess of the Parent Common Stock Consideration Cap, Parent shall have the right (in its sole discretion) to (i) obtain the approval of its stockholders as required by applicable Law for issuances of shares of Parent Common Stock in excess of such amount; or (ii) issue to the holder of such Company Capital Stock shares of Parent Common Stock up to the Parent Common Stock Consideration Cap, and shall pay the remaining balance of such holder's Company Capital Stock in an amount of cash, without interest, equal to the product obtained by *multiplying* (A) the number of shares of Parent Common Stock (rounded down to the nearest whole share) that such holder's remaining Company Capital Stock would have been converted pursuant to **Section 1.6(b)(i)** *by* (B) the Closing Parent Share Value, rounded down to the nearest whole cent.

(f) ***Cash-Only Consideration***. Notwithstanding anything to the contrary in this Agreement, in no event shall Parent be required to issue any Parent Shares to any Person that (A) does not provide a duly completed and executed Accredited Investor Questionnaire establishing that Parent Shares may be issued to such Person in connection with the Mergers and the other Transactions pursuant to an exemption from the registration and prospectus delivery requirements of the Securities Act pursuant to Regulation D and the equivalent state "blue sky" Laws, or (B) in its sole discretion, Parent has determined prior to the Closing is an Unaccredited Investor (in either case, a "**Cash Holder**"). To the extent such Accredited Investor Questionnaire is not provided or Parent has made such determination regarding Unaccredited Investor status, Parent shall inform the Company of such determination prior to the Closing, and the Company shall indicate on the Allocation Schedule that such Person has not provided the Accredited Investor Questionnaire or has been determined to be an Unaccredited Investor. To the extent any such Person would otherwise have been entitled to be issued Parent Shares as consideration or otherwise under this Agreement or any Related Agreement in connection with the Transactions, Parent shall be entitled (but not required) to pay such amounts in cash, rather than issuing Parent Shares. No cash payments shall be required to be made to anyone who has not entered into a Joinder. To the extent any Parent Shares otherwise issuable but for the provisions of this **Section** would, when issued, have been subject to any vesting terms, acceleration terms, repurchase option or obligation, risk of forfeiture or other similar conditions, then any cash payable under this **Section** in respect thereof shall have, and be subject to, such same terms and conditions as would have applied to such Parent Shares had they been so issued; *provided* that Parent shall withhold the underlying cash amount at the Closing, and upon the satisfaction of any such vesting term, or the expiration of any such repurchase option or obligation, risk of forfeiture or similar condition, pay to the applicable recipient the amount of cash that corresponds to the satisfaction of such vesting term, or the expiration of such repurchase option or obligation, risk of forfeiture or similar condition, as applicable.

(g) ***Election Procedures***.

(i) Election Form and Election Deadline. With respect to shares of Series B Preferred Stock only, an election form (an "**Election Form**") providing for the ability to substitute cash for shares of Parent Common Stock pursuant to **Section 1.6(b)(i)(E)**, shall be provided by the Exchange Agent for that purpose to holders of record of shares of Series B Preferred Stock, together with appropriate transmittal materials. Elections shall be made by mailing to the Exchange Agent a duly completed Election Form. To be effective, an Election Form must be properly completed, signed and delivered to the Exchange Agent at its designated office, by 5:00 P.M. (Eastern Time) on the business day that is seven (7) Business Days prior to the anticipated Closing Date (which date shall be communicated to the holders of Series B Preferred Stock at least ten (10) Business Days prior to the anticipated Closing Date) or such other date and time as the Parent and Company may agree (the applicable of such date and times, the "**Election Deadline**"). Parent shall determine, in its sole and absolute discretion, which discretion and authority it may delegate in whole or in part to the Exchange Agent, whether Election Forms (and where applicable, appropriate transmittal materials) have been properly completed, signed and submitted or revoked. The decision of Parent (or the Exchange Agent, as the case may be) in such matters shall be conclusive and binding. An Election Form shall only be effective if a Joinder is duly completed, executed and delivered to Parent by such Stockholder and no Election Form will be valid unless accompanied or preceded by such Joinder.

(ii) Revocation of Election. Any shares owned by a holder of Series B Preferred Stock who has not, as of the Election Deadline, made an election by submission to the Exchange Agent of an effective, properly completed Election Form shall be deemed to have elected to not receive cash pursuant to **Section 1.6(b)(i)(E)**. No Election Form may be revoked after the Election Deadline. An election may be revoked, but only by written notice received by the Exchange Agent prior to the Election Deadline. Upon any such revocation, unless a duly completed Election Form is thereafter submitted prior to the Election Deadline in accordance with **Section 1.6(b)(i)(E)**, such holder shall receive shares of Parent Common Stock and shall not receive cash pursuant to **Section 1.6(b)(i)(E)**.

SECTION 1.7 Payment of Merger Consideration for Company Capital Stock.

(a) ***Exchange Procedures***. Prior to the Closing, Parent shall enter into an agreement reasonably acceptable to the Company with the Exchange Agent relating to the services to be performed by the Exchange Agent. As soon as reasonably practicable after the First Effective Time, Parent or the Exchange Agent shall mail to each Stockholder at the email address and physical address set forth opposite each such Stockholder's name on the Allocation Schedule (i) a letter of transmittal (which shall specify that risk of loss and title to any shares evidenced by Company Stock Certificates or any Book-Entry Shares shall pass, only upon (A) with respect to shares evidenced by Company Stock Certificates delivery of the Company Stock Certificates (or affidavits of loss in lieu thereof as set forth in **Section 1.7(b)**), and (B) with respect to Book-Entry Shares, upon proper delivery of such evidence, if any, of the transfer as the Exchange Agent may reasonably request, as applicable, to the Exchange Agent and shall be in a form and have such other provisions as Parent may reasonably specify) (the "**Letter of Transmittal**"); and (ii) instructions for use in effecting the surrender of the Company Stock Certificates or Book-Entry Shares. Upon surrender of a Company Stock Certificate or Book-Entry Shares to the Exchange Agent together with a Letter of Transmittal and, as applicable, Election Form, duly completed and validly executed, and such other documents (including applicable tax forms) as may reasonably be required by Parent or the Exchange Agent (the "**Exchange Documents**"), Parent shall cause its transfer agent to, as promptly as reasonably practicable, (1) credit to the surrendering Stockholder of such Company Stock Certificate or Book-Entry Shares in the stock ledger and other appropriate books and records of Parent the number of shares of Parent Common Stock (which shall be in uncertificated book-entry form) into which the shares represented by such Company Stock Certificate or such Book-Entry Shares have been converted pursuant to this Agreement (*less* the Holdback Shares as set forth in the Allocation Schedule in accordance with this Agreement); (2) pay the appropriate cash consideration pursuant **Section 1.6(b)(i)(E)** to the Exchange Agent, and, in each case, the Company Stock Certificate or Book-Entry Shares so surrendered shall be forthwith cancelled. The shares of Parent Common Stock and cash amounts so deposited with the Exchange Agent are referred to collectively as the "**Exchange Fund**." No portion of the Merger Consideration will be paid to the holder of any unsurrendered Company Stock Certificate with respect to shares of Company Capital Stock formerly represented thereby until the holder of record of such Company Stock Certificate shall surrender such Company Stock Certificate and validly executed Exchange Documents pursuant hereto.

(b) ***Lost, Stolen or Destroyed Certificates***. In the event any Company Stock Certificate shall have been lost, stolen or destroyed, the Exchange Agent or Parent shall pay, in exchange for such lost, stolen or destroyed certificate, the Merger Consideration, if any, issuable in respect thereto pursuant to **Section 1.6(b)** upon the making of an affidavit of that fact by the holder thereof; *provided*, *however*, that Parent may, in its discretion, or as required by the Exchange Agent, and as a condition precedent to the issuance thereof, require the Stockholder who is the owner of such lost, stolen or destroyed certificates to either (i) deliver a bond in such amount as it may reasonably direct or (ii) provide an indemnification agreement in form and substance acceptable to Parent against any claim that may be made against Parent, the Surviving Company or the Exchange Agent with respect to the certificates alleged to have been lost, stolen or destroyed.

(c) ***Transfers of Ownership***. If any shares of Parent Common Stock are to be issued pursuant to **Section 1.6** and this **Section 1.7** to a Person other than the Person whose name is reflected on the Company Stock Certificate surrendered in exchange therefor, it shall be a condition of the issuance or delivery thereof that the Company Stock Certificate so surrendered is properly endorsed and otherwise in proper form for transfer (if applicable) and that the Person requesting such exchange shall have paid to Parent or any agent designated by it any transfer or other Taxes required by reason of the payment of any portion of the Merger Consideration in any name other than that of the registered holder of the Company Stock Certificate surrendered, or established to the satisfaction of Parent or any agent designated by it that such Tax has been paid or is not required to be paid.

(d) ***Transfer Books; No Further Ownership Rights in Company Capital Stock***. At the First Effective Time, the stock transfer books of the Company shall be closed, and thereafter there shall be no further registration of transfers of Company Capital Stock on the records of the Company. Until surrendered pursuant to the provisions of this **Section 1.7**, each Company Stock Certificate and Book-Entry Share shall represent after the First Effective Time for all purposes only the right to receive a portion of the applicable Merger Consideration with respect to each share of Company Capital Stock represented thereby as provided herein. The Merger Consideration paid in accordance with the terms hereof shall be deemed to have been paid in full satisfaction of all rights pertaining to the shares of Company Capital Stock (including any rights to receive accrued but unpaid dividends or any liquidation preference on such shares of Company Capital Stock, if any). If, after the First Effective Time, any Company Stock Certificates or Book-Entry Shares formerly representing shares of the Company Capital Stock are presented to the Surviving Company or the Exchange Agent for any reason, such Company Stock Certificates or Book-Entry Shares (as applicable) shall be cancelled and exchanged for a portion of the applicable Merger Consideration with respect to each share of Company Capital Stock represented thereby as provided in this **Article I**.

(e) ***No Liability***. Notwithstanding anything to the contrary in this Agreement, none of Parent, the Exchange Agent, the Surviving Company, the Stockholder Representative, or any party hereto shall be liable to a Stockholder (including any former holder of Company Common Stock) or any other Person for any portion of the Merger Consideration or other amounts (including any shares of Parent Common Stock (or dividends or distributions with respect thereto), any CVRs or for any cash amounts) delivered or paid to a public official or Governmental Entity pursuant to any applicable abandoned property, escheat or similar Law. After a thirty (30)-day prior notification to the Stockholder Representative, any amounts in the Exchange Fund remaining unclaimed by Stockholders immediately prior to such time when the amounts would otherwise escheat to or become property of any Governmental Entity shall become, to the extent permitted by applicable Law, the property of Parent free and clear of all claims or interest of any Person previously entitled thereto.

(f) ***No Interest, Dividends or Distributions***. No interest shall be paid or accrue on any portion of the Merger Consideration payable upon surrender of any Company Stock Certificate (or affidavit of loss in lieu thereof in accordance with **Section 1.7**). No dividends or other distributions declared or made with respect to Parent Common Stock with a record date after the First Effective Time shall be paid or otherwise delivered to the holder of any unsurrendered Company Stock Certificate or Book Entry Share with respect to the shares of Parent Common Stock that such holder has the right to receive in the Mergers until such holder surrenders such Company Stock Certificate or Book Entry Share in accordance with this **Section 1.7** (at which time such holder shall be entitled, subject to the effect of applicable abandoned property, escheat or similar laws, to receive all such dividends and distributions, without interest).

(g) ***Shares of Parent Common Stock***. The shares of Parent Common Stock issued by Parent pursuant to **Section 1.6** and this **Section 1.7** shall be reflected in Parent's books and records in book entry only with appropriate notations reflecting the following restrictive legend until such Parent Common Stock is registered for resale pursuant to **Section 1.7(h)**:

> "THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "**SECURITIES ACT**"), OR UNDER THE SECURITIES LAWS OF ANY STATE. WITHOUT SUCH REGISTRATION, SUCH SECURITIES MAY NOT BE SOLD OR OTHERWISE TRANSFERRED AT ANY TIME UNLESS IN THE OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE COMPANY REGISTRATION IS NOT REQUIRED FOR SUCH TRANSFER."

(h) ***Registration Statement***.

(i) Registration of Shares. Parent shall use reasonable efforts to, within forty-five (45) calendar days of the Closing Date, file a registration statement on Form S-3 (or other appropriate form if Parent is not then Form S-3 eligible) (including any amendments or supplements, the "**Registration Statement**") providing for the resale of all Parent Common Stock issued and issuable pursuant to **Section 1.6(b)**. Parent shall use reasonable efforts to cause such Registration Statement to be declared effective as soon as practicable following the initial filing of such Registration Statement, subject to any comments from the SEC).

(ii) Holders of Registrable Securities. As a condition to its obligations under **Section 1.7(h)(i)**, Parent may require each Holder of Registrable Securities as to which any registration is being effected to (A) furnish Parent with such information regarding such Person that is necessary to satisfy the disclosure requirements relating to the registration and the distribution of such securities under the Securities Act and the rules and regulations promulgated thereunder as Parent may from time to time reasonably request in writing, including the properly completed and executed Accredited Investor Questionnaire; and (B) promptly notify Parent in writing of any changes in the information set forth in the applicable Registration Statement after it is prepared regarding the Holder of Registrable Securities; *provided* that any delay in providing or failing to provide such information by any Holder of Registrable Securities shall not delay, eliminate or condition Parent's obligations under **Section 1.7(h)(i)** with respect to any other Holder of Registrable Securities. The Registration Statement and Prospectus shall only include the Registrable Securities of all Accredited Investors for whom Parent has received properly completed Accredited Investor Questionnaire on or before the Closing Date. For the purposes of this **Section 1.7(h)**, a "**Holder of Registrable Securities**" refers solely to an Accredited Investor that is a holder of Registrable Securities as of or following the Closing Date.

SECTION 1.8 Withholding. The Company, the Exchange Agent, Parent and the Surviving Company, shall be entitled to deduct and withhold from any consideration payable or otherwise deliverable pursuant to this Agreement or the CVR Agreement such amounts as may be required to be deducted or withheld therefrom under any provision of federal, local or foreign Tax Law, *provided* that, other than with respect to compensatory payments or if the Company fails to deliver the FIRPTA certificate required by **Section 7.5**, any such person shall (x) use reasonable best efforts to (i) provide prompt prior written notice of the amounts purportedly subject to deduction or withholding; and (ii) provide a reasonable opportunity to provide forms or other evidence that would exempt such amounts from such deduction or withholding; and (y) cooperate in good faith to minimize or eliminate any deduction or withholding that may be applied. To the extent such amounts are so deducted or withheld and property paid over to the applicable Governmental Entity, such amounts shall be treated for all purposes under this Agreement and the CVR Agreement as having been paid to the Person to whom such amounts would otherwise have been paid.

SECTION 1.9 Company Loans to Stockholders. In the event that any Stockholder as a borrower has outstanding loans from the Company as of the First Effective Time, the consideration payable to such Stockholder pursuant to **Section 1.6(b)** hereof shall be reduced by an amount equal to the outstanding principal plus accrued interest, if any, of such Stockholder's loans as of the First Effective Time, plus any other amounts owed by such Stockholder to the Company (collectively, such Stockholder's "**Loan Repayment Amount**"). Such loans shall be satisfied as to the amount by which the consideration is reduced pursuant to this **Section 1.9**. To the extent the consideration payable to such Stockholder is so reduced, such amount shall be treated for all purposes under this Agreement as having been paid to such Stockholder.

SECTION 1.10 Tax Consequences. The Mergers are intended to qualify as a "reorganization" within the meaning of Section 368(a)(1) of the Code, and this Agreement is intended to constitute a "plan of reorganization" within the meaning of Treasury Regulations Sections 1.368-2(g) and 1.368-3. Notwithstanding the foregoing, Parent makes no representations or warranties to the Company or to any securityholder of the Company regarding the Tax treatment of the Mergers, or any of the Tax consequences to the Company or any securityholder of the Company of this Agreement, the Mergers or any of the other Transactions. The Company acknowledges that the Company and the securityholders of the Company are relying solely on their own Tax advisors in connection with this Agreement, the Mergers and the other Transactions.

SECTION 1.11 Further Action. If, at any time after the First Effective Time, Parent, the Initial Surviving Company or the Surviving Company shall consider or be advised that any deeds, bills of sale, assignments, assurances or any other actions or things are necessary or desirable to vest, perfect or confirm of record or otherwise in the Initial Surviving Company or the Surviving Company its right, title or interest in, to or under any of the rights, properties, assets, privileges, powers or franchises of Merger Sub 1, Merger Sub 2 or the Company or otherwise to carry out this Agreement, the officers and directors of each of the Initial Surviving Company, the Surviving Company and Parent shall be fully authorized to execute and deliver, in the name and on behalf of Merger Sub 1, Merger Sub 2 or the Company, all such deeds, bills of sale, assignments and assurances and to take and do, in the name and on behalf of Merger Sub 1, Merger Sub 2 or the Company, all such other actions and things as may be necessary or desirable to vest, perfect or confirm any and all right, title and interest in, to and under such rights, properties, assets, privileges, powers or franchises in the Initial Surviving Company or the Surviving Company or otherwise to carry out this Agreement. Each party hereto shall, from time to time, execute such further instruments and take such other actions as any other parties shall reasonably request (at such requesting party's cost) in order to fulfill its obligations under this Agreement or the Related Agreements, to effectuate the purposes of the Agreement or the Related Agreements and provide for the orderly and efficient transfer of the ownership of the Company to Parent.

SECTION 1.12 CVR Agreement. At or prior to the First Effective Time, Parent will authorize and duly adopt, execute and deliver the CVR Agreement, subject to any reasonable revisions to the CVR Agreement that are requested by the Rights Agent and reasonably agreed by the Stockholder Representative which shall be countersigned by the Rights Agent as of the First Effective Time.

ARTICLE II
REPRESENTATIONS AND WARRANTIES
OF THE COMPANY

As an inducement to Parent, Merger Sub 1 and Merger Sub 2 to enter into this Agreement, except as set forth in the corresponding Section of the Company Disclosure Schedule (with specific reference to the particular Section of this Agreement to which the information in the Company Disclosure Schedule relates, it being agreed that disclosure of any item in any Section of the Company Disclosure Schedule shall be deemed disclosed with respect to any other Section of this Agreement to which the applicability of such item is reasonably apparent on the face of such disclosure), the Company hereby represents and warrants to Parent, Merger Sub 1 and Merger Sub 2 as of the date hereof and as of the Closing Date that:

SECTION 2.1 Organization and Standing. The Company is a corporation duly incorporated, validly existing and in good standing under the laws of the State of Delaware. The Company has the requisite corporate power and authority and all necessary governmental approvals to own, lease and operate its assets and properties and to carry on its business as currently conducted. The Company is duly qualified or licensed to do business and in good standing as a foreign corporation in each jurisdiction where the character or location of its assets or properties (whether owned, leased or licensed) or the nature of its business make such qualification or license necessary, except where the failure to be so qualified, licensed or in good standing would not materially and adversely affect the ability of the Company to conduct its business. The Company has made available true, correct and complete copies of its certificate of incorporation, as amended to date (the "**Certificate of Incorporation**") and its bylaws, as amended to date (the "**Bylaws**"), each in full force and effect on the date hereof. The Company Board of Directors has not approved or proposed any amendment to any of the Governing Documents that has not been made available to Parent. Section 2.1 of the Company Disclosure Schedule lists the directors and officers of the Company and every jurisdiction in which the Company has Employees or facilities or otherwise conducts business as of the date hereof. The Company has never conducted its operations under any other name. There are no outstanding powers of attorney executed by or on behalf of the Company.

SECTION 2.2 Authority and Enforceability.

(a) The Company has all requisite power and authority to execute and deliver this Agreement and any Related Agreements to which it is a party, to perform its obligations hereunder and thereunder and, subject to receipt of the Stockholder Approval, to consummate the Mergers and the other Transactions. The execution and delivery of this Agreement by the Company and any Related Agreements to which it is a party, the performance by the Company of its obligations hereunder and thereunder, and the consummation by the Company of the Mergers and the other Transactions have been duly authorized by all necessary corporate (including the unanimous approval of the Company Board of Directors) and other action on the part of the Company, and no other corporate proceedings on the part of the Company are necessary to authorize this Agreement or to consummate the transactions contemplated hereby (subject to obtaining the Stockholder Approval and other than, with respect to the First Merger, the filing and recordation of the First Certificate of Merger as required by the DGCL, and with respect to the Second Merger, the filing and recordation of the Second Certificate of Merger as required by the DGCL and the LLCA). This Agreement and each of the Related Agreements to which the Company is a party have been duly executed and delivered by the Company and (assuming the due authorization, execution and delivery by the other parties hereto and thereto) constitute the legal, valid and binding obligations of the Company enforceable against it in accordance with their respective terms, in each case, subject to the Enforceability Limitations.

(b) The Company Board of Directors has unanimously (i) approved and declared advisable this Agreement and the Transactions contemplated, including the Mergers; (ii) determined that this Agreement and the Transactions, including the Mergers, are fair to, and in the best interests of, the Company and the Stockholders; (iii) approved the execution, delivery and performance by the Company of this Agreement; (iv) recommended the adoption of this Agreement to the Stockholders; and (v) directed that this Agreement be submitted to the Stockholders for adoption and approval. None of the foregoing actions by the Company Board of Directors have been rescinded or modified in any way.

(c) The Stockholder Approval is the only vote or authorization of any holders of capital stock or other equity interests of the Company necessary to adopt and approve this Agreement and the Transactions, including the Mergers, and the Charter Amendment. No other approvals or consents by the Stockholders are necessary or required for the consummation of the Transactions, including the Mergers.

(d) In accordance with Section 3.4 of the Contribution Agreement, on September 23, 2021, the Company closed a Series B Preferred Stock financing, which fulfilled the requirement in the Contribution Agreement to raise at least $5,000,000 in equity. The Company has complied with and satisfied its obligations under Section 3.4 of the Contribution Agreement. Since the execution of each of such Agreements, the Company has complied with the terms of each of the Contribution Agreement and the Company Warrant and has never been in default or violation thereof. After Closing, the Company, Parent and their Affiliates do not have any obligations under the Contribution Agreement or the Company Warrant, except the right to receive the Replacement Warrant or Merger Consideration as set forth in **Section 1.6(d)**.

SECTION 2.3 Governmental Approvals and Consents. No consent, notice, waiver, approval, Governmental Order or authorization of, or registration, declaration or filing with any Governmental Entity, is required by, or with respect to, the Company in connection with the execution, delivery and performance of this Agreement and any Related Agreement to which the Company is a party or the consummation of the Mergers or any other Transactions, except for the filing of the First Certificate of Merger and the Second Certificate of Merger with the Secretary of State of the State of Delaware.

SECTION 2.4 No Conflicts. The execution and delivery by the Company of this Agreement and any Related Agreement to which the Company is a party does not, and the performance by the Company of this Agreement and any Related Agreement to which the Company is a party and the consummation of the Transactions, including the Mergers will not, (a) conflict with or violate the Governing Documents or any other organizational document of the Company, the Contribution Agreement and the Company Warrant; (b) conflict with or violate any Law applicable to the Company or by which any property or asset of the Company is bound; or (c) violate, conflict with, require consent under, result in any breach of, result in loss of benefit under, or constitute a default (or an event which, with notice or lapse of time or both, would become a default) under, or give to others any right of termination, amendment, acceleration or cancellation of, or result in the creation of a Lien on any property or asset of the Company pursuant to, any note, bond, mortgage, indenture, deed of trust, contract, agreement, license, lease, sublease or other occupancy document, Company Permit or other instrument or obligation to which the Company is a party or by which the Company or any of its assets or properties is bound or affected, except, with respect to **clauses (b)** and **(c)**, for any such conflicts, violations, breaches, defaults or other occurrences which would not, individually or in the aggregate, prevent or materially delay the Company from performing its obligations under this Agreement, or which could not reasonably be expected to be material to the Company.

SECTION 2.5 Company Capital Structure.

(a) The authorized capital stock of the Company consists of 12,213,446 shares of capital stock, consisting of 10,000,000 shares of Company Common Stock, 2,213,446 shares of Company Preferred Stock, of which (A) 400,000 have been designated Series A Preferred Stock, par value $0.0001 per share (the "**Series A Preferred Stock**"); (B) 1,750,000 have been designated Series B Preferred Stock, par value $0.0001 per share (the "**Senior Series B Preferred Stock**"); (C) 63,446 have been designated Series B-1 Preferred Stock, par value $0.0001 per share (the "**Series B-1 Preferred Stock**", and collectively with the Senior Series B Preferred Stock described in **clause (B)**, the "**Series B Preferred Stock**"); and (D) 200,000 shares of Company Common Stock have been reserved for issuance upon exercise of currently-outstanding Company Options and 53,000 shares have been reserved for future awards under the Plan. There are only, (i) 1,654,740 shares of Company Common Stock issued and outstanding; (ii) zero (0) shares of Company Common Stock are held in the Company's treasury; (iii) 400,000 shares of Series A Preferred Stock issued and outstanding which are convertible into 400,000 shares of Company Common Stock; (iv) 961,574 shares of Series B Preferred Stock issued and outstanding which are convertible into 961,574 shares of Company Common Stock; (v) 63,446 shares of Series B-1 Preferred Stock issued and outstanding which are convertible into 63,446 shares of Company Common Stock; (vi) the Company Warrant issued and outstanding, with an exercise price per share of $0.0001, which is exercisable for 400,270 shares of Company Common Stock; and (vii) Company Options issued and outstanding exercisable for 200,000 shares of Company Common Stock. All the outstanding shares of Company Capital Stock are duly authorized, validly issued, fully paid and nonassessable and were not issued or transferred in violation of any purchase option, right of first refusal, right of first offer, preemptive right, subscription right or any similar right. Each share of Company Preferred Stock is convertible on a one-share-for-one-share basis into Company Common Stock. As of the date of this Agreement, the Company Capital Stock, Company Warrant and Company Options are held by the Persons and in the amounts set forth in Section 2.5(a) of the Company Disclosure Schedule, which further sets forth for each such Person the number of shares held, class or series of such shares, the number of the applicable stock certificates representing such shares and the domicile addresses of record of such Persons. All capital stock subject to issuance, upon issuance on the terms and conditions specified in the instruments pursuant to which they are issuable, will be duly authorized, validly issued, fully paid and non-assessable. There are no outstanding contractual obligations of the Company to repurchase, redeem or otherwise acquire any capital stock of, or other equity interests in, any Person, or to provide funds to, make any investment (in the form of a loan, capital contribution or otherwise) in, return capital to, or make any payment to, any Person. All outstanding shares of Company Capital Stock have been duly authorized and issued in compliance with (A) all applicable securities Laws and other applicable Laws and (B) all requirements set forth in applicable Contracts, including the Governing Documents. None of the Stockholders or, to the Knowledge of the Company, any other Person has any claims or other Actions (nor have any claims or any other Actions ever been brought) against the Company or any other Person in connection with the Governing Documents. On September 23, 2021, all of the Company Convertible Notes converted into 63,446 shares of Series B-1 Preferred Stock and accordingly, such Company Convertible Notes have been cancelled in accordance with their terms and the Company has no further obligations in connection with the Company Convertible Notes.

(b) Section 2.5(b) of the Company Disclosure Schedule sets forth for each outstanding Company Option, the name of the holder, the type of award, the type of entity of such holder, the domicile address of record of such holder, whether such holder is an employee of the Company, the number of shares of Company Capital Stock issuable upon the exercise of such Company Option, the date of grant, the exercise price (if any), the vesting schedule, including the extent vested to date and whether such vesting is subject to acceleration as a result of the Transactions or any other events, and, for any Company Option, whether such option is a non-statutory option or qualifies as an incentive stock option as defined in Section 422 of the Code and whether (and to what extent) any such Company Option is or has ever been subject to Section 409A (whether or not subsequently amended to comply with or be exempt from the requirements of Section 409A and any action taken to amend any such Company Option to comply with or be exempt from the requirements of Section 409A).

(c) No Stockholder has exercised any right of redemption, if any, provided in the Certificate of Incorporation with respect to shares of the Company Preferred Stock, and the Company has not received notice that any Stockholder intends to exercise such rights. The Company has not, and will not have, suffered or incurred any Liability or claim, loss, damage, deficiency, cost or expense relating to or arising out of the issuance or repurchase of any Company Capital Stock, or out of any Contracts relating thereto (including any amendment of the terms of any such Contract). There are no declared or accrued but unpaid dividends with respect to any shares of Company Capital Stock. Other than the Company Capital Stock set forth in **Section 2.5(a)**, the Company has no other capital stock authorized, issued or outstanding. True, correct and complete copies of all Contracts relating to any securities of the Company have been made available and such Contracts have not been amended, modified or supplemented, and there are no agreements to amend, modify or supplement such Contracts from the forms thereof provided to Parent.

(d) No bonds, debentures, notes or other Indebtedness of the Company (i) having the right to vote (or convertible into, or exchangeable for, securities having the right to vote) on any matters related to the Company or on which stockholders may vote or (ii) the value of which is in any way based upon or derived from capital or voting stock of the Company, in each case, are issued or outstanding.

(e) Other than the Company Warrant and the Company Options, there are no options, warrants, calls, rights, convertible securities, commitments or agreements of any character, written or oral, to which the Company is a party or by which the Company is bound obligating the Company to issue, deliver, sell, repurchase or redeem, or cause to be issued, delivered, sold, repurchased or redeemed, any shares of the capital stock or other equity interests of the Company or obligating the Company to grant, extend, accelerate the vesting of, change the price of, otherwise amend or enter into any such option, warrant, call, right, commitment or agreement and, except as expressly set forth in the Certificate of Incorporation, there are no other rights, agreements, arrangements or commitments of any character relating to the issued or unissued capital stock of the Company or obligating the Company to issue or sell any shares of capital stock of, or other equity interests in, the Company. Other than this Agreement or as set forth in Section 2.5(e) of the Company Disclosure Schedule, there are no voting trusts, proxies, stockholder agreements or other agreements or understandings with respect to the voting stock or other equity interests of the Company, and there are no agreements to which the Company is a party relating to the registration, sale or transfer (including agreements relating to rights of first refusal, co-sale rights or “drag-along” rights) of any Company Capital Stock. As a result of the First Merger, Parent will be the sole record and beneficial holder of all issued and outstanding Company Capital Stock and all rights to acquire or receive any shares of Company Capital Stock, whether or not such shares of Company Capital Stock are outstanding.

(f) There are no outstanding obligations of the Company (i) restricting the transfer of, (ii) relating to the voting of, or (iii) requiring the registration under any securities Law for sale of, any Company Capital Stock, or any other capital stock of, or other equity interests in, the Company.

(g) No event has occurred, and no circumstance or condition exists, that has resulted in, or that would reasonably be expected to result in, and there is no basis for, any Liability of the Company to any current, former or alleged holder of securities of the Company in such Person’s capacity (or alleged capacity) as a holder of such securities, whether related to the Merger or otherwise.

(h) The information contained in the Allocation Schedule will be true, correct and complete as of the Closing Date and the calculations performed to compute the information contained therein will be true and accurate and in accordance with applicable Laws, the terms of this Agreement, the Governing Documents and all other agreements and instruments among the Company and any of the Stockholders, and no Stockholder or Company Option Holder will be entitled to any amounts except as provided in the Allocation Schedule.

(i) Neither Parent nor any Parent Related Person owns or, prior to the First Effective Time, will own (including through partnerships, intermediaries or other third parties) any stock of the Company.

SECTION 2.6 Company Subsidiaries. The Company does not own and has never owned any capital stock, equity or ownership interest, or other securities (or any interest convertible or exchangeable or exercisable for, any equity or ownership interest), whether direct or indirect, in any Person.

SECTION 2.7 Company Financial Statements; Internal Financial Controls.

(a) Section 2.7(a) of the Company Disclosure Schedule sets forth a true and complete copy of the Company's (i) unaudited balance sheets as of December 31, 2020 and December 31, 2019, and the related statements of income, cash flow and stockholders' equity for the fiscal years ended December 31, 2020 and December 31, 2019; and (ii) unaudited balance sheet as of September 30, 2021, and the related unaudited statements of income, cash flow and stockholders' equity for the three (3) months then ended March 31, 2021, June 30, 2021 and September 30, 2021 (the "**Interim Financial Statements**" and, together with the foregoing **clause (i)** of this **Section 2.7(a)**, the "**Financial Statements**"). The Financial Statements (1) were prepared in accordance with the accounting principles set forth on Section 2.7(c) of the Company Disclosure Schedule on a basis consistent with the past practices of the Company and on a consistent basis throughout the periods indicated and (2) were prepared on the basis of the Books and Records of the Company. The Financial Statements: (x) present fairly in all material respects the financial condition, operating results and cash flows of the Company as of the dates thereof or for the periods covered thereby (subject, in the case of the Interim Financial Statements, to the absence of footnotes and normal year-end adjustments (the effect of which, in each case, would not be material)) and (y) in the case of the Interim Financial Statements, include all year-end adjustments (consisting only of normal recurring accruals) that are necessary for a fair presentation of the financial condition of the Company and the results of the operations of the Company as of the dates thereof or for the periods covered thereby and which are not material in amount or significance in any individual case or in the aggregate.

(b) The Books and Records of the Company (i) reflect all items of income and expense and all assets and liabilities required to be reflected therein on a basis consistent with the past practices of the Company; (ii) are in all material respects complete and correct, and do not contain or reflect any material inaccuracies or discrepancies; and (iii) have been, and are being, maintained in all material respects in accordance with applicable legal and accounting requirements.

(c) The Company maintains and has maintained for all periods reflected in the Financial Statements, proper and adequate internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations and (ii) transactions are recorded as necessary to permit preparation of the Financial Statements in accordance with the accounting principles set forth on Section 2.7(c) of the Company Disclosure Schedule. The Company has made available to Parent complete and correct copies of, all written descriptions of, and all policies, manuals and other documents promulgating, such internal accounting controls. Since August 31, 2018, neither the Company nor, to the Knowledge of the Company, any Representative of the Company, has received or otherwise had or obtained knowledge of any complaint, allegation, assertion or claim regarding the accounting or auditing practices, procedures, methodologies, methods or controls of the Company.

(d) The Company is not, and has never been, required to file any forms, reports or comment letter responses with the SEC.

(e) The information set forth in the Closing Date Balance Sheet will be true, correct and complete as of immediately prior to the First Effective Time.

SECTION 2.8 No Undisclosed Liabilities. The Company does not have any Liabilities of any nature, except (a) those which are adequately reflected or reserved against in the Interim Financial Statements or (b) for Liabilities incurred since March 31, 2021 in the ordinary course of business, consistent with past practice, of the Company and which are not, individually or in the aggregate, material to the Company.

SECTION 2.9 Absence of Certain Changes or Events. Since December 31, 2020, (a) the Company has conducted its business only in the ordinary course and in a manner consistent with past practice; (b) there has not been any Effect that, individually or in the aggregate, has had or would be reasonably expected to have a Material Adverse Effect; and (c) the Company has not taken any action that, if taken after the date of this Agreement, would constitute a breach of any of the covenants set forth in **Section 4.1(b)**.

SECTION 2.10 Regulatory Matters.

(a) The Company has filed with the applicable Governmental Entities (including the FDA or any other Governmental Entity performing functions similar to those performed by the FDA or otherwise having jurisdiction over the safety, efficacy, approval, development, testing, labeling, manufacture, storage, marketing, promotion, sale, commercialization, shipment, import, export or distribution of drugs or pharmaceutical products (such Governmental Entities, collectively, the "**Specified Governmental Entities**")) all required filings, applications, notices, amendments, supplements, responses, declarations, listings, registrations, reports or submissions, including adverse event reports and responses to post-marketing commitments. All such filings, applications, notices, amendments, supplements, responses, declarations, listings, registrations, reports or submissions were in compliance in all material respects with applicable Laws when filed (or were corrected or supplemented by a subsequent submission), and no material deficiencies have been asserted by any Specified Governmental Entity with respect to any such filings, applications, declarations, listing, registrations, reports or submissions. The Company has not received any material FDA Form 483, Warning Letter, untitled letter, or other similar correspondence or notice from the FDA or any other Specified Governmental Entity alleging or asserting any material noncompliance with any applicable Laws or Company Permits, the subject matter of which remains unresolved.

(b) Neither the Company nor any of its Affiliates, with respect to the Company's business, is currently conducting or sponsoring, or has ever conducted or sponsored, any clinical studies, tests or trials, nor have any clinical studies, tests or trials been conducted or sponsored on behalf of the Company or any of its Affiliates related to any Company Product. Neither the Company nor any of its Affiliates have placed into commercial distribution, promoted, marketed, sold or delivered any Company Products.

(c) The Company has not (i) made any untrue statement of a material fact or fraudulent statement to any Specified Governmental Entity; (ii) failed to disclose a material fact required to be disclosed to any Specified Governmental Entity; or (iii) committed any other act, made a statement or failed to make a statement that, at the time such disclosure was made, would provide a reasonable basis for the FDA or any other Specified Governmental Entity to invoke its policy regarding "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Final Policy" set forth in 56 Fed. Reg. 46191 (September 10, 1991) or other equivalent policy. The Company is not the subject of any pending or, to the Company's Knowledge, threatened investigation by the FDA pursuant to its policy regarding "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Final Policy" set forth in 56 Fed. Reg. 46191 (September 10, 1991) or by any other Specified Governmental Entity pursuant to an equivalent policy. None of the Company nor, to the Knowledge of the Company, any officers, employees, agents, consultants or clinical investigators of the Company has been suspended or debarred or convicted of any crime or engaged in any conduct that would reasonably be expected to result in (a) debarment under 21 U.S.C. Section 335a or any similar Law or (b) exclusion under 42 U.S.C. Section 1320a-7 or any similar Law. No debarment or exclusionary claims, actions, proceedings or investigations are pending or, to the Knowledge of the Company, threatened against the Company or any of its officers, employees, agents, consultants or clinical investigators.

(d) The Company is in compliance in all material respects and, since August 31, 2018, has been in compliance in all material respects with all healthcare laws and Device Regulatory Laws applicable to the operation of the Company's business as currently conducted, including (i) any federal, state and local fraud and abuse laws, including the federal Anti-Kickback Statute (42 U.S.C. Section 1320a-7(b)), the civil False Claims Act (31 U.S.C. Section 3729 *et seq.*) and the regulations promulgated pursuant to such statutes, and the Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1 *et seq.*); (ii) the Health Insurance Portability and Accountability (HIPAA) Act of 1996, the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, and the regulations promulgated pursuant thereto; (iii) Laws which are cause for exclusion from any federal health care program; (iv) any applicable security and privacy standards regarding protection of health information; and (v) Laws relating to the billing or submission of claims, collection of accounts receivable, underwriting the cost of, or provision of management or administrative services in connection with, any of the foregoing, by the Company. No enforcement, regulatory or administrative proceeding is pending or, to the Company's Knowledge, has been threatened, against the Company under the FDCA, the Anti-Kickback Statute or similar Laws. Without limiting the generality of the foregoing, the Company is in compliance in all material respects and, since August 31, 2018, has been in compliance in all material respects, with all applicable Laws administered, issued or enforced by the FDA or any Specified Governmental Entity relating to the sourcing and procurement or the import of the raw materials for the Company Products and the methods and materials used in, and the facilities and controls used for, the design, manufacture, processing, packaging, labeling, storage, distribution and export of the Company Products and, since August 31, 2018, all such raw materials and all Company Products have been sourced, procured, processed, manufactured, packaged, labeled, stored, handled and distributed by the Company in compliance in all material respects with all applicable Laws, including Laws administered, issued or enforced by the FDA or any Specified Governmental Entity. Since August 31, 2018, the Company has maintained records relating to the development, manufacture, testing, storage, handling, labeling, packaging, sale, marketing, promotion, distribution, import, or export of the Company Products in compliance in all material respects with all applicable Laws, specifically all applicable Device Regulatory Laws.

(e) The Company Products (or any component thereof) have not been recalled, withdrawn, suspended, discontinued or seized (whether voluntarily or otherwise) and to the Company's Knowledge, there are no facts or circumstances that would reasonably be expected to give rise to any such recall, withdrawal, suspension, discontinuation or seizure. No Action seeking the recall, withdrawal, suspension, discontinuation or seizure of the Company Products or pre-market approvals or marketing authorizations is pending or, to the Company's Knowledge, threatened against the Company.

(f) To the Knowledge of the Company, there has been no adverse event reportable to the FDA or other Specified Governmental Entity with respect to the safety or efficacy of the Company Products. The Company has made available to Parent all material information about material adverse drug experiences (as defined in 21 C.F.R. 314.80) that (i) has been obtained or otherwise received by the Company from any source in the United States or outside of the United States as of the date hereof, including information derived from clinical investigations, surveillance studies or registries, reports in the scientific literature and unpublished scientific papers relating to any Company Product that is or has been manufactured, tested, distributed, held or marketed by or on behalf of the Company and (ii) the Company is required to track and document under applicable Laws.

(g) The Company is not a party to any material corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any Specified Governmental Entity.

SECTION 2.11 Taxes.

(a) ***Tax Returns and Payments***. All income and other material Tax Returns required to be filed by or on behalf of the Company with any Governmental Entity: (i) have been filed on or before the applicable due date (including any extensions of such due date); and (ii) have been accurately and completely prepared in all material respects in compliance with all applicable Laws. All material Taxes required to be paid by the Company have been or will be timely paid. "**Tax Return**" shall mean any return (including any information return), report, statement, declaration, estimate, schedule, notice, notification, form, election, certificate or other document or information filed with or submitted to, or required to be filed with or submitted to, any Governmental Entity in connection with the determination, assessment, collection or payment of any Tax or in connection with the administration, implementation or enforcement of or compliance with an Law relating to any Tax, including any amendment thereof or attachment thereto.

(b) ***Reserves for Payment of Taxes***. The Financial Statements fully accrue all actual and contingent liabilities for Taxes with respect to all periods through the dates thereof.

(c) ***Audits; Claims; Etc***. The Company has not received from any Governmental Entity any: (i) written notice indicating an intent to open an audit or other review with respect to any material Taxes; (ii) request for information related to Tax matters; or (iii) written notice of deficiency or proposed Tax adjustment. No claim or legal proceeding is pending or has been threatened in writing against the Company in respect of any Tax. There are no Liens for Taxes upon any of the assets of the Company except Liens for current Taxes not yet due and payable or Taxes that are being contested in good faith (in either case, for which there are adequate accruals, in accordance with GAAP). The Company has not (A) filed an outstanding request for an extension of time within which to file any Tax Return, (B) executed a waiver or consent extending any statute of limitations for the assessment or collection of any Taxes which waiver or consent remains outstanding and no such waiver or consent is pending, (C) applied for a ruling relating to Taxes which will be binding on Parent or any of its Affiliates (including the Surviving Company) after the Closing Date, or (D) entered into a "closing agreement" as described in Section 7121 of the Code (or any comparable provisions of state, local or foreign Laws) with any Governmental Entity that will be binding on Parent or any of its Affiliates (including the Surviving Company) after the Closing Date. No power of attorney that is currently in force has been granted with respect to any matter relating to Taxes that could affect the Company.

(d) ***Legal Proceedings; Etc***. There are no unsatisfied liabilities for Taxes with respect to any notice of deficiency or similar document received by the Company with respect to any Tax (other than liabilities for Taxes asserted under any such notice of deficiency or similar document which are being contested in good faith by the Company with respect to which adequate reserves for payment have been established in accordance with GAAP).

(e) ***Distributed Stock***. In the past two (2) years, the Company has not distributed stock of another Person, and the Company has not had its stock distributed by another Person, in a transaction that was purported or intended to be governed in whole or in part by Section 355 or Section 361 of the Code.

(f) ***280G; 404; 4999***. There is no agreement, plan, arrangement or other Contract (i) covering any Employee that, considered individually or considered collectively with any other such Contracts, will, or could reasonably be expected to, give rise directly or indirectly to the payment of any amount that would not be deductible pursuant to Section 280G or Section 404 of the Code or that would be characterized as a "parachute payment" within the meaning of Section 280G(b)(1) of the Code or (ii) by which the Company is bound to compensate any Employee for excise taxes paid pursuant to Section 4999 of the Code. Section 2.11(f) of the Company Disclosure Schedule lists all persons who are "disqualified individuals" (within the meaning of Section 280G of the Code and the Treasury Regulations promulgated thereunder) as determined as of the date hereof.

(g) ***Tax Indemnity Agreements; Etc***. The Company is not and has never been, a party to or bound by any tax indemnity agreement, tax sharing agreement, tax allocation agreement or similar Contract, and after the Closing Date, the Company will not be bound by any such agreement or similar arrangement or have any liability thereunder for any amounts, in each case, other than any commercial Contracts with customers, vendors, lenders, lessors or the like, in each case entered into in the ordinary course of business and the principal purpose of which is not the allocation or sharing of Taxes. The Company does not have any liability for Taxes of any Person under Section 1.1502-6 of the Treasury Regulations (or any similar provision of state, local or foreign Laws), as a transferee or successor, by Contract, by operation of law or otherwise.

(h) ***No Other Jurisdictions for Filing Tax Returns***. No claim has ever been made in writing by a Governmental Entity in the past three (3) years in a jurisdiction where the Company does not file Tax Returns that the Company is or may be subject to taxation by that jurisdiction.

(i) ***Tax Shelters; Listed Transactions; Etc***. The Company has not consummated or participated in, nor is the Company currently participating in, any transaction which was or is a "tax shelter" transaction as defined in Sections 6662 and 6111 of the Code and Treasury Regulations promulgated thereunder. The Company has not participated in, nor is currently participating in, a "Listed Transaction" within the meaning of Section 6707A(c) of the Code or Treasury Regulations Section 1.6011-4(b) (or a corresponding or similar provision of state, local, or foreign Laws). The Company has disclosed on its Tax Returns any Tax reporting position taken in any Tax Return which could result in the imposition of penalties under Section 6662 of the Code (or any comparable provisions of state, local or foreign Laws).

(j) ***Section 83(b)***. No Person holds shares of Company Common Stock that are non-transferable and subject to a substantial risk of forfeiture within the meaning of Section 83 of the Code with respect to which a valid election under Section 83(b) of the Code has not been made.

(k) ***Withholding***. The Company: (i) has complied in all material respects with all applicable Laws relating to the payment, reporting and withholding of Taxes (including withholding of Taxes pursuant to Sections 1441, 1442, 1445 and 1446 of the Code or similar provisions under any foreign Law); (ii) has, within the time and in the manner prescribed by applicable Law, withheld from employee wages or consulting compensation and timely paid over to the proper Governmental Entities (or is properly holding for such timely payment) all material Taxes required to be so withheld and paid over under all applicable Laws, including federal and state income and employment Taxes, Federal Insurance Contribution Act, Medicare, Federal Unemployment Tax Act, and relevant non-U.S. income and employment Tax withholding Laws; and (iii) has timely filed all material withholding Tax Returns, for all periods.

(l) ***Change in Accounting Methods; Closing Agreements; Etc***. The Company will not be required to include any item of income in, or exclude any item of deduction from, taxable income for any taxable period (or portion thereof) ending after the Closing Date as a result of any: (i) change in method of accounting made prior to the First Effective Time; (ii) closing agreement as described in Section 7121 of the Code (or any corresponding or similar provision of state, local, or foreign Tax law) executed prior to the First Effective Time; (iii) installment sale or open transaction disposition made on or prior to the First Effective Time; or (iv) deferred income or prepaid amount received at or prior to the First Effective Time and outside of the ordinary course of business.

(m) ***Consolidated Groups***. The Company has never been a member of an affiliated, combined, consolidated or unified group (including within the meaning of Section 1504(a) of the Code) filing a consolidated federal income Tax Return and has never been a party to any joint venture, partnership, or, to the Company's Knowledge, other agreement that could be treated as a partnership for tax purposes.

(n) ***Section 409A***.

(i) Each Company Employee Plan and Contract, agreement or arrangement between the Company or any ERISA Affiliate and any Employee, in each case, that is a "nonqualified deferred compensation plan" (as such term is defined in Section 409A(d)(1) of the Code) subject to Section 409A of the Code (or any state law equivalent) and the regulations and guidance thereunder ("**Section 409A**"), if any, has been at all times since the Company's incorporation in operational and documentary compliance with Section 409A. No nonqualified deferred compensation plan that was originally exempt from application of Section 409A has been "materially modified" (within the meaning of IRS Notice 2005-1) at any time since the Company's incorporation. No compensation shall be includable in the gross income of any Employee as a result of the operation of Section 409A with respect to any Company Employee Plan or other arrangements or agreements which is or has been in effect at any time prior to the First Effective Time. To the extent required, the Company has properly reported or withheld and remitted on amounts deferred under any nonqualified deferred compensation plan subject to Section 409A. There is no Contract, agreement, plan or arrangement to which the Company or any of its ERISA Affiliates is a party, including the provisions of this Agreement, covering any Employee of the Company, which individually or collectively could require the Company or any of its Affiliates to pay a Tax gross-up payment to, or otherwise indemnify or reimburse, any Employee for Tax-related payments under Section 409A. There is no contract, agreement, plan or arrangement to which the Company is a party, including the provisions of this Agreement, which, individually or collectively, could give rise to a Parent, Company, Surviving Company, or Subsidiary Tax under Section 409A or that would give rise to an Employee Tax or Parent, Company, Surviving Company or Subsidiary reporting obligations under Section 409A.

(ii) No Company Option or other stock right (as defined in U.S. Treasury Department regulation 1.409A-1(l)) (w) has an exercise price that was less than the fair market value of the underlying equity as of the date such option or right was granted, (x) has any feature for the deferral of compensation other than the deferral of recognition of income until the later of exercise or disposition of such option or rights, (y) has been granted with respect to any class of stock of the Company that is not "service recipient stock" (within the meaning of applicable regulations under Section 409A), or (z) has ever been accounted for other than in the Company's financial statements provided to Parent.

SECTION 2.12 Real Property.

(a) The Company does not own any real property, nor has the Company ever owned any real property.

(b) Section 2.12(b) of the Company Disclosure Schedule sets forth a true, correct and complete list of: (i) the street address or location of each parcel of Leased Real Property; (ii) the identity of the lessor, lessee, current occupant (if different from lessee) of each such parcel of Leased Real Property and any guarantor; and (iii) the current use of each such parcel of Leased Real Property. The Leased Real Property listed on Section 2.12(b) of the Company Disclosure Schedule represents all the real property used, occupied or held for use in the business of the Company. The Company has a valid leasehold interest in all the Leased Real Property, free and clear of all Liens, except for Permitted Liens. The Company does not owe brokerage commissions or finders' fees with respect to any such Leased Real Property or would owe any such fees if any existing Lease Agreement were renewed pursuant to any renewal options contained in such Lease Agreements. All rent and other sums and charges currently due under all Lease Agreements have been paid or will be paid within the applicable notice and grace period. The rental payment amount set forth in each lease provided to the Company for the Leased Real Property is the actual rental payment amount being paid, and there are no separate agreements or understandings with respect to the same. No uncured default by the Company, or, to the Knowledge of the Company, by any landlord exists with respect to the Leased Real Property, and to the Knowledge of the Company, no event has occurred or condition exists, which, with the giving of notice or the lapse of time or both, would constitute such a default.

(c) The Company has made available to Parent true and complete copies, for each parcel of Leased Real Property, of (i) all Leases and (ii) to the extent in the possession of the Company, all certificates of occupancy, environmental reports and audits, appraisals, permits and other documents relating to or otherwise affecting the Leased Real Property, the operations of the Company thereon or any other uses thereof. The Company is in peaceful and undisturbed possession of each parcel of the Leased Real Property, and there are no contractual or legal restrictions that preclude or restrict the ability to use the Leased Real Property for the purposes for which it is currently being used. The Company has not leased or subleased any parcel or any portion of any parcel of the Leased Real Property to any other Person and no other Person has any rights to the use, occupancy or enjoyment thereof pursuant to any Lease Agreement. The Company has performed all of its obligations under any termination agreements pursuant to which it has terminated any leases, subleases, licenses or other occupancy agreements for real property that are no longer in effect and has no continuing liability with respect to such terminated agreements.

(d) To the Knowledge of the Company, there are no condemnation proceedings or eminent domain proceedings of any kind pending or threatened against any parcel of the Leased Real Property. To the Knowledge of the Company, there are no material latent defects or material adverse physical conditions affecting the Leased Real Property or any of the facilities, buildings, structures, erections, improvements, fixtures, fixed assets or personal property of a permanent nature annexed, affixed or attached to, located on or forming part of the Leased Real Property.

(e) Neither the operation of the Company on the Leased Real Property, nor to the Knowledge of the Company, such Leased Real Property, including the improvements thereon, violate in any material respect any applicable building code, zoning requirement or statute relating to such Leased Real Property or operations thereon, and any such non-violation is not dependent on so-called non-conforming use exceptions.

SECTION 2.13 Tangible Property. The Company has good and valid title to, or, in the case of leased properties and assets, valid leasehold interests in, all of its tangible properties and assets, real, personal and mixed, used or held for use in its business (the "**Assets**"). The Assets are not subject to any Liens other than Permitted Liens. Each item of material tangible personal property included in the Assets is in all material respects in good operating condition and state of repair (ordinary wear and tear excepted) and the Assets are in all material respects suitable for the purposes for which they are used and intended to be used. The Assets are sufficient for the continued conduct of the Company's business after the Closing in substantially the same manner as conducted prior to the Closing, and constitute all of the rights, property and assets necessary to conduct the business of the Company as currently conducted.

SECTION 2.14 Intellectual Property.

(a) ***Company Registrations***. Section 2.14(a) of the Company Disclosure Schedule contains a complete and accurate list, as of the date hereof, of all of the Company's (i) Registered IP, in each case enumerating specifically the applicable filing or registration number, title, jurisdiction in which filing was made or from which registration issued, date of filing or issuance and names of all current applicant(s) and registered owner(s), as applicable; (ii) material unregistered Intellectual Property; and (iii) material Licensed IP. All assignments of Intellectual Property to the Company are valid and enforceable and have been properly executed and recorded. To the Knowledge of the Company, all Registered IP contains patentable subject matter and all issuance, renewal, maintenance and other payments that are or have become due with respect to Registered IP have been timely paid by or on behalf of the Company. The Registered IP is (A) valid, subsisting and enforceable; (B) currently in compliance with any and all legal requirements necessary to maintain the validity and enforceability thereof; and (C) not subject to any outstanding judgment, order decree, legal proceeding, security interest or agreement adversely affecting the Company's use thereof or rights thereto, or that would impair the validity or enforceability thereof.

(b) ***Filings with Governmental Authorities***. Section 2.14(b) of the Company Disclosure Schedule contains a complete and accurate list, as of the date hereof, of all of the Company's filings with Governmental Entities relating to all Company IP or the Company Products not otherwise captured by this **Section 2.14(b)**.

(c) ***Prosecution Matters***. There are no inventorship challenges, *inter partes* review, opposition or nullity proceedings or interferences declared, commenced or provoked or, to the Knowledge of the Company, threatened, with respect to any Company IP. The Company has complied with its duty of candor and disclosure to the United States Patent and Trademark Office and any relevant foreign patent office with respect to all Intellectual Property applications filed by or on behalf of the Company and have made no material misrepresentation in such applications. The Company has no knowledge of any information that would preclude the Company from having clear title to the Company IP.

(d) ***Ownership Free and Clear***. The Company exclusively owns all right, title and interest to and in the Company IP free and clear of any Liens and of all licenses, including all Intellectual Property embodied by or relating to the Company Products (but excluding Licensed IP). Without limiting the generality of the foregoing:

(i) all documents and instruments necessary to perfect the rights of the Company in any Registered IP have been validly executed, delivered and filed in a timely manner with the applicable Governmental Entity;

(ii) each Employee who is or was involved in the authorship, invention, creation, conception, reduction to practice, improvement or development of any Intellectual Property for or on behalf of the Company (including current and former employees, agents and contractors) has entered into a valid, binding and enforceable written agreement (A) sufficient to irrevocably assign all right, title and interest in and to such Intellectual Property to the Company, (B) containing a waiver of moral rights to the extent not prohibited under applicable Laws, and (C) containing confidentiality provisions protecting the Company IP, with each such agreement substantially in the Company's Standard Form IP Contract for employees (a copy of which has been made available to Parent (the "**Employee Proprietary Information Agreement**")) or substantially in the Company's Standard Form IP Contract for consultants or independent contractors (a copy of which has been made available to Parent (the "**Consultant Proprietary Information Agreement**")), as the case may be;

(iii) no Employee or former employer of any Employee has any claim, right or interest to or in any Company IP;

(iv) the Company is not utilizing any Intellectual Property authored, invented, created, conceived or developed by any Employees or, to the Knowledge of the Company, Persons who the Company currently intends to hire, or any confidential information of any other Persons to which such Employees were exposed, prior to their employment by the Company;

(v) no Employee is in breach of any Contract with any former employer or other Person concerning Intellectual Property or confidentiality or a covenant not to compete;

(vi) no funding, facilities or personnel of any Governmental Entity, university, military, educational institution or research center were used to develop or create any Company IP;

(vii) the Company has taken all necessary steps to maintain the confidentiality of all proprietary information held by the Company, or purported to be held by the Company, as a trade secret, including any confidential information or trade secrets provided to the Company by any Person under an obligation of confidentiality, and no such proprietary information has been authorized to be disclosed or has actually been disclosed to any Person other than pursuant to a valid written confidentiality Contract, that have not been breached, restricting the disclosure and use of such proprietary information;

(viii) no Person that has licensed or provided Licensed IP to the Company has retained or obtained sole ownership of, or an exclusive license to, any Intellectual Property in any improvements or derivative works that are made solely by the Company, or jointly by the Company together with any other Person, under such license; and

(ix) the Company owns or otherwise has, and after the Closing will continue to have, all Intellectual Property needed to conduct the business of such entity as currently conducted and currently planned by such entity to be conducted.

(e) ***Effects of the Mergers***. Each item of Company IP will be owned or available for use by Parent immediately following the Closing without any impairment and on the same terms and conditions as it was available to the Company immediately prior to the Closing. Neither the execution, delivery or performance of this Agreement or any Related Agreement nor the consummation of the Mergers or any of the other Transactions will, with or without notice or the lapse of time, result in or give any other Person the right or option to cause or declare: (i) a loss of, or Lien on, any Company IP; (ii) a security interest on or license to any Intellectual Property that is owned by or licensed to Parent or any of its Affiliates prior to the Closing; (iii) a breach of any Contract listed or required to be listed in Section 2.15(a)(xxi) and Section 2.15(a)(xxiv) of the Company Disclosure Schedule; (iv) the release, disclosure or delivery of any Company IP by or to any escrow agent or other Person; (v) the grant, assignment or transfer to any other Person of any license or other right or interest under, to or in any of the Company IP or any Intellectual Property owned by, or licensed to, Parent; (vi) Parent or any of its Affiliates being bound by or subject to any non-compete or licensing obligation, covenant not to sue, or other restriction on the operation or scope of its business, which Parent or its Affiliates were not bound by or subject to prior to the Closing; or (vii) payment of any royalties, honoraria, fees or other license fees with respect to Intellectual Property of any other Person in excess of those payable by the Company in the absence of this Agreement or the Transactions.

(f) ***No Third-Party Infringement of Company IP***. To the Company's Knowledge, no Person has infringed, misappropriated, or otherwise violated, and no Person is currently infringing, misappropriating or otherwise violating, any Company IP. The Company has not brought any actions or lawsuits alleging (i) infringement, misappropriation or other violation of any Company IP or (ii) breach of any license, sublicense or other agreement authorizing another party to use any Company IP, and, to the Knowledge of the Company, there do not exist any facts which could currently form the basis of any such action or lawsuit. The Company has not sent or received any correspondence concerning the infringement, misappropriation, or other violation of any Company IP. The Company has not entered into any agreement granting any Person the right to bring infringement actions with respect to, or otherwise to enforce rights with respect to, the Company IP.

(g) ***Use of Licensed IP***. All Intellectual Property that is used, held for use or practiced by the Company but are not owned or purported to be owned by the Company are validly licensed to the Company pursuant to: (i) a Licensed IP Contract set forth on Section 2.14(g) of the Company Disclosure Schedule (but specifically excluding generally commercially available off-the-shelf Software that has not been modified by or for the Company and is licensed to the Company for a one-time or annual fee of $10,000 or less); or (ii) each agreement, contract, assignment or other instrument pursuant to which the Company has obtained any joint or sole ownership interest in or to each item of Company IP. The Company has valid written licenses in respect of all Licensed IP of sufficient scope to permit the Company to conduct its business without infringing or violating the rights of any other Person. Neither the Company nor, to the Knowledge of the Company, any other Person, is in breach of any Licensed IP Contract. The use of the Licensed IP by the Company does not, and since August 31, 2018 has not, infringed, misappropriated or otherwise violated any Intellectual Property rights of any Person.

(h) ***Outbound IP Agreements***. Section 2.14(h) of the Company Disclosure Schedule contains a complete and accurate list of each license, covenant or other agreement (including any options to license) pursuant to which the Company has assigned, transferred, licensed, distributed or otherwise granted any right or access to any Person, or covenanted not to assert any right, with respect to any past, existing or future Company IP. The Company has not agreed to indemnify any Person against any infringement, misappropriation or other violation of any Intellectual Property, except as set forth in the Contracts listed in Section 2.15(a) of the Company Disclosure Schedule. The Company is not a member of or party to any patent pool, industry standards body, trade association or other organization pursuant to the rules of which it is obligated to license any existing or future Intellectual Property to any Person.

(i) ***No Infringement of Third-Party IP Rights***. The Company is not infringing, misappropriating or otherwise violating, or has ever infringed, misappropriated or otherwise violated, any Intellectual Property of any other Person, and the conduct of the business of the Company, when conducted by the Company in substantially the same manner after the date hereof and by Parent after the Closing Date, will not infringe, misappropriate or otherwise violate any Intellectual Property of any other Person (including patents issuing on patent applications filed as of the date hereof), violate any right of any Person (including any right to privacy or publicity), or constitute unfair competition or trade practices under any Law. The Company has not sent or received any correspondence concerning the infringement, misappropriation or other violation of any Intellectual Property of any third party by the Company. There are no legal proceedings pending or threatened against the Company relating to any of the foregoing, except as disclosed in the Company Disclosure Schedule, which lists any written complaint, claim or notice, or threat of any of the foregoing (including any notification that a license under any patent is or may be required), received by the Company alleging any such infringement, misappropriation or other violation by the Company and any request or demand for indemnification or defense received by the Company from any third party; and the Company shall provide to Parent copies of all such complaint, claims, notices, requests, demands or threats in its possession relating to any alleged or potential infringement, misappropriation or other violation.

(j) ***Sufficiency of IP***. The Company IP and the Licensed IP together constitute all of the Intellectual Property necessary and sufficient to operate the business of the Company as currently conducted and as proposed to be conducted.

(k) ***Protection Measures***. The Company has taken all reasonable measures necessary to protect the proprietary nature of each item of Company IP which is material to the Company, and to maintain in confidence all trade secrets and confidential information comprising a part of the Company IP. No confidential information or trade secrets comprising a part of the Company IP have been disclosed by the Company to any Person except pursuant to valid and appropriate non-disclosure or license agreements that have not been breached and, to the Knowledge of the Company, no Person has discovered or gained unauthorized access to any such confidential information or trade secrets. The Company has complied in all material respects with all applicable contractual and legal requirements, including all applicable Privacy Laws and the Company's privacy policies, pertaining to information and data privacy and security and the processing, storing, collection, use, transfer, modification, destruction and disclosure of personal information. There have been no legal proceedings brought against the Company, and no notice made in writing to, or to the Knowledge of the Company, threatened against the Company relating to an improper use or disclosure of, or a breach in the security of, any such information. To the Knowledge of the Company, the Company is not the subject of any investigation by a Governmental Entity relating to any of the foregoing. There has been no unauthorized disclosure by the Company of any third-party proprietary or confidential information or personal information in the possession, custody or control of the Company.

SECTION 2.15 Material Contracts.

(a) Section 2.15(a) of the Company Disclosure Schedule contains a complete list of the following types of Contracts in effect as of the date hereof, (x) to which the Company is a party, (y) by which the Company or any of its assets is or may become bound or under which the Company has, or may become subject to, any obligation, or (z) under which the Company has any right or interest (such Contracts as are required to be set forth in Section 2.15(a) of the Company Disclosure Schedule, the "**Material Contracts**"):

(i) all Contracts for the purchase by the Company of equipment, materials (including raw materials), products, supplies or for the receipt of services, which involve, or is reasonably likely to involve, consideration or payments in excess of $50,000 in the aggregate during the year ended December 31, 2020 or December 31, 2021;

(ii) all Contracts relating to Company Products containing terms addressing or relating to (A) product development, research services, pilot programs, clinical trials or other testing programs, including any material collaboration, joint development or other similar agreement; (B) the marketing, supply, manufacturing, distribution, commercialization, purchase or sale of the Company Products (including any sole source supply, co-promotion, sales representative, distribution, wholesaler, reseller or other similar agreement); or (C) the pricing or reimbursement terms for the Company Products, in each case, that does not otherwise constitute a Material Contract under another subclause of this **Section 2.15(a)**;

(iii) all Contracts that form or purport to form a partnership, joint venture or similar entity with a third party and any profit sharing, strategic alliance or similar Contracts involving the sharing of profits or expenses;

(iv) all Contracts which grant any Person an option or a first refusal, first offer or similar preferential right to purchase or acquire any material assets or properties of the Company;

(v) all mortgages, indentures, loans or credit agreements, security agreements or other Contracts relating to Indebtedness of the Company;

(vi) all Contracts relating to the sale of Company Common Stock, Company Preferred Stock, Company Warrants, Company Convertible Notes or any other equity interests of the Company;

(vii) all Contracts relating to rights and obligations of Stockholders to which the Company is a party, including any stockholder agreement, voting agreement, registration rights agreement, investors rights agreement or similar agreement;

(viii) all Contracts that constitute a guaranty of any obligation of any Person;

(ix) all Contracts that purport to bind or otherwise could bind Parent or any Affiliate of Parent (other than the Company) in any way;

(x) all Contracts (A) with any Governmental Entity or (B) pursuant to which the Company provides products, services or other benefits that are used by any third party in satisfying such third party's obligations under any Contract with any Governmental Entity;

(xi) all Contracts that limit, or purport to limit (or that would purport to limit the freedom of Parent or any of its Affiliates), the ability of the Company or any of the Employees to compete in any line of business or with any Person or entity or in any geographic area or during any period of time, including any exclusivity obligations or restrictions or otherwise limiting the freedom or right of the Company to sell, distribute or manufacture any products or services or any technology or other assets to or for any other Person;

(xii) all Contracts that contain any "most favored nation" terms or similar pricing arrangements, minimum purchase, "take or pay," "requirements" provisions or similar obligations;

(xiii) all Contracts that relate to the disposition by the Company of any asset or property that is material to the Company's business, in each case other than dispositions of inventory in the ordinary course of business;

(xiv) all Contracts for capital expenditures or the acquisition or construction of fixed assets involving future payments in excess of $50,000, in the aggregate;

(xv) all Contracts pursuant to which the Company is required to make any loan, advance or capital contribution to any Person, or investment in any other Person, in each case in excess of $50,000;

(xvi) all Contracts between or among the Company, on the one hand, and any of its Affiliates or any Interested Party, on the other hand;

(xvii) all Contracts pursuant to which the Company is bound that includes a continuing indemnification, warranty, "earn out" or other contingent payment obligation;

(xviii) all Contracts entered into after August 31, 2018 or not yet consummated, in each case for the acquisition or disposition, directly or indirectly (including by merger, consolidation, combination or amalgamation), of assets (other than assets purchased pursuant to capital expenditures) or capital stock or other equity interests of another Person;

(xix) all Lease Agreements;

(xx) all Contracts with an Employee, which is not cancellable without material penalty or without more than thirty (30) days' notice;

(xxi) all Contracts with a third party concerning the research, development or commercialization of Intellectual Property or with confidentiality, noncompetition or non-solicitation obligations;

(xxii) all collectively bargained agreements or similar Contracts, including all Contracts with any union, works council, personnel delegates or similar labor entity, or specifically authorized employees;

(xxiii) all Contracts that grant any severance or termination payments or benefits or post-termination payments (in cash or otherwise) to any Employee and all consulting or sales Contracts or commitments with a firm or other Person;

(xxiv) all Company IP Contracts and all Contracts relating to the acquisition of any Company IP;

(xxv) all Contracts imposing any restriction on the right or ability of the Company (or that would purport to limit the freedom of Parent or any of its Affiliates) to develop or license any Intellectual Property or solicit the employment of, or hire, any potential employees, consultants or independent contractors;

(xxvi) all hedging, swap, derivative or similar Contracts; and

(xxvii) all other Contracts, whether or not made in the ordinary course of business, which are material to the Company or the conduct of its businesses, or the absence of which would materially and adversely affect the ability of the Company to conduct its business.

(b) The Company has made available to Parent true, correct and complete copies of all Material Contracts, including all amendments, waivers or changes thereto. Each Material Contract is in full force and effect and is a legal, valid and binding obligation of the Company and the other parties thereto, enforceable against the Company and, to the Company's Knowledge, the other parties thereto in accordance with its terms, subject to the Enforceability Limitations. The Company has not violated or breached in any material respect, or is in default under, any Material Contract, and, to the Knowledge of the Company, no other party thereto has violated or breached, or is in default under, any such Material Contract. No event has occurred or not occurred through the Company's action or inaction or, to the Company's Knowledge, the action or inaction of any third party, and no circumstance or condition exists, that (with or without notice or lapse of time or both) would, or would reasonably be expected to: (i) result in a violation or breach of any of the provisions of any Material Contract; (ii) give any Person the right to declare a default or exercise any remedy under any Material Contract; (iii) give any Person the right to accelerate the maturity or performance of any Material Contract; or (iv) give any Person the right to cancel, terminate or modify any Material Contract. The Company has not received any claim or notice of breach or default, termination or cancellation under any Material Contract.

SECTION 2.16 Employee Benefit Plans.

(a) No Person, other than an Employee, is or was a member or former member of any Company Employee Plan. None of the Company or any ERISA Affiliate has made any plan or commitment to establish any new Company Employee Plan or Employee Agreement, to modify any Company Employee Plan or Employee Agreement (except to the extent required by law or to conform any such Company Employee Plan or Employee Agreement to the requirements of any applicable law, in each case as previously disclosed to Parent in writing, or as required by this Agreement), or to enter into any Company Employee Plan or Employee Agreement.

(b) Section 2.16(b) of the Company Disclosure Schedule sets forth a true, correct and complete list of each Employee Agreement and Company Employee Plan maintained, established or sponsored by the Company, or that the Company participates in, contributes to, or is required to contribute to, whether funded or unfunded, whether or not tax qualified and whether or not subject to ERISA. The Company has made available (i) correct and complete copies of all documents embodying each Company Employee Plan and each Employee Agreement, including all amendments thereto and all related trust documents and all related management and/or monitoring, information documents, and/or records required by Laws; (ii) the three (3) most recent annual reports (Form Series 5500 and all schedules and financial statements attached thereto), if any, required under ERISA or the Code in connection with each Company Employee Plan; (iii) if the Company Employee Plan is funded, the most recent annual and periodic accounting of Company Employee Plan assets; (iv) the most recent summary plan description together with the summaries of material modifications thereto, if any, required under ERISA with respect to each Company Employee Plan; (v) all material written agreements and contracts relating to each Company Employee Plan and Employee Agreement, including administrative service agreements and group or other insurance contracts; (vi) all communications material to any Employee or Employees relating to any Company Employee Plan and any proposed Company Employee Plan and any Employee Agreement or proposed Employee Agreement, in each case, relating to any amendments, terminations, establishments, increases or decreases in compensation benefits, acceleration of payments or vesting schedules or other events which would result in any material liability to the Company; (vii) all correspondence and/or notifications to or from any governmental agency or administrative service relating to any Company Employee Plan or Employee Agreement; (viii) all privacy notices under HIPAA and all Business Associate Agreements to the extent required under HIPAA; and (ix) the most recent IRS determination, opinion, notification or advisory letters issued with respect to each Company Employee Plan. There is no fact, condition, or circumstance since the date the documents were made available in accordance with this **Section 2.16(b)** which would materially affect the information contained therein, and in particular, and without limiting the generality of the foregoing, no promises or commitments have been made to amend any Company Employee Plan or Employee Agreement or to provide increased or improved benefits thereunder or accelerate vesting or funding thereunder. No verbal promises or representations have been made to any Employees to increase their compensation or to continue their employment for any specific duration.

(c) The Company and its ERISA Affiliates (i) have performed all obligations required to be performed by them under, and are in compliance with, the requirements prescribed by any and all applicable statutory or regulatory Laws; (ii) are not in default or violation of, and the Company has no Knowledge of any default or violation by any other party to, any Company Employee Plan or Employee Agreement; and (iii) each Company Employee Plan and Employee Agreement has been established and maintained in accordance with its terms and in compliance with all applicable laws, statutes, orders, rules and regulations, including ERISA and the Code. No Company Employee Plan is or has ever been a plan or arrangement that is, or intended to be, qualified under Section 401(a) of the Code. No "prohibited transaction," within the meaning of Section 4975 of the Code or Sections 406 and 407 of ERISA, and not otherwise exempt under Section 408 of ERISA, has occurred with respect to any Company Employee Plan. There are no actions, suits or claims pending or threatened or reasonably anticipated (other than routine claims for benefits) against any Company Employee Plan or against the assets of any Company Employee Plan. Each Company Employee Plan can be amended, terminated or otherwise discontinued after the First Effective Time in accordance with its terms, without liability to Parent, the Company or any ERISA Affiliate (other than ordinary administration expenses or with respect to benefits, other than bonuses, commissions or amounts under other compensation plans, that were previously earned, vested or accrued under Company Employee Plans prior to the First Effective Time). There are no audits, inquiries or proceedings pending or threatened by the IRS, DOL, or any other Governmental Entity with respect to any Company Employee Plan. None of the Company or any ERISA Affiliate is subject to any penalty or Tax with respect to any Company Employee Plan under Section 502(i) of ERISA or Sections 4975 through 4980 of the Code. The Company and its ERISA Affiliates have timely made all contributions and other payments required by and due under the terms of each Company Employee Plan and/or pursuant to applicable Laws.

(d) The Company is not delinquent in payments to any of its Employees for any wages, salaries, commissions, bonuses or other direct compensation for any service performed for it to the Closing Date or amounts required to be reimbursed to such Employees. The Company is in compliance with all of its bonus, commission and other compensation plans and has paid any and all amounts required to be paid under such plans, including any and all bonuses and commissions (or pro rata portion thereof) that may have accrued or been earned through the calendar quarter preceding the Closing Date, and is not liable for any payments, taxes or penalties for failure to comply with any of the terms or conditions of such plans or the laws governing such plans.

(e) None of the Company or any ERISA Affiliate has ever maintained, established, sponsored, participated in, contributed to or had any liability with respect to any Pension Plan subject to Part 3 of Subtitle B of Title I of ERISA, Title IV of ERISA or Section 412 of the Code.

(f) None of the Company or any ERISA Affiliate has ever maintained, established, sponsored, participated in, contributed to or had any liability with respect to any self-insured plan that provides benefits to employees (including any such plan pursuant to which a stop-loss policy or contract applies).

(g) At no time has the Company or any ERISA Affiliate contributed to or been obligated to contribute to any multiemployer plan (as defined in Section 3(37) of ERISA). None of the Company or any ERISA Affiliate has at any time ever maintained, established, sponsored, participated in or contributed to any multiple employer plan or to any plan described in Section 413 of the Code, a "funded welfare plan" within the meaning of Section 419 of the Code, or a Multiple Employer Welfare Arrangement, as defined under Section 3(40)(A) of ERISA (without regard to Section 514(b)(6)(B) of ERISA).

(h) No Company Employee Plan or Employee Agreement provides, or reflects or represents any liability to provide, post-termination or retiree or post-employment life insurance, health or other employee welfare benefits to any person for any reason, except as may be required by COBRA or other applicable Laws, and the Company has never represented, promised or contracted (whether in oral or written form) to any Employee (either individually or to Employees as a group) or any other person that such Employee(s) or other person would be provided with life insurance, health or other employee welfare benefits, except to the extent required by statute or other applicable Laws.

(i) The Company has at all times complied in all material respects with the FFCRA, the CARES Act, the Centers for Disease Control and Prevention guidelines, the Occupational Safety and Health Administration and U.S. Department of Labor guidelines, rules and regulations and all other federal, state, local and foreign Laws, executive ordinances, regulations, and guidelines regarding COVID-19 and infectious diseases, business closures and re-openings, stay at home requirements, employee testing and screening, social distancing and safety requirements, paid and unpaid leave, unemployment compensation, occupational health and safety and the handling of positive COVID-19 cases (including any confidentiality obligations and privacy Laws applicable to personal or health related information), including all COVID-19 Measures. Except as set forth on Section 2.16(j) of the Company Disclosure Schedule, the Company has not, in response to COVID-19, furloughed or otherwise temporarily laid-off any employee of the Company, terminated the employment or service of any Employee, reduced hours, wages or benefits of any Employee or provided written notice of any intent to do any of the foregoing.

(j) Neither the execution and delivery of this Agreement nor the consummation of the Mergers or the other Transactions (alone or in connection with additional or subsequent events) or any termination of employment or service in connection therewith will (i) result in any payment or benefit (including severance, golden parachute, bonus or otherwise) becoming due to any Employee, (ii) result in any forgiveness of Indebtedness, (iii) increase any payments or benefits otherwise payable or to be provided by the Company, or (iv) result in the acceleration of the time of payment or vesting of any such payments or benefits, except as required under Section 411(d)(3) of the Code.

SECTION 2.17 Employment Matters.

(a) The Company is in material compliance with all applicable foreign, federal, state and local laws, rules and regulations respecting employment, termination of employment, employment practices, terms and conditions of employment, worker classification, tax withholding, social security contributions withholding, prohibited discrimination, working time, employee representation, equal employment, fair employment practices, meal and rest periods, immigration status, employee safety and health, wages (including overtime wages), compensation, and hours of work, and in each case, with respect to Employees: (i) has withheld and reported all amounts required by law or by agreement to be withheld and reported with respect to wages, salaries and other payments to Employees; (ii) is not liable for any arrears of wages, severance pay or any Taxes or social security contributions or any penalty for failure to comply with any of the foregoing; and (iii) is not liable for any payment to any trust or other fund governed by or maintained by or on behalf of any governmental authority, with respect to unemployment compensation benefits, social security or other benefits or obligations for Employees (other than routine payments to be made in the normal course of business and consistent with past practice). All Employees characterized and treated by the Company as independent contractors or consultants are properly treated as independent contractors under all applicable laws and all Employees of the Company classified as exempt under the Fair Labor Standards Act and state and local wage and hour laws are properly classified, and none of the Company or any ERISA Affiliate has direct or indirect liability with respect to any misclassification of any person as an independent contractor, intern and/or temporary worker rather than as an employee, with respect to any employee leased from another employer or with respect to any employee currently or formerly classified as exempt from overtime wages. There are no material actions, suits, claims or administrative matters pending, threatened or reasonably anticipated against the Company or Employees relating to any Employee, Employee Agreement or Company Employee Plan. There are no pending or threatened or reasonably anticipated claims or actions against the Company or any trustee under any worker's compensation policy or long-term disability policy of the Company. The Company is not party to a conciliation agreement, consent decree or other agreement or order with any federal, state, or local agency or governmental authority with respect to employment practices. The services provided by each of the Company's and its ERISA Affiliates' Employees are terminable at the will of the Company and its ERISA Affiliates, and any such termination would result in no liability to the Company or any ERISA Affiliate (other than ordinary administration expenses or with respect to benefits, other than bonuses, commissions or amounts under other compensation plans, that were previously earned, vested or accrued under Company Employee Plans prior to the First Effective Time).

(b) No strike, labor dispute, slowdown, concerted refusal to work overtime, or work stoppage or labor strike against the Company is pending, or to the Knowledge of the Company, threatened, or reasonably anticipated. The Company has no Knowledge of any activities or proceedings of any labor union to organize any Employees. There are no Actions, labor disputes or grievances pending or threatened or reasonably anticipated relating to any labor matters involving any Employee, including charges of unfair labor practices. The Company has not engaged in any unfair labor practices within the meaning of the National Labor Relations Act or similar Law. The Company is not presently, nor has it been in the past, a party to, or bound by, any collective bargaining agreement, works council, union or similar contract with respect to Employees and no such agreement is being negotiated by the Company.

(c) The Company has not in the last three (3) years conducted a "mass layoff" within the meaning of the Worker Adjustment and Retraining Notification Act of 1988, and similar state, local and foreign laws related to plant closings, relocations, mass layoffs and employment losses.

(d) To the Knowledge of the Company, no stockholder, director, officer, Employee or consultant of the Company is obligated under any Contract, or is subject to any judgment, decree, or order of any court or administrative agency, that would interfere with such Person's efforts to carry out their functions to promote the interests of the Company or that would interfere with the Company's business. Neither the execution nor delivery of this Agreement, nor the carrying on of the Company's business as currently conducted or proposed to be conducted nor any activity of such officers, directors, Employees or consultants in connection with the carrying on of the Company's business as currently conducted or currently proposed to be conducted will, to the Knowledge of the Company, conflict with or result in a breach of the terms, conditions, or provisions of, or constitute a default under, any Contract under which any of such officers, directors, Employees, or consultants is now bound.

SECTION 2.18 Litigation. There is no, and since August 31, 2018 there has not been any, Action of any nature pending, or to the Knowledge of the Company, threatened, against the Company, its properties or assets (tangible or intangible) or any of its officers or directors (in their capacities as such). No Person has at any time challenged or questioned in writing the legal right of the Company to conduct its operations as currently or previously conducted. There is no Action of any nature pending, or to the Knowledge of the Company, threatened, against any Person who has a contractual right or a right pursuant to applicable Laws to indemnification from the Company related to facts and circumstances existing prior to the First Effective Time, nor is there any reasonable basis therefor.

SECTION 2.19 Compliance with Laws; Permits.

(a) The Company, the operation of its business and its use and ownership of its assets are, and since August 31, 2018 have been, in compliance in all material respects with all applicable Laws, Governmental Orders, and settlement agreements entered by or with any Governmental Entity. There are no pending, or to the Knowledge of the Company, threatened, violations of any Law, Governmental Order or settlement agreement entered by or with any Governmental Entity alleged against the Company by any Governmental Entity or other Person, and the Company has not received any written notice since August 31, 2018, nor, to the Knowledge of the Company, are there any facts or circumstances that would be reasonably expected to result in the receipt of any written notice, from any Governmental Entity or other Person with respect to the Company's operation of its business or the ownership or use of any of its assets claiming any violation or alleged violation of any Law, Governmental Order or settlement agreement entered by or with any Governmental Entity.

(b) The Company is in possession of all Company Permits, except for any Company Permits that would not, individually or in the aggregate, be material to the Company. No suspension, revocation, withdrawal, cancellation or modification of any of the Company Permits is pending or, to the Knowledge of the Company, threatened. All Company Permits are valid and in full force and effect, and none of the Company Permits is subject to any term, provision, condition or limitation which may adversely change or terminate such Company Permits by virtue of the completion of the Mergers. The Company is, and since August 31, 2018 has been, in compliance with the terms, requirements and conditions of the Company Permits.

(c) The Company has at all times conducted its export and re-export transactions in accordance in all material respects with (x) all applicable U.S. export and re-export control Laws, including the Export Administration Regulations maintained by the U.S. Department of Commerce, trade and economic sanctions maintained by the Treasury Department's Office of Foreign Assets Control, and the International Traffic in Arms Regulations maintained by the Department of State, and (y) all other applicable import/export controls in each of the other countries in which the Company conducts business. Without limiting the foregoing, (i) the Company has obtained all export and import licenses, license exceptions and other consents, notices, waivers, approvals, Governmental Orders, authorizations, registrations, declarations and filings with any Governmental Entity required for (A) the export, import and re-export of products, services, software and technologies and (B) releases of technologies and software to foreign nationals located in the United States and abroad ("**Export Approvals**"); (ii) the Company is in compliance with the terms of all applicable Export Approvals; (iii) there are no pending, or to the Company's Knowledge, threatened, claims against the Company with respect to such Export Approvals or export or re-export transactions; and (iv) no Export Approvals for the transfer of export licenses to Parent or the Surviving Company are required, or if required, such Export Approvals can be obtained expeditiously without material cost.

(d) None of the Company, any director, officer or employee, or to the Company's Knowledge, any distributor, reseller, consultant, agent or other third party acting on behalf of the Company has provided, attempted to provide, or authorized the provision of anything of value (including payments, meals, entertainment, travel expenses or accommodations, or gifts), directly or indirectly, to any person, including a "foreign official", as defined by the Foreign Corrupt Practices Act ("**FCPA**"), which includes employees or officials working for state-owned or controlled entities, a foreign political party or candidate, any individual employed by or working on behalf of a public international organization, or any other person, for the purpose of (i) obtaining or retaining business; (ii) influencing any act or decision of a foreign government official in their official capacity; (iii) inducing a foreign government official to do or omit to do any act in violation of their lawful duties; (iv) directing business to another; or (v) securing any advantage in violation of the FCPA or United Kingdom Bribery Act of 2010 ("**UKBA**") or any applicable local, domestic, or international anticorruption laws. Neither the Company nor any director, officer, employee or agent of the Company has used any corporate funds to maintain any off-the-books funds or engage in any off-the-books transactions nor has any of the before-stated parties falsified any documents of the Company. None of the Company's current or former directors, officers, employees or consultants is currently an officer, agent or employee of a Governmental Entity. The Company has not made any provisions to any person (including foreign government officials) that would constitute an improper rebate, commercial bribe, influence payment, extortion, kickback, or other improper payment in violation of the FCPA, UKBA, or any other applicable anticorruption law. The Company maintains sufficient internal controls and compliance programs to detect and prevent violations of anticorruption laws (including the FCPA and UKBA), ensure its books and records are accurately maintained, and track any payments made to third parties and foreign government officials. The Company has not conducted any internal or government-initiated investigation, or made a voluntary, directed, or involuntary disclosure to any governmental body or similar agency with respect to any alleged act or omission arising under or relating to any noncompliance with any anticorruption law, including the FCPA and UKBA. Upon request, the Company agrees to provide Parent with anticorruption law certifications.

SECTION 2.20 Environmental Matters. The Company has complied in all material respects with all applicable Environmental Laws. There is no pending or, to the Knowledge of the Company, threatened Action, written notice of violation, formal administrative proceeding, or, to the Knowledge of the Company, investigation, inquiry or information request, relating to any Environmental Law involving the Company. The Company has no Liabilities arising from the release or threatened release of any Materials of Environmental Concern into the environment. The Company is not a party to or bound by any court order, administrative order, consent order or other Contract entered into in connection with any legal obligation or Liability arising under any Environmental Law. The Company is not aware of any environmental Liability of any solid or hazardous waste transporter or treatment, storage or disposal facility that has been used by the Company.

SECTION 2.21 Interested Party Transactions. No officer, director (or any immediate family member of any of such Persons, or any trust, partnership or corporation in which any of such Persons has or has had an interest or is otherwise affiliated with) or, any other stockholder or employee of the Company (nor any immediate family member of any of such Persons, or any trust, partnership or corporation in which any of such Persons has or has had an interest or is otherwise affiliated with) (each, an "**Interested Party**"), has or has had, directly or indirectly, (i) any interest in any Person which furnished or sold, or furnishes or sells, services, products, or Intellectual Property that the Company furnishes or sells, or proposes to furnish or sell; (ii) any interest in any Person that purchases from, or sells or furnishes to, the Company, any goods or services; or (iii) any interest in, or is a party to, any Contract to which the Company is a party, other than employment arrangements between the Company and such Interested Party that have been made available to Parent; *provided*, *however*, that ownership of no more than one percent (1%) of the outstanding voting stock of a publicly traded corporation shall not be deemed to be an "interest in any Person" for purposes of this **Section 2.21**. The Company is not indebted, directly or indirectly, to an Interested Party. There are no Contracts with regard to contribution or indemnification between or among any of the Stockholders. All transactions pursuant to which any Interested Party has purchased, licensed, received, obtained, accessed or otherwise acquired any services, products, or Intellectual Property from, or sold, licensed, distributed, provided or otherwise made available any services, products, or Intellectual Property to, the Company have been on an arm's-length basis on terms no less favorable to the Company than would be available from an unaffiliated party.

SECTION 2.22 Certain Business Relationships With Affiliates. Except as set forth in Section 2.22 of the Company Disclosure Schedule, no Affiliate of the Company (a) owns any property or right, tangible or intangible, which is used in the current activities of the Company, or (b) has any claim or cause of action against the Company, or (c) owes any money to, or is owed any money by, the Company. There have not been any commercial transactions or relationships between the Company and any Affiliate thereof which occurred or have existed since the Company's inception.

SECTION 2.23 Certain Information. Except as expressly set forth in this Agreement, no representation or warranty of any kind, express or implied, has been made by Parent, or any other Person, with respect to the risks or consequences of an investment in Parent, and the Stockholders and Company Option Holders have not relied on any such representation or warranty. Without limiting the generality of the foregoing, neither Parent nor any officer, director or other representative of Parent has made any representation or warranty, express or implied, with respect to any business plan, presentation, projection, estimate or budget delivered to or made available to any Stockholder or Company Option Holders with respect to future results of operations, future financial condition or the future business and operations of Parent or its Subsidiaries, and the Stockholders or Company Option Holders have not relied on any such representation or warranty.

SECTION 2.24 Insurance. Section 2.24 of the Company Disclosure Schedule sets forth a complete and correct list of all material insurance policies and fidelity bonds covering the assets, business, operations, employees, officers and directors, as applicable, of the Company (each, a "**Company Policy**", and collectively, the "**Company Policies**"). There is no claim by the Company or any ERISA Affiliate pending under any of Company Policies as to which coverage has been questioned, denied or disputed or that the Company or any ERISA Affiliate has a reason to believe will be denied or disputed by the underwriters of such Company Policies. There is no pending claim of which its total value (inclusive of defense expenses) would reasonably be expected to exceed the applicable limits of the Company Policies. All premiums due and payable under all the Company Policies have been paid (or if installment payments are due, will be paid if incurred prior to the First Effective Time), and the Company and its ERISA Affiliates are otherwise in material compliance with the terms of the Company Policies. The Company Policies (or other policies and bonds providing substantially similar coverage) have been in effect since the Company's inception and remain in full force and effect. To the Knowledge of the Company, the Company does not have any knowledge or reasonable belief of threatened termination of, or premium increase with respect to, any Company Policies. None of the Company or any Affiliate has ever maintained, established, sponsored, participated in or contributed to any self-insurance plan.

SECTION 2.25 Books and Records. The minute books of the Company have been made available, are complete and up-to-date, and have been maintained in accordance with sound and prudent business practice. The minutes of the Company contain true, correct and complete records of all actions taken, and summaries of all meetings held, by its stockholders and the Company Board of Directors (and any committees thereof) since the time of incorporation of the Company. The Company has made and kept business records, financial books and records, personnel records, ledgers, sales accounting records, tax records and related work papers and other books and records (collectively, the "**Books and Records**") that are true, correct and complete in all material respects and accurately and fairly reflect, in all material respects, the business activities of the Company. The Company has not engaged in any material transaction, maintained any bank account or used any corporate funds except as reflected in its normally maintained Books and Records. At the Closing, all the minute books and other Books and Records will be in the possession of the Company.

SECTION 2.26 Accounts Receivable and Accounts Payable. The Company does not have any accounts or notes receivable or any accounts or notes payable.

SECTION 2.27 Brokers. Except as set forth in Section 2.27 of the Company Disclosure Schedules, no broker, finder or investment banker is entitled to any brokerage, finder's or other fee or commission in connection with the transactions contemplated hereby based upon arrangements made by or on behalf of the Company.

ARTICLE III
REPRESENTATIONS AND WARRANTIES OF PARENT, MERGER SUB 1 AND MERGER SUB 2

As an inducement to the Company to enter into this Agreement, except as (x) disclosed in any Parent SEC Documents filed or furnished by Parent with the SEC since January 1, 2019 and publicly available prior to the date hereof (including any exhibits and other information incorporated by reference therein but excluding any predictive, cautionary or forward-looking disclosures contained under the captions "risk factors," or "forward-looking statements" or (y) as set forth in the corresponding Section of the Parent Disclosure Schedule (with specific reference to the particular Section of this Agreement to which the information in the Parent Disclosure Schedule relates, it being agreed that disclosure of any item in any Section of the Parent Disclosure Schedule shall be deemed disclosed with respect to any other Section of this Agreement to which the applicability of such item is reasonably apparent on the face of such disclosure), Parent, Merger Sub 1 and Merger Sub 2 hereby, jointly and severally, represent and warrant to the Company as of the date hereof and as of the Closing Date that:

SECTION 3.1 Organization and Standing. Each of Parent, Merger Sub 1 and Merger Sub 2 is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Each of Parent, Merger Sub 1 and Merger Sub 2 has the requisite power and authority and all necessary governmental approvals to own, lease and operate its properties and assets and to conduct its business as it is currently being conducted, except where the failure to be so organized, existing or in good standing or to have such power, authority and governmental approvals would not, individually or in the aggregate, prevent or materially delay the consummation of the Mergers or otherwise prevent Parent, Merger Sub 1 or Merger Sub 2 from performing its obligations under this Agreement.

SECTION 3.2 Authority and Enforceability. Each of Parent, Merger Sub 1 and Merger Sub 2 has all requisite corporate power and authority to execute and deliver this Agreement and any Related Agreements to which it is a party, to perform its obligations hereunder and thereunder and to consummate the Mergers and the other Transactions. The execution and delivery by each of Parent, Merger Sub 1 and Merger Sub 2 of this Agreement and any Related Agreements to which it is a party, the performance by Parent, Merger Sub 1 and Merger Sub 2 of their obligations hereunder and thereunder and the consummation by Parent, Merger Sub 1 and Merger Sub 2 of the Mergers and the other Transactions have been duly authorized by all necessary corporate and other action on the part of Parent, Merger Sub 1 and Merger Sub 2, and no other corporate proceedings on the part of Parent, Merger Sub 1 and Merger Sub 2 are necessary to authorize this Agreement or to consummate the transactions contemplated hereby (other than, with respect to the Mergers, the filing and recordation of the First Certificate of Merger and the Second Certificate of Merger as required by the DGCL). This Agreement and any Related Agreements to which each of Parent, Merger Sub 1 and Merger Sub 2 is a party have been duly executed and delivered by Parent, Merger Sub 1 and Merger Sub 2 and (assuming due authorization, execution and delivery by the other parties hereto and thereto) constitute the legal, valid and binding obligations of Parent, Merger Sub 1 and Merger Sub 2, enforceable against each of Parent, Merger Sub 1 and Merger Sub 2 in accordance with their terms, subject to the Enforceability Limitations.

SECTION 3.3 No Conflict; Governmental Approvals and Consents.

(a) The execution and delivery by each of Parent, Merger Sub 1 and Merger Sub 2 of this Agreement and any Related Agreements to which it is a party do not, and the performance by each of Parent, Merger Sub 1 and Merger Sub 2 of this Agreement and any Related Agreements to which it is a party, and the consummation by Parent, Merger Sub 1 and Merger Sub 2 of the Mergers and the other Transactions, will not, (i) conflict with or violate the organizational documents of either Parent, Merger Sub 1 or Merger Sub 2; (ii) conflict with or violate any Law applicable to Parent, Merger Sub 1 or Merger Sub 2 or by which any property or asset of either of them is bound; or (iii) violate, conflict with, require consent under, result in any breach of, result in any loss of any benefit under, or constitute a default (or an event which, with notice or lapse of time or both, would become a default) under, or give to others any right of termination, amendment, acceleration or cancellation of, or result in the creation of a Lien on any property or asset of Parent, Merger Sub 1 or Merger Sub 2 pursuant to, any note, bond, mortgage, indenture, deed of trust, contract, agreement, lease, sublease or other occupancy document, permit or other instrument or obligation to which Parent, Merger Sub 1 or Merger Sub 2 is a party or by which Parent, Merger Sub 1 or Merger Sub 2 or any property or asset of either of them is bound or affected, except, with respect to **clauses (ii)** and **(iii)**, for any such conflicts, violations, breaches, defaults or other occurrences which would not, individually or in the aggregate, prevent or materially delay Parent, Merger Sub 1 or Merger Sub 2 from performing its obligations under this Agreement, or which would not be reasonably expected to be material to Parent, Merger Sub 1 and Merger Sub 2, taken as a whole.

(b) No consent, waiver, approval, Governmental Order or authorization of, or registration, declaration or filing with, any Governmental Entity is required by or with respect to Parent, Merger Sub 1 or Merger Sub 2 in connection with the execution and delivery by each of Parent, Merger Sub 1 and Merger Sub 2 of this Agreement and any Related Agreements to which it is a party, the performance by Parent, Merger Sub 1 and Merger Sub 2 of their obligations hereunder and thereunder and the consummation by Parent, Merger Sub 1 and Merger Sub 2 of the Mergers and the other Transactions, except for (i) such consents, waivers, approvals, Governmental Orders, authorizations, registrations, declarations and filings as may be required under applicable securities laws and state “blue sky” laws; (ii) such consents, notices, waivers, approvals, orders, authorizations, registrations, declarations and filings as may be required under any applicable antitrust or merger control Laws; (iii) the filing of the First Certificate of Merger and Second Certificate of Merger with the Secretary of State of the State of Delaware; and (iv) such other consents, waivers, approvals, Governmental Orders, authorizations, registrations, declarations and filings which, if not obtained or made, would not materially impair Parent’s ability to consummate the Mergers.

SECTION 3.4 Operations of Merger Sub 1 and Merger Sub 2. Merger Sub 1 is a corporation and Merger Sub 2 is a disregarded entity for U.S. federal income Tax purposes. Each of Merger Sub 1 and Merger Sub 2 will be a wholly-owned direct Subsidiary of Parent immediately prior to the First Effective Time. Merger Sub 1 was formed solely for the purpose of engaging in a transaction similar to the transactions contemplated by this Agreement and, since its formation, Merger Sub 1 has not and, as of the First Effective Time, will not have, (a) carried on any business, (b) conducted any operations, (c) incurred any liabilities or obligations other than the execution of this Agreement, the performance of its obligations hereunder and matters ancillary thereto, (d) owned any assets (other than assets with nominal value contributed upon its formation and assets that are part of the consideration that will be distributed in the First Merger), or (e) issued any stock or other equity interests to any Person other than Parent. Merger Sub 2 was formed solely for the purpose of engaging in the transactions contemplated by this Agreement and, since its formation, Merger Sub 2 has not and, as of the First Effective Time, will not have, (i) carried on any business, (ii) conducted any operations, (iii) incurred any liabilities or obligations other than the execution of this Agreement, the performance of its obligations hereunder and matters ancillary thereto, (iv) owned any assets (other than assets with nominal value contributed upon its formation and assets that are part of the consideration for the Second Merger), or (v) issued any stock or other equity interests to any Person other than Parent. The Surviving Company will be a wholly-owned direct Subsidiary of Parent immediately after the Second Effective Time.

SECTION 3.5 Merger Consideration. The Parent Common Stock to be issued by Parent as part of the Merger Consideration has been duly authorized, and upon consummation of the First Merger and the issuance of such shares of Parent Common Stock pursuant to and in accordance with the terms hereof, will be validly issued, fully paid and non-assessable.

SECTION 3.6 Brokers. No broker, finder or investment banker is entitled to any brokerage, finder's or other fee or commission in connection with the transactions contemplated hereby based upon arrangements made by or on behalf of Parent, Merger Sub 1 or Merger Sub 2.

ARTICLE IV
COVENANTS RELATING TO CONDUCT OF BUSINESS
DURING PENDENCY OF THE MERGERS

SECTION 4.1 Conduct of Business by the Company Pending the Mergers.

(a) During the period from the date of this Agreement and continuing until the earlier of the valid termination of this Agreement pursuant to **Section 9.1** or the First Effective Time, the Company agrees that, except (i) as set forth in Section 4.1(a) of the Company Disclosure Schedule, (ii) as expressly contemplated by any other provision of this Agreement or (iii) with the prior written consent of Parent, the business of the Company shall be conducted only in, and the Company shall not take any action except in, the ordinary course of business and in a manner consistent with past practice, and, except as otherwise prohibited pursuant to **Section 4.1(b)**, the Company shall use its reasonable best efforts to (A) preserve substantially intact its business organization, (B) keep available the services of, and not give notice of revocation or termination to any of, its current officers, Employees and consultants, (C) maintain its Intellectual Property and (D) maintain and preserve intact its current relationships with customers, suppliers, distributors, creditors and other Persons with which the Company has significant business relations.

(b) In furtherance, and not in limitation, of **Section 4.1**, during the period from the date of this Agreement and continuing until the earlier of the valid termination of this Agreement pursuant to **Section 9.1** or the First Effective Time, except (A) as set forth in Section 4.1(b) of the Company Disclosure Schedule, (B) as expressly contemplated by any other provision of this Agreement or (C) with the prior written consent of Parent (not to be unreasonably withheld, conditioned or delayed), the Company shall not, directly or indirectly, do, or propose to do, any of the following:

(i) modify, amend or otherwise change the Governing Documents of the Company, except for amending the Certificate of Incorporation as set forth in **Exhibit H**;

(ii) (A) issue, grant, sell, pledge or dispose of, (B) grant any Liens on or permit any Liens to exist on, or (C) authorize the issuance, grant, sale, pledge or disposition of, or granting or placing of any Liens on, any shares of any class or series of Company Capital Stock or other equity interests of the Company, or options, restricted stock units or other equity-based awards (whether payable in cash, stock or otherwise), or any securities convertible into, exercisable or exchangeable for, or subscriptions, warrants, options or other rights of any kind to acquire, or other agreements or commitments of any character obligating the Company to issue or purchase, any such shares, interests or other convertible securities;

(iii) declare, set aside, or pay any dividends on or make any other distributions (whether payable in cash, stock or otherwise) in respect of any Company Capital Stock, or split, reduce, subdivide, combine or reclassify any Company Capital Stock or issue or authorize the issuance of any other securities in respect of, in lieu of or in substitution for shares of Company Capital Stock, or repurchase, redeem or otherwise acquire, directly or indirectly, any shares of Company Capital Stock (or options, warrants or other rights convertible into, exercisable or exchangeable for Company Common Stock);

(iv) enter into any agreement and arrangement with respect to voting or registration of, or file any registration statement (including any registration statement in draft form or that is confidentially submitted) with the SEC with respect to, any Company Capital Stock or other equity interests or any other securities;

(v) form, or enter into any commitment to form, a Subsidiary, or acquire (including by merger, consolidation or acquisition of stock or assets or any other business combination), or enter into any commitment to acquire, any Person or other business entity or any division thereof or any assets (other than assets purchased under ordinary course agreements with suppliers);

(vi) (A) sell, pledge or dispose of, (B) grant any Liens on or permit any Liens to exist on, or (C) authorize the sale, pledge or disposition of, or granting or placing of any Liens on, any material assets of any of the Company; or effect any sale (whether by merger, sale of assets, sale of equity or otherwise) of the business of the Company or the Company or of all or substantially all of its assets;

(vii) authorize, make or agree to make any capital expenditure or commitment exceeding $25,000 individually or $50,000 in the aggregate;

(viii) modify or remove any Company Privacy Policy, or publish or make available any new Company Privacy Policy;

(ix) enter into any agreement, contract or commitment for the (A) sale, lease, license or transfer of any Company IP or any agreement, contract or commitment or modification or amendment to any agreement with respect to Company IP with any Person, except in connection with the provision of products and services to customers in the ordinary course of business consistent with past practice, (B) purchase or license of any Intellectual Property or execution, modification or amendment of any agreement with respect to the Intellectual Property of any Person, or (C) change in pricing or royalties set or charged by the Company to its customers or licensees or in pricing or royalties set or charged by Persons who have licensed Intellectual Property to the Company;

(x) engage in any activity that will result or would be reasonably expected to result in noncompliance with any applicable Laws administered or issued by the FDA or any similar Governmental Entity, including the FDCA and all other Laws regarding developing, testing, labeling, manufacturing, storing, marketing, promoting, selling, commercializing, shipping, importing, exporting or distributing Company Products.

(xi) propose or adopt a plan of complete or partial liquidation, dissolution, merger, consolidation, restructuring, recapitalization or other reorganization of the Company;

(xii) incur any Indebtedness, or issue any debt securities or assume, guarantee or endorse, or otherwise become responsible for, the obligations of any Person, or amend the terms of any outstanding loan agreement, or make any loans or advances or capital contribution to, or investment in, any Person;

(xiii) commence or settle any Action by or against the Company or relating to its business, properties or assets;

(xiv) adopt or change the accounting methods or practices (including any change in depreciation or amortization policies or rates or any change to practices that would impact the methodology for recognizing revenue) other than as required by GAAP;

(xv) make or change any election in respect of Taxes, adopt or change any accounting method in respect of Taxes, enter into any agreement in respect of Taxes, settle any claim or assessment in respect of Taxes, consent to any extension or waiver of the limitation period applicable to any claim or assessment in respect of Taxes, make or request any Tax ruling, enter into any Tax sharing or similar agreement or arrangement, enter into any transactions giving rise to deferred gain or loss, amend any Tax Return or file any income Tax Return (including any estimated Tax Return) or other material Tax Return;

(xvi) adopt, amend or terminate, or start a termination process of, any Company Employee Plan or any Employee Agreement, including any indemnification agreement;

(xvii) hire any employees (A) at the executive level or higher, or (B) other than in the ordinary course of business consistent with past practice, other Employees; *provided*, *however*, that equity and equity-based awards (whether payable in cash, stock or otherwise) may not be offered in connection with any such hiring;

(xviii) increase or make any other change that would result in increased cost to the Company with respect to the salary, wage rate, incentive compensation opportunity, employment status, title or other compensation (including equity-based compensation or benefits) payable or to become payable by the Company to any Employee;

(xix) make any declaration, payment, commitment or obligation of any kind for the payment (whether payable in cash, stock or otherwise) of a severance payment or other change in control payment, retention or termination payment, bonus, special remuneration or other additional salary or compensation (including equity-based compensation) to any Employee, except (A) severance, change in control, or similar payments made pursuant to written agreements existing on the date of this Agreement and disclosed in Section 2.16(j) of the Company Disclosure Schedule in accordance with their terms as in effect as of the date hereof, and (B) annual bonus payments made in the ordinary course of business consistent with past practice in connection with the Company's customary performance review procedures;

(xx) terminate any Employees or otherwise cause any Employees to resign, in each case other than (A) in the ordinary course of business consistent with past practice or (B) for cause or poor performance (documented in accordance with the Company's past practices);

(xxi) take any action to accelerate the vesting or payment of, or otherwise modify, the terms of or accelerate the vesting or payment of, any compensation to any Employee;

(xxii) terminate, cancel, materially amend or modify, let lapse or fail to renew any insurance policy maintained by the Company unless such policy is replaced by a reasonably comparable policy;

(xxiii) send any written communications (including electronic communications) to Employees regarding this Agreement or the Transactions or make any representations or issue any communications to Employees that, in each case, are inconsistent with this Agreement or the Transactions, including any representations regarding offers of employment from Parent or a Subsidiary of Parent;

(xxiv) enter into any Material Contract other than in the ordinary course of business consistent with past practice, or amend, modify or consent to the termination of any Material Contract or any of the Company's rights thereunder (including any waiver or modification of prepayment obligations of customers thereunder, but not including the expiration of a Material Contract), or enter into any agreement that would have been required to be scheduled pursuant to **Section 2.15**;

(xxv) voluntarily terminate or modify or waive any material right under any Company Permit;

(xxvi) convene any special meeting (or any adjournment or postponement thereof) of the Stockholders other than the Company Stockholder's Meeting;

(xxvii) cancel or forgive any debts or claims;

(xxviii) (A) defer payment of any accounts payable, if any, or (B) accelerate, or offer any discount, accommodation or other concession in order to accelerate or induce the collection of, any accounts receivable, if any; or

(xxix) announce an intention, enter into any formal or informal agreement or otherwise commit, authorize or agree, in writing or otherwise, to do any of the foregoing or take any of the foregoing actions.

ARTICLE V
ADDITIONAL AGREEMENTS

SECTION 5.1 Access to Information. The Company shall afford Parent and its Representatives reasonable access (including electronic access, to the extent available, and the right to make legible photocopies) to during the period from the date hereof and prior to the First Effective Time to (a) all of the properties, offices, Books and Records of the Company, including all Company IP, (b) all other information concerning the business, properties and personnel, including additional financial and operating data, of the Company as Parent may reasonably request (subject to restrictions imposed by applicable Law), and (c) all Employees of the Company as identified by Parent. The Company agrees to provide to Parent and its accountants, counsel and other Representatives copies of internal financial statements (including Tax Returns and supporting documentation) promptly upon request.

SECTION 5.2 Non-Solicitation of Competing Acquisition Proposals.

(a) Commencing on the date hereof and continuing at all times until the earlier to occur of the First Effective Time and the valid termination of this Agreement pursuant to the provisions of **Section 9.1**, the Company shall not, and shall cause its Representatives not to, directly or indirectly (i) solicit, initiate, consider, encourage, promote, recommend, approve, agree to, accept or support any inquiry or proposal that could reasonably be expected to lead to any approaches, understandings, agreements, proposals or offers (including any letter of intent, term sheet or other similar document) from; (ii) furnish or make available any non-public information regarding the Company or any of its Affiliates (other than in connection with the sale of products and services in the ordinary course of business consistent with past practice or license of intellectual property in connection therewith) to; (iii) enter into, continue or otherwise participate in any discussions, conversations, negotiations or other communications with, or otherwise cooperate in any way with, in each case, any Person or group of Persons (other than Parent and its Representatives acting in their capacities as such) (each, a "**Third Party**") regarding an Alternative Transaction; or (iv) enter into any Alternative Acquisition Agreement.

(b) The Company agrees that between the date of this Agreement and the earlier to occur of the First Effective Time and the termination of this Agreement in accordance with **Section 9.1**, the Company shall immediately notify Parent of any Alternative Transaction or any request for disclosure of information or access of the type referenced in **clause (ii)** of **Section 5.2(a)** and indicate in reasonable detail the terms and conditions of such Alternative Transaction (including a copy of any written material and electronic communications received from such Third Party) and the identity of the Person making such Alternative Transaction. The Company shall keep Parent informed on a reasonably current basis in all material respects of the status and details (including material amendments or proposed amendments) of any such Alternative Transaction.

(c) The Company agrees that between the date of this Agreement and the earlier to occur of the First Effective Time and the termination of this Agreement in accordance with **Section 9.1**, the Company shall, and shall cause its Representatives to, immediately cease and cause to be terminated any such solicitation, discussions, negotiations or agreements with any Person (other than with Parent) that may be ongoing with respect to any Alternative Transaction, or any inquiry, proposal or offer that would reasonably be expected to lead to an Alternative Transaction, and shall promptly request the prompt return or destruction of all non-public information previously furnished to any such Person in connection with an Alternative Transaction and promptly terminate all physical and electronic data room access previously granted to any such Person or its Representatives.

(d) The Company understands and agrees that any violation of the restrictions set forth above by any Representative of the Company shall be deemed to be a breach of this Agreement by the Company.

SECTION 5.3 Preparation of Proxy Statement. As promptly as practicable after the date of this Agreement, the Company shall prepare a proxy statement relating to the matters to be submitted to the Company stockholders at the Company Stockholders' Meeting and the solicitation of the Stockholder Approval in accordance with applicable Law (such proxy statement, and all amendments, supplements, annexes and exhibits thereto, the "**Proxy Statement**"). The Proxy Statement shall be reasonably acceptable to Parent. If at any time prior to the Closing any information relating to any of the Parties, or their respective Affiliates, officers or directors, should be discovered by a Party which should be set forth in an amendment or supplement to the Proxy Statement so that such documents would not include any misstatement of a material fact or omit to state any material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, the Party which discovers such information shall promptly notify and consult with the other Parties and, to the extent required by applicable Law, shall cooperate with the other Parties (including giving due consideration to the comments received from the other Parties) to provide that an appropriate amendment or supplement describing such information shall be promptly disseminated to the stockholders of the Company. None of the information supplied or to be supplied by the Company, Parent or any of their respective directors, officers, employees or agents for inclusion or in the Proxy Statement shall, at the time of the Company Stockholders' Meeting, contain any untrue statement of a material fact or omit to state any material fact with respect to the Company or Parent, as the case may be, necessary in order to make the statements therein with respect to the Company or Parent, as the case may be, in light of the circumstances under which they are made, not misleading.

SECTION 5.4 Company Stockholders' Meeting.

(a) As promptly as practicable after the date of this Agreement (but in no event later than thirty (30) Business Days following the date of this Agreement), the Company: (i) shall take all action necessary under all applicable Laws to duly call, give notice of and, in accordance with this **Section 5.4**, convene a meeting of the holders of Company Capital Stock (the "**Company Stockholders' Meeting**") to vote on a proposal to adopt this Agreement and the Transactions, including the Mergers and the Charter Amendment; and (ii) shall submit such proposal to such holders at the Company Stockholders' Meeting and shall not submit any other proposal to such holders in connection with the Company Stockholders' Meeting without the prior written consent of Parent. The Company, in consultation with Parent, shall set a record date for Persons entitled to notice of, and to vote at, the Company Stockholders' Meeting, and shall amend the Company Bylaws to the extent necessary to effect such record date. The Company shall provide the notice set forth in Section 4(d) of the Company Warrant and the applicable provisions of Governing Documents to provide notice of the record date and the Company Stockholders' Meeting. The Company shall use commercially reasonable efforts to ensure that all proxies solicited by the Company and its Representatives in connection with the Company Stockholders' Meeting are solicited in compliance with all applicable Laws. Notwithstanding anything to the contrary contained in this Agreement, if either Parent or the Company reasonably believes it is necessary to ensure that (A) the Company will receive proxies sufficient to obtain the required approval of the holders of Company Capital Stock at the Company Stockholders' Meeting for the adoption of this Agreement and the Transactions, including the Mergers, whether or not a quorum would be present at the Company Stockholders' Meeting, or (B) the Company will have sufficient shares of Company Capital Stock represented (whether in person or by proxy) to constitute a quorum necessary to conduct the business of the Company Stockholders' Meeting, the Company may with the written consent of Parent, or, at the request of Parent, shall, postpone or adjourn the Company Stockholders' Meeting, on one or multiple occasions, as long as the date of the Company Stockholders' Meeting is not postponed or adjourned more than an aggregate of fifteen (15) calendar days in connection with such postponement or adjournment. The Company agrees that, unless this Agreement shall have been terminated in accordance with **Article IX**, its obligation to hold the Company Stockholders' Meeting pursuant to this **Section 5.4(a)** shall not be affected by the commencement, public proposal, public disclosure or communication to the Company of any Acquisition Proposal or by any Company Adverse Change in Recommendation.

(b) Subject to **Section 5.2(c)** and **Section 9.1(f)**: (i) the Proxy Statement shall include a statement to the effect that the Company Board of Directors has determined that this Agreement and the Transactions, including the Mergers and the Charter Amendment, are advisable and fair to, and in the best interests of, the Company and its stockholders, and recommends that the Company's stockholders vote to adopt this Agreement and the Transactions, including the Mergers, and approve the Charter Amendment at the Company Stockholders' Meeting (the recommendation of the Company Board of Directors that the Company's stockholders vote to adopt this Agreement and the Transactions, including the Mergers, being referred to as the "**Company Board Recommendation**"); (ii) until the Specified Time, neither the Company Board of Directors nor any committee thereof shall (1) (A) withhold, withdraw, qualify or modify in a manner adverse to Parent, or resolve to or publicly propose to withhold, withdraw, qualify, or modify in a manner adverse to Parent, the Company Board Recommendation, (B) remove the Company Board Recommendation from or fail to include the Company Board Recommendation in the Proxy Statement or (C) approve, recommend or declare advisable, or publicly propose to approve, recommend or declare advisable, any Acquisition Proposal or Alternative Transaction (any action described in this **clause (1)** being referred to as a "**Company Adverse Change in Recommendation**"); or (2) adopt, approve, recommend, submit to stockholders or declare advisable, or propose to adopt, approve, recommend, submit to stockholders or declare advisable, or allow the Company to execute or enter into any letter of intent (whether or not binding), term sheet, merger agreement, acquisition agreement, option agreement, agreement in principle or similar agreement providing for any Acquisition Proposal, or requiring the Company to abandon, terminate, delay or fail to consummate the Transactions (any such Contract, an "**Alternative Acquisition Agreement**").

(c) Notwithstanding anything to the contrary contained in this Agreement, at any time prior to the adoption of this Agreement by the Stockholder Approval:

(i) if the Company has received a bona fide written Acquisition Proposal (which Acquisition Proposal did not arise out of a material breach of **Section 5.2**) from any Person that has not been withdrawn and after consultation with outside legal counsel and independent financial advisors, the Company Board of Directors shall have determined in good faith that such Acquisition Proposal is a Superior Offer, (x) the Company Board of Directors may make a Company Adverse Change in Recommendation, and/or (y) the Company may terminate this Agreement to substantially concurrently therewith enter into a Specified Agreement with respect to such Superior Offer and pay the Termination Fee pursuant to **Section 9.3**, in each case if and only if: (A) the Company Board of Directors determines in good faith, after consultation with the Company's outside legal counsel and independent financial advisors, that the failure to take such action could reasonably be expected to be inconsistent with the fiduciary duties of the Company Board of Directors to the Company's stockholders under applicable Law; (B) the Company shall have given Parent prior written notice of its intention to consider making a Company Adverse Change in Recommendation or terminate this Agreement pursuant to **Section 9.1(f)** at least seven (7) Business Days prior to making any such Company Adverse Change in Recommendation or termination (a "**Determination Notice**") (which notice shall not in and of itself constitute a Company Adverse Change in Recommendation or a termination of this Agreement); and (C) (1) the Company shall have made available to Parent the identity of the offeror, a summary of the material terms and conditions of the Acquisition Proposal and copies of all written materials and other documents required by **Section 5.2(b)**, (2) the Company shall have given Parent the seven (7) Business Days after the Determination Notice to propose revisions to the terms of this Agreement or make other proposals and shall have made available its Representatives to negotiate with Parent with respect to such proposed revisions or other proposal, if any (*provided* that Parent may revise such offer or proposal in response to any revisions to a Superior Offer), (3) after considering any such revised proposal from Parent, including whether such proposal was a written, binding and irrevocable offer, and the results of any such negotiations and giving effect to the proposals made by Parent, if any, after consultation with outside legal counsel and its independent financial advisors, the Company Board of Directors shall have determined in good faith that such Acquisition Proposal is a Superior Offer and that the failure to make the Company Adverse Change in Recommendation and/or terminate this Agreement pursuant to **Section 9.1(f)** could reasonably be expected to be inconsistent with the fiduciary duties of the Company Board of Directors to the Company's stockholders under applicable Law and (4) if the Company intends to terminate this Agreement to enter into a Specified Agreement, the Company shall have complied with **Section 9.1(f)**. The provisions of this **Section 5.4(c)(i)** shall also apply to any material amendment (which shall include any revision to the amount, form or mix of consideration the Company's stockholder would receive) to any Acquisition Proposal and require a new Determination Notice, except that, in the case of material amendments to any Acquisition Proposal, the references to seven (7) Business Days shall be deemed to be four (4) Business Days.

(d) The Company shall ensure that any withdrawal or modification of the Company Board Recommendation does not have the effect of causing any corporate takeover law of the State of Delaware or any other state to be applicable to this Agreement, the Mergers or any of the other Transactions.

SECTION 5.5 280G Approvals.

(a) The Company will obtain and deliver to Parent, at least one (1) Business Day before the initiation of the procedure described in **Section 5.5(b)**, an excess parachute payment waiver, in substantially the form of **Exhibit E**, from each Person who the Company (after consultation with Parent) reasonably believes is, with respect to the Company, a "disqualified individual" (within the meaning of Section 280G of the Code) with respect to the Transactions and who has received or could otherwise receive or have the right or entitlement to receive a "parachute payment" (as defined in Section 280G(b)(2) of the Code) from the Company, or from Parent or any trade or business (whether or not incorporated) that is a member of a controlled group or which is under common control with Parent within the meaning of Section 414 of the Code, pursuant to Section 280G of the Code as a result of the Closing or the consummation of the Mergers (including in connection with certain changes in any such Person's employment circumstances following the consummation of the Mergers). By the execution of such waiver agreement, the Person executing the waiver will agree to waive all of their right and entitlement to receive (or if already paid, their right and entitlement to keep) any portion of such "parachute payments" which would cause the Person executing the waiver to receive an "excess parachute payment" (as defined in Section 280G(b)(1) of the Code), unless the Company's stockholders approve such waived payments in accordance with Section 280G(b)(5)(A)(ii) of the Code.

(b) Prior to the First Effective Time, the Company will submit the payments which are waived pursuant to the waiver agreements described in **Section 5.5(a)** to its stockholders and the holders of the voting power of any entity stockholder for their approval in accordance with all applicable requirements of such Section 280G(b)(5)(B) of the Code and the Treasury Regulations thereunder, including Q-7 of Section 1.280G-1 of such Treasury Regulations. Within four (4) Business Days after the date of this Agreement, the Company will provide, or cause to be provided, to Parent a draft of all solicitation and related documents (including any calculations of the parachute payments) contemplated in this **Section 5.5(b)**, including any disclosure documents. The Company will incorporate any reasonable comments into such documents that are made timely by Parent.

SECTION 5.6 General Efforts to Close. Subject to the terms and conditions provided in this Agreement, each of the parties hereto shall use commercially reasonable efforts to take promptly, or cause to be taken promptly, all actions, and to do promptly, or cause to be done promptly, all things necessary, proper or advisable under applicable Law to consummate and make effective the Mergers and the other Transactions as promptly as practicable, including by using commercially reasonable efforts to take all action necessary to satisfy all of the conditions to the obligations of the other party or parties hereto to effect the Mergers set forth in **Article VI**, to obtain all necessary waivers, consents, approvals and other documents required to be delivered hereunder and to effect all necessary registrations and filings, in each case in order to consummate and make effective the Mergers and the other Transactions.

SECTION 5.7 Notification of Certain Matters. From the date hereof to the First Effective Time, the Company shall give prompt notice to Parent, and Parent, Merger Sub 1 and Merger Sub 2 shall give prompt notice to the Company, of: (a) any notice or other communication received by such party from any Governmental Entity in connection with the Mergers or the Transactions or from any Person alleging that the consent of such Person is or may be required in connection with the Mergers if the subject matter of such communication or the failure of such party to obtain such consent purports to materially affect the consummation of the Mergers; (b) any Action commenced or, to such party's knowledge, threatened in writing against such party or any of its Affiliates which purports to materially affect the consummation of the Mergers; (c) the occurrence, or non-occurrence of, any event, the occurrence, or non-occurrence, of which would reasonably be expected to cause any representation or warranty contained in this Agreement to be untrue or inaccurate such that the conditions in **Section 6.2(a)** would not be satisfied; and (d) any failure of the Company, Parent, Merger Sub 1 or Merger Sub 2, as the case may be, to comply with or satisfy any covenant or agreement to be complied with or satisfied by it hereunder; *provided*, *however*, that the delivery of any notice pursuant to this **Section 5.7** shall not (i) limit or otherwise affect any remedies available to the party receiving such notice, or (ii) constitute an acknowledgment or admission of a breach of this Agreement.

SECTION 5.8 Consents; Joinders.

(a) The Company shall, and shall cause its Affiliates to, use reasonable best efforts to obtain all necessary consents, waivers and approvals of any third parties to any Contract (including all of the Contracts set forth in Section 2.4 of the Company Disclosure Schedule) as are required thereunder in connection with the Mergers in order for such Contract to remain in full force and effect following the Mergers. Such consents, waivers and approvals shall be in a form reasonably acceptable to Parent. None of the Company or its Affiliates shall accept or agree to any consent conditioned on the undertaking of any obligations by the Company, Parent, Merger Sub 1, Merger Sub 2, the Initial Surviving Company or the Surviving Company (whether in the form of payment, non-monetary consideration, a guarantee, any other agreements or otherwise) without the prior written consent of Parent. In the event that the Mergers do not close for any reason, neither Parent, Merger Sub 1 nor Merger Sub 2 shall have any liability to the Company, the Stockholders or any other Person for any costs, claims, liabilities or damages resulting from the Company seeking to obtain such consents, modifications, waivers and approvals.

(b) The Company shall use commercially reasonable efforts to obtain Joinders from all Stockholders and Company Option Holders prior to the Closing.

SECTION 5.9 Employee Matters.

(a) ***Proprietary Information and Inventions Assignment Agreements***. Prior to the Closing, the Company shall use its reasonable best efforts to cause each current and former employee of the Company to have entered into and executed, and each person who becomes an employee of the Company after the date hereof and prior to the Closing shall be required by the Company to enter into and execute, an Employee Proprietary Information Agreement with the Company effective as of such employee's first date of employment or service. The Company shall use reasonable best efforts to cause each current and former consultant or contractor of the Company to have entered into and executed, and each Person who becomes a consultant or contractor of the Company after the date hereof and prior to the Closing shall be required by the Company to enter into and execute, a Consultant Proprietary Information Agreement with the Company effective as of such consultant or contractor's first date of service.

(b) ***Termination of Employee Plans***. Unless instructed otherwise by Parent, effective as of no later than the day immediately preceding the Closing Date, the Company shall terminate any and all Company Employee Plans and shall provide Parent with evidence that any such Company Employee Plan has been terminated pursuant to resolutions of the board of directors (or similar body) of the Company or its ERISA Affiliates, as the case may be. The form and substance of such resolutions shall be subject to review and approval of Parent. The Company shall also take such other actions in furtherance of terminating any such other Company Employee Plan as Parent may require.

(c) ***Payment of Accrued Employee Amounts***. Prior to the Closing, the Company shall pay out all vacation and paid time off that has been accrued but unused as of the Closing Date by any Employee, as well as all accrued wages, pro-rated bonuses and other accrued but unpaid benefits of any Employee as of the Closing Date.

(d) ***No Employment Commitment or Plan Amendments***. No provision of this Agreement is intended, or shall be interpreted, to provide or create any third-party beneficiary rights or any other rights of any kind or nature whatsoever in any Stockholder, Employee, or any other Person, including any rights of employment for any specified period and/or any employee benefits, in favor of any Person, union, association, Continuing Employee, Employee, consultant or contractor or any other Person, other than the parties hereto and their respective successors and permitted assigns, and all provisions hereof will be personal solely among the parties to this Agreement. In addition, no provision of this Agreement is intended, or shall be interpreted, to amend any term or condition of the Plan or any other employee related plan, program or policy of the Company, Parent or any Subsidiary of Parent.

(e) ***Amendment of Trigger Rights and Vesting Provisions***. Prior to the Closing, the Company shall, with respect to each Contract with any Continuing Employee containing Trigger Rights, take any and all actions necessary to deliver to Parent and to cause each such Continuing Employee to deliver to Parent (i) a signed waiver from each applicable Continuing Employee entitled to any such Trigger Rights on a form satisfactory to Parent that the Closing of the Mergers and/or commencement of employment with Parent or a Parent subsidiary shall not trigger payment, or constitute one of the triggers for the payment, of any Trigger Rights; and (ii) a signed amendment from each applicable Continuing Employee entitled to any such Trigger Rights on a form satisfactory to Parent. The Company shall make any payments required to effect the amendment or modification contemplated by this **Section 5.9(e)** and to reflect such payment or other consideration incurred by the Company as of the Closing Date or anticipated to be incurred or payable after the Closing in a form reasonably acceptable to Parent, setting forth in reasonable detail all unpaid Third-Party Expenses owing by or on behalf of the Company as of the Closing Date, or anticipated to be incurred or payable by or on behalf of the Company after the Closing (the "**Statement of Expenses**").

SECTION 5.10 Termination of Certain Agreements and Rights; Certain Actions Thereunder.

(a) The Company shall cause any stockholder agreements, voting agreements, registration rights agreements, investor's rights agreements, co-sale agreements, warrants and any other similar Contracts (including the Company Warrant) between the Company and any holders of the Company Capital Stock, including any such Contract granting any Person investor rights, rights of first refusal, registration rights or director registration rights (collectively, the "**Investor Agreements**"), to be terminated immediately prior to the First Effective Time, without any Liability being imposed on the part of Parent or the Surviving Company (other than the survival of confidentiality and drag-along provisions).

(b) The Company shall take all actions requested by Parent under Section 2 of the Voting Agreement in connection with the transactions contemplated by this Agreement and the Related Agreements.

SECTION 5.11 Closing Date Balance Sheet.

(a) Not less than three (3) Business Days prior to the anticipated Closing, the Company shall deliver to Parent an estimated balance sheet and income statement of the Company as of the Closing Date (the "**Closing Date Balance Sheet**"), in a form reasonably acceptable to Parent, that has been prepared in accordance with the accounting principles set forth on Section 2.7(c) of the Company Disclosure Schedule on a basis consistent with the Financial Statements and that fairly presents an estimate by the Company in good faith based on reasonable assumptions of the balance sheet of the Company as of the Closing Date, after giving effect to the Closing. The Closing Date Balance Sheet shall set forth all information required to calculate, and shall calculate in good faith, the Closing Indebtedness, Closing Cash and Third-Party Expenses. The Closing Date Balance Sheet shall also contain a true, complete and correct asset ledger and line item for each Liability set forth in such balance sheet.

(b) Not less than three (3) Business Days prior to the anticipated Closing, the Company shall deliver to Parent the Statement of Expenses. Neither the Company nor any of its Affiliates shall take any action that may result in Third-Party Expenses being incurred after the Closing without Parent's prior written consent, *provided* that the Company may make any payment of accounts payable in the ordinary course of business.

SECTION 5.12 Allocation Schedule. Not less than three (3) Business Days prior to the anticipated Closing, the Company shall prepare in good faith and deliver to Parent a statement, which shall be updated by the Company at the close of business on the day immediately preceding the Closing (each, an "**Allocation Schedule**") setting forth the following information, in form and substance reasonably acceptable to Parent and accompanied by documentation reasonably acceptable to Parent in support of the calculation of the information set forth therein:

(a) calculations of the Total Consideration and all components thereof, as well as the Total Outstanding Shares, Remaining Consideration, the Cash Amount, the Tail Cost, Indebtedness, Closing Cash, Closing Indebtedness, the Series A Liquidation Amount, the Senior Series B Liquidation Amount and the Series B-1 Liquidation Amount and Third-Party Expenses (in each case, on the basis of the Books and Records of the Company and prepared in accordance with this Agreement and reasonably acceptable to Parent);

(b) calculation of the Exchange Ratio;

(c) with respect to each Stockholder, each Company Option Holder and each holder of Company Warrants: (i) the name and address of such holder, and, if available, the e-mail address of such holder, (ii) whether such holder is a current or former employee of the Company, (iii) whether such holder is an Accredited Investor, (iv) the number, class and series of shares of Company Capital Stock or other securities held by such holder and the respective certificate numbers, (v) the date of acquisition of such shares or securities, (vi) whether any Taxes are to be withheld in accordance with **Section 1.8** from the consideration that such holder is entitled to receive pursuant to **Section 1.6(b)(i)**, (vii) the stock consideration that such holder is entitled to receive pursuant to **Section 1.6(b)(i)** (on a certificate-by-certificate basis, if applicable, and in the aggregate), (viii) such Stockholder's Loan Repayment Amount, if any, (ix) the Pro Rata Portion of such holder, (x) the amount of Holdback Shares (rounded down to the nearest whole share) allocable to such Stockholder, (xi) the net stock amounts to be paid to such holder in accordance with **Section 1.6(b)(i)** after deduction of the amounts referred to in **clauses (vi)** and **(x)** in this **Section 5.12(c)** (on a certificate-by-certificate basis, if applicable, and in the aggregate), (xii) the Cash Amount (on a certificate-by-certificate basis, if applicable, and in the aggregate), and (xiii) such other additional information which Parent may reasonably request; and

(d) a funds flow spreadsheet and wire instructions for each payment and distribution required to be made on the Closing Date pursuant to this Agreement.

SECTION 5.13 Verification of Allocation Schedule. The Company shall permit Parent and its Representatives reasonable access during normal business hours upon reasonable advance notice to the relevant Books and Records relating to the preparation of the Closing Date Balance Sheet, Statement of Expenses and Allocation Schedule, as may be reasonably required for the purpose of Parent's review and verification of the Closing Date Balance Sheet, Statement of Expenses and Allocation Schedule. Parent may propose, and the Company shall review and consider, in good faith, any appropriate changes to the Closing Date Balance Sheet, Statement of Expenses and Allocation Schedule.

SECTION 5.14 Takeover Statutes. If any takeover statute is or may become applicable to this Agreement (including the Mergers and the other Transactions) or the Related Agreements, the Company, Parent, Merger Sub 1 and Merger Sub 2 and their respective boards of directors shall grant all such approvals and take all such actions as are necessary so that the Transactions, including the Mergers, may be consummated as promptly as practicable hereafter on the terms contemplated hereby and thereby and otherwise act to eliminate or minimize the effects of such statute on the Transactions.

ARTICLE VI
CONDITIONS TO THE MERGERS

SECTION 6.1 Conditions to the Obligations of Each Party. The respective obligations of Parent, Merger Sub 1, Merger Sub 2 and the Company to effect the Mergers shall be subject to the satisfaction, at or prior to the Closing Date, of each of the following conditions (any and all of which may be waived in whole or in part by Parent, Merger Sub 1, Merger Sub 2 and the Company, as the case may be, to the extent permitted by applicable Law):

(a) ***Stockholder Approval***. The Stockholder Approval shall have been obtained.

(b) ***No Legal Prohibitions***. No Governmental Entity shall have enacted, issued, promulgated, enforced, threatened or entered any Law or Governmental Order (whether temporary, preliminary or permanent) that restrains, enjoins, prohibits or seeks to restrain, enjoin or prohibit the consummation of all or a portion of the Mergers or any of the other Transactions.

(c) ***Governmental Approvals***. Any Regulatory Approvals that are required by Law shall have been obtained or shall have occurred or the applicable waiting period shall have expired.

SECTION 6.2 Conditions to the Obligations of Parent, Merger Sub 1 and Merger Sub 2. The obligations of Parent, Merger Sub 1 and Merger Sub 2 to effect the Mergers shall be further subject to the satisfaction at or prior to the Closing Date of each of the following conditions (any and all of which may be waived in whole or in part by Parent to the extent permitted by applicable Law):

(a) ***Accuracy of Representations and Warranties***. (i) The Company Fundamental Representations and the Stockholder Fundamental Representations shall be true and correct in all respects as of the date of this Agreement and as of the Closing Date with the same effect as though made at and as of such date (except those representations and warranties that address matters only as of a specified date, which shall be true and correct in all respects as of that specified date), and (ii) the other representations and warranties of the Company contained in this Agreement (other than the Company Fundamental Representations) and those contained in the Joinders shall be true and correct (without giving effect or taking into account any limitation as to materiality, knowledge or "Material Adverse Effect" or words of like meaning set forth therein) in all material respects as of the date of this Agreement and as of the Closing Date with the same effect as though made at and as of such date (except those representations and warranties that address matters only as of a specified date, which shall be true and correct in all material respects as of that specified date).

(b) ***Covenants***. The Stockholders, Company Option Holders and the Company shall have performed or complied in all material respects with all agreements and covenants required by this Agreement and the Related Agreements to be performed or complied with by the Stockholders, and Company Option Holders and the Company, as applicable, at or prior to the First Effective Time.

(c) ***No Material Adverse Effect***. Since the date of this Agreement, there have not been any events that, individually or in the aggregate, have had, or would reasonably be expected to have, a Material Adverse Effect.

(d) ***Officer's Certificate***. Parent shall have received a certificate executed by the Chief Executive Officer of the Company certifying that the conditions set forth in **Sections 6.2(a)**, **6.2(b)** and **6.2(c)** have been duly satisfied.

(e) ***No Legal Proceeding***. No Action shall be pending or threatened in writing wherein an unfavorable judgment, order, decree, stipulation or injunction could reasonably be expected to (i) prevent consummation of the transactions contemplated by this Agreement, (ii) cause the transactions contemplated by this Agreement to be rescinded following consummation or (iii) be material to the Company or Parent (as determined by Parent in its sole discretion), and no such judgment, order, decree, stipulation or injunction shall be in effect.

(f) ***Related Agreements***. Each of the Related Agreements (other than this Agreement) shall have been executed and delivered by the parties thereto, and each shall be in full force and effect and shall not have been revoked, rescinded, or otherwise repudiated by the respective signatories thereto, and true and complete copies thereof shall have been delivered to Parent and the Company. Each Company Option Holder shall have entered into an Option Cancellation Agreement with the Company. Stockholders representing on hundred percent (100%) of the issued and outstanding shares of the Company Common Stock on an as-converted basis and all Company Option Holders shall have executed and delivered Joinders to Parent.

(g) ***Employment and Service Arrangements***.

(i) Each of the Non-Competition and Non-Solicitation Agreements executed concurrently with this Agreement shall be in full force and effect and shall not have been revoked, rescinded, or otherwise repudiated by the respective signatories thereto.

(ii) The Offer Letter executed by the applicable Key Holder concurrently with this Agreement shall be in full force and effect and shall not have been revoked, rescinded or otherwise repudiated by the respective signatories thereto, and the Key Holders shall not have terminated their employment with or provision of services to the Company or expressed an intention or interest (whether formally or informally) in, or taken action toward, terminating their employment with or provision of services to the Company at or prior to the Closing, or with the Surviving Company or Parent or any of its Subsidiaries following the Closing. Each of the Key Holders (A) shall have satisfied Parent's customary employee background investigation (which includes the absence of a record of any criminal conviction in all applicable court and police records), (B) shall have executed Parent's form of inventions and proprietary rights assignment agreement and Code of Business Conduct and Ethics, if applicable, and (C) shall be eligible to work in the jurisdiction of his or her employing entity.

(iii) The Company has assigned to Parent each agreement pursuant to which the Other Employees provide services to the Company (the "**Service Agreements**") as provided under the terms of the Service Agreements, and each Service Agreement is in full force and effect and shall not have been revoked, rescinded or otherwise repudiated by the respective signatories thereto. No Other Employee (A) has expressed an intention or interest (whether formally or informally) in, or taken action toward, terminating his or her service relationship with the Company at or prior to the Closing, or with the Surviving Company or Parent or any of its Subsidiaries following the Closing, (B) shall have failed to satisfy Parent's customary background investigation (which includes the absence of a record of any criminal conviction in all applicable court and police records), (C) shall have failed to execute Parent's form of inventions and proprietary rights assignment agreement and Code of Business Conduct and Ethics, and (D) shall fail to be eligible to provide his or her services in the applicable jurisdiction.

(h) ***Documentary Deliverables***. The Company shall have delivered to Parent the Allocation Schedule, Statement of Expenses and Closing Date Balance Sheet.

(i) ***Termination of Investor Agreements***. The Investor Agreements shall have been terminated (or will be terminated as of the Closing) (without survival of any provision other than confidentiality and drag-along provisions) in a manner reasonably acceptable to Parent.

(j) ***Resolutions***. The Company shall have delivered, in form and substance reasonably acceptable to Parent, a certified copy of the resolutions of the Company Board of Directors authorizing the execution and delivery of this Agreement and the Related Agreements and the consummation of the Transactions, including the Mergers.

(k) ***Resignations***. The Company shall have delivered, in form and substance reasonably acceptable to Parent, written resignations of those directors and officers of the Company designated by Parent.

(l) ***Payoff Letters***. The Company shall have delivered to Parent, in a form and substance reasonably acceptable to Parent, debt payoff letters and related ancillary documents in respect of all Indebtedness and Third-Party Expenses to be paid off at the Closing pursuant to this Agreement.

(m) ***Company Warrant***. The Company shall have complied with Section 4(d) of the Company Warrant and the twenty (20)-Business Day notice period thereunder shall have expired.

(n) ***Stockholder Vote and Appraisal***. At least eighty percent (80%) of the voting power of the shares of Company Capital Stock outstanding on the record date for the Company Stockholders' Meeting and entitled to vote, voting together as a class, shall have voted in favor of (i) the adoption of this Agreement and the Transactions, including the Mergers and (ii) the Charter Amendment. A majority of voting power of each of (1) the shares of Company Preferred Stock outstanding on the record date for the Company Stockholders' Meeting and entitled to vote, voting as a class, (2) the shares of Senior Series B Preferred Stock outstanding on the record date for the Company Stockholders' Meeting and entitled to vote, voting as a class, (3) the shares of Series B-1 Preferred Stock outstanding on the record date for the Company Stockholders' Meeting and entitled to vote, voting as a class, (4) the shares of Series A Preferred Stock outstanding on the record date for the Company Stockholders' Meeting and entitled to vote, voting as a class, and (5) the shares of Company Common Stock outstanding on the record date for the Company Stockholders' Meeting and entitled to vote, voting as a class shall have each voted in favor of (x) the adoption of this Agreement and the Transactions, including the Mergers and (y) the Charter Amendment. Stockholders representing not more than ten percent (10%) of issued and outstanding shares of Company Capital Stock shall have indicated they are seeking appraisal rights pursuant to Section 262 of DGCL.

(o) ***Cash***. The Company shall have no less than $3,500,000 in immediately available funds not subject to any Liens.

(p) ***Securities Act Exemption***. The issuance of all Parent Shares contemplated by this Agreement in connection with the Mergers and the other Transactions shall validly qualify for an exemption from the registration and prospectus delivery requirements of the Securities Act pursuant to Regulation D and the equivalent state "blue sky" Law.

(q) ***Company Charter Amendment***. The Certificate of Incorporation shall have been amended in the form of **Exhibit H** (the "**Charter Amendment**").

SECTION 6.3 Conditions to Obligations of the Company. The obligations of the Company to effect the Mergers shall be further subject to the satisfaction at or prior to the Closing Date of the following conditions (any and all of which may be waived in whole or in part by the Company to the extent permitted by applicable Law):

(a) ***Accuracy of Representations and Warranties***. (i) The Parent Fundamental Representations shall be true and correct in all respects as of the date of this Agreement and as of the Closing Date with the same effect as though made at and as of such date (except those representations and warranties that address matters only as of a specified date, which shall be true and correct in all respects as of that specified date), and (ii) the other representations and warranties of Parent contained in this Agreement (other than the Parent Fundamental Representations) shall be true and correct (without giving effect or taking into account any limitation as to materiality, knowledge or "Material Adverse Effect" or words of like meaning set forth therein) in all material respects as of such date (except those representations and warranties that address matters only as of a specified date, which shall be true and correct as of that specified date).

(b) ***Covenants***. Parent, Merger Sub 1 and Merger Sub 2 shall have performed or complied in all material respects with all agreements and covenants required by this Agreement to be performed or complied with by Parent, Merger Sub 1 and Merger Sub 2 at or prior to the First Effective Time.

(c) ***Officer's Certificate***. The Company shall have received a certificate executed by an executive officer of Parent certifying that the conditions set forth in **Section 6.3(a)** and **Section 6.3(b)** have been duly satisfied.

ARTICLE VII
TAX MATTERS

SECTION 7.1 Tax Returns. The Company shall prepare or cause to be prepared (at the Company's expense) and timely file or cause to be timely filed all Tax Returns of the Company for any Pre-Closing Tax Period that first becomes due after the Closing Date and for any Straddle Period. Such Tax Returns shall be prepared by treating items on such Tax Returns in a manner consistent with the past practices of the Company with respect to such items, except to the extent otherwise required by applicable law. In the event that a Tax Return prepared by Company with respect to a Pre-Closing Tax Period or Straddle Period gives rise to a liability for indemnified Taxes pursuant **Section 8.2(a)(vi)**, Parent shall provide the Stockholder Representative with a draft of each such Tax Return at least twenty (20) Business Days prior to the due date for filing of such Tax Returns (taking into account extensions validly obtained). The Stockholder Representative shall be entitled to comment on such Tax Returns and request reasonable revisions, subject to the consent of Parent.

SECTION 7.2 Tax Contests.

(a) Parent shall promptly notify the Stockholder Representative in writing upon receipt by Parent, the Company or any of their respective Affiliates of a written notice of any claims, assessments, audit or similar events with respect to Taxes of the Company for which the Stockholders and the Company Option Holders would be liable under this Agreement (a "**Tax Claim**"); *provided* that no failure or delay by Parent to provide such notice of a Tax Claim shall reduce or otherwise affect the obligation of the Stockholders and the Company Option Holders hereunder except to the extent the Stockholder Representative is actually and materially prejudiced thereby.

(b) Following the Closing, the Stockholder Representative shall, solely at the cost and expense of the Stockholders and the Company Option Holders, have the right in its sole discretion to control the conduct of, and to settle, any such Tax Claim; *provided* that (A) the Stockholder Representative shall notify Parent of its intent to represent the interests of the Company within ten (10) days of receipt of the notice described in **Section 7.2(a)**, (B) the Stockholder Representative shall provide Parent with a timely and reasonably detailed account of each phase of such proceeding relating to a Tax Claim, (C) Parent shall have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Stockholder Representative, (D) the Stockholder Representative shall consult with Parent and offer Parent an opportunity to comment before submitting any written materials prepared or furnished in connection with such proceeding and (E) if the settlement or compromise of such proceeding would have the effect of increasing the amount of Taxes payable by Parent or any of its Affiliates in a Post-Closing Tax Period, the Stockholder Representative shall not settle or compromise such proceeding without first obtaining the prior written consent of the Parent, which consent shall not be unreasonably withheld, conditioned or delayed.

(c) Notwithstanding anything to the contrary in this Agreement, this **Section 7.2**, shall control with respect to any Tax Claim.

SECTION 7.3 Cooperation. Parent and the Stockholder Representative agree to furnish or cause to be furnished to the other, upon request, as promptly as practicable, such information and assistance relating to Taxes, including access to books and records, as is reasonably necessary for the filing of all Tax Returns by Parent or the Stockholders or the preparation by the Stockholder Representative of all Tax Returns it is required to prepare (or cause to be prepared), the making of any election relating to Taxes, the preparation for any audit by any Tax authority and the prosecution or defense of any claim, suit or proceeding relating to any Tax. Each of Parent and the Company shall retain all books and records in their possession with respect to Taxes for a period of at least seven (7) years following the Closing Date or, if later, on the date specified under any record retention agreement, *provided* that, at least thirty (30) days before disposing of books and records, the Parent shall (x) offer such books and records to the Stockholder Representative and (y) if the Stockholder Representative accepts them, transfer the books and records to the Stockholder Representative (at no cost to the Stockholder Representative).

SECTION 7.4 Certain Post-Closing Actions. Notwithstanding any provision of this Agreement to the contrary except to the extent required by applicable Law, without the prior written consent of the Stockholder Representative (which consent shall not be unreasonably withheld, conditioned, or delayed), after the Closing, neither Parent nor any of its Affiliates (including the Company) shall (a) file any Tax Return (other than pursuant to **Section 7.1**), (b) file any amended Tax Return, (c) make, change, or revoke any Tax election, (d) initiate discussions or examinations with a taxing authority or make any voluntary disclosures with respect to Taxes, or (e) take any action or position related to Taxes, in each case, if such filing, settlement, action, or position could cause or increase a Tax or Tax-related indemnification liability of the Stockholders. Neither the Parent nor any of its Affiliates (including the Company) shall make any election under Section 338 of the Code with respect to the transactions contemplated by this Agreement.

SECTION 7.5 FIRPTA Certificate. Prior to the Closing, the Company shall deliver, or cause to be delivered, to Parent a certificate pursuant to Treasury Regulation Section 1.1445-2(c)(3) stating that the Company is not, nor has it been, a U.S. real property holding corporation (as defined in Section 897(c)(2) of the Code) during the applicable period specified in Section 897(c) of the Code, *provided* that the Parent's only remedy for the Company's failure to provide such certificate will be for Parent to withhold from the payments to be made pursuant to this Agreement to Stockholders in accordance with **Section 1.8** any required withholding Tax under applicable Law and the Company's failure to provide such certificate shall not be deemed to be a failure of the condition set forth in **Article VI** to have been met.

SECTION 7.6 Transfer Taxes. All Transfer Taxes incurred in connection with consummation of the transactions contemplated by this Agreement shall be borne by the Parent. The Parent agrees to file all Tax Returns associated with such Taxes and all required change of ownership and similar statements, and the Stockholders and the Stockholder Representative shall reasonably cooperate with respect thereto.

SECTION 7.7 Apportionment of Taxes

(a) ***Closing of Tax Year***. To the extent permitted or required by applicable law, the taxable year of the Company shall be treated as closing on (and including) the Closing Date.

(b) ***Apportionment Principles***. The parties agree that, notwithstanding anything to the contrary in this Agreement or otherwise, the following principles shall apply for purposes of calculating Taxes that are included in Indebtedness and for determining any Taxes for which the Stockholders are liable, or Tax refunds to which the Stockholders are entitled, under this Agreement (and the principles in **Section 7.7(b)(ii)**, **Section 7.7(b)(iii)** and **Section 7.7(b)(iv)** shall also apply in connection with the preparation of any Tax Returns for Tax periods that end on or before, or include, the Closing Date):

(i) In the case of any Straddle Period, (A) in the case of Taxes (other those described in **clause (B)** of this sentence), the Taxes attributable to the pre-Closing portion of a Straddle Period shall be determined on the basis of a closing of the books as of the close of business on the Closing Date; and (B) any real or personal property Taxes or similar ad valorem Taxes attributable to the pre-closing portion of a Straddle Period shall equal the amount of such Tax for the entire taxable period multiplied by a fraction, the numerator of which is the number of days in the taxable period up to and including the Closing Date, and the denominator of which is the total number of days in the taxable period.

(ii) All determinations necessary to give effect to the foregoing allocations shall be made in a manner consistent with prior practice (including reporting positions, elections and accounting methods) of the Company in preparing Tax Returns, unless otherwise required by Law.

(iii) The election under Revenue Procedure 2011-29, 2011-18 I.R.B. 746 to apply the 70% safe harbor to any "success based fee" as defined in Treasury Regulation section 1.263(a)-5(f) incurred in connection with the transactions contemplated by this Agreement shall be made for U.S. federal income tax purposes (and, as applicable, applied for state and local income tax purposes).

(iv) Any gain, income, deduction or loss from transactions outside the ordinary course of business occurring on the Closing Date but after the Closing shall be treated as occurring after the Closing Date, and any Taxes attributable to transactions outside the ordinary course of business on the Closing Date after the time the Closing shall be excluded.

(v) For the sake of clarity, any liabilities or accruals or reserves established or required to be established under GAAP methodologies that require the accrual for contingent Taxes or with respect to uncertain Tax positions and all deferred Tax liabilities established for GAAP purposes shall not be taken into account or otherwise impact the calculation of Taxes included in Indebtedness.

SECTION 7.8 Intended Tax Treatment.

(a) Neither Parent nor any Person related to Parent within the meaning of Treasury Regulations Section 1.368-1(e)(4) (a "**Parent Related Person**") has any present plan or intention to take any of the following actions, in each case, other than to the extent described in Treasury Regulation Section 1.368-2(k):

(i) sell or otherwise dispose of "substantially all of the properties" (within the meaning of Code Section 368(a)(2)(D)) of the Surviving Company and its Subsidiaries;

(ii) merge the Surviving Company with or into another Person;

(iii) sell or otherwise dispose of any stock of the Surviving Company;

(iv) acquire, or allow any Parent Related Person to acquire, directly or indirectly (including through partnerships, intermediaries or other third parties), any equity interests of the Surviving Company (other than pursuant to this Agreement);

(v) redeem or otherwise reacquire, or allow any Parent Related Person to redeem or otherwise reacquire, directly or indirectly (including through partnerships, intermediaries or other third parties), any Parent Common Stock issued in the First Merger (other than pursuant to this Agreement or any employment-related forfeiture provisions with respect to such Parent Common Stock or with respect to any Qualified Repurchase of Parent Common Stock). For the avoidance of doubt, nothing contained herein shall preclude Parent from repurchasing its stock in the open market through a broker or investment bank or through an accelerated share repurchase program or Rule 10b5-1 plan; *provided* that the following requirements are satisfied (any such repurchase meeting these requirements, a "**Qualified Repurchase**"): (i) the repurchase was not negotiated with the Company or any Stockholder; (ii) the total number of shares of Parent Common Stock repurchased will not exceed the total number of shares of Parent Common Stock outstanding immediately prior to the First Merger; (iii) in the case of an open market repurchase, (a) the repurchase of shares of Parent Common Stock is on the open market, through a broker, for the prevailing market price and (b) Parent does not know the identity of the seller and the seller does not know the identity of Parent; and (iv) in the case of an accelerated share repurchase program or Rule 10b5-1 plan, (a) Parent's counterparty is an investment bank or dealer in Parent Common Stock not related to Parent as set forth in Treasury Regulation Section 1.368-1(e)(4), (b) Parent does not know the identity of any person from whom such counterparty borrows or acquires Parent Common Stock, (c) any shares of Parent Common Stock borrowed by such counterparty will be borrowed from unaffiliated third-party stock lenders that lend Parent Common Stock as part of their ordinary course of business and (d) any shares of Parent Common Stock used by such counterparty to close out open positions established in connection with an accelerated share repurchase program will be shares of Parent Common Stock (x) purchased by such counterparty (or any affiliate thereof) in open market transactions (including, for the avoidance of doubt, any transactions executed on an exchange, off exchange, on electronic trading platforms and on other alternative trading systems, it being understood that such counterparty shall not know the identity of the seller in any of such transactions), (y) obtained by such counterparty (or any affiliate thereof) from unaffiliated third-party stock lenders that lend Parent Common Stock as part of their ordinary course business, so long as any open short positions with respect to such loans are closed out in the manner consistent with **clauses (x)** and **(y)** of this paragraph, or (z) received by such counterparty (or any affiliate thereof) in settlement of any listed option transactions in which such counterparty does not know the identity of the option counterparty;

(vi) fail to cause Parent or another member of the Parent's qualified group (within the meaning of Treasury Regulations Section 1.368-1(d)(4)(ii)) to continue the "historic business" of the Surviving Company or use a "significant portion" of the Surviving Company's "historic business assets" in a business, as such terms are defined in Treasury Regulations Section 1.368-1(d); or

(vii) make, or allow any Parent Related Person to make, any distribution or other payment, directly or indirectly, to former holders of stock of the Company on account of their status as former stockholders of the Company, other than pursuant to this Agreement or any ancillary agreement and other than dividend distributions made to all holders of the Parent Common Stock.

(b) Parent and the Company shall file all Tax Returns consistent with the Intended Tax Treatment unless (i) there is a contrary assessment or determination made by a Taxing Authority upon audit or (ii) for Tax periods that do not end on or include the Closing Date, based on a change of law after the date of this Agreement, Parent and the Stockholder Representative agree, acting reasonably and in good faith, that there is not substantial authority to support such a position. The Company acknowledges and agrees that it has, through competent advisors, completed its own analysis as to the Tax treatment of the Mergers and, except with respect to this **Section 7.8(b)**, that Parent has not made any representations as to the Tax treatment of the Mergers.

ARTICLE VIII
POST-CLOSING INDEMNIFICATION

SECTION 8.1 Survival of Representations, Warranties, Covenants and Agreement. The representations and warranties of the parties hereto contained in this Agreement and the Joinders survive the Closing for a period of sixteen (16) months after the Closing; *provided* that the Parent Fundamental Representations, the Stockholder Fundamental Representations and the Company Fundamental Representations shall survive for the period of the later of (x) the applicable statute of limitations and (y) six (6) years; *provided* that the representations and warranties set forth in **Section 2.11** shall survive until thirty (30) days following the expiration of all applicable statutes of limitations in respect of the matters addressed by such representations and warranties (including all periods of extension, whether automatic or permissive). The covenants and agreements of the parties hereto contained in this Agreement shall survive the Closing, and claims may be brought (i) in respect of a breach of such covenants and agreements that by their nature are required to be performed by or prior to the Closing, for a period of sixteen (16) months after the Closing and (ii) in respect of a breach of such covenants and agreements that expressly contemplate performance after the Closing, for the period of the applicable statute of limitations. The survival periods specifically set forth in this **Section 8.1** are in lieu of, and the parties hereto expressly waive, any otherwise applicable statute of limitations, whether arising at law or in equity. Notwithstanding the foregoing, any claim made in accordance with **Section 8.5** by the party seeking to be indemnified within the time period set forth in this **Section 8.1** shall survive until such claim is finally and fully resolved.

SECTION 8.2 Indemnification by Stockholders and Company Option Holders.

(a) From and after the Closing, subject to the terms of this **Article VIII**, Parent and its Affiliates (including the Surviving Company), officers, directors, employees, agents, successors and assigns (each, a "**Parent Indemnified Party**"), shall be indemnified and held harmless jointly and severally from the Holdback Shares and the CVRs from and against all losses (including diminution in value), liabilities, damages, claims, deficiencies, Taxes, fines, costs, interest, awards, judgments, settlements, penalties and expenses, including reasonable attorneys' and consultants' fees and expenses (hereinafter individually, a "**Loss**" and collectively, "**Losses**") paid, incurred or suffered by the Parent Indemnified Parties resulting from, arising out of or relating to any of the following:

(i) any breach of or inaccuracy in, as of the date hereof or as of the Closing Date, a representation or warranty (other than such representations and warranties that are expressly made as of another date, in which case as of such other date) made by the Company contained in this Agreement or any Related Agreement or any certificate or schedule delivered hereunder (it being understood that any materiality, knowledge or similar limitations or qualifications set forth in such representations and warranties (including the words "material," "materially," "in all material respects," "Material Adverse Effect," and "Knowledge") shall not be considered or given any effect for purposes of determining if there is an inaccuracy or breach thereof and for determining the amount of any Losses);

(ii) the breach of any covenant or agreement by the Company or the Stockholder Representative set forth in this Agreement or any Related Agreement;

(iii) the exercise of appraisal rights by the holders of the Dissenting Shares or any payment in respect of any Dissenting Shares in excess of the consideration that otherwise would have been payable in respect of such shares in accordance with this Agreement;

(iv) any Action relating to this Agreement or the Transactions;

(v) any inaccuracy in the Allocation Schedule;

(vi) any Third-Party Expenses that are unpaid as of the First Effective Time; or

(vii) (A) all Taxes of the Company attributable to any Pre-Closing Tax Period (including any Deferred Payroll Taxes) as determined under the apportionment principles of **Section 7.7**; (B) any Taxes as a result of the Company being on or prior to the Closing Date (1) a member of an affiliated or combined group pursuant to Treasury Regulations Section 1.1502-6 or any similar provision of state, local or foreign law prior to the Closing Date or (2) a transferee or successor by contract or otherwise, which Taxes relates to an event occurring on or before the Closing Date; (C) any breach of **Sections 7.1**, **7.2** or **7.4**; (D) all Taxes of the Company arising from any breach of or inaccuracy in, as of the date hereof or as of the First Effective Time, of any representation contained in **Section 2.11** (it being understood that any materiality or similar limitations or qualifications set forth in such representations and warranties (including the words "material," "materially," "in all material respects," and "Material Adverse Effect") shall not be considered or given any effect for purposes of determining if there is an inaccuracy or breach thereof and for determining the amount of any Losses); or (E) Taxes of a Person receiving Merger Consideration under this Agreement imposed on or payable by Parent, the Company or any of their Affiliates (including any amounts payable by Parent or the Company arising from the failure to withhold the correct amount from any payment of Merger Consideration under this Agreement); *provided* that, in each case, the Indemnifying Parties shall not be responsible for Taxes arising from any transaction entered into, or action taken, outside the ordinary course of business by Parent or any of its Affiliates on the Closing Date after the Closing;

(b) From and after the Closing, the Parent Indemnified Parties shall be indemnified and held harmless jointly and severally from the Holdback Shares and the CVRs and by and from each Stockholder and Company Option Holder severally (and not jointly), for, from and against all Losses paid, incurred or suffered by such Parent Indemnified Parties resulting from, arising out of or relating to the breach as of the date hereof or as of the Closing Date (other than such representations and warranties that are expressly made as of another date, in which case as of such other date) of any representation or warranty made by such Stockholder or Company Option Holder contained in the Joinder executed by such Stockholder or Company Option Holder (it being understood that any materiality or similar limitations or qualifications set forth in such representations and warranties (including the words "material," "materially," "in all material respects," and "**Material Adverse Effect**") shall not be considered or given any effect for purposes of determining if there is an inaccuracy or breach thereof and for determining the amount of any Losses); or (ii) the breach of any covenant or agreement by such Stockholder or Company Option Holder contained in the Joinder executed by such Stockholder or Company Option Holder (or to which such Stockholder or Company Option Holder is bound pursuant to such Joinder).

(c) In order to satisfy any indemnification obligations under this **Article VIII,** Parent (as a Parent Indemnified Party) shall have the right to withhold or deduct from, or off-set or set-off against, all or any portion of the Holdback Shares or any and all amounts otherwise payable to any Stockholder or Company Option Holder in connection with the CVRs.

(d) Any payments made to an Indemnified Party pursuant to any indemnification obligations under this **Article VIII** will be treated as adjustments to the Total Consideration for Tax purposes and such agreed treatment will govern for purposes of this Agreement, unless otherwise required by applicable Laws.

(e) Nothing in this Agreement shall limit the right of Parent or any other Parent Indemnified Party to pursue remedies under any Related Agreement against the parties thereto.

SECTION 8.3 Indemnification by Parent.

(a) From and after the Closing, subject to the terms of this **Article VIII**, Parent agrees to indemnify and hold harmless each Stockholder and its respective Affiliates, officers, directors, employees, agents, successors and assigns (each, a "**Seller Indemnified Party**") from and against all Losses paid, incurred or suffered by such Seller Indemnified Party resulting from, arising out of or relating to any of the following:

(i) any breach of or inaccuracy in, as of the date hereof or as of the Closing Date, a representation or warranty (other than such representations and warranties that are expressly made as of another date, in which case as of such other date) made by Parent contained in this Agreement or in any certificate delivered hereunder (it being understood that any materiality, knowledge or similar limitations or qualifications set forth in such representations and warranties (including the words "material," "materially," "in all material respects," and "knowledge") shall not be considered or given any effect for purposes of determining if there is an inaccuracy or breach thereof and for determining the amount of any Losses); or

(ii) the breach of any covenant or agreement by Parent, Merger Sub 1 or Merger Sub 2 set forth in this Agreement;

(b) Any claim for indemnification in respect of Losses suffered by any Seller Indemnified Party hereunder may be made and enforced by the Stockholder Representative only, on behalf of such Seller Indemnified Party, and may not be made or enforced directly by any Seller Indemnified Party.

SECTION 8.4 Limitations on Indemnification.

(a) Notwithstanding anything to the contrary in this Agreement, an Indemnifying Party shall not be liable for any Losses pursuant to **Section 8.2(a)(i)** and **Section 8.3(a)(i)**: (i) other than Losses in excess of $25,000 resulting from any single claim or series of related claims arising out of substantially the same facts, events or circumstances; and (ii) unless and until the aggregate amount of such indemnifiable Losses which may be recovered from the Indemnifying Party equals or exceeds $50,000 (the "**Deductible**"), whereupon the Indemnified Parties shall be entitled to the full amount of such Losses in excess of the Deductible; *provided, however*, that the limitations set forth in this **Section 8.4(a)** shall not apply to Losses related to any breach of the Parent Fundamental Representations, Stockholder Fundamental Representations or the Company Fundamental Representations or to Losses arising out of, resulting from or relating to fraud.

(b) With respect to **Section 8.2(a)**, the Parent Indemnified Parties shall first proceed against the Holdback Shares before proceeding against the CVRs (it being understood and agreed that the Parent Indemnified Parties may proceed against both the Holdback Shares and the CVRs on a joint and several basis to recover any and all Losses). With respect to **Section 8.2(b)**, the Parent Indemnified Parties shall first proceed against the breaching Stockholder or Company Option Holder for Losses; *provided* that if such Stockholder or Company Option Holder does not acknowledge and pay such Losses within forty-five (45) days or notice thereof; the Parent Indemnified Parties may proceed against all Holdback Shares and CVRs on a joint and several basis to recover any and all Losses.

(c) Notwithstanding anything to the contrary in this Agreement, the indemnification provided for herein shall not cover, and in no event shall any party hereto be liable for, any punitive damages (except to the extent necessary to reimburse an Indemnified Party for judgments actually awarded to third parties in respect of such types of damages and reasonable costs and expenses).

(d) Notwithstanding anything to contrary in this Agreement, the Stockholders and Company Option Holders shall not be obligated to indemnify any Parent Indemnified Party with respect to any Taxes for any Tax period (or portion thereof) beginning after the Closing Date, other than with respect to a breach of the representations contained in **Section 2.11(g)** and **Section 2.11(n)**.

(e) For all purposes of **Article VII**, "**Losses**" (including Taxes) shall be net of any net Tax benefit actually realized by the Parent or its Affiliates (including the Company) as a result of Losses giving rise to the indemnity payment as of the time that the indemnity payment is made or the succeeding two (2) years.

(f) ***Recovery from Holdback Shares and CVRs***. Except in the case of fraud, the Parent Indemnified Parties' sole and exclusive source of recoveries for indemnification claims under **Section 8.2(a)** shall be limited to (1) the forfeiture and cancellation of any and all Holdback Shares (assuming for all purposes that the value of each Holdback Share shall be equal to the Parent Share Value on the date of a Loss is satisfied by such cancellation) and (2) the right of the Parent Indemnified Parties to off-set or set-off against (on a joint and several basis) any amounts payable in connection with the CVRs. The limitations set forth in this **Section 8.4(f)** shall not apply to any indemnification claim under **Section 8.2(b)**. For purposes of determining the number of Parent Shares that Parent may be entitled to recover pursuant to this **Article VIII**, each Parent Share shall be deemed to have a value equal to the Parent Share Value on the date of determination, and the number of shares recoverable shall be rounded down to the nearest whole share. Upon such application by Parent to any Holdback Shares, such Holdback Shares shall be forfeited and cancelled and cease to exist (and Stockholders and Company Option Holders shall have no rights thereunder). Upon such application by Parent to the CVRs, each CVR shall be deemed adjusted proportionally such that any payments that would otherwise be payable shall first satisfy the liability under this Agreement to the Parent Indemnified Parties. The Stockholder Representative shall take all such actions as are necessary to cause any such forfeiture to Parent for no additional consideration. Parent shall be entitled to cancel Holdback Shares to satisfy any indemnification obligations in whole or in part. If a Holdback Share is cancelled to satisfy an indemnification claim, Parent shall be entitled to cancel the whole Holdback Share.

(g) The rights of the Indemnified Parties to indemnification, compensation or reimbursement, payment of Losses or any other remedy under this Agreement or any Related Agreement shall not be affected by any information obtained in any investigation conducted with respect to, or any knowledge acquired (or capable of being acquired) at any time, whether before, on or after the execution and delivery of this Agreement or the Closing Date, with respect to the accuracy or inaccuracy of or compliance with, any representation, warranty, covenant or agreement made by the Company, any Stockholder or Company Option Holder or any other matter. The waiver of any condition based on the accuracy of any such representation or warranty, or on the performance of or compliance with any such covenant or agreement, will not affect the right to indemnification, compensation or reimbursement, payment of Losses, or any other remedy based on any such representation, warranty, covenant or agreement. No Indemnified Party shall be required to show reliance on any representation, warranty, certificate or other agreement in order for such Indemnified Party to be entitled to indemnification, compensation or reimbursement hereunder.

(h) Nothing in this Agreement shall limit the liability of an Indemnifying Party in connection with a claim based on fraud committed by such Indemnifying Party.

SECTION 8.5 Indemnification Claim Procedures.

(a) An Indemnified Party shall give the Indemnifying Party notice of any matter which an Indemnified Party has determined has given or could give rise to a right of indemnification under this Agreement within thirty (30) days of such determination, stating the amount of the Loss, if known, and method of computation thereof, and containing a reference to the provisions of this Agreement in respect of which such right of indemnification is claimed or arises; *provided* that the failure to provide (or to timely provide) such notice will not affect the Indemnified Party's right to indemnification unless (and then solely to the extent) the Indemnifying Party is actually and materially prejudiced by such delay.

(b) If an Indemnified Party shall receive notice of any Action third-party claim for which indemnification may be sought by an Indemnified Party (a "**Third-Party Claim**") which may give rise to a claim for Loss under this **Article VIII**, the Indemnified Party shall within thirty (30) days deliver to the Indemnifying Party notice of such Third-Party Claim; *provided* that the failure to provide (or to timely provide) such notice will not affect the Indemnified Party's right to indemnification unless (and then solely to the extent) the Indemnifying Party is actually and materially prejudiced by such delay. The Parent Indemnified Parties shall keep the Indemnifying Party reasonably informed about the status of any settlement discussions relating to the Third-Party Claim and shall reasonably consult with the Indemnified Party with respect thereto; *provided* that the Parent Indemnified Parties shall have sole right to settle, compromise and defend all Third-Party Claims without consent. The Indemnifying Party shall cooperate with the Parent Indemnified Parties in respect of the defense of any such Third-Party Claim, and will render to the Parent Indemnified Parties such assistance as they may reasonably require in order to insure prompt and adequate defense of any such Third-Party Claim, and any costs and expenses incurred by the Indemnified Party in connection with such cooperation shall be deemed Losses hereunder. The Parent Indemnified Parties may take such actions with respect to such Third-Party Claim as they deem reasonably necessary. The Indemnifying Party shall have the right to employ its own counsel, but, the fees and expenses of such counsel shall be at the Indemnified Party's expense.

(c) Procedure for Claims Not Involving Third Parties. An Indemnified Party wishing to assert a claim for indemnification under this **Article VIII** that does not involve a Third-Party Claim shall deliver to the Indemnifying Party a written notice (the "**Claim Notice**"). In the event the Indemnifying Party shall in good faith dispute the validity of all or any amount of such claim, the Indemnifying Party shall, within thirty (30) days of its receipt of the Claim Notice (the "**Final Date**"), deliver to the Indemnified Party a notice setting forth with reasonable particularity the grounds and the basis upon which the claim or any portion thereof is disputed (the "**Dispute Statement**"). In the event the Indemnifying Party does not deliver a Dispute Statement on or before the Final Date, then the amount of the claim or the portion thereof not disputed shall be deemed to be admitted and paid promptly to the Indemnified Party. If the Indemnifying Party delivers a Dispute Statement on or before the Final Date, then the amount of the claim disputed by the Indemnifying Party in such Dispute Statement (or a portion thereof) shall become payable upon the earlier of (i) the Indemnifying Party and the Indemnified Party agreeing in writing to the resolution of the amount of the claim disputed by the Indemnifying Party in such Dispute Statement or (ii) a court of competent jurisdiction entering a final Governmental Order directing the payment to such Indemnified Party of the amount of the claim disputed by the Indemnifying Party in such Dispute Statement (or a portion thereof); *provided* that the Indemnifying Party and the Indemnified Party shall first attempt in good faith to resolve such dispute and shall not submit such dispute to a court of competent jurisdiction prior to the date that is forty (40) days following the delivery by the Indemnified Party of the applicable Claim Notice. Upon such written agreement or Governmental Order, as the case may be, and subject to the limitations set forth in this **Article VIII**, the Indemnifying Party shall be liable to the Indemnified Party for an amount equal to the amount of such claim so agreed or ordered to be paid. The Indemnifying Party may not dispute a Third-Party Claim.

SECTION 8.6 Stockholder Representative.

(a) To facilitate the administration of the transactions contemplated by this Agreement and the Related Agreements, including the resolution of any disputes relating to the claims for indemnification pursuant to **Section 8.2** through **Section 8.5** and any other actions required or permitted to be taken by the Stockholder Representative under this Agreement and the Related Agreements, each Stockholder and Company Option Holder, by virtue of the execution and delivery of a Joinder (as applicable), and the adoption of this Agreement and the Related Agreements, and approval of the Transactions, including the Mergers, hereby agrees to appoint, authorize and empower James Wilkie as its agent and attorney-in-fact, with full power of substitution: (i) as the Stockholder Representative for and on behalf of the Indemnifying Parties to give and receive notices and communications in respect of indemnification claims under this Agreement, to authorize payment to any Indemnified Party in satisfaction of any indemnification claims hereunder by any Indemnified Party, to object to such payments, to agree to, negotiate, enter into settlements and compromises of, and demand arbitration and comply with orders of courts and awards of arbitrators with respect to, to assert, negotiate, enter into settlements and compromises of, any such indemnification claims by any Indemnified Party against any Indemnifying Party or by any such Indemnifying Party against any Indemnified Party or any dispute between any Indemnified Party and any such Indemnifying Party, in each case relating to this Agreement, the Related Agreements or the Transactions, and to take all other actions that are either (x) necessary or appropriate in the judgment of the Stockholder Representative for the accomplishment of the foregoing or (y) specifically mandated by the terms of this Agreement and the Related Agreements; (ii) to make all decisions and determinations and to act (or not act) and execute, deliver and receive all agreements, documents, instruments and consents on behalf of and as agent for each Stockholder and Company Option Holder at any time in connection with, and that may be necessary or appropriate to accomplish the intent and implement the provisions of this Agreement or the Related Agreements and to facilitate the consummation of the transactions contemplated hereby, including without limitation for purposes of (x) negotiating and settling, on behalf of the Stockholders and Company Option Holders, any dispute that arises under this Agreement or the Related Agreements after the First Effective Time and (y) negotiating and settling matters with respect to the amounts to be paid to the Stockholders and Company Option Holders pursuant to this Agreement and the Related Agreements; (iii) to take any and all additional action as is contemplated to be taken by or on its behalf or by the Stockholder Representative by the terms of this Agreement and the Related Agreements; and (iv) to hold Stockholder Representative expense amount in the amount of $75,000 (the "**Representative Expense Amount**") on behalf of the Indemnifying Parties, to retain and to pay legal counsel and other professionals, and for the services provides by the Stockholders Representative, in connection with any and all matters referred to herein or relating hereto, and to make such payments from the Representative Expense Amount as the Stockholder Representative deems necessary or appropriate following the Mergers. If any amount remains under the Representative Expense Amount, such amount shall be distributed by the Stockholder Representative to the Stockholders and Company Option Holders consistent with **Section 1.6(b)** as if such remaining amount was part of the Merger Consideration. All such actions shall be deemed to be facts ascertainable outside this Agreement and the Related Agreements and shall be binding on the Stockholders and Company Option Holders. Such agency may be changed by the Stockholders and Company Option Holders from time to time upon not less than thirty (30) days prior written notice to Parent; *provided*, *however*, that the Stockholder Representative may not be removed unless holders of a majority interest of the Holdback Shares agree to such removal and to the identity of the substituted agent. Notwithstanding the foregoing, in the event of a resignation of the Stockholder Representative or other vacancy in the position of Stockholder Representative, such vacancy may be filled by the holders of a majority in interest of the Holdback Shares. No bond shall be required of the Stockholder Representative.

(b) Notices or communications to or from the Stockholder Representative shall constitute notice to or from the Indemnifying Parties.

(c) The Stockholder Representative shall not be liable for any act done or omitted hereunder as Stockholder Representative while acting in good faith and in the exercise of reasonable judgment. The Indemnifying Parties shall indemnify the Stockholder Representative and hold the Stockholder Representative harmless against any and all Losses arising out of or in connection with the acceptance or administration of the Stockholder Representative's duties hereunder, including the reasonable fees and expenses of any legal counsel, financial advisors, auditors or other agents retained by the Stockholder Representative ("**Stockholder Representative Expenses**"). Any decision, act, consent or instruction of the Stockholder Representative in connection with this Agreement and the Related Agreements, including an amendment, extension or waiver of this Agreement pursuant to **Section 10.2** or **Section 10.3** or an amendment, extension or waiver of any Related Agreement, shall constitute a decision of all the Stockholders and Company Option Holders and shall be final, binding and conclusive upon each Stockholder and Company Option Holder, and no Stockholder or Company Option Holder shall have the right to object, dissent, protest or otherwise contest the same. Parent may rely upon any such decision, act, consent or instruction of the Stockholder Representative as being the decision, act, consent or instruction of all the Stockholders and Company Option Holders. Parent is hereby relieved from any Liability to any Person for any acts done by them in accordance with such decision, act, consent or instruction of the Stockholder Representative.

(d) Parent and the Surviving Company shall be entitled to rely conclusively on the decisions, acts, consents, waivers and instructions of the Stockholder Representative as to any determination relating to the transactions contemplated by this Agreement and the CVR Agreement as being the decision, act, consent, waiver or instruction of every Stockholder and Company Option Holder, including the resolution and disposition of any claims for indemnification pursuant to **Section 8.2** through **Section 8.5** and any other actions required or permitted to be taken by the Stockholder Representative under this Agreement and the Related Agreements. No Person shall have any cause of action against Parent, the Surviving Company, or any of their respective directors, officers, employees, agents or Affiliates for any action taken by Parent in reliance upon any decision, act, consent, waiver or instruction of the Stockholder Representative; and Parent and the Surviving Company are each hereby relieved from any Liability to any Person for any acts done by it in accordance with such decision, act, consent, waiver or instruction of the Stockholder Representative.

(e) No Stockholder or Company Option Holder shall have any cause of action against the Stockholder Representative for any action taken, decision made or instruction given by the Stockholder Representative under this Agreement and the Related Agreements in its capacity as such, except for fraud or intentional breach of this Agreement and the Related Agreements by the Stockholder Representative.

(f) The Stockholders and Company Option Holders recognize and intend that the power of attorney granted in this **Section 8.6** is coupled with an interest and is irrevocable and will survive the death, incapacity, dissolution, liquidation or winding up of each of the Stockholders and Company Option Holders.

(g) Notwithstanding anything to the contrary contained in this Agreement, the Related Agreements or in any other agreement executed in connection with the Transactions: (i) Parent, Merger Sub 1, Merger Sub 2 the Initial Surviving Company, the Surviving Company and each Parent Indemnified Party will be entitled to deal exclusively with the Stockholder Representative on all matters relating to this Agreement and the Related Agreements and (ii) Parent, Merger Sub 1, Merger Sub 2, the Initial Surviving Company, the Surviving Company and each Parent Indemnified Party will be entitled to rely conclusively (without further evidence of any kind whatsoever) on any document executed or purported to be executed on behalf of any Stockholder or Company Option Holder by the Stockholder Representative and on any other action taken or purported to be taken on behalf of any Stockholder or Company Option Holder by the Stockholder Representative as fully binding upon such Stockholder or Company Option Holder, and none of Parent, Merger Sub 1, Merger Sub 2, the Initial Surviving Company, the Surviving Company and each Parent Indemnified Party will be liable to any Stockholder or Company Option Holder for any act taken or omitted by Parent, Merger Sub 1, Merger Sub 2, the Initial Surviving Company, the Surviving Company and each Parent Indemnified Party in such reliance.

The provisions of this **Section 8.6** are independent and severable, are irrevocable and coupled with an interest, and shall be enforceable notwithstanding any rights or remedies that Parent or any Stockholder or Company Option Holder may have in connection with the transactions contemplated by this Agreement.

SECTION 8.7 Directors' and Officers' Indemnification.

(a) Parent agrees that all rights to indemnification or exculpation now existing in favor of the directors of the Company as provided in the Company's certificate of incorporation or bylaws, whether asserted or claimed prior to, at or after the Closing (other than with respect to claims and Losses for which indemnification is provided to the Parent Indemnified Parties under this Agreement, without giving effect to any limitations, deductibles or caps thereon) shall survive the Closing and shall continue in full force and effect for a period of not less than six (6) years and that the Company will perform and discharge the obligations to provide such indemnity and exculpation after the Closing. From and after the Closing, Parent shall not, and shall cause each of its Subsidiaries and Affiliates (including the Company) not to, amend, repeal or otherwise modify the indemnification provisions of the Company's certificate of incorporation or bylaws as in effect at the Closing in any manner that would adversely affect the rights thereunder of individuals who at the Closing were directors of the Company (other than with respect to claims and Losses for which indemnification is provided to the Parent Indemnified Parties under this Agreement, without giving effect to any limitations, deductibles or caps thereon).

(b) For a period of six (6) years from the Closing Date, Parent shall maintain in effect any "tail policy," purchased by the Company prior to the Closing. The aggregate cost of such "tail policy" over such six (6)-year period is referred to as the "**Tail Cost**." The Tail Cost shall reduce the Total Consideration paid hereunder.

(c) The provisions of this **Section 8.7** shall survive the consummation of the Closing and continue for the periods specified herein. This **Section 8.7** is intended to benefit the directors of the Company (and their respective heirs, successors and assigns) referenced in this **Section 8.7** or indemnified hereunder, each of whom may enforce the provisions of this **Section 8.7** (whether or not parties to this Agreement). Each of the Persons referenced in the immediately preceding sentence are intended to be third-party beneficiaries of this **Section 8.7**.

ARTICLE IX
PRE-CLOSING TERMINATION OF AGREEMENT

SECTION 9.1 Termination. This Agreement may be terminated and the Transactions, including the Mergers, may be abandoned at any time prior to the Closing, whether before or after the Stockholder Approval as follows (with any termination by Parent also being an effective termination by Merger Sub 1 and Merger Sub 2):

(a) by mutual written consent of the Company and Parent;

(b) by either Parent or the Company if the Closing shall not have occurred on or before February 15, 2022 (the "**End Date**"); *provided* that the right to terminate this Agreement under this **Section 9.1(b)** shall not be available to any party whose failure to fulfil any obligation under this Agreement has been the principal cause of or principally resulted in the failure of the Closing to occur on or before such date;

(c) by either Parent or the Company if any Governmental Entity shall have enacted, issued, promulgated, enforced or entered any Law or Governmental Order (whether temporary, preliminary or permanent) which has become final and nonappealable and has the effect of making consummation of the Mergers or any other Transactions illegal or otherwise prohibiting consummation of the Mergers or any other Transactions;

(d) by either Parent or the Company if: (i) the Company Stockholders' Meeting (including any adjournments and postponements thereof) shall have been held and completed and the Company's stockholders shall have taken a final vote on a proposal to adopt this Agreement; and (ii) this Agreement shall not have been adopted at the Company Stockholders' Meeting (and shall not have been adopted at any adjournment or postponement thereof) by the Stockholder Approval;

(e) by Parent (at any time prior to the adoption of this Agreement by the Stockholder Approval) if, whether or not permitted to do so: (i) the Company Board of Directors or any committee thereof shall have made a Company Adverse Change in Recommendation; (ii) the Company, Company Board of Directors or any committee thereof shall have adopted, approved, recommended, or the Company Board of Directors or any committee thereof shall have declared advisable, executed or entered into (or resolved, determined or proposed to adopt, approve, recommend, declare advisable, execute or enter into) any Alternative Acquisition Agreement; (iii) following the making of an Acquisition Proposal or the submission of an Alternative Acquisition Agreement, the Stockholder Approval is not obtained; (iv) the Company shall have materially breached its obligations under **Section 5.2**, **Section 5.3**, or **Section 5.4**; or (v) other than in connection with an Acquisition Proposal, the Company shall have failed to issue a press release that reaffirms the Company Board Recommendation within five (5) Business Days after Parent so requests in writing (*provided* that Parent may only make such request on two (2) occasions);

(f) by the Company (at any time prior to the adoption of this Agreement by the Stockholder Approval) in order to, substantially concurrent with such termination, enter into a binding written definitive acquisition agreement providing for the consummation of a transaction constituting a Superior Offer (a "**Specified Agreement**") if (i) the Company has not materially breached the requirements of **Section 5.2**, **Section 5.3**, or **Section 5.4** with respect to such Superior Offer, (ii) the Company Board of Directors shall have authorized the Company to enter into such Specified Agreement and (iii) substantially concurrently with such termination, the Company pays the Termination Fee as provided in **Section 9.3(a)**;

(g) by Parent if there has been a breach of or inaccuracy in any representation, warranty, covenant or agreement of the Company set forth in this Agreement, or the CVR Agreement or of the Stockholders or Company Option Holders set forth in the Joinders such that the conditions set forth in **Section 6.2(a)** or **Section 6.2(b)** would not be satisfied as of the time of such breach or inaccuracy and such breach or inaccuracy has not been cured within ten (10) calendar days after written notice thereof to the Company; *provided*, *however*, that no cure period shall be required (i) for a breach or inaccuracy which by its nature cannot be cured or (ii) if any of the conditions to Closing in **Article VI** for the benefit of Parent are incapable of being satisfied on or before the End Date; or

(h) by the Company if there has been a breach of or inaccuracy in any representation, warranty, covenant or agreement of Parent set forth in this Agreement, the Joinders or the CVR Agreement such that the conditions set forth in **Section 6.3(a)** or **Section 6.3(b)** and would not be satisfied as of the time of such breach or inaccuracy and such breach or inaccuracy has not been cured within ten (10) calendar days after written notice thereof to Parent; *provided*, *however*, that no cure period shall be required (i) for a breach or inaccuracy which by its nature cannot be cured or (ii) if any of the conditions to Closing in **Article VI** for the benefit of the Company are incapable of being satisfied on or before the End Date.

SECTION 9.2 Effect of Termination. In the event of termination of this Agreement as provided in **Section 9.1**, this Agreement shall forthwith become void, and there shall be no liability or obligation on the part of Parent, Merger Sub 1, Merger Sub 2 or the Company, or their respective officers, directors or stockholders, if applicable; *provided*, *however*, each party hereto and each Person shall remain liable for any breaches of this Agreement, any Related Agreements or in any certificate or other instruments delivered pursuant to this Agreement prior to its termination; and *provided further*, that the provisions of **Section 8.2(a)(iv)**, this **Section 9.2**, **Section 9.3** and **Article X** shall remain in full force and effect and survive any termination of this Agreement pursuant to the terms of this **Article IX**.

SECTION 9.3 Termination Fees.

(a) If this Agreement is terminated:

(i) by the Company pursuant to **Section 9.1(f)**;

(ii) by (A) Parent pursuant to **Section 9.1(e)** or (B) by Parent or the Company pursuant to **Section 9.1(d)** and, in the case of this **clause (B)**, this Agreement could have been terminated pursuant to **Section 9.1(e)**; or

(iii) by Parent or the Company pursuant to **Section 9.1(d)**, by Parent or the Company pursuant to **Section 9.1(b)**, or by Parent pursuant to **Section 9.1(g)** and: (A) any Person shall have made an Acquisition Proposal after the date of this Agreement and prior to such termination; and (B) within twenty-four (24) months of such termination, the Company shall have consummated an Acquisition Proposal or shall have entered into a definitive agreement with respect to any Acquisition Proposal that is thereafter consummated),

then, in any such event under **clause (i)**, (**ii)** or **(iii)** of this **Section 9.3(a)**, the Company shall pay to Parent the Termination Fee by wire transfer of same day funds (x) in the case of **Section 9.3(a)(i)**, prior to or concurrently with the termination of this Agreement and execution of the Specified Agreement; (y) in the case of **Section 9.3(a)(ii)**, within two (2) Business Days after such termination; or (z) in the case of **Section 9.3(a)(ii)**, two (2) Business Days after consummation of the Acquisition Proposal; it being understood that in no event shall the Company be required to pay the Termination Fee on more than one occasion. As used herein, "**Termination Fee**" means a cash amount equal to $500,000.

(b) If this Agreement is terminated by Parent or the Company pursuant to **Section 9.1(d)**, the Company shall reimburse Parent promptly upon demand (but in any event within two (2) Business Days after the date of such demand), by wire transfer of same-day funds, the reasonable and documented costs and expenses (including disbursements and fees of outside legal counsel and outside strategic advisors) incurred by Parent in connection with this Agreement or Transactions ("**Parent Expenses**"); *provided* that the Parent Expenses shall not exceed $400,000.

(c) The Parties acknowledge that the agreements contained in this **Section 9.3** are an integral part of this Agreement and the Transactions and that, without these agreements, the Parties would not enter into this Agreement; accordingly, if the Company fails to timely pay any amount due pursuant to this **Section 9.3**, and, in order to obtain the payment, Parent commences an Action which results in a judgment against the Company, the Company shall pay Parent its reasonable and documented costs and expenses (including reasonable and documented fees of outside legal counsel) in connection with such Action, together with interest on such amount and the Termination Fee or Parent Expenses at the prime rate as published in the Wall Street Journal in effect on the date such payment was required to be made, plus two percent (2%) per annum, through the date such payment was actually received.

ARTICLE X
GENERAL PROVISIONS

SECTION 10.1 Certain Interpretations. When a reference is made in this Agreement to an Annex, Exhibit or Schedule, such reference shall be to an Annex, Exhibit or Schedule to this Agreement unless otherwise indicated. When a reference is made in this Agreement to an Article or a Section, such reference shall be to an Article or a Section of this Agreement unless otherwise indicated. The use of "or" is not intended to be exclusive unless expressly indicated otherwise. The words "include," "includes" and "including" when used herein shall be deemed in each case to be followed by the words "without limitation." All references in this Agreement to "$" or dollars shall mean U.S. denominated dollars. The table of contents and headings set forth in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement. The terms defined in the singular have a comparable meaning when used in the plural, and vice versa. The words "hereof," "herein," "hereto" and "hereunder" and words of similar import refer to this Agreement as a whole, including all Annexes, Exhibits, and Schedules, and not to any particular provision of this Agreement, and the words "date herein" refer to the date of this Agreement. The parties hereto agree that they have been represented by counsel during the negotiation and execution of this Agreement and, therefore, waive the application of any Law holding or rule of construction providing that ambiguities in an agreement or other document will be construed against the party drafting such agreement or document. All references to "day" or "days" are to calendar days. Where used with respect to information, the phrases "delivered" or "made available" mean that the information referred to has been physically or electronically delivered to the relevant parties or their respective Representatives including, in the case of information "made available" to Parent, material that has been posted in the electronic sharefile established and operated by the Company at https://ltx.egnyte.com/navigate/folder/c36abd8a-48db-46d7-bcee-be7f2b586a80 under the name "AcelRx" at least two (2) Business Days prior to the date hereof. When calculating the period of time before which, within which or following which any act is to be done or step taken pursuant to this Agreement, the date that is the reference date in calculating such period shall be excluded and if the last day of such period is a non-Business Day, the period in question shall end on the next succeeding Business Day.

SECTION 10.2 Amendment. This Agreement may be amended by the parties hereto at any time by execution of an instrument in writing signed on behalf of the party against whom enforcement is sought. For purposes of this **Section 10.2**, the Stockholders and Company Option Holders are deemed to have agreed that any amendment of this Agreement signed by the Stockholder Representative shall be binding upon and effective against the Stockholders and Company Option Holders whether or not they have signed such amendment.

SECTION 10.3 Waiver. At any time prior to the Closing, Parent on the one hand, and the Company and the Stockholder Representative, on the other hand, may, to the extent permitted under any applicable Laws, (a) extend the time for the performance of any of the obligations of the other party hereto, (b) waive any inaccuracies in the representations and warranties made to such party set forth herein or in any document delivered pursuant hereto, and (c) waive compliance with any of the covenants, agreements or conditions for the benefit of such party set forth herein. Any agreement on the part of a party hereto to any such extension or waiver shall be valid only if set forth in an instrument in writing signed on behalf of such party. For purposes of this **Section 10.3**, the Stockholders and Company Option Holders are deemed to have agreed that any extension or waiver signed by the Stockholder Representative shall be binding upon and effective against all Stockholders and Company Option Holders whether or not they have signed such extension or waiver.

SECTION 10.4 Assignment. This Agreement may not be assigned by operation of Law or otherwise without the express written consent of the Stockholder Representative and Parent (which consent may be granted or withheld in the sole discretion of the Stockholder Representative or Parent), as the case may be, except that Parent, Merger Sub 1 or Merger Sub 2 may assign without the express written consent of the Stockholder Representative their respective rights and obligations to any Affiliate of Parent (including the Surviving Company) or any Person that acquires Parent or the Surviving Company or all or substantially all of the assets of Parent or the Surviving Company; *provided* that no such assignment shall relieve Parent of any of its obligations hereunder. The provisions of this Agreement shall be binding upon and inure to the benefit of the parties and their respective successors and assigns.

SECTION 10.5 Notices. All notices, requests, claims, demands and other communications hereunder shall be in writing and shall be given or made (and shall be deemed to have been duly given or made upon receipt) by delivery in person, by an internationally recognized overnight courier service, by registered or certified mail (postage prepaid, return receipt requested) or by electronic mail (so long as confirmation of transmission is electronically or mechanically generated and kept on file by the sending party) to the respective parties hereto at the following addresses (or at such other address for a party as shall be specified in a notice given in accordance with this **Section 10.5**):

(a) if to Parent, Merger Sub 1 or Merger Sub 2, to:

AcelRx Pharmaceuticals, Inc.
25821 Industrial Boulevard, Suite 400
Hayward, CA 94545
Attention: General Counsel
E-mail: legal@acelrx.com

with a copy (which shall not constitute notice) to:

Shearman & Sterling LLP
599 Lexington Avenue
New York, NY 10022-6069
Attention: Robert Masella
E-mail: robert.masella@shearman.com

(b) if to the Company (prior to the Closing), to:

Lowell Therapeutics, Inc.
110 Canal St.
Lowell MA 01852
Attention: James Wilkie
E-mail: wilkie@ltx.life

with a copy (which shall not constitute notice) to:

Burns & Levinson LLP
125 High Street
Boston, MA 02110
Attention: Gil Breiman
E-mail: gbreiman@burnslev.com

(c) if to the Stockholder Representative, to:

James Wilkie
C/O Burns & Levinson LLP
125 High Street
Boston, MA 02110
Attention: Gil Breiman
E-mail:

with a copy (which shall not constitute notice) to:
Burns & Levinson LLP
125 High Street
Boston, MA 02110
Attention: Gil Breiman
E-mail: gbreiman@burnslev.com

SECTION 10.6 Confidentiality. Each of the parties hereto hereby agrees that the information obtained in any investigation pursuant to **Section 5.1** or any information obtained pursuant to the notice requirements of **Section 5.7**, or otherwise pursuant to the negotiation and execution of this Agreement or the effectuation of the Transactions, shall be governed by the terms of the Confidentiality Agreement dated as of April 24, 2021 (the "**Confidentiality Agreement**"), between the Company and Parent, the terms of which are hereby incorporated herein by reference (for the avoidance of doubt, solely with respect to the parties thereto) and shall continue in full force and effect until the Closing, at which time the Confidentiality Agreement and the obligations of Parent with respect to Confidential Information (as such term is defined in the Confidentiality Agreement) relating to the Company or its business (including the Company Products), shall terminate; *provided*, *however*, that nothing herein or in the Confidentiality Agreement shall prevent Parent from making a public announcement regarding the Mergers or any other disclosure it deems advisable under Law, including any regulation of any securities exchange. In this regard, the Company acknowledges that the Parent Common Stock is publicly traded and that any information obtained during the course of its due diligence could be considered to be material non-public information within the meaning of federal and state securities laws. Accordingly, the Company acknowledges and agrees not to engage in any discussions, correspondence or transactions in the Parent Common Stock in violation of applicable securities laws.

SECTION 10.7 Public Announcements. The Company, the Stockholders, the Company Option Holders and the Stockholder Representative shall not make any public release or public announcement concerning the Transactions without the prior consent of Parent, except as such release or announcement may be required by Law, in which case the party required to make the release or announcement shall use its reasonable efforts to allow Parent reasonable time to comment on such release or announcement in advance of such issuance. Notwithstanding the foregoing, following Closing and the public announcement of the Mergers in compliance with the foregoing sentence, the Stockholder Representative shall be permitted to publicly announce that it has been engaged to serve as the Stockholder Representative in connection herewith, as long as such announcement does not disclose any of the other terms hereof.

SECTION 10.8 Entire Agreement. This Agreement, **Annex A** hereto, the Exhibits and Schedules hereto, the Company Disclosure Schedule, the Parent Disclosure Schedule, the Related Agreements, and the documents and instruments and other agreements among the parties hereto referenced herein constitute the entire agreement among the parties hereto with respect to the subject matter hereof and supersede all prior agreements and understandings both written and oral, among the parties with respect to the subject matter hereof, and are not intended to confer upon any other person any rights or remedies hereunder.

SECTION 10.9 No Third-Party Beneficiaries. Nothing in this Agreement is intended to, or shall be construed to, confer upon any other person any rights or remedies hereunder, except for the Indemnified Parties under **Article VIII**.

SECTION 10.10 Specific Performance and Other Remedies.

(a) The parties to this Agreement agree that, in the event of any breach or threatened breach by the other party or parties hereto, any Stockholder or Company Option Holder or the Stockholder Representative of any covenant, obligation or other agreement set forth in this Agreement, (i) each party shall be entitled, without any proof of actual damages (and in addition to any other remedy that may be available to it), to seek a decree or order of specific performance or mandamus to enforce the observance and performance of such covenant, obligation or other agreement and an injunction preventing or restraining such breach or threatened breach, and (ii) no party hereto shall be required to provide or post any bond or other security or collateral in connection with any such decree, order or injunction or in connection with any related action or legal proceeding.

(b) Any and all remedies herein expressly conferred herein upon a party hereto shall be deemed to be cumulative with, and not exclusive of, any other remedy conferred hereby, or by law or in equity upon such party, and the exercise by a party hereto of any one remedy will not preclude the exercise of any other remedy.

(c) The liability of any Person under **Article VIII** will be in addition to, and not exclusive of, any other liability that such Person may have at law or in equity based on such Person's fraudulent acts or omissions, or intentional misconduct. Notwithstanding anything to the contrary set forth in this Agreement, none of the provisions set forth in this Agreement, including the provisions set forth in **Article VIII**, shall be deemed a waiver by any party to this Agreement of any right or remedy which such party may have at law or in equity based on any other Person's fraudulent acts or omissions or intentional misconduct, nor will any such provisions limit, or be deemed to limit, (i) the amounts of recovery sought or awarded in any such claim for fraud or intentional misconduct, (ii) the time period during which a claim for fraud or intentional misconduct may be brought or (iii) the recourse which any such party may seek against another Person with respect to a claim for fraud or intentional misconduct.

SECTION 10.11 Severability. In the event that any provision of this Agreement or the application thereof, becomes or is declared by a court of competent jurisdiction to be illegal, void or unenforceable, the remainder of this Agreement will continue in full force and effect and the application of such provision to other persons or circumstances will be interpreted so as reasonably to effect the intent of the parties hereto. The parties further agree to replace such void or unenforceable provision of this Agreement with a valid and enforceable provision that will achieve, to the extent possible, the economic, business and other purposes of such void or unenforceable provision.

SECTION 10.12 Governing Law. This Agreement and any Actions based upon or arising out of this Agreement shall be governed by and construed in accordance with the laws of the State of Delaware (regardless of the laws that might otherwise govern under applicable principles of conflicts of laws thereof).

SECTION 10.13 Exclusive Jurisdiction. The parties hereto agree that any Action seeking to enforce any provision of, or based on any matter arising out of or in connection with this Agreement, including the Mergers, shall be brought and determined exclusively in the Delaware Court of Chancery. The parties hereto hereby (i) irrevocably submit to the exclusive personal jurisdiction of such court for the purpose of any Action arising out of or relating to this Agreement, including the Mergers, brought by any Party, (ii) agree that all claims in respect of such Action or proceeding shall be heard and determined exclusively in such court, and (iii) irrevocably waive, and agree not to assert by way of motion, defense, or otherwise, in any such Action, any claim that it is not subject to the personal jurisdiction of the above-named court, that its property is exempt or immune from attachment or execution, that the Action is brought in an inconvenient forum, that the venue of the Action is improper, or that this Agreement or the Mergers may not be enforced in or by any of the above-named courts.

SECTION 10.14 Waiver of Jury Trial. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT, OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE ACTIONS OF ANY PARTY HERETO IN NEGOTIATION, ADMINISTRATION, PERFORMANCE OR ENFORCEMENT HEREOF.

SECTION 10.15 Expenses. Except as otherwise specified in this Agreement, all costs and expenses, including fees and disbursements of counsel, financial advisors and accountants, incurred in connection with this Agreement, the Related Agreements and the Transactions shall be borne by the party incurring such costs and expenses, whether or not the Closing shall have occurred; *provided* that all Third-Party Expenses shall be deducted from the Total Consideration payable hereunder as contemplated by the definition of Total Consideration.

SECTION 10.16 Counterparts. This Agreement may be executed in one or more counterparts, all of which shall be considered one and the same agreement and shall become effective when one or more counterparts have been signed by each of the parties and delivered to the other party, it being understood that all parties need not sign the same counterpart. The exchange of a fully executed Agreement (in counterparts or otherwise) by electronic transmission in .PDF format or by facsimile shall be sufficient to bind the parties to the terms and conditions of this Agreement.

[*Remainder of Page Intentionally Left Blank*]

IN WITNESS WHEREOF, Parent, Merger Sub 1, Merger Sub 2, the Company and the Stockholder Representative have caused this Agreement to be executed as of the date first written above.

ACELRX PHARMACEUTICALS, INC.

By: /s/ Vincent J. Angotti
Name: Vincent J. Angotti
Title: Chief Executive Officer

ACELRX INTERMEDIATE SUB, INC.

By: /s/ Vincent J. Angotti
Name: Vincent J. Angotti
Title: Chief Executive Officer

ACELRX CONSOLIDATION SUB, LLC

By: /s/ Vincent J. Angotti
Name: Vincent J. Angotti
Title: Chief Executive Officer

[*Signature Page to Agreement and Plan of Merger*]

LOWELL THERAPEUTICS, INC.

By: /s/ James Wilkie
Name: James Wilkie
Title: Chief Executive Officer

[*Signature Page to Agreement and Plan of Merger*]

STOCKHOLDER REPRESENTATIVE

/s/ James Wilkie

JAMES WILKIE, solely in his capacity as the Stockholder Representative

[*Signature Page to Agreement and Plan of Merger*]

ANNEX A

CERTAIN DEFINED TERMS

"280G Waivers" shall mean the 280G Waivers executed and delivered by each Key Holder and certain other Employees on the date of this Agreement substantially in the form attached hereto as **Exhibit E**.

"Accredited Investor" shall mean "accredited investor" as defined in Regulation D under the Securities Act.

"Accredited Investor Questionnaire" shall mean the Accredited Investor Questionnaire in the form attached to the Joinder.

"Acquisition Proposal" shall mean any offer or proposal (other than an offer or proposal by Parent) for an Alternative Transaction.

"Action" shall mean any action, suit, claim, complaint, litigation, investigation, audit, proceeding, arbitration or other similar dispute.

"Affiliate" of any Person shall mean another Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such first Person.

"Agreement" shall have the meaning assigned to it in the **Preamble**.

"Allocation Schedule" shall have the meaning assigned to it in **Section 5.12**.

"Alternative Acquisition Agreement" shall have the meaning assigned to it in **Section 5.4(b)**.

"Alternative Transaction" shall mean any transaction or series of related transactions (other than the Transactions) for:

(a) any acquisition or purchase from the Company by any Person or "group" (as defined in or under Section 13(d) of the Exchange Act), directly or indirectly, of more than a fifteen percent (15%) beneficial or record interest in the total outstanding voting securities of any class (or instruments convertible into or exercisable or exchangeable for more than fifteen percent (15%) of any such class) of the Company, including pursuant to a stock purchase, merger, consolidation, tender offer, share exchange or other transaction involving the Company or any of its Subsidiaries;

(b) any tender offer (including self-tender) or exchange offer that, if consummated, would result in any Person or "group" (as defined in or under Section 13(d) of the Exchange Act) owning (beneficially or on record) more than fifteen percent (15%) of the total outstanding voting securities of any class (or instruments convertible into or exercisable or exchangeable for more than fifteen percent (15%) of any such class) of the Company;

(c) any merger, consolidation, business combination, share exchange, issuance of securities, acquisition of securities, option agreement, reorganization, recapitalization or other similar transaction for more than fifteen percent (15%) of the voting securities of the Company;

(d) any sale, lease, exchange, transfer, joint venture, partnership, option agreement, license or disposition, in each case, of more than fifteen percent (15%) of the assets of the Company (measured by the lesser of book or fair market value thereof); or

(e) any combination of the foregoing.

"Assets" shall have the meaning assigned to it in **Section 2.13**.

"**Book-Entry Share**" shall have the meaning assigned to it in **Section 1.6(b)(ii)**.

"Books and Records" shall have the meaning assigned to it in **Section 2.25**.

"**Business Day**" shall mean any day that is not a Saturday, a Sunday or other day on which banking institutions are required or authorized by Law to be closed in the City of New York, New York.

"Bylaws" shall have the meaning assigned to it in **Section 2.1**.

"Cancelled Shares" shall have the meaning assigned to it in **Section 1.6(b)(iii)**.

"**CARES Act**" shall mean the Coronavirus Aid, Relief, and Economic Security Act, Pub.L. 116–136 (116th Cong.) (March 27, 2020).

"Cash Allocation" shall have the meaning assigned to it in **Section 1.6(b)(i)(E)**.

"Cash Amount" shall have the meaning assigned to it in **Section 1.6(b)(i)(E)**.

"Cash Election" shall have the meaning assigned to it in **Section 1.6(b)(i)(E)**.

"Cash Holder" shall have the meaning assigned to it in **Section 1.6(f)**.

"**CERCLA**" shall mean the federal Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended

"Certificate of Incorporation" shall have the meaning assigned to it in **Section 2.1**.

"Change of Control" shall have the meaning assigned to it in **Section 1.6(b)(ii)(D)**.

"Charter Amendment" shall have the meaning assigned to it in **Section 6.2(q)**.

"Claim Notice" shall have the meaning assigned to it in **Section 8.5(c)**.

"Closing" shall have the meaning assigned to it in **Section 1.2(a)**.

"**Closing Cash**" shall mean the amount of any unrestricted cash and cash equivalents of the Company as of immediately prior to the First Effective Time.

"Closing Date" shall have the meaning assigned to it in **Section 1.2(a)**.

"**Closing Date Balance Sheet**" shall have the meaning assigned to it in **Section 5.11(a)**.

"**Closing Indebtedness**" shall mean the aggregate amount of all Indebtedness of the Company as of immediately prior to the First Effective Time, including any termination, pre-payment or balloon or similar penalties or premiums that are paid or become payable as a result of the full repayment and retirement of such Indebtedness immediately following the First Effective Time (whether or not such Indebtedness is actually repaid or retired).

"**Closing Parent Share Value**" shall mean the Parent Share Value as of the closing of trading on the Business Day immediately prior to the Closing.

"COBRA" shall mean the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

"Code" shall mean the Internal Revenue Code of 1986, as amended.

"Company" shall have the meaning assigned to it in the **Preamble**.

"Company Adverse Change in Recommendation" shall have the meaning assigned to it in **Section 5.4(b)**.

"Company Board of Directors" shall have the meaning assigned to it in the **Recitals**.

"Company Board Recommendation" shall have the meaning assigned to it in **Section 5.4(b)**.

"Company Capital Stock" shall mean the Company Common Stock, the Company Preferred Stock and any other shares of capital stock or equity interests, if any, of the Company, taken together.

"Company Common Stock" shall mean shares of common stock, par value $0.0001 per share, of the Company.

"Company Convertible Notes" shall mean that certain Note Purchase Agreement, dated as of May 25, 2021, by and among the Company and each of the lenders that is a party thereto.

"Company Disclosure Schedule" shall mean the Company Disclosure Schedule, dated as of the date hereof, delivered by the Company to Parent in connection with this Agreement, attached hereto as **Schedule D**.

"Company Employee Plan" shall mean any plan, program, policy, practice, contract, agreement or other arrangement providing for compensation, severance, change of control, termination pay, deferred compensation, performance awards, equity or equity-related awards, welfare benefits, health benefits or medical insurance, retirement benefits, fringe benefits or other employee benefits or remuneration of any kind, whether written, unwritten or otherwise, funded or unfunded, including each "employee benefit plan," within the meaning of Section 3(3) of ERISA which is or has been maintained, contributed to or required to be contributed to by the Company or any ERISA Affiliate for the benefit of any Employee, or with respect to which the Company or any ERISA Affiliate has or may have any liability or obligation, including, for the avoidance of doubt, any plan that is subject to laws outside of the United States.

"Company Fundamental Representations" shall mean those representations and warranties made in **Section 2.1, Section 2.2, Section 2.5, Section 2.6** and **Section 2.27**.

"Company IP" shall mean any and all Intellectual Property that is owned by or exclusively licensed by, or purported to be owned by or exclusively licensed by, the Company.

"Company IP Contract" shall mean any Contract to which the Company is or was a party or by which the Company is or was bound, that contains any assignment or license of, or any covenant not to assert or enforce, any Company IP.

"Company Option Consideration" shall have the meaning assigned to it in **Section 1.6(c)(i)**.

"Company Option Holder" shall mean a holder of Company Options.

"Company Options" shall mean all issued and outstanding options to purchase or otherwise acquire Company Common Stock (whether or not vested) held by any Person.

"Company Permits" shall mean all franchises, grants, authorizations, licenses, permits, easements, variances, exceptions, consents, concessions, registrations, clearances, exemptions, certificates, approvals and orders of any Governmental Entity necessary for the Company to own, lease and operate its properties and assets or to carry on its business as it is currently being conducted.

"Company Policies" shall have the meaning assigned to it in **Section 2.24**.

"Company Preferred Stock" shall mean the Series A Preferred Stock, Senior Series B Preferred Stock and Series B-1 Preferred Stock.

"Company Privacy Policy" shall mean each external or internal, past or present privacy policy or privacy- or security-related representation, obligation or promise of the Company, including any notice, policy, representation, obligation or promise relating to: (i) the privacy of users of any Company Product or any website or service operated by or on behalf of the Company or; (ii) the collection, use, storage, hosting, disclosure, transmission, transfer, disposal, retention, interception or other processing of, or security of, any Personal Data; or (iii) information about individuals who are Employees or are associated with Persons with which the Company has an agreement.

"Company Product" shall mean NIYAD™ and any other product, medical device or Product Candidate that is being researched, tested, developed, commercialized, manufactured, sold or distributed by or on behalf of the Company (whether or not in collaboration with another Person).

"Company Stock Certificate" shall have the meaning assigned to it in **Section 1.6(b)(ii)**.

"Company Stockholders' Meeting" shall have the meaning assigned to it in **Section 5.4(a)**.

"Company Warrant" shall mean that certain Common Stock Warrant to purchase Company Common Stock dated October 23, 2018, by and between the Company and La Jolla Pharmaceutical Company.

"Company Warrant Holder" shall mean and La Jolla Pharmaceutical Company.

"Company's Knowledge", "**Knowledge of the Company**" or similar terms used in this Agreement shall mean the knowledge of the Persons listed in **Exhibit F** after reasonable inquiry by each such Person of such Person's direct reports.

"Confidentiality Agreement" shall have the meaning assigned to it in **Section 10.6**.

"Consultant Proprietary Information Agreement" shall have the meaning assigned to it in **Section 2.14(d)(ii)**.

"Continuing Employee" shall mean an Employee who is employed by the Company as of the Closing Date and continues their employment with Parent or one of its Subsidiaries on the Business Day following the Closing Date.

"Contract" shall mean any contract, statement of work, mortgage, indenture, lease, license, filing, covenant, plan, insurance policy or other agreement, instrument, arrangement, understanding or commitment, permit, concession, franchise or obligation, whether written or oral.

"Contribution Agreement" means that certain Contribution Agreement, dated as of October 23, 2018, by and between the Company and the Company Warrant Holder.

"control" (including the terms "**controlled by**" and "**under common control with**"), with respect to the relationship between or among two or more Persons, means the possession, directly or indirectly or as trustee, personal representative or executor, of the power to direct or cause the direction of the affairs or management of a Person, whether through the ownership of voting securities, as trustee, personal representative or executor, by Contract, credit arrangement or otherwise.

"COVID-19" shall mean SARS-CoV-2 or COVID-19, and any evolutions or mutations thereof or related or associated epidemics, pandemics or disease outbreaks.

"COVID-19 Measures" shall mean any quarantine, "shelter in place," "stay at home," workforce reduction, social distancing, shut down, closure, sequester, safety or similar Law, directive, guideline or recommendation promulgated by any Governmental Entity, including the Centers for Disease Control and Prevention, the World Health Organization and the Occupational Safety and Health Administration, in each case, in connection with or in response to COVID-19.

"CVR" shall have the meaning assigned to it in **Section 1.6(b)(i)(A)**.

"CVR Agreement" shall mean a contingent value rights agreement in substantially the form attached as **Exhibit G**.

"Deductible" shall have the meaning assigned to it in **Section 8.4(a)**.

"Deferred Payroll Taxes" shall mean any payroll Taxes that otherwise would have been due and payable in a Pre-Closing Tax Period but were deferred pursuant to a taxable period (or portion thereof) beginning after the Closing Date under the Coronavirus, Aid, Relief, and Economic Security Act or other executive order or related Laws and comparable provisions of state and local tax laws enacted prior to the Closing.

"Determination Notice" shall have the meaning assigned to it in **Section 5.4(c)(i)**.

"Device Regulatory Laws" means Laws administered by the FDA relating to the regulation of the procurement, design, research, development, testing, studying, manufacturing, quality, licensing, production, processing, handling, packaging, labeling, storage, advertising, use, promotion, marketing, importation, exportation, sale and distribution of medical devices or components thereof, and any analogous applicable Laws of any applicable State or jurisdiction.

"DGCL" shall mean the General Corporation Law of the State of Delaware.

"Dispute Statement" shall have the meaning assigned to it in **Section 8.5(c).**

"Dissenting Shares" shall have the meaning assigned to it in **Section 1.6(b)(iv).**

"DOL" shall mean the United States Department of Labor.

"Election Deadline" shall have the meaning assigned to it in **Section 1.6(g)(i)**.

"Election Form" shall have the meaning assigned to it in **Section 1.6(g)**.

"Employee" shall mean any current or former employee, officer, director, individual consultant or independent contractor (who is a natural person) of the Company or any ERISA Affiliate.

"Employee Agreement" shall mean each management, employment, severance, separation, settlement, consulting, contractor, relocation, change of control, retention, bonus, repatriation, expatriation, loan, visa, work permit or other agreement, or contract (including, any offer letter or any other agreement providing for compensation or benefits) between the Company or any ERISA Affiliate, as applicable, and any Employee.

"Employee Proprietary Information Agreement" shall have the meaning assigned to it in **Section 2.14(d)(ii)**.

"End Date" shall have the meaning assigned to it in **Section 9.1(b)**.

"Enforceability Limitations" shall mean the effect of any applicable bankruptcy, insolvency (including, all Laws relating to fraudulent transfers), reorganization, moratorium or similar Laws affecting creditors' rights generally and the effect of general principles of equity (regardless of whether considered in a proceeding at law or in equity).

"Environmental Law" shall mean any Law relating to the environment, occupational health and safety, or exposure of Persons or property to Materials of Environmental Concern, including any statute, regulation, administrative decision or order pertaining to: (i) the presence of or the treatment, storage, disposal, generation, transportation, handling, distribution, manufacture, processing, use, import, export, labeling, recycling, registration, investigation or remediation of Materials of Environmental Concern or documentation related to the foregoing; (ii) air, water or noise pollution; (iii) surface water, groundwater or soil contamination; (iv) the release, threatened release, or accidental release of Materials of Environmental Concern, including emissions, discharges, injections, spills, escapes or dumping of Materials of Environmental Concern; (v) transfer of interests in or control of real property which may be contaminated; (vi) community or worker right-to-know disclosures with respect to Materials of Environmental Concern; (vii) the protection of wild life, marine life and wetlands, and endangered and threatened species; and (viii) storage tanks, vessels, containers, abandoned or discarded barrels and other closed receptacles. As used above, the term "release" shall have the meaning set forth in CERCLA

"ERISA" shall mean the Employee Retirement Income Security Act of 1974, as amended.

"ERISA Affiliate" shall mean any other Person under common control with the Company or that, together with the Company, could be deemed a "single employer" within the meaning of Section 4001(b)(1) of ERISA or within the meaning of Section 414(b), (c), (m) or (o) of the Code, and the regulations issued thereunder.

"Exchange Act" shall mean the Securities Exchange Act of 1934, as amended.

"Exchange Agent" shall mean a reputable bank or trust company selected by Parent and reasonably satisfactory to the Company to act as exchange agent in the Mergers.

"Exchange Documents" shall have the meaning assigned to it in **Section 1.7(a)**.

"Exchange Fund" shall have the meaning assigned to it in **Section 1.7(a)**.

"Exchange Ratio" shall mean the quotient obtained by *dividing* (x) the Per Share Merger Consideration *by* (y) the Closing Parent Share Value.

"Export Approvals" shall have the meaning assigned to it in **Section 2.19(c)**.

"FCPA" shall have the meaning assigned to it in **Section 2.19(d)**.

"FDA" shall mean the United States Food and Drug Administration.

"FDCA" shall mean the Federal Food, Drug and Cosmetic Act of 1938 (including the rules and regulations promulgated thereunder).

"FFCRA" shall mean the Families First Coronavirus Response Act, Pub. L. No. 116-127 (116th Cong.) (March 18, 2020).

"Final Date" shall have the meaning assigned to it in **Section 8.5(c)**.

"Financial Statements" shall have the meaning assigned to it in **Section 2.7(a)**.

"First Certificate of Merger" shall have the meaning assigned to it in **Section 1.2(b)**.

"First Effective Time" shall have the meaning assigned to it in **Section 1.2(b)**.

"First Merger" shall have the meaning assigned to it in the **Recitals**.

"GAAP" shall mean United States generally accepted accounting principles, consistently applied.

"Governing Documents" shall mean (i) the Certificate of Incorporation, (ii) the Bylaws, and (iii) the Voting Agreement.

"Governmental Entity" shall mean any federal, national, state, regional, local or other government, governmental, regulatory, self-regulatory, legislative or administrative authority, agency, commission, department, board or instrumentality, or any court, tribunal, or judicial or arbitral body, in each case, whether U.S. or non-U.S.

"Governmental Order" shall mean any award, decision, injunction (preliminary, temporary or permanent), judgment, order, writ, decree, stipulation, determination, ruling, subpoena, or verdict entered, issued, made, rendered or enforced by any court, administrative agency, or other Governmental Entity or by any arbitrator.

"HIPAA" shall mean the Health Insurance Portability and Accountability Act of 1996, as amended.

"Holdback Period" shall have the meaning assigned to it in **Section 1.6(b)(ii)(B)**.

"Holdback Shares" shall mean a number of shares of Parent Common Stock (rounded up to the nearest whole share) equal to $800,000 *divided by* the Closing Parent Share Value.

"Indebtedness" of any Person shall mean, without duplication: (i) all Liabilities of such Person for borrowed money, whether current or funded, secured or unsecured, all obligations evidenced by bonds, debentures, notes or similar instruments and all Liabilities in respect of mandatorily redeemable or purchasable share capital or securities convertible into share capital; (ii) all Liabilities of such Person for the deferred purchase price of property or services (including any earn-out, purchase price adjustment, release of "holdback" or similar payment); (iii) all Liabilities created or arising under any conditional sale or other title retention agreement with respect to property acquired by such Person (even if the rights and remedies of the seller or lender under such agreement in the event of default are limited to repossession or sale of such property); (iv) all Liabilities of such Person as lessee under leases that have been or should be, in accordance with GAAP, recorded as capital leases; (v) all Liabilities of such Person under interest rate and currency swaps, caps, collars and similar agreements or hedging devices under which payments are obligated to be made by such Person, whether periodically or upon the happening of a contingency, including any net payments that such Person would have to make in the event of an early termination; (vi) all Liabilities of such Person evidenced by any letter of credit, banker's acceptance or similar facilities in each case to the extent drawn as of such time; (vii) all Liabilities of such Person in respect of dividends declared but not yet paid by such Person or other distributions payable, in each case, to any other Person; (viii) all Liabilities of such Person, whether interest bearing or otherwise, owed to any shareholder, stockholder or member of such Person or any Affiliate of any shareholder, stockholder or member of such Person; (ix) all Liabilities of such Person for Unpaid Pre-Closing Taxes; (x) all Liabilities for unpaid salaries, bonuses and employee profit sharing or similar payment liabilities; (xi) all accounts payable, accrued expenses and any other current liabilities; (xii) all interest, fees, change of control payments, prepayment premiums, penalties and other amounts owed with respect to the indebtedness referred to in **clauses (i)** through **(xi)** above; (xiii) all Liabilities of others referred to in **clauses (i)** through **(xii)** above guaranteed (or in effect guaranteed) directly or indirectly in any manner by such Person; and (xiv) all Liabilities of others referred to in **clauses (i)** through **(xii)** above secured by (or for which the holder of such indebtedness has an existing right, contingent or otherwise, to be secured by) any Lien on property (including accounts and Contract rights) owned by such Person, even though such Person has not assumed or become liable for the payment of such indebtedness.

"Indemnified Party" means a Parent Indemnified Party or a Seller Indemnified Party, as the case may be.

"Indemnifying Party" means each of the Stockholders pursuant to **Section 8.2(a)**, or Parent pursuant to **Section 8.3**, as the case may be.

"Initial Surviving Company" shall have the meaning assigned to it in **Section 1.1(a)**.

"Intellectual Property" shall mean all rights of the following types, which may exist or be created under the laws of any jurisdiction in the world: (i) rights associated with works of authorship, including exclusive exploitation rights, mask works, copyrights and moral rights; (ii) trademarks, service marks, business names, brand names, domain names, logos, corporate names and trade name rights and similar rights, and the goodwill associated with the foregoing; (iii) trade secret rights and confidential and proprietary information; (iv) patents, patent applications, utility models, design rights and all related patent rights, together with all statutory invention registrations, patent disclosures, corrections, amendments, reissuances, divisionals, continuations, continuations-in-part, revisions, renewals, extensions and reexaminations and counterparts thereof; (v) other proprietary rights in intellectual property; (vi) rights in or relating to applications, registrations, renewals, extensions, combinations, divisions, continuations and reissues of, and applications for, any of the rights referred to in **clauses (i)** through **(v)** above; and (vii) all causes of action and rights to sue or seek other remedies arising from or relating to the foregoing, including for any past or ongoing infringement, misuse or misappropriation.

"Intended Tax Treatment" shall have the meaning assigned to it in the **Recitals**.

"Interested Party" shall have the meaning assigned to it in **Section 2.21**.

"Interim Financial Statements" shall have the meaning assigned to it in **Section 2.7(a)**.

"Investor Agreements" shall have the meaning assigned to it in **Section 5.10**.

"IRS" shall mean the United States Internal Revenue Service.

"Joinders" shall have the meaning assigned to it in the **Recitals**.

"Key Holder" shall have the meaning assigned to it in the **Recitals**.

"Law" means any federal, national, supranational, state, regional, provincial, local or similar statute, law, directive, ordinance, regulation, rule, code, order, constitution, treaty, common law, judgment, decree, other requirement or rule of law of any Governmental Entity.

"Lease Agreements" shall mean, collectively, all leases, lease guaranties, subleases, agreements for the leasing, use or occupancy of, or otherwise granting a right in or relating to the Leased Real Property, and all amendments, terminations and modifications thereof.

"Leased Real Property" shall mean the real property leased, subleased, licensed or otherwise occupied by the Company as tenant, subtenant, licensee or occupant together with, to the extent leased, subleased, licensed or otherwise occupied by the Company, all buildings and other structures, facilities or improvements currently or hereafter located thereon, all fixtures, systems, equipment and items of personal property of the Company affixed or appurtenant thereto and all easements, licenses, rights, hereditaments and appurtenances relating to the foregoing.

"Letter of Transmittal" shall have the meaning assigned to it in **Section 1.7(a)**.

"Liabilities" means any and all Indebtedness, liabilities and obligations, whether accrued or fixed, absolute or contingent, known or unknown, matured or unmatured or determined or determinable, including those arising under any Law, Action or Governmental Order and those arising under any Contract.

"Licensed IP" shall mean (i) all Intellectual Property incorporated into, or used in the development, delivery, hosting or distribution of, the Company Products; and (ii) all other Intellectual Property used or held for use in the conduct of the business of the Company that is not owned by, or purported to be owned by, the Company.

"Licensed IP Contract" shall mean any Contract to which the Company is or was a party or by which the Company is or was bound, pursuant to which the Company is granted a license, covenant not to sue, or other rights with respect to Licensed IP.

"Lien" shall mean any lien, pledge, charge, claim, mortgage, assessment, claim, hypothecation, infringement, deed of trust, lease, option, right of first refusal, easement, right of way, security interest, preemptive right, covenant, exclusive license, servitude, transfer restriction or other encumbrance of any kind or character whatsoever.

"LLCA" shall have the meaning assigned to it in **Section 1.1(b)**.

"Loan Repayment Amount" shall have the meaning assigned to it in **Section 1.9**.

"Loss" and "**Losses**" shall have the meaning assigned to them in **Section 8.2(a)**.

"Material Adverse Effect" shall mean any event, change, circumstance, change, development or effect (any such item, an "**Effect**") that, individually or in the aggregate with all other Effects (a) has had or would reasonably be expected to have a material adverse effect on the business, assets, Liabilities, condition (financial or otherwise) or results of operations of the Company or (b) prevents or materially impairs or delays the consummation of the Transactions, including the Mergers, or the ability of the Company to perform its obligations under this Agreement; *provided*, *however*, that, in the case of the foregoing **clause (a)**, in no event shall any Effect resulting from any of the following, either alone or in combination, be taken into account in determining whether there has been a Material Adverse Effect: (i) changes after the date of this Agreement in general economic conditions, including changes in currency exchange rates, or changes in securities markets in general that do not have a materially disproportionate effect (relative to other companies in the Company's industry) on the Company; (ii) changes after the date of this Agreement in applicable Law or GAAP or any interpretation thereof that do not have a materially disproportionate effect (relative to other companies in the Company's industry) on the Company; (iii) acts of war, armed hostilities or terrorism, or any escalation or worsening of any such acts of war, armed hostilities or terrorism under way as of the date of this Agreement that do not have a materially disproportionate effect (relative to other companies in the Company's industry) on the Company; (iv) the failure by the Company to meet any revenue or earnings projections or forecasts (but not, in each case, the underlying cause of such failure); (v) any act of God, epidemic, pandemic (including COVID-19 or any subsequent wave of COVID-19), other outbreak of illness or public health event (whether human or animal), earthquakes, floods or other natural disasters in the United States or any other country that do not have a materially disproportionate effect (relative to other companies in the Company's industry) on the Company; or (vi) any failure by the Company to meet their internal budgets, plans, or revenue or earnings forecasts of their financial performance (but, in each case, not the underlying cause of such failure).

"Material Contracts" shall have the meaning assigned to it in **Section 2.15(a)**.

"Materials of Environmental Concern" shall mean any: pollutants or contaminants (as such terms are defined under the Clean Water Act, 33 U.S.C. Section 401 et seq.) or hazardous substances (as such terms are defined under CERCLA), pesticides (as such term is defined under the Federal Insecticide, Fungicide and Rodenticide Act), solid wastes and hazardous wastes (as such terms are defined under the Resource Conservation and Recovery Act), chemicals, other hazardous, radioactive or toxic materials, oil, petroleum and petroleum products (and fractions thereof), listed or subject to regulation under any Law, statute, rule, regulation, order, Permit, or directive due to its potential, directly or indirectly, to harm the environment or the health of humans or other living beings.

"Merger Consideration" shall mean the amounts payable pursuant to **Section 1.6**.

"Merger Sub 1" shall have the meaning assigned to it in the **Preamble**.

"Merger Sub 2" shall have the meaning assigned to it in the **Preamble**.

"Mergers" shall have the meaning assigned to it in the **Recitals**.

"Non-Competition and Non-Solicitation Agreements" shall have the meaning assigned to it in the **Recitals**.

"Offer Letter" shall have the meaning assigned to it in the **Recitals**.

"Option Cancellation Agreement" shall have the meaning assigned to it in the **Recitals**.

"Other Employees" shall mean the Employees providing services to the Company as of the Closing Date, other than the Key Holders.

"Parent" shall have the meaning assigned to it in the **Preamble**.

"Parent Common Stock" shall mean shares of the common stock, par value $0.001 per share, of Parent.

"Parent Common Stock Consideration Cap" shall have the meaning assigned to it in **Section 1.6(e)**.

"Parent Disclosure Schedule" shall mean the Parent Disclosure Schedule, dated as of the date hereof, delivered by Parent to the Company in connection with this Agreement, attached hereto as **Schedule E**.

"Parent Expenses" shall have the meaning assigned to it in **Section 9.3(b)**.

"Parent Fundamental Representations" shall mean those representations and warranties made in **Section 3.1**, **Section 3.2** and **Section 3.6**.

"Parent Indemnified Party" shall have the meaning assigned to it in **Section 8.2(a)**.

"Parent Related Person" shall have the meaning assigned to it in **Section 7.8(a)**.

"Parent SEC Documents" shall mean all forms, statements, schedules, documents and reports filed or furnished since January 1, 2019 through the date hereof by Parent to the SEC.

"Parent Share Value" shall mean: (i) if Parent Common Stock is not publicly traded or quoted on a national securities exchange or automated quotation system, the fair market value as determined in good faith by Parent's Board of Directors and (ii) if Parent Common Stock is publicly traded or quoted on a national securities exchange or automated quotation system, the arithmetic average of the daily volume weighted average price per share of the Parent Common Stock during the five (5) consecutive full trading days ending on and including the last full trading day immediately prior to the date of determination of value as reported by such national securities exchange.

"Parent Shares" shall mean the Parent Common Stock issuable to the Stockholders and Company Option Holders (including the Parent Common Stock issuable pursuant to the CVRs, if any) pursuant to this Agreement.

"Pension Plan" shall mean each Company Employee Plan that is an "employee pension benefit plan" within the meaning of Section 3(2) of ERISA.

"Per Share Merger Consideration" shall mean the quotient obtained by *dividing* (x) the Remaining Consideration *by* (y) the Total Outstanding Shares.

"Permits" shall mean all permits, licenses, registrations, certificates, orders, approvals, franchises, variances, waivers and similar rights issued by or obtained from any Governmental Entity (including those issued or required under Environmental Laws).

"Permitted Liens" shall mean such of the following as to which no enforcement, collection, execution, levy or foreclosure proceeding shall have been commenced and as to which the Company is not otherwise subject to civil or criminal liability due to its existence: (a) Liens for Taxes not yet due and payable for which appropriate reserves have been established in accordance with GAAP; (b) materialmen's, mechanics', carriers', workmen's and repairmen's Liens and other similar Liens arising or incurred in the ordinary course of business securing obligations which are not yet delinquent or which are being contested in good faith by appropriate proceedings diligently conducted and for which appropriate reserves have been established on the books of the Company; (c) pledges or deposits to secure obligations under workers' compensation Laws or similar legislation or to secure public or statutory obligations; and (d) minor survey exceptions, customary utility easements and other minor customary encumbrances on title to Leased Real Property that (i) were not incurred in connection with any Indebtedness, (ii) do not render title to the property encumbered thereby unmarketable and (iii) are not in excess of $5,000 in the case of a single property or $50,000 in the aggregate at any time.

"Person" shall mean any individual, corporation, partnership, limited liability company, estate, trust, association, joint stock company, joint venture, organization or other entity, including any Governmental Entity (or any department, agency, or political subdivision thereof).

"Personal Data" shall mean, in addition to all information defined or described by the Company as "personal information," "personally identifiable information," "PII," or using any similar term in any Company Privacy Policy or other public-facing statement: (i) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or tax identification number, driver's license number, passport number, credit card number, bank information or customer or account number, biometric identifiers, device or machine identifier, IP address, or any other piece of information that alone or in combination with other information directly or indirectly allows the identification or location of, or contact with, a natural person or a particular computing system or device (and for greater certainty includes all such information with respect to employees) and (ii) any information that is associated, directly or indirectly (by, for example, records linked via unique keys), with any of the foregoing.

"Plan" shall mean the Company's 2018 Stock Incentive Plan, as adopted as of August 31, 2018.

"Pre-Closing Tax Period" shall mean any taxable period (or portion of a straddle period) ending on or before the Closing Date.

"Privacy Law" shall mean a Law, rule of a self-regulatory organization that the Company or any Person performing for or on behalf of the Company is or was required to comply with, the U.S.-European Union and U.S.-Swiss Safe Harbor programs administered by the Department of Commerce, and any applicable published industry best practice or other standard (including the PCI Data Security Standard, other requirements of payment card brands and payment networks, and the Digital Advertising Alliance's Self-Regulatory Principles for Online Behavioral Advertising and Multi-Site Data Collection, respectively) or contractual requirement, as it may in each case be or have been amended from time to time, that pertains to (i) privacy or restrictions or obligations related to the collection, use, disclosure, transfer, transmission, storage, hosting, disposal, retention, interception or other processing of, or the security of, Personal Data; or (ii) consumers' communication or consumer protection.

"Pro Rata Portion" shall mean, the amount obtained by *dividing* (x) one (1) by (y) the number of Total Outstanding Shares.

"Product Candidate" shall mean all device, drug or biological product candidates being researched, developed, tested, labeled, manufactured or stored by the Company.

"Proxy Statement" shall have the meaning assigned to it in **Section 5.3**.

"Qualified Repurchase" shall have the meaning assigned to it in **Section 7.8(a)(v)**.

"Reference Property" shall have the meaning assigned to it in **Section 1.6(b)(ii)(D)**.

"Registered IP" shall mean all Intellectual Property that is registered, filed or issued under the authority of, with or by any Governmental Entity, including all patents, registered copyrights and registered trademarks, business names and domain names, and all applications for any of the foregoing.

"Registrable Securities" shall mean the Parent Shares issued pursuant to the terms of this Agreement.

"Registration Statement" shall have the meaning assigned to it in **Section 1.7(h)(i)**.

"Regulatory Approvals" shall mean any consent, notice, waiver, approval, authorization of, registration, declaration or filing with, a Governmental Entity that is required under applicable Law for the consummation of the Mergers or the other Transactions.

"Related Agreements" shall mean the Option Cancellation Agreements, the Warrant Cancellation Agreement, the Joinders, the Non-Competition and Non-Solicitation Agreements, the 280G Waivers, the CVR Agreement and all other agreements and certificates entered into by the Company or any of the Stockholders, Company Option Holders or Company Warrant Holder in connection with the Transactions; *provided* that "Related Agreements" shall not include the Non-Competition and Non-Solicitation Agreements for purposes of **Section 8.6**.

"Releasable Shares" shall mean a number of shares of Parent Common Stock (rounded down to the nearest whole share) equal to (a) the number of Holdback Shares, *minus* (b) the number of shares of Parent Common Stock that have be used to satisfy any indemnification claims of the Parent Indemnified Parties, *minus* (c) the number of shares of Parent Common Stock (rounded down to the nearest whole share) equal to the quotient obtained by (i) the amount of all Losses, if any, for which Parent has theretofore become entitled to indemnification pursuant to **Section 8.2** and that will result in the forfeiture of the right to be issued the Holdback Shares pursuant to **Section 1.6(b)(ii)(B)**, *plus* the amount of any unresolved claim reflected in a notice delivered in accordance with **Section 8.5**, *divided by* (ii) the Parent Share Value immediately prior to the date of release of any Releasable Shares.

"Remaining Consideration" shall mean an amount equal to the Total Consideration *less* (i) the Series A Liquidation Amount, (ii) the Senior Series B Liquidation Amount, and (iii) the Series B-1 Liquidation Amount.

"Replacement Warrant" shall have the meaning set forth in **Section 1.6(d)**.

"Representative Expense Amount" shall have the meaning assigned to it in **Section 8.6(a)**.

"Representatives" shall mean, with respect to any Person, such Person's Affiliates and its and their respective officers, directors, employees, agents, consultants, auditors, insurers and advisors.

"Rights Agent" shall have the meaning set forth in the CVR Agreement.

"SEC" shall mean the United States Securities and Exchange Commission.

"Second Certificate of Merger" shall have the meaning assigned to it in **Section 1.2(c)**.

"Second Effective Time" shall have the meaning assigned to it in **Section 1.2(c)**.

"Second Merger" shall have the meaning assigned to it in the **Recitals**.

"Section 409A" shall have the meaning assigned to it in **Section 2.11(n)(i)**.

"Securities Act" shall mean the Securities Act of 1933, as amended.

"Seller Indemnified Party" shall have the meaning assigned to it in **Section 8.3(a)**.

"Senior Series B Liquidation Amount" shall mean $2.60 *multiplied by* the number of shares of Senior Series B Preferred Stock issued and outstanding immediately prior to the First Effective Time.

"Senior Series B Liquidation Payment" shall have the meaning assigned to it in **Section 1.6(b)(ii)(A)**.

"Senior Series B Preferred Stock" shall have the meaning assigned to it in **Section 2.5(a)**.

"Series A Liquidation Amount" shall mean $2.50 *multiplied by* the number of shares of Series A Preferred Stock issued and outstanding immediately prior to the First Effective Time.

"Series A Liquidation Payment" shall have the meaning assigned to it in **Section 1.6(b)(i)(B)**.

"Series A Preferred Stock" shall have the meaning assigned to it in **Section 2.5(a)**.

"Series B-1 Liquidation Amount" shall mean $2.08 *multiplied by* the number of shares of Senior Series B-1 Preferred Stock issued and outstanding immediately prior to the First Effective Time.

"Series B-1 Liquidation Payment" shall have the meaning assigned to it in **Section 1.6(b)(i)(B)**.

"Series B-1 Preferred Stock" shall have the meaning assigned to it in **Section 2.5(a)**.

"Series B Preferred Stock" shall have the meaning assigned to it in **Section 2.5(a)**.

"Service Agreement" shall have the meaning assigned to it in **Section 6.2(g)(iii)**.

"Software" means computer software and databases, together with, as applicable, object code, source code, firmware, files, development tools and embedded versions thereof, and documentation related thereto.

"Specified Agreement" shall have the meaning assigned to it in **Section 9.1(f)**.

"Specified Governmental Entities" shall have the meaning assigned to it in **Section 2.10(a)**.

"Specified Time" shall mean the earlier of (a) the time at which this Agreement is terminated in accordance with the terms hereof and (b) the date on which the Stockholder Approval is obtained.

"Standard Form IP Contract" shall mean each standard form of Company IP Contract used by the Company at any time, including each standard form of the following types of agreements, to the extent the Company actually utilizes such a standard form in the conduct of its business: (i) license and/or service agreements; (ii) development agreements; (iii) distributor, reseller or affiliate agreements; (iv) employee agreements containing any assignment or license of Intellectual Property or any confidentiality provision; (v) professional services, outsourced development, consulting, or independent contractor agreements containing any assignment or license of Intellectual Property or any confidentiality provision; and (vi) confidentiality or nondisclosure agreements.

"Statement of Expenses" shall have the meaning assigned to it in **Section 5.9(e)**.

"Stockholder" shall mean any holder of any Company Capital Stock as of immediately prior to the First Effective Time.

"Stockholder Approval" shall mean (i) the adoption of this Agreement and the Transactions, including the Mergers; and (ii) the Charter Amendment by a majority of the voting power of (x) the shares of Company Capital Stock outstanding on the record date for the Company Stockholders' Meeting and entitled to vote, voting together as a class; and (y) the shares of Company Preferred Stock outstanding on the record date for the Company Stockholders' Meeting and entitled to vote, voting as a class.

"Stockholder Fundamental Representations" shall mean the representations and warranties of a Stockholder or Company Option Holder set forth in such Stockholder's Joinder.

"Stockholder Representative" shall have the meaning assigned to it in the **Preamble**.

"Stockholder Representative Expenses" shall have the meaning assigned to it in **Section 8.6(c)**.

"Straddle Period" shall mean any taxable period beginning on or before the Closing Date and ending after the Closing Date.

"Subsidiary" of any Person shall mean any corporation, limited liability company, partnership, limited partnership, association, trust, unincorporated organization or other legal entity of which such Person (either alone or through or together with any other Subsidiary) owns, directly or indirectly, a majority of the stock or other equity interests, the holders of which are generally entitled to vote for the election of the board of directors or other governing body of such corporation or other legal entity, or any Person that would otherwise be deemed a "subsidiary" under Rule 12b-2 promulgated under the Exchange Act.

"Superior Offer" means any bona fide written Acquisition Proposal involving an Alternative Transaction that is not subject to any financing contingency, which the Company Board of Directors shall have determined (after consultation with its independent financial advisor and its outside legal counsel) (a) is reasonably likely to be consummated in accordance with its terms, taking into account all legal, regulatory and financing aspects (including certainty of financing and certainty of closing) of the proposal, the Person making the proposal and other aspects of the Acquisition Proposal that the Company Board of Directors deems relevant and (b) if consummated, would be more favorable to the Company's stockholders (in their capacity as such) than the Contemplated Transactions; *provided* that for purposes of the definition of "Superior Offer", the references to "15%" in the definition of Alternative Transaction shall be deemed to be references to "80%."

"Surviving Company" shall have the meaning assigned to it in **Section 1.1(b)**.

"Tail Cost" shall have the meaning assigned to it in **Section 8.7(b)**.

"Tax" shall mean (i) any income, alternative or add-on minimum tax, gross income, estimated, gross receipts, sales, use, ad valorem, value-added, transfer, franchise, capital stock, profits, license, registration, withholding, payroll, social security (or equivalent), employment, unemployment, disability, escheat, excise, severance, stamp, occupation, premium, property (real, tangible or intangible), environmental or windfall profit tax, custom duty or other tax, governmental fee or other like assessment or charge of any kind whatsoever, together with any interest or any penalty, addition to tax or additional amount (whether disputed or not) imposed by any Governmental Entity responsible for the imposition of any such tax (domestic or foreign), (ii) any liability for the payment of any amounts of the type described in **clause (i)** of this sentence as a result of being a member of an affiliated, consolidated, combined, unitary, aggregate or similar group for any taxable period, and (iii) any liability for the payment of any amounts of the type described in **clause (i)** or **(ii)** of this sentence as a result of being a transferee of or successor to any Person or as a result of any express or implied obligation to assume such Taxes or to indemnify any other Person, including by operation of law.

"Tax Claim" shall have the meaning assigned to it in **Section 7.2(a)**.

"Tax Return" shall have the meaning assigned to it in **Section 2.11(a)**.

"Termination Fee" shall have the meaning assigned to it in **Section 9.3(a)**.

"Third Party" shall have the meaning assigned to it in **Section 5.2(a)**.

"Third-Party Claim" shall have the meaning assigned to it in **Section 8.5(b)**.

"Third-Party Expenses" shall mean, without duplication, all fees, costs and expenses incurred by or on behalf of the Company in connection with this Agreement, the Related Agreements, the Mergers and the other Transactions, including (i) all legal, accounting, financial advisory, consulting, finders', and all other fees and expenses of third parties incurred by or on behalf of the Company in connection with the negotiation and effectuation of the terms and conditions of this Agreement, all other agreements, instruments and other documents referenced herein or contemplated hereby, the Related Agreements, the Mergers and the other Transactions, (ii) any termination, pre-payment, balloon or similar fees or payments (including penalties) of the Company resulting from the early termination of outstanding Indebtedness in connection with the consummation of the Mergers and the other Transactions, other than any amounts included in Closing Indebtedness, (iii) any bonus, severance, change-in-control payments or similar payment obligations of the Company that become due or payable in connection with the consummation of the Mergers and the other Transactions (and any payroll Taxes payable by the Company in connection therewith), other than any amounts included in Closing Indebtedness, (iv) any costs, expenses and fees of the Stockholder Representative (including any Stockholder Representative Expenses), (v) any termination or similar fees or payments (including penalties and premiums) resulting from the early termination of Contracts or the prepayment of Indebtedness by the Company in connection with the Transactions (it being understood that this **clause (v)** shall not include any amounts included in the Closing Indebtedness), (vi) any payment or other consideration arising under or in relation to obtaining any consents, waivers or approvals required under any Contract of the Company as a result of or in connection with the Transactions, and (vii) all filing fees and other fees payable to any Governmental Entity in connection with any filings made by the Company as a result of or in connection with the Transactions.

"Total Consideration" shall mean an amount equal to (i) $6,500,000, *less* (ii) $800,000, representing the value of the Holdback Shares (calculated at the Closing Parent Share Value), *less* (iii) the amount, if any, of any Closing Indebtedness in excess of $175,000, *plus* (iv) the amount of any Closing Cash, *less* (v) any Third-Party Expenses that are incurred by the Company prior to or as of the Closing and that are unpaid as of immediately prior to the First Effective Time, *less* (vi) the Tail Cost, *less* (vii) the Representative Expense Amount.

"Total Outstanding Shares" shall mean (without duplication) (i) the aggregate number of shares of Company Capital Stock issued and outstanding as of immediately prior to the First Effective Time, including Dissenting Shares and Cancelled Shares, on an as converted to Company Common Stock basis, *plus* (ii) the maximum aggregate number of shares of Company Capital Stock issuable upon full exercise, exchange or conversion of all Company Warrants issued and outstanding as of immediately prior to the First Effective Time, on an as converted to Company Common Stock basis, *plus* (iii) the maximum aggregate number of shares of Company Capital Stock issuable upon full exercise, exchange or conversion of any other rights, including options, whether vested or unvested, that are convertible into, exercisable for or exchangeable for, shares of Company Capital Stock issued and outstanding as of immediately prior to the First Effective Time, on an as converted to Company Common Stock basis.

"Transactions" shall have the meaning assigned to it in the **Recitals**.

"Transfer Taxes" shall mean any and all transfer, documentary, sales, use, registration, real property transfer, stamp, excise or stock transfer Taxes and other similar Taxes, and any penalties or interest with respect thereto, with respect to the Transactions.

"Trigger Rights" shall mean any acceleration of vesting, release of restrictions or similar benefit to an Employee relating to the exercise, vesting, or settlement provisions of any equity award of the Company held by such Employee, in each case, that would be triggered by or result in an increase in benefits or acceleration of the time of vesting due to either one ("single-trigger") or both ("double-trigger") of (i) the consummation of the Transactions or (ii) an actual or constructive termination of employment.

"UKBA" shall have the meaning assigned to it in **Section 2.19(d)**.

"Unaccredited Investor" shall mean a Stockholder or Company Option Holder that is not an Accredited Investor.

"Unpaid Pre-Closing Taxes" shall mean (i) all Taxes of the Company attributable to any Pre-Closing Tax Period, to the extent that any such Taxes relate to any Tax period commencing on or after January 1, 2021, and first become due and payable after the Closing Date determined in the case of the pre-Closing portion of any Straddle Period, in the manner set forth in **Section 8.2(a)(vii)** and (ii) any Deferred Payroll Taxes that are due and payable after the Closing Date.

"Voting Agreement" means that certain Voting Agreement, dated as of September 20, 2021, the Company, the holders of the shares of Series A Preferred Stock, Senior Series B Preferred Stock and Series B-1 Preferred Stock of the Company and certain stockholders of the Company as listed on Schedule B thereto.

"Warrant Cancellation Agreement" shall have the meaning assigned to it in **Section 1.6(d)**.

Exhibit 10.1

[***] = CERTAIN INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS CONFIDENTIAL, (II) IS NOT MATERIAL, AND (III) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

LICENSE AND COMMERCIALIZATION AGREEMENT (EU)

RELATING TO DZUVEO

BETWEEN

ACELRX PHARMACEUTICALS, INC.

AND

LABORATOIRE AGUETTANT

EFFECTIVE AS OF JULY 14, 2021

This License and Commercialization Agreement (this "**Agreement**") is entered into and effective as of July 14, 2021 (the "**Effective Date**"), by and between AcelRx Pharmaceuticals, Inc., a corporation organized and existing under the laws of the State of Delaware, 25821 Industrial Boulevard, Suite 400, Hayward, CA 94545, USA ("**AcelRx**"), and **Laboratoire Aguettant,** a corporation organized and existing under the laws of France, 1 rue Alexander Fleming, 69007 Lyon, France ("**Aguettant**"). AcelRx and Aguettant are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

Recitals

WHEREAS, AcelRx is a biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute pain, including the product referred to as DZUVEO® (sufentanil);

WHEREAS, AcelRx owns or controls data, know-how and other intellectual property relating to such product;

WHEREAS, Aguettant is a pharmaceutical company that develops, manufactures, and distributes injectable medications, primarily in Europe;

WHEREAS, Aguettant desires to obtain from AcelRx certain rights and licenses to commercialize and import such product in Europe, and AcelRx is willing to supply such product and to grant Aguettant such rights and licenses in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, AcelRx and Aguettant hereby agree as follows:

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ARTICLE 1

DEFINITIONS AND USAGE

1.1 Definitions. Capitalized terms used in this Agreement shall have the meaning ascribed thereto herein, including in Schedule 1.1.

1.2 Headings, Gender and Number. All section and article titles or captions contained in this Agreement and in any exhibit, schedule or certificate referred to herein or annexed to this Agreement are for convenience only, shall not be deemed a part of this Agreement and shall not affect the meaning or interpretation of this Agreement. Words used herein, regardless of the number and gender specifically used, shall be deemed and construed to include any other number, singular or plural, and other gender, masculine, feminine, or neuter, as the context requires.

1.3 References. Unless explicitly provided for, references to articles, sections, schedules or exhibits are references to articles, sections, schedules or exhibits of this Agreement.

1.4 Usage. Unless otherwise indicated to the contrary herein by context or use hereof, words importing the singular shall also include the plural, and vice versa. All references to days in this Agreement shall mean calendar days, unless otherwise specified. The words “include,” “includes” and “including” shall be deemed to be followed by the phrase “but not limited to” unless expressly stated otherwise. The word “or” shall mean “and/or”, unless otherwise specified.

ARTICLE 2

GRANT OF LICENSE AND RIGHT REGARDING ZALVISO®

2.1 License Grant.

(a) **AcelRx IP**. Subject to the terms and conditions set forth in the Agreement and except as set out in Sections 2.1(b) and 2.1(c), AcelRx, on behalf of itself and its Affiliates, hereby grants to Aguettant for the Term an exclusive, royalty-bearing, non-transferable, non-assignable (except as set forth in Section 14.4), non-sublicensable (except as provided in Section 2.2) right and license under the AcelRx IP (other than Brand Name, AcelRx Inventions, and Product Improvements, which are addressed in Sections (b) and (c) below) to (i) Develop, solely to the extent expressly permitted by the Agreement, (ii) Fill and Finish, and (iii) Commercialize, in each case, the Product in the Field in the Territory, provided that AcelRx retains the right to use the Core Pharmaceutical Dossier for products other than the Product, including the product commercialized as of the Effective Date under the brand Zalviso®, and provided further that, should Aguettant elect not to sublicense in the Dental Field as further set out in Section 2.2, Aguettant shall promptly notify AcelRx of such election, upon which notice AcelRx may award a semi-exclusive license (semi-exclusive to Aguettant) to a Third Party for the Commercialization of the Product solely in the Dental Field in the Territory.

(b) **Brand Name**. Subject to the terms and conditions set forth in the Agreement, AcelRx, on behalf of itself and its Affiliates, hereby grants to Aguettant for the Term an exclusive, royalty-free, non-transferable, non-assignable (except as provided in Section 14.4), non-sublicensable (except as provided in Section 2.2) right and license under the Brand Name to use the Brand Name in the Territory to Commercialize the Product in the Field in the Territory.

(c) **Inventions and Improvements**. Subject to the terms and conditions set forth in the Agreement, AcelRx, on behalf of itself and its Affiliates, hereby grants to Aguettant for the Term an exclusive, royalty-free, non-transferable, non-assignable (except as provided in Section 14.4), non-sublicensable (except as provided in Section 2.2) right and license under the AcelRx Inventions and Product Improvements to use any such AcelRx Inventions or Product Improvements to (i) Develop, solely to the extent expressly permitted by the Agreement, and (ii) Commercialize, in each case, the Product in the Field in the Territory.

2.2 Sublicense to Affiliates or Third Parties. Aguettant shall have the right to grant sublicenses under the licenses granted in Section 2.1 to its Affiliates or, with the prior written approval of AcelRx, to Third Parties (the "**Sublicensees**"), provided that [***].

2.3 No Implied Licenses. No right or license under the AcelRx IP is granted or shall be granted by implication or estoppel. All rights or licenses that are or shall be granted between AcelRx and Aguettant are only those rights or licenses expressly provided in this Agreement.

2.4 Right regarding Zalviso®. For eighteen (18) months as of the Effective Date, before entering a collaboration regarding ZALVISO® in Europe with a third party, AcelRx shall notify Aguettant in writing that it may pursue such a potential collaboration and Aguettant shall have [***] from the receipt of such notice to provide AcelRx written notice that it desires to enter into good faith negotiations with AcelRx regarding ZALVISO® in Europe. If Aguettant does not provided such notice, then AcelRx shall have no further obligation and shall be free to negotiate and enter into any ZALVISO® collaboration in Europe with any third party.

ARTICLE 3

COMMERCIALIZATION AND MARKETING

3.1 Re-registration of Regulatory Filings and Marketing Authorizations. Within [***] after the Effective Date, AcelRx shall arrange, [***] for the Re-registration of Marketing Authorizations and re-registration of Regulatory Filings, pending or held by AcelRx (or its legal EU representative, FGK Representative Service GmbH) at that time, to Aguettant. For the avoidance of doubt, AcelRx retains all rights to the underlying data including the Core Pharmaceutical Dossier.

3.2 Commercialization of the Product in the Territory. Aguettant shall Commercialize the Product in the Field in the Territory, and shall fulfill responsibilities in support thereof, including the following: legal, compliance, finance, audit, human resources, regulatory, safety, market access, strategy, government affairs and stakeholder management, public affairs and any other operational requirements (excluding Development and Manufacturing performed by AcelRx). Without limiting the foregoing, Aguettant shall be responsible for Commercialization, including marketing, strategy, pricing, promotion, physician targeting, reimbursement, branding, distribution and sale of the Product in the Field in the Territory. All costs and expenses of Commercialization, including for distribution, marketing and selling, of the Product in the Field in the Territory shall be for Aguettant's account.

3.3 Aguettant's Commercialization Rights and Obligations. Aguettant, in consultation with AcelRx and the JSC, without prejudice to the minimum sales obligations set out in Section 5.5, shall have the right and shall use Commercially Reasonable Efforts, including its usual level of sales presence and number of offices, to: (a) establish the strategy for Commercialization of the Product in the Field in the Territory (the "**Commercialization Strategy**") and (b) Commercialize the Product in the Field in the Territory. Aguettant shall conduct all such activities in accordance with the Commercialization Plan, and shall satisfy all diligence therein. Without limiting the foregoing, Aguettant shall use Commercially Reasonable Efforts to (i) [***] and to (ii) Launch the Product according to the Commercialization Plan submitted to the JSC and reviewed by AcelRx, provided that Aguettant shall Launch the Product in at least [***] of the Territory as soon as practical but no later than [***] from the completion date of Re-registration of Marketing Authorizations to Aguettant (the date of the conclusion of such [***] period, the "**Deadline**"). The Deadline is subject to AcelRx's capacity to deliver the Bulk Products at least [***] prior to the agreed Launch Date. Both Parties agree to use their reasonable efforts to ensure that a Product can be placed on the market by [***] in order to meet the EU sunset regulation of marketing authorization expiration after 3 years of a product not being placed on the market, now extended into 2022. If the Parties are unable, despite their efforts, to place on the market a Product by [***], AcelRx shall request another derogation for the EU sunset regulation of marketing authorization expiration at its costs.

3.4 Commercialization Coordination.

(a) **Commercialization Plan**. No later than [***] before the expected Launch Date, and thereafter every [***] for the first Marketing Year and every [***] after the first Marketing Year, Aguettant shall prepare and submit to the JSC for review, alteration and approval a plan setting forth: [***] (the "**Commercialization Plan**"). The Parties shall decide together, notably in the event of specific requirements for the market access of a specific country of the Territory, the opportunity to Launch the Product in the corresponding country of the Territory.

(b) **Commercial Updates**. Aguettant shall consult with and provide regular updates to AcelRx including through the JSC regarding the Commercialization Strategy and all Commercialization activities in the Field in the Territory ("**Commercialization Updates**"), which activities shall be coordinated by the JSC with activities outside the Field in the Territory. Without limiting the generality of the foregoing, Aguettant shall provide (i) a Commercialization Update to AcelRx through the JSC at least [***] in MYs 1 and 2, and at least [***] in MY 3 and thereafter, and (ii) current sales reports to AcelRx in writing at least [***].

(c) **Commercialization Covenants**. In connection with its Commercialization of the Product in the Field in the Territory pursuant to the Commercialization Plan, Aguettant shall:

(i) maintain complete and accurate distribution records of all Products sold to customers or purchasers in the Territory by or on behalf of Aguettant;

(ii) retain, for a period of [***] from the date of creation, any and all training records related to the Products;

(iii) provide AcelRx and its designees with reasonable access to all premises and records relating to its activities involving the Products to the extent necessary to enable AcelRx to exercise its rights under the Agreement, provided a [***] prior notice has been provided to Aguettant and such designees of AcelRx have been previously approved by Aguettant, which approval shall not be unreasonably withheld or delayed; and

(iv) make no representations or warranties with respect to the Products other than those in the label for the Product or otherwise as specifically authorized in writing by AcelRx.

3.5 Compliance. Aguettant shall conduct, and shall ensure that all of its Affiliates, Distributors, Sublicensees and other subcontractors conduct, all Commercialization of the Product in the Field in the Territory in compliance with Applicable Laws and the EFPIA Code and all ethics policies applicable in the Territory, as well as those provided by AcelRx to be mutually agreed upon by the Parties in good faith. Aguettant shall make all related disclosures with respect to and record all transfers of value to health care providers in the Territory as required by Applicable Laws and shall provide an annual summary thereof to AcelRx.

3.6 Regulatory and Pharmacovigilance Responsibilities. Upon the completion of the Re-registration of Marketing Authorizations to Aguettant, Aguettant shall be responsible for all regulatory and pharmacovigilance obligations, at its sole cost and expense unless explicitly provided otherwise herein, including subsequent mandatory clinical trials, further Development of the Product to the extent such Development is requested by Aguettant or Regulatory Authorities, and obtaining and maintaining all Marketing Authorizations and Other Approvals for the Product in the Field in the Territory. AcelRx shall reasonably support Aguettant in such obligations, as the Core Pharmaceutical Dossier owner and Product manufacturer, at the sole discretion of AcelRx.

3.7 Medical Affairs. Aguettant shall provide medical and scientific support for the Product in the Field in the Territory. Aguettant shall, subject to Applicable Laws, comply with AcelRx's policies on engaging and sponsoring healthcare providers. In any event, AcelRx shall reasonably support Aguettant in this obligation, as the Core Pharmaceutical Dossier owner, at the sole discretion of AcelRx.

3.8 Promotional Materials. Aguettant shall have the right to develop all written, printed, electronic or graphic material intended for use by sales representatives in promoting the Product in the Field in the Territory, including visual aids, file cards, premium items, clinical study reports, reprints, drug information updates, and any other promotional support items (collectively, the "**Promotional Materials**"); provided that (a) all Promotional Materials shall comply with Applicable Laws; (b) Aguettant shall provide an English translation of all Promotional Materials to the JSC for discussion within JSC, prior to finalization thereof and at least [***] prior to use or distribution in the Territory, provided that Aguettant may repeatedly use or distribute any Promotional Materials previously approved by the JSC without any additional JSC review; (c) all Promotional Materials shall be compliant with AcelRx's global branding guidelines and core materials (including Indication) for the Product, as provided by AcelRx to Aguettant upon execution of the Agreement; and (d) no Promotional Material shall be detrimental to AcelRx's products other than the Product, including the product commercialized as of the Effective Date under the brand Zalviso®. Within [***] after the Effective Date, AcelRx shall provide Aguettant, [***] all existing marketing and promotional materials (including website and digital content) regarding the Product, whether electronic (including source code thereof, if applicable) or physical copies, provided that AcelRx shall have no obligations under this Agreement to assist with the technical aspects of the creation and maintenance of such website or to provide such digital content in any particular format.

3.9 Territory Compliance. Aguettant shall not, and shall ensure its Affiliates, Distributors and Sublicensees do not: (i) directly or indirectly, promote, sell or distribute the Product outside the Field in the Territory, or (ii) actively promote, sell or distribute the Product for any use outside the Territory, which other territories are exclusively reserved to AcelRx or its licensees.

ARTICLE 4

FURTHER DEVELOPMENT AND REGULATORY ACTIVITIES

4.1 Further Development.

(a) **AcelRx Responsibilities**. AcelRx shall be responsible for all CMC and Manufacturing activities, and provide all data related thereto, to the extent necessary to support any updates or any new filings or MA variations required for submission by Aguettant to the Regulatory Authorities. For the avoidance of doubt, the MA variations in relation to (i) the switch of lines in the Manufacturing process at AcelRx's subcontractor and (ii) the addition of the new Manufacturing process of the active pharmaceutical ingredient shall be under the responsibility, and at the cost and expense, of AcelRx. AcelRx shall, at its own expense, cooperate with Aguettant in connection with all activities conducted by Aguettant under Section 4.1(b), provided that Aguettant shall remain fully responsible for such activities and shall carry the burden of such activities, the cooperation of AcelRx being limited to reasonable support and assistance throughout the registration process, pricing and reimbursement. AcelRx shall be responsible for any variations outside the Field in the Territory or outside the Territory, and for any variations it has decided to conduct; all costs and expenses pertaining thereto shall consequently be borne by AcelRx. AcelRx undertakes to transfer any necessary methods related to quality control to Aguettant's laboratory, [***] within [***] following the Effective Date. AcelRx will support the transfer of the remaining quality control methods to Aguettant upon Aguettant's reasonable request [***] in the event such transfer would be necessary in Aguettant's opinion. For avoidance of doubt, any personnel support from AcelRx stays at AcelRx's charge.

(b) **Aguettant Responsibilities**. Aguettant shall (i) conduct all further Development activities for the Product in the Territory that are not expressly the responsibility of AcelRx under Section 4.1(a), (ii) be responsible for market access activities in the Territory, and shall pay related costs specific to the Territory, and shall fulfill responsibilities in support of the foregoing, including: Post-Approval Commitments required by Regulatory Authorities; language translations; design and any approval required by Regulatory Authorities of the final artwork and packaging material, including labels, stickers, leaflets and carton boxes (collectively, the "**Final Artwork**"), in local language; commercial batch release; management of communications and interactions with the local Regulatory Authorities; and reformatting of the Core Pharmaceutical Dossier to support any and all Regulatory Filings, including submission of an MAA to Swissmedic; with AcelRx's reasonable support and assistance throughout the registration process, pricing and reimbursement.

(c) **Access to Development results**. AcelRx shall have, for the Term of this Agreement, the irrevocable, sublicensable right to use, worldwide and on a royalty-free basis, in connection with the Development, Manufacturing and Commercialization of products by AcelRx, its Affiliates or its or their sublicensees, all Marketing Authorizations and all data (including safety and efficacy data, clinical data package, and data related to drug formulation and method of administration) that are generated by Aguettant in connection with the Development of the Product, and Aguettant shall update AcelRx of and shall provide AcelRx with any such Development results at least on an annual basis. The Parties shall determine the process for exchange of such Development results through the JSC.

4.2 Conduct of Development Activities.

(a) **Compliance**. Each Party shall conduct, and in Aguettant's case, shall ensure that all of its Affiliates, Sublicensees and other subcontractors conduct, the Development activities for which it is the responsible Party (i) in accordance with the terms and conditions of this Agreement, and (ii) in compliance in all material respects with all Applicable Laws (including GMP, GLP and GCP, if applicable) applicable in the country in which such activities are conducted.

(b) **Information Regarding Development Activities**. Each Party shall maintain records, in sufficient detail and in good scientific manner appropriate for patent, quality, compliance and regulatory purposes, which shall fully and properly reflect all work done and results achieved by or on behalf of such Party in the performance of its Development activities under this Agreement. Each Party shall keep the Joint Steering Committee appropriately informed of the status of the Development activities and other activities with respect to the Product in the Field in the Territory.

4.3 Regulatory Information; Right of Reference.

(a) **Dossier Information**. Upon Aguettant's reasonable request, AcelRx shall provide to Aguettant any previously generated pre-clinical, clinical and CMC data in the AcelRx Know-How necessary to any new filing or to support and maintain Regulatory Approvals in the Field in the Territory and to Commercialize the Product in the Field in the Territory, provided that CMC data from the closed part of the drug master file shall be provided to Aguettant through a letter of access by which Regulatory Authorities may directly rely on such CMC data that shall remain at AcelRx or any of its subcontractors.

(b) **Right of Reference**. To the extent Controlled by a Party, the other Party shall have the right to (i) cross-reference the Regulatory Approvals and other regulatory documentation specifically related to the Products, (ii) access such Regulatory Approvals and regulatory documentation and any information therein, and (iii) use such information, in each case in connection with the performance of its obligations and exercise of its rights under this Agreement or, in the case of AcelRx, (aa) its development and commercialization of products outside the Field or the Territory or (bb) in case Aguettant elects not to sublicense in the Dental Field, for Commercialization of the Products in the Dental Field in the Territory. Each Party hereby grants to the other Party a "right of reference" (as that term is defined in 21 C.F.R. § 314.3(b) in the United States), or an equivalent right of access/reference in any other jurisdiction, to any data Controlled by such Party, including any Party's Regulatory Approvals and regulatory documentation, that specifically relate to a Product for use by the other Party as may be necessary to Develop Products for Commercialization by Aguettant in the Territory pursuant to this Agreement or, in the case of AcelRx, (aa) also outside the Territory or (bb) in case Aguettant elects not to sublicense in the Dental Field, for Commercialization of the Products in the Dental Field in the Territory. Each Party shall, or shall cause its Affiliates to, provide a signed statement to this effect, if requested by the other Party, in accordance with 21 C.F.R. § 314.50(g)(3) or the equivalent as required in any other jurisdiction or otherwise provide appropriate notification of such right to the applicable Regulatory Authority. For clarity, access to and copies and use of any of the Regulatory Approvals, regulatory documentation and any information therein shall be subject to the terms and conditions of any agreement with a licensee or sublicensee of a Party providing access or right of reference pursuant to this Section 4.3; provided that Aguettant shall ensure that each Sublicensee provides the applicable rights to Aguettant so that Aguettant may grant such rights to AcelRx under this Section 4.3.

4.4 Global Dossier. As between the Parties and notwithstanding anything to the contrary provided in this Agreement, AcelRx shall retain the full unfettered ownership of the Core Pharmaceutical Dossier.

ARTICLE 5

MANUFACTURE AND SUPPLY; QUALITY

5.1 Supply and Purchase of the Product.

(a) **Responsibility for Manufacturing**. Except as may otherwise be agreed in writing by the Parties or in the Supply Agreement, AcelRx shall Manufacture and supply Products in the form of Bulk Products to Aguettant, or its Affiliates or Sublicensees, for Commercialization in the Territory, provided that sufficient DEA quota is available. AcelRx shall be responsible for obtaining the DEA quota. Aguettant shall be responsible for Fill and Finishing. AcelRx shall conduct quality control testing and quality assurance release, in compliance with the European MA, for Bulk Products at Aguettant's cost and expense. The current costs for quality release for Bulk Product are set out in Exhibit 5.1(a), which may be amended from time to time by AcelRx. Aguettant, or its designated vendors, shall conduct final EU testing and Qualified Person release for Finished Products. In the event that Aguettant designates a testing and release facility different from the one named in the Marketing Authorization, AcelRx shall support method transfer activities at Aguettant's sole cost and expense. Aguettant shall, and shall ensure that all of its Affiliates, Sublicensees and other subcontractors, Fill and Finish using Commercially Reasonable Efforts in compliance with all Applicable Laws applicable in the country in which such activities are conducted.

(b) **Commercial Supply**. Within [***] after the Effective Date, the Parties shall enter into a supply agreement for the commercial supply by AcelRx of the Products to Aguettant (such agreement, the "**Supply Agreement**"), which shall be consistent with the terms and conditions of the Agreement. Aguettant shall purchase the Products exclusively from AcelRx. AcelRx shall supply the Product in the Territory exclusively to Aguettant. AcelRx shall supply the Product to Aguettant at a price of USD [***] per Unit from the Effective Date until the last day in MY 3 and of USD [***] per Unit for MY 4 and thereafter (each, a "**Supply Price**") FCA (Incoterms 2020) at the dock of the 3PL.

(c) **Adjustment of Supply Price**. Provided that AcelRx can provide written documentation that the average variable cost per Unit charged to AcelRx by its suppliers (the "**Unit Cost**") exceeds the applicable Supply Price in any Calendar Quarter, the Supply Price shall be adjusted to be the Unit Cost (the "**Adjusted Supply Price**") effective as of the acceptance by AcelRx of the next order of Aguettant delivered to AcelRx after the date that such written documentation is delivered to Aguettant. Notwithstanding the foregoing [***].

(d) **Cure Period**. AcelRx shall notify Aguettant as soon as reasonably possible after it becomes aware that [***] in such Calendar Quarter. The Parties shall have [***] upon such notice by AcelRx (the "**Cure Period**") to work together diligently and in good faith to cure the situation in such a way as to make continuing performance under the Agreement economically feasible for both Parties. During the Cure Period, the Adjusted Supply Price shall be [***].

(e) **Minimum Batch Size**. The minimum batch size shall be [***] Units (the "**Minimum Batch Size**"), provided that the Minimum Batch Size may be [***] Units until the Manufacturing Line Change Approval. Each order of the Product by Aguettant shall be for one (1) or a multiple of the Minimum Batch Size.

5.2 Forecast and Orders.

(a) **Initial Forecast**. Upon execution of the Agreement, Aguettant shall provide to AcelRx a written [***] forecast of its expected orders of Products in the Territory.

(b) **Rolling Forecast**. Within the first [***] of every calendar month following the Effective Date, Aguettant shall provide a rolling non-binding forecast. Such forecast shall specify quantities of Products for which Aguettant reasonably expects to submit orders in each calendar month during the following [***] months.

(c) **Orders**. The first [***] of each rolling forecast shall be binding and the balance of each forecast will constitute a non-binding good faith estimate of expected orders for Products, provided that for the further [***] of each rolling forecast (i.e., months [***]), Aguettant shall place at the minimum binding purchase orders with AcelRx for quantities of Products of [***]% of the non-binding forecasts. The first non-binding forecast for a specific calendar month shall be decisive for this threshold for the applicable month. As of the Manufacturing Line Change Approval, AcelRx shall use Commercially Reasonable Efforts to meet demand by Aguettant up to [***]% of the forecasted quantity for the applicable calendar month following the binding [***] period.

(d) **Order Frequency**. Aguettant shall place not more than [***].

5.3 Delivery. AcelRx shall deliver Products to Aguettant by making them available for pick-up at the dock of the 3PL: (a) for the first order no later than [***] after both a delivery date is agreed upon between the Parties and there is an order confirmation by AcelRx, provided that the Parties have mutually approved the Final Artwork; and (b) for orders following the first order no later than [***] after both a delivery date is agreed upon between the Parties and there is an order confirmation by AcelRx (the respective agreed date for such [***] period, a "**Requested Delivery Date**"), provided that the Requested Delivery Date shall be amended on a case-by-case basis following good faith discussions between the Parties to take into account long lead times for export and import permits for narcotics, if applicable. AcelRx may deliver the Product [***] in advance of standard lead time, provided that Aguettant accepts such early delivery before any shipping from AcelRx. AcelRx shall not deliver later than the Requested Delivery Date. AcelRx shall deliver to Aguettant Products with, at minimum, [***] remaining of the three (3)-year shelf life. Once a four (4)-year shelf life is approved in the Territory, AcelRx shall deliver to Aguettant Products with a minimum of [***] of shelf life remaining. Aguettant shall: (i) obtain import permits into the EU; (ii) coordinate with the 3PL to obtain matching export permits; and (iii) bear all costs associated with freight, transportation and shipping except for such costs incurred before AcelRx makes Products available for pick-up at the dock of the 3PL, which costs shall be borne by AcelRx. Any responsibility for the delivery of Products shall transfer from AcelRx to Aguettant upon AcelRx making Products available for pick-up at the dock of the 3PL. Without limiting the foregoing, in the event AcelRx selects a new 3PL, which selection results in an increase of more than [***] in the transportation and insurance costs for the shipment of Products from the dock of the 3PL to Aguettant's premises, as demonstrated by contemporary written documentation, AcelRx and Aguettant shall renegotiate in good faith the financial terms under this Agreement solely with respect to such increase in the transportation and insurance costs.

5.4 Collaborative Efforts. AcelRx and Aguettant shall collaborate (i) to optimize the number of languages included on packaging to minimize the number of different packaging formats required, and (ii) to ensure that regional SKU's codes, instead of country codes, are created as much as possible and where approved by the local Regulatory Authorities.

5.5 Annual Minimum Sales.

(a) **Minimum Sales Obligations**. Aguettant shall achieve levels of minimum sales after MY 2 as set forth in Exhibit 5.5 (the "**Minimum Sales Obligations**"). [***] At the end of MY 2, the Parties shall discuss, through the JSC, and state new binding Minimum Sales Obligations, and amend the Agreement accordingly. Subject to AcelRx's ability to supply Products in conformity with the Requested Delivery Date and/or in sufficient quantity due to DEA quotas, Aguettant shall make Commercially Reasonable Efforts, starting from the local MA delivery, throughout the Launch and Commercialization phases, to create the Product DZUVEO® market within the current severe to moderate pain management market in the Field in the Territory so as to reach the Minimum Sales Obligation for MY 5 set forth in Exhibit 5.5.

(b) **Failure to Meet Obligations**. In the event of any Failure by Aguettant in any MY after the Line Change MY or MY 2, whichever is later, the Parties shall meet in order to assess the reasons for such Failure and decide a recovery plan. [***] Aguettant shall apply such recovery plan and deploy it within the timeline agreed in such recovery plan. The Parties may decide in JSC, or after a decision regarding a recovery plan, to amend the Minimum Sales Obligations retroactively. In the event of Failure by Aguettant in two consecutive MYs after the Line Change MY or MY 2, whichever is later, or in the event that Aguettant fails to apply the agreed recovery plan, AcelRx has the right to terminate the Agreement as set forth in Section 13.3(b).

ARTICLE 6

QUALITY AND PHARMACOVIGILANCE

6.1 Quality Agreement. Upon execution of the Agreement, the Parties shall use best efforts to sign a quality agreement (the "**Quality Agreement**") to comply with the requirements of Regulatory Authorities in the Territory affecting each Party, and, to the extent necessary, each country within the Territory hereunder, as soon as possible. No later than [***] after the Effective Date, the Parties shall enter into the Quality Agreement, setting forth in detail the Specifications and customary representations and warranties with respect to the Product, including quality assurance arrangements and procedures with respect to the Manufacturing and supply of the Product, reporting customer complaints, conducting timely investigations, Recalls, logistics (including warehousing and shipping requirements) and testing requirements, which Quality Agreement shall be incorporated herein by reference following execution by both Parties. In the event of a conflict between any of the provisions of this Agreement or the Supply Agreement and the Quality Agreement, this Agreement or the Supply Agreement, as applicable, shall govern.

6.2 Record retention. Aguettant shall establish and maintain a written records retention policy with respect to the Products, including maintaining quality system documents in a central, controlled location and using Commercially Reasonable Efforts to prevent any loss, destruction, deterioration or unauthorized access to such documents. Aguettant shall, for a period of the Term and [***] years thereafter (or such longer period as required by Applicable Laws) retain original documents with original signatures in a central file within Aguettant's quality assurance or document control records.

6.3 Stability Testing and Quality Reports. Upon execution of the Agreement, AcelRx shall conduct [***] stability testing [***] and provide to Aguettant [***] quality review reports of the Product and the stability data thereof concerning: (i) long-term real-time stability data; (ii) accelerated stability data, if required by Regulatory Authorities, to support MA variations for Product changes or improvements; (iii) excursion temperature stability data; (iv) any other stability data generated by AcelRx for the Core Pharmaceutical Dossiers and on commercial batches of the Product in the Field in the Territory; and (v) any other excursion stability data, i.e., low temperature if available (vi) if necessary, excursion temperature stability data after the Product is exposed to 60°C for three (3) days until the end of its shelf life at Aguettant's cost and expense. The current costs for stability testing are set out in Exhibit 6.3, which may be amended by AcelRx from time to time. Any quality failure to GMP (critical and / or major) and / or any information which could affect and / or impact the effective status of the Core Pharmaceutical Dossier in Europe has to be shared with Aguettant within [***].

6.4 Audit. As soon as possible, and not later than [***] from the Effective Date, the AcelRx Qualified Person shall conduct an audit of AcelRx's contract manufacturers, and use Commercially Reasonable Efforts to include the Aguettant Qualified Person in such audit. In any event, Aguettant shall receive the audit report of that audit. Should that audit report reveal major findings that threaten the timely supply of Product to the European Union, AcelRx shall use Commercially Reasonable Efforts to rectify these findings as soon as reasonably possible in a reasonable period of time to ensure such timely supply.

6.5 Pharmacovigilance; Safety Data.

(a) **Pharmacovigilance**. Upon execution of the Agreement, the Parties shall use best efforts to sign a pharmacovigilance agreement (the "**Pharmacovigilance Agreement**") to comply with the requirements of Regulatory Authorities in the Territory affecting each Party, and, to the extent necessary, each country within the Territory hereunder, as soon as possible. No later than [***] after the Effective Date, the Parties shall enter into the Pharmacovigilance Agreement setting forth the specific details and processes pursuant to which the Parties shall share adverse event, device incident and other safety data, which agreement shall include those terms required by ICH guidelines.

(b) Aguettant shall be solely responsible for Pharmacovigilance of the product in the Territory included by not limited to all safety review, collection, reporting to appropriate authorities, and timely transfer to AcelRx of safety data for the Product in the Field in the Territory. Aguettant shall transfer such safety data to AcelRx in a timely manner in an electronic format agreed by both Parties as further set out in the Pharmacovigilance Agreement, at Aguettant's sole cost and expense.

6.6 Complaints Handling and Reporting.

(a) Notifications, communications, handling and reporting of the Product complaints and adverse events shall be addressed by the Pharmacovigilance Agreement.

(b) Notifications, communications, handling and reporting of the Product complaints that relate to the Manufacturing of the Product shall be addressed by the Quality Agreement. The Quality Agreement shall provide a right for Aguettant to access AcelRx's premises and to audit the Manufacturing facilities in order to conduct research and investigation to determine causes.

6.7 Returns and Recalls.

(a) **Returns**. Aguettant shall handle all returns, at its sole cost and expense, as needed. Unless the Parties agree otherwise, Aguettant shall only allow returns in customary conditions (e.g., a defect in the Product, Product not produced as specified) or due to a safety regulatory decision in any country of the Territory. Further processing of returns by Aguettant shall be governed by the Quality Agreement.

(b) **Recalls**. Each Party agrees to notify the other Party within [***] if it discovers any issue that it reasonably believes could lead to a Recall. If practicable, the Parties shall promptly, following notification, discuss the plans for a Recall, provided that the Parties shall have joint responsibility for determining whether a Recall in the Territory is necessary. If the Parties, through the JSC, decide that a Recall is necessary, the Parties shall work together to develop and implement a Recall plan, which, unless agreed otherwise, shall be implemented by Aguettant. All costs and expenses associated with implementing a Recall in the Territory shall be borne by Aguettant, except to the extent it arises from AcelRx's failure to supply the Products in accordance with the Specifications or to transport the Products to the dock of the 3PL in accordance with Section 5.3. The Parties shall jointly determine the cause of a Recall, or in the event of disagreement between the Parties regarding such cause, an independent laboratory mutually agreed upon by the Parties shall determine such cause.

(c) **Costs**. For clarity, if a return or a Recall is due to AcelRx's failure to supply the Products in accordance with Specifications or to transport the Products to the dock of the 3PL in accordance with Section 5.3, AcelRx shall bear all costs and expenses which directly result from such return, Recall, or potential destruction of Products.

ARTICLE 7

GOVERNANCE

7.1 Joint Steering Committee. Within [***] following the Effective Date, the Parties shall establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**") to oversee matters related to the Development, Manufacturing and Commercialization of the Product in the Field in the Territory, including Regulatory Strategy, marketing, reimbursement, sales and revenue targets, and scientific and market access matters.

(a) **Composition**. The JSC shall consist of individuals appropriately qualified and of appropriate seniority and having decision-making authority to discuss and make decisions with respect to the Development, Manufacturing and Commercialization of Products in the Field in the Territory and shall be responsible for coordinating communications and managing the roles, responsibilities and timelines for such activities. The Joint Steering Committee shall be composed of four (4) members, two (2) of whom shall be nominated by AcelRx and two (2) of whom shall be nominated by Aguettant. Any member of the Joint Steering Committee may designate an appropriately qualified substitute to attend and perform the functions of that member at any meeting of the Joint Steering Committee. Each Party may, with the consent of the other Party, which consent shall not be unreasonably withheld or delayed, invite non-member representatives of such Party to attend meetings of the Joint Steering Committee.

(b) **Duties**. The Joint Steering Committee shall:

(i) discuss and align on Regulatory Strategy for Products;

(ii) review each Commercialization Plan and Commercialization Strategy in the Territory (on a country-by-country basis), including all updates and amendments thereto, including for the purpose of alignment with AcelRx's global commercialization strategy for Products, including any modification of branding of the Products in the Territory;

(iii) discuss and approve all Development of the Product in the Field in the Territory, including all Post-Approval Commitments and Post-Marketing Studies, including any investigator-sponsored trials, and approve the protocol, enrollment criteria and endpoints of each such study;

(iv) exchange information with regard to Development results achieved by either Party relating to the Product in the Field;

(v) exchange information with respect to pre-Launch, Launch and subsequent Commercialization activities with respect to the Product in the Territory;

(vi) recommend to the Parties for approval any extension of the Territory, which extension would be implemented by amendment to this Agreement;

(vii) discuss pricing in countries in the Territory relative to countries outside the Territory;

(viii) approve any Recall or termination of Commercialization of any Product in any country in the Territory, and discuss any cause for Product defects or any complaints;

(ix) perform such other duties as are specifically assigned by the Parties to the Joint Steering Committee pursuant to this Agreement or otherwise in writing;

(x) discuss any litigation in relation to the AcelRx IP in the Territory; and

(xi) be the first forum for resolution of material disputes between the Parties under this Agreement.

The JSC shall have only the powers expressly assigned to it in this Section 7.1(b) and elsewhere in this Agreement, and shall have no power to amend, modify, or waive compliance with this Agreement. For clarity, (A) the JSC is not responsible for tactical and operational matters relating to the Commercialization of the Product in the Field in the Territory, which are Aguettant's responsibility, and (B) each Party shall maintain final decision-making authority over specific areas related to the Product as set forth expressly herein.

(c) **JSC Decision-Making**. The JSC shall act by consensus, and shall use reasonable efforts to reach consensus on all matters within its scope of responsibility. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party. If the JSC cannot reach consensus on an issue that comes before the JSC and over which the JSC has oversight, then the issue will be determined in accordance with Section 7.3.

(d) **JSC Meetings**. Joint Steering Committee meetings will be held as often as the members may determine, but at least twice per Calendar Year. Such meetings may be held in person, or by any means of telecommunications or video conference, as the members deem necessary or appropriate.

(e) **Minutes**. Minutes for each Joint Steering Committee meeting shall be prepared by an Aguettant or an AcelRx member of the Joint Steering Committee on an alternating basis. The draft minutes shall be sent to all members of the Joint Steering Committee for comment promptly after each such meeting (but in no event more than [***] days after each such meeting). All actions noted in the minutes shall be reviewed and approved at subsequent meetings of the Joint Steering Committee; provided that if the Parties cannot agree as to the content of the minutes by the time the Joint Steering Committee next meets, such minutes shall be finalized to reflect any areas of disagreement.

(f) **Expenses**. Each Party shall bear its own costs and expenses incurred by its members in connection with their activities as members of the Joint Steering Committee.

(g) **Subcommittees**. From time to time, the Joint Steering Committee may establish subcommittees to oversee particular projects or activities within the scope of authority of the Joint Steering Committee, as it deems necessary or advisable. Each subcommittee shall consist of such number of representatives of each Party as the Joint Steering Committee determines is appropriate from time to time and shall meet with such frequency as the Joint Steering Committee shall determine.

7.2 Alliance Managers. Each of AcelRx and Aguettant shall appoint one senior representative who possesses a general understanding of clinical, regulatory, manufacturing and marketing issues to act as its respective alliance manager for this relationship (each, an "**Alliance Manager**"). Each Party may appoint and replace its respective Alliance Manager at any time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment between the Parties. Each Alliance Manager will also be responsible for: (a) coordinating the relevant functional representatives of the Parties, in developing and executing strategies and plans for the Product; (b) providing a single point of communication for seeking consensus both internally within the respective Party's organization and together regarding key strategy and plan issues, including where all questions coming up will be channeled, where joint timelines, budget and capacity requirement are aligned; and (c) planning and coordinating: (i) collaboration efforts, (ii) the establishment of new work streams proactively at each Party, and (iii) internal and external communications. The Alliance Managers shall be entitled to attend meetings of the JSC and of any subcommittee, but shall not have, or be deemed to have, any rights or responsibilities of a member of the JSC or subcommittee unless formally appointed to such committees. Each Alliance Manager may bring any matter to the attention of the JSC or subcommittee when such Alliance Manager reasonably believes that such matter requires such attention.

7.3 Dispute Resolution. In the event that any subcommittee or the JSC is unable to reach a consensus or a dispute otherwise arises in such subcommittee or the JSC, then either Party may initiate the initial dispute resolution process in this Section 7.3 by providing written notice to the other Party identifying the particular dispute (the "**Dispute Notice**"). If any subcommittee is unable to resolve the dispute at the subcommittee level within [***] following the receipt of the Dispute Notice, then the dispute shall be referred to the Joint Steering Committee for resolution. If the Joint Steering Committee is unable to resolve any dispute that either (a) arises at the JSC level and is identified by a Party by a Dispute Notice or (b) is referred to it by a subcommittee pursuant to the preceding sentence, in each case, within [***] after a Party's receipt of written notice or the date of the referral, as applicable, then either Party may, by written notice to the other Party, have such dispute referred to the Senior Executives in accordance with Section 14.12, and such dispute shall thereafter be handled in accordance with Section 14.12.

7.4 Discontinuation of Participation. The Joint Steering Committee (and any subcommittee established under this Article 7) shall continue to exist until the first to occur of: (a) the Parties mutually agreeing to disband the committee; or (b) AcelRx providing to Aguettant written notice of its intention to disband and no longer participate in such committee at any time during the Term. Once AcelRx has provided such written notice, AcelRx shall have no further obligations under this Agreement with respect to any such committee or subcommittee, and (i) any matters that would previously have been addressed by a subcommittee will be handled by the JSC, and (ii) any matters that would previously have been addressed by the JSC will be handled by the Parties in accordance with the terms of this Agreement, except that Aguettant will have the right to decide all matters previously decided by the JSC.

ARTICLE 8

PAYMENTS AND RECORDS

8.1 In consideration of the rights and licenses granted to Aguettant by AcelRx hereunder, Aguettant shall pay to AcelRx the amounts set forth in this Article 8.

8.2 Supply Cost Payment. Aguettant shall place its Product purchase orders, which orders shall not be cancelled or modified once placed, to AcelRx and, within [***] upon receipt of invoice, pay to AcelRx an amount equal to the total number of Units AcelRx supplied to Aguettant, in the course of the applicable period, multiplied by the applicable Supply Price, or the Adjusted Supply Price, if applicable, that is effective on the date the purchase order is accepted by AcelRx ("**Supply Cost Payment**"). For clarity, the applicable Supply Price, or the Adjusted Supply Price, if applicable, shall be the minimum price to be paid by Aguettant to AcelRx for any Unit of the Product. AcelRx shall only provide an invoice to Aguettant after AcelRx makes Products available in accordance with Section 5.3.

8.3 Transfer Price Adjustment Payment.

(a) **Quarterly Sales Report**. No later than [***] after each Calendar Quarter, Aguettant shall send AcelRx an aggregated report of Net Sales in such Calendar Quarter, on a Product-by-Product and country-by-country basis, at Aguettant's cost.

(b) **Transfer Price**. For [***], the transfer price shall be an amount equal to thirty-five percent (35%) of Net Sales in the applicable period (the "**Transfer Price**"). From [***] and thereafter, the Transfer Price shall be an amount equal to forty-five percent (45%) of Net Sales in the applicable period. Without limiting the foregoing, the effective per Unit Transfer Price shall be the higher of (i) USD [***] in MYs 1 through 3, and USD [***] in MY 4 and thereafter or (ii) the quotient obtained by dividing the Transfer Price (the Euro amount being converted, for purposes of the comparison and calculation, to USD in accordance with Section 8.5) by the total number of Units used to calculate the Net Sales applicable to such Transfer Price (such higher price, the "**Effective Per Unit Transfer Price**").

(c) **Adjustment Payment**. After the end of each Calendar Quarter within a MY, within [***] after Aguettant has received a corresponding invoice from AcelRx, Aguettant shall pay to AcelRx an adjustment calculated based on the quantity of Units as used to calculate the Net Sales in such Calendar Quarter multiplied by [***] which shall apply to the quantity of Units supplied by AcelRx to Aguettant thereunder on a first-in first-out basis, [***] which shall apply to Units beyond the quantity of Units supplied by AcelRx to Aguettant under the immediately preceding Supply Price or Adjusted Supply Price (as applicable) on a first-in first-out basis. [***].

8.4 Milestone Payments. Aguettant shall pay to AcelRx one-time, non-refundable (except as otherwise provided in this Agreement), and non-creditable milestone payments not subject to set-off (i) in the amount of two million five hundred thousand Euro (EUR 2,500,000) within [***] as of the Effective Date and (ii) the first time that Net Sales in a MY reach the sales milestone threshold levels set forth in Exhibit 8.4 (the "**Sales Milestone Threshold**"), within [***] after the end of such MY. For the avoidance of doubt, should more than one Sales Milestone Threshold be met within the same MY, all related Sales Milestones become due cumulatively, but only once. The invoice shall be in Euros. The applicable currency conversion rate mentioned in Section 8.5 shall be the one prevailing on December 31 of such MY.

8.5 Mode of Payment. All payments under the Agreement shall be made in Dollars by bank wire transfer in immediately available funds to an account in the name of AcelRx as AcelRx may designate from time to time by written notice to Aguettant, or in the name of Aguettant as Aguettant may designate from time to time by written notice to AcelRx. Except as otherwise provided in Section 8.4, if any currency conversion shall be required in connection with the amounts hereunder, such conversion shall be made by using the currency conversion rate prevailing at the European Central Bank on the last Business Day of the Calendar Quarter reporting period to which such payments relate.

8.6 Taxes.

(a) **Cooperation and Coordination**. The Parties acknowledge and agree that they shall use their reasonable efforts to cooperate and inform each other for the purpose of facilitating income and other tax payments in relation to their activities under the Agreement.

(b) **Payment of Tax**. A Party receiving a payment shall pay any and all taxes levied on such payment. If the fiscal or taxing authorities of any relevant jurisdiction assert that amounts are required to be withheld from the payments due to a Party hereunder, or the tax laws in one or more jurisdictions have changed so as to explicitly require such treatment, the Party made aware of such assertion or change in law shall inform the other Party within [***] and shall consult with the other Party regarding the consequences of such assertion or change. If Applicable Laws require that taxes be deducted and withheld from a payment, the remitting Party shall (i) deduct those taxes from the payment, (ii) pay the taxes to the proper taxing authority, (iii) send evidence of the obligation together with proof of payment to the other Party within [***] days following that payment, and (iv) provide such assistance as the other Party may reasonably require in obtaining any refund of such amounts to which the other Party may be entitled, to the extent that such assistance does not cause the remitting Party to incur any liability in respect of the taxes asserted to be due. Notwithstanding the foregoing, if Aguettant takes any action (including sublicensing its rights hereunder) that would create or cause an increase in withholding liability, above the withholding required prior to such action, then Aguettant will be responsible for paying any amounts resulting from such increase. All payments made under this Agreement are net prices and shall be free and clear of any and all taxes (like sales and use taxes, consumption taxes, goods and sale taxes or value-added taxes or comparable taxes), duties, levies, fees or other charges, applicable to the concerned Party under Applicable Laws, except for withholding taxes.

8.7 Records. Aguettant shall keep, and require its Affiliates, Sublicensees and Distributors to keep, complete, true and accurate books of accounts and records for the purpose of determining the amounts payable to AcelRx pursuant to this Agreement. Such books and records shall be kept for such period of time as required by law, but no less than [***] following the end of the Calendar Quarter to which they pertain. Such records shall be subject to audit by AcelRx in accordance with Section 8.8.

8.8 Audits. AcelRx, at its expense, through an independent, internationally recognized certified public accountant reasonably acceptable to Aguettant, shall have the right to access Aguettant's relevant books and records in relation to the sales of Products in the Field in the Territory for the sole purpose of verifying Aguettant's payments to AcelRx hereunder during any portion of the Term; such access shall be conducted after [***] prior notice by AcelRx to Aguettant during Aguettant's ordinary business hours, shall not be more frequent than [***] during any Calendar Year and shall not include any books and records that were previously accessed pursuant to this Section 8.8. Such accountant shall execute a confidentiality agreement with Aguettant in customary form and shall only disclose to AcelRx whether Aguettant paid AcelRx the correct amounts during the audit period and if not, any information necessary to explain the source of the discrepancy. If such audit determines that Aguettant paid AcelRx less than the amount properly due, then Aguettant shall pay AcelRx within [***] after conclusion of the audit an amount equal to such underpayment, along with interest under Section 8.9, and if the amount underpaid exceeds [***] of the amount due over the audited period, Aguettant shall also reimburse AcelRx for the reasonable costs of such audit (including the fees and expenses of the certified public accountant). If such audit determines that Aguettant paid AcelRx more than the amount properly due, then Aguettant shall be entitled to credit such overpayment against future payments due to AcelRx; provided, however, that if no future payments to AcelRx hereunder are reasonably anticipated, then AcelRx shall promptly issue a refund to Aguettant of such overpayment.

8.9 Late Payment. Any amounts not paid by the date due under the Agreement shall be subject to interest of [***] from the due date through and including the date upon which payment is received.

ARTICLE 9

INTELLECTUAL PROPERTY

9.1 Ownership of Intellectual Property.

(a) **Background IP**. Subject to the licenses and other rights expressly granted herein, each Party shall retain all right, title and interest in and to its Background Intellectual Property.

(b) **Product Improvements**. AcelRx shall solely own all right, title, and interest in and to the Product Improvements. Aguettant agrees to assign and hereby assigns and transfers to AcelRx all of its right, title and interest in and to the Product Improvements and agrees to take, and to cause its Affiliates, Sublicensees and its or their employees and agents to take, all further acts reasonably required to evidence such assignment and transfer to AcelRx, at AcelRx's reasonable expense. Aguettant hereby appoints AcelRx as its attorney-in-fact to sign such documents as AcelRx deems necessary for AcelRx to obtain ownership and to apply for, secure, and maintain patent or other proprietary protection of the Product Improvements if AcelRx is unable, after reasonable inquiry, to obtain Aguettant's (or its employee's or agent's) signature on such a document. Aguettant shall notify AcelRx in writing of any and all Product Improvements generated or reduced to practice by or on behalf of Aguettant or its Affiliates, promptly after each such Product Improvement is made or generated. For clarity, the Product Improvements shall be automatically incorporated in the definition of the AcelRx Patents and AcelRx Know-How. Aguettant shall ensure that each individual and entity conducting any activities under this Agreement on its behalf is under written obligation to assign all right, title and interest in and to the Product Improvements to Aguettant.

9.2 Prosecution and Maintenance. AcelRx shall be solely responsible for the preparation, filing, prosecution and maintenance of the AcelRx IP using counsel of its choice. AcelRx shall keep Aguettant informed of any material events or progress with regard to the preparation, filing, prosecution and maintenance of the AcelRx IP.

9.3 Infringement by Third Parties and Defense.

(a) **Monitoring**. Aguettant shall use Commercially Reasonable Efforts to monitor Third Party infringement of the AcelRx Patents in the Territory. Aguettant shall keep AcelRx timely informed of any activities by Aguettant in regard thereto.

(b) **Notice**. In the event that either AcelRx or Aguettant becomes aware of any infringement or threatened infringement by a Third Party of any AcelRx IP, it will notify the other Party in writing to that effect. Any such notice shall include evidence to support an allegation of infringement or threatened infringement by such Third Party.

(c) **Enforcement and Defense of AcelRx IP**. As between the Parties, AcelRx shall have the sole right to enforce and defend the AcelRx IP, including initiating, conducting, defending and managing any declaratory judgment action or infringement action (collectively, "**IP Adversarial Actions**") during the Term. Aguettant shall provide AcelRx with all reasonable assistance and cooperation in initiating, conducting or defending against any such IP Adversarial Action, including joining in any such IP Adversarial Action, at AcelRx's reasonable request and reasonable expense, provided that AcelRx shall at all times have full control over such IP Adversarial Action. Except as otherwise agreed to by the Parties in writing as part of a cost-sharing arrangement, any sums recovered or obtained in connection with a IP Adversarial Action shall be used first to reimburse the Parties' documented out-of-pocket legal expenses relating to such IP Adversarial Action on a pro-rata basis, and any remaining sums shall be retained by AcelRx, provided that if Aguettant joins in such IP Adversarial Action at its sole cost and expense, any remaining sums shall be divided between the Parties on such pro-rata basis.

9.4 Third Party Rights. Each Party shall promptly notify the other in writing of any allegation by a Third Party that the activity of either Party pursuant to this Agreement infringes or may infringe the intellectual property rights of such Third Party. Article 12 applies to the defense against such allegations.

9.5 Brand Name. If and wherever Regulatory Authorities in the Territory do not permit promotion under the Brand Name, AcelRx shall use Commercially Reasonable Efforts to provide an alternative brand name or trademark, registered and maintained at its cost, to Aguettant, which shall become part of the AcelRx IP. In such event, Aguettant shall Commercialize the Product under such new brand name or trademark.

ARTICLE 10

CONFIDENTIALITY

10.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, during the Term and [***] years thereafter, the receiving Party (the "**Receiving Party**") shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any confidential or proprietary information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, visual or otherwise) which are disclosed to it by the other Party (the "**Disclosing Party**"), including all information concerning the Product and all information disclosed by one Party to the other pursuant to the Confidentiality Agreement and any other technical or business information of whatever nature (collectively, "**Confidential Information**").

10.2 Exceptions. Notwithstanding Section 10.1 above, the Receiving Party's obligations of confidentiality and non-use shall not apply to Confidential Information of the Disclosing Party that, in each case, the Receiving Party can demonstrate by competent evidence:

(a) was already known to the Receiving Party or any of its Affiliates, other than under an obligation of confidentiality, at the time of disclosure;

(b) was generally available to the public or was otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure by the Disclosing Party and other than through any act or omission of the Receiving Party or any of its Affiliates in breach of this Agreement;

(d) was subsequently lawfully disclosed to the Receiving Party or any of its Affiliates by a Person other than the Disclosing Party, and who, to the knowledge of the Receiving Party, did not receive such information directly or indirectly from the Disclosing Party under an obligation of confidence; or

(e) was independently developed by the Receiving Party or any of its Affiliates without use of or reference to the Confidential Information of the Disclosing Party.

Specific aspects or details of the Disclosing Party's Confidential Information shall not be deemed to be within the public domain or known to the Receiving Party merely because such Confidential Information is embraced by more general information in the public domain or known to the Receiving Party. Further, any combination of the Disclosing Party's Confidential Information shall not be considered in the public domain or known to the Receiving Party merely because individual elements of such Confidential Information are in the public domain or known to the Receiving Party unless the combination and its principles are in the public domain or known to the Receiving Party.

10.3 Permitted Disclosures. Notwithstanding the provisions of Section 10.1, each Party may disclose Confidential Information belonging to the other Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) filing or prosecuting Patents as permitted by this Agreement;

(b) prosecuting or defending litigation as permitted by this Agreement;

(c) complying with applicable court orders or governmental regulations;

(d) disclosing to its Affiliates, employees, directors, consultants, attorneys, and other professional advisors, and in Aguettant's case, to its Sublicensees, in each case who have a legitimate need to know such information, data, or materials and who are bound by written confidentiality obligations at least as restrictive as those set forth herein; and

(e) disclosure to Third Parties in connection with due diligence or similar investigations by or on behalf of a Third Party in connection with a potential license to, distribution agreement with or collaboration with such Third Party (including entry into any such agreement), or a potential merger or acquisition by such Third Party, and disclosure to potential or actual Third Party investors in confidential financing documents, provided, in each case, that any such Third Party agrees to be bound by similar terms of confidentiality and non-use at least as stringent as those set forth in this Article 10 (provided that the term may be shorter, but at least [***].

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 10.3(b) or (c), it shall, to the extent permitted by Applicable Laws, give reasonable advance notice to the other Party of such disclosure and use efforts to secure confidential treatment of such information at least as diligent as such Party would use to protect its own confidential information, but in no event less than reasonable efforts; provided that any Confidential Information so disclosed shall still be subject to the restrictions on use set forth in this Article 10. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder.

10.4 Confidentiality of this Agreement and its Terms. Except as otherwise provided in this Article 10, each Party agrees not to disclose to any Third Party the existence of this Agreement or the terms of this Agreement without the prior written consent of the other Party hereto, except that each Party may disclose the terms of this Agreement that are not otherwise made public as contemplated by Section 10.5 and as permitted under Section 10.3.

10.5 Public Announcements.

(a) As soon as practicable following the Effective Date, the Parties shall issue a joint press release announcing the existence of this Agreement substantially in the form attached hereto as Exhibit 10.5(a). Except as required by law (including disclosure requirements of the U.S. Securities and Exchange Commission ("SEC"), the Nasdaq stock market or any other stock exchange on which securities issued by a Party or its Affiliates are traded), neither Party shall make any other public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed; provided that it shall not be unreasonable for a Party to withhold consent with respect to any public announcement containing any of such Party's Confidential Information. In the event of a required public announcement, to the extent practicable under the circumstances, the Party making such announcement shall provide the other Party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other Party a reasonable opportunity to review and comment upon the proposed text.

(b) The Parties shall coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the SEC, the Nasdaq stock market or any other stock exchange or governmental agency on which securities issued by a Party or its Affiliate are traded, and each Party shall use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; provided that each Party shall ultimately retain control over what information to disclose to the SEC, the Nasdaq stock exchange or any other stock exchange or governmental agency, as the case may be, and provided further that the Parties shall use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither Party (nor its Affiliates) shall be obligated to consult with or obtain approval from the other Party with respect to any filings to the SEC, the Nasdaq stock market or any other stock exchange or governmental agency.

10.6 Publication of the Product Information. Without limiting the foregoing, Aguettant shall not, and shall ensure its Affiliates and Sublicensees do not, publish or publicly present any non-public scientific or technical information with respect to the Product without AcelRx's prior written consent.

10.7 Prior Non-Disclosure Agreements. As of the Effective Date, the terms of this Article 10 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) dealing with the subject of this Agreement, including the Confidentiality Agreement; provided that the existing Confidentiality Agreement between the Parties is hereby terminated and any and all Confidential Information pursuant to the Confidentiality Agreement shall be deemed "Confidential Information" of a Party pursuant to this Article 10.

ARTICLE 11

REPRESENTATIONS, WARRANTIES AND COVENANTS

11.1 Mutual Representations, Warranties and Covenants. Each Party hereby represents and warrants to the other Party, as of the Effective Date, as follows:

(a) **Duly Organized**. Such Party is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, and is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent such Party from performing its obligations under this Agreement.

(b) **Due Authorization; Binding Agreement**. The execution, delivery and performance of this Agreement by such Party have been duly authorized by all necessary corporate or organizational action. This Agreement is a legal and valid obligation binding on such Party and enforceable in accordance with its terms and does not (i) to such Party's knowledge and belief, violate any law, rule, regulation, order, writ, judgment, decree, determination or award of any court, governmental body or administrative or other agency having jurisdiction over such Party, or (ii) conflict with, or constitute a default under, any agreement, instrument or understanding, oral or written, to which such Party is a party or by which it is bound.

(c) **Consents**. Such Party has obtained, will obtain following the Effective Date before Commercialization in the Field in the Territory, or is not required to obtain, the consent, approval, order or authorization of any Third Party, and has completed, or is not required to complete, any registration, qualification, designation, declaration, or filing with any Regulatory Authority or Governmental Authority, in connection with the execution and delivery of this Agreement and the performance by such Party of its obligations under this Agreement (except for any Marketing Authorizations to be obtained in accordance with the terms of this Agreement).

(d) **Debarment**. Such Party is not debarred under the United States Federal Food, Drug and Cosmetic Act or similar Applicable Laws outside the U.S. and it does not, and will not during the Term, employ or use the services of any Person who is debarred, in connection with the Development, Manufacturing or Commercialization of the Products under this Agreement.

11.2 Representations, Warranties and Covenants of AcelRx. As used in this Section 11.2, "Knowledge" means, as applied to AcelRx, that any of AcelRx's executive officers knows of a particular fact or other matter, without any duty to perform diligence or due inquiry. AcelRx represents and warrants to Aguettant that as of the Effective Date:

(a) **Right to Grant License**. (i) AcelRx owns all right, title and interest in and to, or has a license, sublicense or otherwise permission to use and license, all of the AcelRx IP, free and clear of all encumbrances; (ii) AcelRx has not previously assigned, transferred, conveyed or otherwise encumbered or granted, and will not during the Term assign, transfer, convey or otherwise encumber its right, title and interest in any of the AcelRx IP or any rights granted to Aguettant hereunder, in each case (i) and (ii), that would adversely affect Aguettant's rights under this Agreement.

(b) **Scope of License**. To the Knowledge of AcelRx as of the Effective Date, Exhibit A sets forth all Patents included in the AcelRx Patents, as of the Effective Date, and Exhibit B sets forth all Trademarks included in the AcelRx IP, as of the Effective Date.

(c) **Patent and Trademark Status**. To AcelRx's Knowledge, (i) all issued Patents listed in Exhibit A and Trademarks listed on Exhibit B are in full force and effect, valid, subsisting and enforceable; (ii) none of the Patents listed in Exhibit A and Trademarks listed in Exhibit B is currently involved in any interference, reissue, reexamination, or opposition proceeding; (iii) neither AcelRx nor any of its Affiliates has received any written notice from any Person, or has knowledge, of any such actual or threatened proceeding; and (iv) all official fees, maintenance fees and annuities for the AcelRx Patents and the Trademarks listed in Exhibit B that are required to be paid to prevent abandonment or other loss of rights have been paid through the Effective Date to the extent due on or before the Effective Date.

(d) **Non-Infringement by Third Parties**. To AcelRx's Knowledge, there are no activities by Third Parties that would constitute infringement of the AcelRx IP or misappropriation of the AcelRx Know-How in the Territory.

(e) **Non-Infringement of Third Party Rights**. To AcelRx's Knowledge, the sale or importation of the Product, as in existence as of the Effective Date, in the Field in the Territory, including the use of the Brand Name, does not infringe or misappropriate any Patent, Trademark or other intellectual property right of a Third Party. Neither AcelRx nor any of its Affiliates has received any written notice from any Person, or has knowledge of, any actual or threatened claim or assertion that the use of the AcelRx Patents, AcelRx Trademarks, or the Brand Name in the Field in the Territory infringes or misappropriates the intellectual property rights of a Third Party.

(f) **Additional Legal Compliance**.

(i) To AcelRx's Knowledge, AcelRx and its Affiliates have complied in all material respects with all Applicable Laws in conducting Development and Manufacturing of the Product prior to the Effective Date, and neither AcelRx nor any of its Affiliates has received any written notice from any Governmental Authority in the Territory claiming that any such activities as conducted by them are not in such compliance.

(ii) No Governmental Authority in the Territory has commenced or, to AcelRx's Knowledge, threatened to initiate any action to enjoin production of the Product at any facility, nor has AcelRx or any of its Affiliates or, to the Knowledge of AcelRx, any of its contractor manufacturers, received any notice to such effect, nor has AcelRx received any order not to import the Product into the Territory.

ARTICLE 12

DISCLAIMER, LIMITATION OF LIABILITY AND INDEMNIFICATION

12.1 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, OR ANY OTHER AGREEMENT CONTEMPLATED HEREUNDER, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AND EACH PARTY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE OR USE, NON-INFRINGEMENT, VALIDITY AND ENFORCEABILITY OF PATENTS, OR THE PROSPECTS OR LIKELIHOOD OF DEVELOPMENT OR COMMERCIAL SUCCESS OF THE LICENSED PRODUCT.

12.2 Limitation of Liability. THE LIABILITY OF EITHER PARTY SHALL NOT EXCEED [***] IN THE AGGREGATE. FOR THE AVOIDANCE OF DOUBT, THIS DOES NOT APPLY TO PAYMENT OBLIGATIONS EXPLICITLY ORIGINATING FROM THE AGREEMENT. IN ANY EVENT, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; PROVIDED, HOWEVER, THAT THIS SECTION 12.2 SHALL NOT BE CONSTRUED TO LIMIT (A) EITHER PARTY'S INDEMNIFICATION OBLIGATIONS UNDER THIS ARTICLE 12 (B) EITHER PARTY'S REMEDIES FOR BREACH OF ARTICLE 10 BY THE OTHER PARTY, (C) EITHER PARTY'S REMEDIES FOR INFRINGEMENT OR MISAPPROPRIATION OF SUCH PARTY'S INTELLECTUAL PROPERTY RIGHTS BY THE OTHER PARTY, OR (D) EITHER PARTY'S LIABILITY FOR WILLFUL INTENT.

12.3 Indemnification of AcelRx. Aguettant shall indemnify, defend and hold harmless each of AcelRx and its Affiliates, and the directors, officers, shareholders, employees and agents of such entities and the successors and assigns of any of the foregoing (the "**AcelRx Indemnitees**"), from and against any and all losses, liabilities, damages, penalties, fines, costs and expenses (including reasonable attorneys' fees and other expenses of litigation) ("**Losses**") resulting from any claims, actions, suits or proceedings brought by a Third Party (a "**Third Party Claim**") incurred by any AcelRx Indemnitee, to the extent arising from (a) the negligence or willful misconduct of any Aguettant Indemnitees or any Sublicensees, Distributors or other subcontractors of Aguettant; (b) the Development, regulatory and Commercialization activities relating to the Product conducted by or on behalf of Aguettant, its Affiliates, Sublicensees, subcontractors and Distributors (other than AcelRx and its Affiliates and licensees) in connection with this Agreement, other than the Development and regulatory activities relating to the Product conducted by or on behalf of AcelRx and its Affiliates (other than Aguettant and its Affiliates and Sublicensees) in connection with this Agreement; or (c) any breach of any representations, warranties or covenants by Aguettant under this Agreement or the Supply Agreement; except in each case (a)-(c) to the extent such Third Party Claims fall within the scope of the indemnification obligations of AcelRx set forth in Section 12.4(a) or (c).

12.4 Indemnification of Aguettant. AcelRx shall indemnify, defend and hold harmless each of Aguettant and its Affiliates, and the directors, officers, shareholders, employees and agents of such entities and the successors and assigns of any of the foregoing (the "**Aguettant Indemnitees**"), from and against any and all Losses resulting from any Third Party Claims incurred by any Aguettant Indemnitee, to the extent arising from (a) the negligence or willful misconduct of any AcelRx Indemnitee; (b) the Development and regulatory activities relating to the Product conducted by or on behalf of AcelRx and its Affiliates (other than Aguettant and its Affiliates and Sublicensees) in connection with this Agreement; or (c) any breach of any representations, warranties or covenants by AcelRx under this Agreement or the Supply Agreement; except in each case (a)-(c) to the extent such Third Party Claims fall within the scope of the indemnification obligations of Aguettant set forth in Section 12.3(a) or (c).

12.5 Procedure. A Party that intends to claim indemnification under this Article 12 shall promptly notify the indemnifying Party in writing of any Third Party Claim, in respect of which the indemnitee intends to claim such indemnification. The indemnified Party shall provide the indemnifying Party with reasonable assistance, at the indemnifying Party's expense, in connection with the defense of the Third Party Claim for which indemnity is being sought. The indemnitee may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the indemnitor shall have the right to assume and conduct the defense of the Third Party Claim with counsel of its choice. The indemnitor shall not settle any Third Party Claim without the prior written consent of the indemnified Party, which consent shall not be unreasonably withheld, unless the settlement involves only the payment of money. So long as the indemnitor is actively defending the Third Party Claim in good faith, the indemnitee shall not settle any such Third Party Claim without the prior written consent of the indemnifying Party. If the indemnitor does not assume and conduct the defense of the Third Party Claim as provided above, (a) the indemnitee may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Third Party Claim in any manner the indemnitee may deem reasonably appropriate (and the indemnitee need not consult with, or obtain any consent from, the indemnitor in connection therewith), and (b) the indemnitor will remain responsible to indemnify the indemnitee as provided in this Article 12. The failure to deliver written notice to the indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the indemnitor of its indemnification obligations under this Article 12 if and to the extent the indemnitor is actually prejudiced thereby.

ARTICLE 13

TERM AND TERMINATION

13.1 Term. This Agreement shall commence on the Effective Date and shall continue for an initial term of ten (10) Marketing Years (the "**Initial Term**"), and shall automatically renew for successive five (5) Marketing Year periods (each, a "**Renewal Term**", the Initial Term and each Renewal Term collectively the "**Term**"), unless either Party notifies the other Party of its intention to not renew at least six (6) months prior to the expiration of the then-current Term.

13.2 Termination for Cause.

(a) Each Party shall have the right to terminate this Agreement upon written notice if the other Party is in material breach of this Agreement and has not cured such breach within [***] days ([***] days with respect to any payment breach) after notice from the terminating Party requesting cure of the breach. Any such termination shall become effective at the end of such [***] day ([***]-day with respect to any payment breach) period unless the breaching Party has cured any such breach or default prior to the end of such period.

(b) Each Party shall have the right to terminate this Agreement upon written notice upon the bankruptcy or insolvency of, or the filing of an action to commence insolvency proceedings against, the other Party, or the making or seeking to make or arrange an assignment for the benefit of creditors of the other Party, or the initiation of proceedings in voluntary or involuntary bankruptcy, or the appointment of a receiver or trustee of such Party's property, in each case that is not discharged within [***] days.

(c) Each Party shall have the right to terminate this Agreement upon written notice if the other Party claims the benefit of a Force Majeure Event for a period of more than [***] consecutive days, as set forth in Section 14.1.

(d) Each Party shall have the right to terminate this Agreement after the Cure Period as set forth in Section 5.1(d) upon [***] days written notice, if the Parties are unable, after diligent and good faith efforts, to cure the situation in such a way as to make continuing performance under the Agreement economically feasible for both Parties, provided that AcelRx shall have the right, at its sole discretion, to terminate this Agreement in its entirety or on a country-by-country basis, including for multiple countries.

13.3 AcelRx shall have the right to terminate this Agreement with immediate effect by giving written notice to Aguettant:

(a) if Aguettant does not Launch the Product in the first country in the Territory within the Deadline, and this is not justified or due to AcelRx's failure in any of its contractual obligations;

(b) if Aguettant has a Failure in two consecutive MYs after the Line Change MY or MY 2, whichever is later;

(c) if Aguettant fails to apply the agreed recovery plan, as set forth in Section 5.5(b);

(d) in the event of a Change of Control in Aguettant; or

(e) if Aguettant or its Affiliates or Sublicensees bring or join any challenge to the validity or enforceability of any AcelRx IP (an "**IP Challenge**"); provided that (i) an IP Challenge does not include Aguettant's or its Affiliates' or its Sublicensees (A) responding to compulsory discovery, subpoenas or other requests for information in a judicial or arbitration proceeding or (B) complying with any Applicable Law or a court order; and (ii) the foregoing right of termination shall not apply with respect to any IP Challenge where the IP Challenge is based solely on the scope of a Patent or whether a claim therein qualifies as a valid claim and is made in defense of a claim first brought by AcelRx or its Affiliates.

13.4 Aguettant shall have the right to terminate this Agreement:

(a) in its entirety, if AcelRx is unable to rectify the major finding(s) of the audit referenced in 6.4, as soon as reasonably possible within a reasonable period of time to ensure supplies to the European market in accordance with 6.4, subject to Aguettant having provided AcelRx a prior written notice that AcelRx has not rectified the major finding(s) and AcelRx not having cured the major finding(s) within three (3) months after receipt of the notice;

(b) in its entirety, upon [***] days prior written notice, in the event of any failure of supply by AcelRx or delayed supply of Products by AcelRx for more than [***] months beyond the Requested Delivery Date for [***] consecutive confirmed orders, if, after Aguettant provides written notice to AcelRx of such failure or delay, AcelRx and Aguettant fail to reach a resolution on the issues causing such failure or delay within [***] days after such written notice; or

(c) in its entirety or partially, if AcelRx and/or one of its manufacturers have lost its certificate to Manufacture the Products, or the Marketing Authorization for the Product is lost due to Regulatory Authorities' decision affecting in whole or in part the Territory.

13.5 Accrued Obligations. The termination of this Agreement for any reason shall not release either Party from any liability which, at the time of such termination, has already accrued to such Party or which is attributable to a period prior to such termination, nor will any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement.

13.6 Effects of Termination. Upon the termination of this Agreement, the following will apply:

(a) **Termination of Licenses**. All rights and licenses granted to Aguettant with respect to Products, and all sublicenses granted by Aguettant and its Affiliates, will terminate.

(b) **Winding Down of Development Activities**. In the event there are any on-going clinical trials of the Product being conducted by or on behalf of Aguettant in the Field in the Territory, the Parties shall work together in good faith to adopt, and AcelRx shall have the final decisional power with respect to, a plan to wind down such Development activities in an orderly fashion, with due regard for patient safety and the rights of any subjects that are participants in any clinical trials of the Product, and take any actions it deems reasonably necessary or appropriate to avoid any human health or safety problems, in compliance with all Applicable Laws.

(c) **Inventory**. AcelRx shall have the right to purchase from Aguettant, at the cost incurred by Aguettant for purchase, all of Aguettant's and its Affiliates' then-current inventory of Product, provided that in the event the Parties agree before the effective date of the termination of the Agreement upon a period for Aguettant to sell and Commercialize such inventory after the Term of the Agreement, Aguettant may sell or Commercialize such inventory within such period. Except otherwise provided for in this Agreement and except in cases of termination for cause (Sections 13.1 and 13.4), any binding orders placed by Aguettant prior to termination of the Agreement shall be paid for by Aguettant, provided further that if Aguettant opts for shipment of binding orders in cases of termination for cause, also such binding orders shall be paid for by Aguettant.

(d) **Re-registration of Regulatory Filings or Regulatory Approvals**. To the extent permitted under Applicable Laws, Aguettant shall arrange for the re-registration to AcelRx or its designee (or to the extent not so re-registrable, Aguettant shall take all reasonable actions to make available to AcelRx or its designee the benefits thereof) of all Regulatory Filings and Regulatory Approvals for the Product in the Territory, including any such Regulatory Filings and Regulatory Approvals made by or registered to its Affiliates or Sublicensees; all such re-registration or transfer shall be at AcelRx's sole cost and expense, unless AcelRx is the terminating Party under Section 13.2(a), 13.2(c) or 13.3, in which case all such re-registration or transfer shall be at Aguettant's sole cost and expense. AcelRx shall notify Aguettant before the effective date of termination, whether the foregoing should be re-registered to AcelRx or its designee, and if the latter, identify the designee, and provide Aguettant with all necessary details to enable Aguettant to effect the re-registration (or availability of the benefit thereof).

(e) **License Grant by Aguettant to AcelRx**. Aguettant hereby grants AcelRx, effective upon the effective date of such termination, a fully-paid, royalty-free, non-exclusive license, with the right to grant sublicenses through multiple tiers, under any and all Patents (to the extent not previously assigned) and Know-How Controlled by Aguettant or its Affiliates and incorporated into the Product at the time of such termination for AcelRx to use and Commercialize the Product or any other products with substantially the same chemical composition or active pharmaceutical ingredient as the Product anywhere in the world.

(f) **Ancillary Agreements**. The Supply Agreement, the Quality Agreement and the Pharmacovigilance Agreement shall terminate effective upon the effective date of termination of this Agreement, except as provided otherwise in the Quality Agreement and the Pharmacovigilance Agreement in conformity with Applicable Laws.

(g) **Transition**. Each Party shall use Commercially Reasonable Efforts to cooperate with the other Party to effect a smooth and orderly transition in the Development and Commercialization of the Product in the Territory during the notice and wind-down periods. Aguettant shall provide reasonable transition support to enable AcelRx to assume all Commercialization responsibility. Aguettant shall, at AcelRx's request, assign to AcelRx all Third Party contracts, including contracts with Distributors, to the extent related to the Product, and if any such contract is not assignable, and if such Third Party agrees to it, Aguettant shall introduce AcelRx to such Third Party, and shall ensure that AcelRx and such Third Party are in contact, to facilitate the discussions regarding the relationship between AcelRx and such Third Party after the Term of the Agreement.

(h) **Return of Confidential Information**. Except to the extent necessary or reasonably useful for a Party to exercise its rights surviving such termination, each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that such Party may keep one copy of such materials to ensure compliance obligations of such Party are met.

(i) **Return of Upfront Milestone**. Solely in the case of a termination by Aguettant in accordance with Section 13.4(a) AcelRx shall refund the milestone payment in accordance with 8.4(i) – if received from Aguettant – to Aguettant within [***] after receipt of such notice of termination from Aguettant by AcelRx.

(j) **Survival**. All rights and obligations of the Parties under this Agreement shall terminate, except those described in the following Articles and Sections: Sections 1.1, 8.6, 8.7, 8.8, 8.9, 9.1, 13.5, 13.6, and 13.7, and Article 10, Article 12, and Article 14.

13.7 Rights Upon Bankruptcy. All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar laws in any jurisdiction in the Territory or where a Party is situated (collectively, the "**Bankruptcy Laws**"), licenses of rights to "intellectual property" as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under Bankruptcy Laws then, unless and until this Agreement is rejected as provided in such Bankruptcy Laws, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall perform all of the obligations provided in this Agreement to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws, this Agreement is rejected as provided in the Bankruptcy Laws and the other Party elects to retain its rights hereunder as provided in the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee) shall provide to the other Party copies of all information necessary for such other Party to prosecute, maintain and enjoy its rights under the terms of this Agreement promptly upon such other Party's written request therefor. All rights, powers and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws. In particular, it is the intention and understanding of the Parties that the rights granted to the Parties under this Section 13.7 are essential to the Parties' respective businesses and the Parties acknowledge that damages are not an adequate remedy.

ARTICLE 14

MISCELLANEOUS

14.1 Force Majeure. If the performance of any part of this Agreement by either Party is prevented, restricted, interfered with or delayed by any reason or cause beyond the reasonable control of such Party (including fire, flood, embargo, power shortage or failure, acts of war, insurrection, riot, terrorism, strike, lockout or other labor disturbance, shortage of raw materials, epidemic, pandemic, actions by Government Authorities to address epidemics or pandemics, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, or storm or like catastrophe, acts of God or any acts, omissions or delays in acting of the other Party) (each, a "**Force Majeure Event**"), the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such Force Majeure Event, provided that the affected Party shall use its substantial efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed. The Parties agree the effects of the COVID-19 pandemic that is ongoing as of the Effective Date (including related government orders) may be invoked as a Force Majeure Event for the purposes of this Agreement even though the pandemic is ongoing and those effects may be reasonably foreseeable as of the Effective Date. In addition, a Force Majeure Event may include reasonable measures affirmatively taken by a Party or its Affiliates to respond to any epidemic, pandemic, or spread of infectious disease (including the COVID-19 pandemic), or other Force Majeure Event, such as requiring employees to stay home, closures of facilities, delays of Development, or cessation of activities in response to an epidemic or pandemic or other Force Majeure Event.

(a) **Notification**. If either Party becomes aware that such a Force Majeure Event has occurred or is imminent or likely, it shall immediately notify the other.

(b) **Efforts to Overcome**. The Party which is subject to such Force Majeure Event shall exert all reasonable efforts to overcome it; provided that if the Force Majeure Event continues unabated for a period of [***] days, the other Party may terminate the Agreement upon [***] days written notice to the affected Party.

(c) **Keeping the Other Informed**. Such Party shall keep the other informed as to the progress of overcoming such Force Majeure Event.

14.2 Waiver of Breach. No delay or waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

14.3 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to perform all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

14.4 Affiliates; Continuing Responsibility. Either Party shall have the right to assign, sublicense, subcontract or delegate this Agreement or any or all of its obligations or rights hereunder to an Affiliate upon written notice to the other Party; *provided*, however, the assigning, sublicensing, subcontracting or delegating Party hereby guarantees and shall remain fully and unconditionally obligated and responsible for the full and complete performance of this Agreement by such Affiliate and in no event shall such assignment, sublicensing, subcontracting or delegation be deemed to relieve such Party's liabilities or obligations to the other Party under this Agreement. The other Party shall, at the request of the assigning, sublicensing, subcontracting or delegating Party, enter into such supplemental agreements with the applicable Affiliates as may be necessary or advisable to permit such Affiliates to avail itself of any rights or perform any obligations of the assigning, sublicensing, subcontracting or delegating Party hereunder.

14.5 Modification. No amendment or modification of any provision of this Agreement shall be effective unless in a prior writing signed by both Parties hereto. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by both Parties hereto.

14.6 Severability. In the event any provision of this Agreement should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate in good faith and enter into a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties. All other provisions of this Agreement shall remain in full force and effect in such jurisdiction. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

14.7 Entire Agreement. This Agreement (including the schedules and exhibits attached hereto) constitutes the entire agreement between the Parties relating to the subject matter hereof and supersedes and cancels all previous express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect of the subject matter hereof, including the Confidentiality Agreement. Each of the Parties acknowledges and agrees that in entering into this Agreement, and the documents referred to in it, it does not rely on, and shall have no remedy in respect of, any statement, representation, warranty or understanding (whether negligently or innocently made) of any person (whether party to this Agreement or not) other than as expressly set out in this Agreement. Nothing in this clause shall, however, operate to limit or exclude any liability for fraud.

14.8 Language. The language of this Agreement and all activities to be pursued under this Agreement is English. Any and all documents proffered by one Party to the other in fulfillment of any provision of this Agreement shall only be in compliance if in English. Any translation of this Agreement in another language shall be deemed for convenience only and shall never prevail over the original English version. This Agreement is established in the English language.

14.9 Notices. Any notice, request, or other communication required or permitted under this Agreement shall be in writing in the English language, delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by internationally-recognized courier, sent by registered or certified mail, postage prepaid to the following addresses of the Parties (or such other address for a Party as may be at any time thereafter specified by like notice), or sent by email:

To AcelRx:

AcelRx Pharmaceuticals, Inc.
25821 Industrial Boulevard, Suite 400
Hayward, CA 94545
Attention: Chief Executive Officer
Email: [***]

with a copy to:

AcelRx Pharmaceuticals, Inc.
25821 Industrial Boulevard, Suite 400
Hayward, CA 94545
Attention: Legal Department
Email: [***]

To Aguettant:

Laboratoire Aguettant SAS
1 rue Alexander Fleming
69007 Lyon, France
Attention: Chief Executive Officer
Email: [***]

with a copy to:

Laboratoire Aguettant SAS
1 rue Alexander Fleming
69007 Lyon, France
Attention: Legal Department
Email: [***]

Any such notice shall be deemed to have been given (a) when delivered if personally delivered; (b) on the next Business Day after dispatch if sent by confirmed facsimile or by internationally-recognized overnight courier; (c) on the fifth (5th) Business Day following the date of mailing if sent by mail; or (d) upon confirmation of receipt if sent by email. Notices hereunder will not be deemed sufficient if provided only between or among each Party's representatives on the Joint Steering Committee.

14.10 Assignment. Subject to Sections 2.2 and 14.4, this Agreement shall not be assignable or otherwise transferred, nor may any rights or obligations hereunder be assigned or transferred, by either Party to any Third Party without the prior written consent of the other Party; except that either Party may assign or otherwise transfer this Agreement without the consent of the other Party to an entity that acquires all or substantially all of the business or assets of the assigning Party relating to the subject matter of this Agreement, whether by merger, acquisition or otherwise. Subject to the foregoing, this Agreement shall inure to the benefit of each Party, its successors and permitted assigns. Any assignment of this Agreement in contravention of this Section 14.10 shall be null and void.

14.11 No Partnership or Joint Venture. Nothing in this Agreement or any action which may be taken pursuant to its terms is intended, or shall be deemed, to establish a joint venture or partnership between Aguettant and AcelRx. Except as set forth in this Agreement, neither Party to this Agreement shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, or to bind the other Party to any contract, agreement or undertaking with any Third Party.

14.12 Dispute Resolution Process. The Parties recognize that disputes as to certain matters may from time to time arise during the Term that relate to (i) interpretation of a Party's rights or obligations hereunder, (ii) any alleged breach of this Agreement, (iii) any issue that is unable to be resolved pursuant to informal channels of resolution, or (iv) Section 5.1(d). If the Parties cannot resolve any such dispute within [***] days after written notice of a dispute from one Party to another, either Party may, by written notice to the other Party, have such dispute referred to the JSC. If the JSC cannot resolve such dispute within [***] days after such dispute is referred thereto, either Party may, by written notice to the other Party, have such dispute referred to the Chief Executive Officer of AcelRx and the Chief Executive Officer of Aguettant (collectively, the "**Senior Executives**"). The Senior Executives shall negotiate in good faith to resolve the dispute within [***] days. If the Senior Executives are unable to resolve the dispute within such time period, the parties shall submit the dispute for arbitration in accordance with Section 14.14. Notwithstanding anything in this Article 14 to the contrary, AcelRx and Aguettant shall each have the right at all times to apply to any court of competent jurisdiction for appropriate interim or provisional relief, as necessary to protect the rights or property of that Party.

14.13 Governing Law. This Agreement and all questions regarding the existence, validity, interpretation, breach or performance of this Agreement, shall be exclusively governed by, and construed and enforced in accordance with, the laws of the State of New York, United States, without reference to its conflicts of law principles.

14.14 Arbitration. Any disputes arising in connection with this Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce ("**ICC**") as amended herein, and judgment on the arbitration award may be entered in any court having jurisdiction thereof. The Parties agree that:

(a) The arbitration shall be conducted by a panel of three (3) arbitrators, or such lesser number as the Parties may agree. Each of the Parties shall nominate an arbitrator and these two arbitrators shall endeavor to agree on the third arbitrator, who shall act as chairman of the arbitral tribunal, within [***] days from the date when both Parties have received from the ICC confirmation of the second arbitrator by the ICC court. All arbitrators shall have a legal qualification. The chairman shall have chaired at least one ICC arbitration before, and the arbitrators nominated by the Parties shall have at the minimum ten (10) years working experience in the pharmaceutical industry. The seat, or legal place, of arbitration shall be New York City, New York, U.S., and the Parties consent to the personal jurisdiction of the U.S. federal courts for any case arising out of or otherwise related to this arbitration, its conduct and its enforcement. The language of the arbitration proceedings shall be English. The decision and award of the arbitral tribunal shall be final and binding on the Parties. The Parties acknowledge that this Agreement evidences a transaction involving interstate commerce.

(b) Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect its rights hereunder. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees of arbitration.

(c) Any award shall be promptly paid, free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by Applicable Laws, be charged against the Party resisting enforcement. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Section 14.14, and agrees that judgment may be entered upon the final award in the Federal District Court in the Southern District of New York and that other courts may award full faith and credit to such judgment in order to enforce such award. Judgment on the award may also be entered in any other court of competent jurisdiction. The award shall include interest from the date of any damages incurred for breach of this Agreement, and from the date of the award until paid in full, at a rate fixed by the arbitrators.

(d) The existence and content of the arbitral proceeding, including any rulings or award, shall be kept confidential by the Parties and the arbitrator except to the extent (i) required by Applicable Laws; (ii) required to protect or pursue a legal right; (iii) required to enforce or challenge an award; or (iv) approved by written consent of the Parties. Notwithstanding anything to the contrary herein, either Party may disclose matters relating to the arbitration or the arbitral proceedings where necessary for the preparation or presentation of a claim or defense in such arbitration. The arbitrator shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by Applicable Laws, no Party shall make (or instruct the arbitrator to make) any public announcement with respect to the proceedings, rulings or award without prior written consent of the other Party.

(e) Any duty to arbitrate under this Agreement shall remain in effect and be enforceable after termination of this Agreement for any reason.

14.15 Fees and Expenses. Each Party shall bear its own attorneys' fees and fees and expenses associated with all aspects of the negotiation and diligence of the transaction contemplated hereunder.

14.16 Cessation of US Commercialization. In the event that AcelRx makes a binding decision to cease the Commercialization of the US counterpart of the Product in the United States, it shall inform Aguettant without undue delay and shall permit interactions between Aguettant and AcelRx's subcontractors for the purpose of continuation of execution of the Agreement. AcelRx shall use Commercially Reasonable Efforts to arrange for its contract manufacturers to manufacture the Products for as long as Aguettant Commercializes the Products in the Territory.

14.17 Data privacy. AcelRx is informed and accepts that Aguettant, acting as "data controller," as defined in Article 4 of the EU General Data Protection Regulation, collects and processes Personal Data concerning its contact persons within AcelRx (the "**Data Contacts**") in the context of the management of its relations with AcelRx as follows:

(a) performance of the Agreement;

(b) ensure the security of information systems;

(c) ensure the follow-up and management of its commercial relations and communication with AcelRx;

(d) conduct audits (if applicable);

(e) administer, manage and defend against legal claims or actions (if applicable); and

(f) comply with its legal, regulatory and contractual obligations.

Aguettant shall retain Personal Data of such Data Contacts for the period necessary to fulfil the purposes specified above in this Section 14.17, and shall retain such Personal Data in compliance with applicable laws and regulations. In accordance with applicable laws and regulations, AcelRx's Data Contacts have a right of access and rectification of Personal Data concerning such Data Contacts, limitation of processing of such Personal Data, and opposition to such processing for legitimate reasons. Such rights can be exercised by written notice to personaldata@aguettant.fr. AcelRx undertakes to inform concerned Data Contacts of the existence of these rights and shall obtain the necessary consent from concerned Data Contacts for the processing of their Personal Data. Each Party undertakes to comply with all obligations prescribed by laws and regulations relating to the protection of personal data.

14.18 Anti-Bribery, Anti-Gift and Sunshine Obligations.

In connection with this Agreement, any Products and any performance, activity, act or omission under, each Party undertakes not to make, give, provide, offer, or promise, directly or indirectly, any payment, benefit, or other incentive to:

(a) any governmental officials, political parties, party officials, candidates for public or political party office,

(b) any other person acting in an official capacity for or on behalf of any government, government-owned corporation, organization or entity, or any department, agency, or instrumentality thereof, or a public international organization,

(c) any director, officer, manager, employee, subcontractor, and/or agent of any partner or potential partner, or

(d) any other person, individual or entity,

at the suggestion, request or direction, or engage in acts or transactions, in order to influence the acts of the above-described persons and/or entities in their official capacity or to induce them to use their influence with a government to obtain or retain business or gain an improper advantage in connection with the Agreement in manner that would be in violation of the applicable domestic anti-bribery legislation of any government, and more specifically the French law of December 9th, 2016 on transparency, fight against corruption and modernization of economic life (and known as "SAPIN II Law"), the United Kingdom Bribery Act 2010, the United States Foreign Corrupt Practices Act ("FCPA"), any applicable country legislation implementing the OECD Convention on Combating Bribery of Foreign Officials (the "OECD Convention") or, in the absence of any such implementing legislation, the OECD Convention itself.

Each Party also undertakes not to solicit or accept illegally, at any time, directly or indirectly, offers, promises, donations, gifts or incentives, for itself or for anybody, so as to, accomplish or for having accomplished, refrain from accomplishing or from having accomplished, an action related to its activity or function, or in order to facilitate or having facilitated an action through its activity or function, within the framework of the Agreement.

In addition, Aguettant undertakes to comply with the provisions and obligations arising out of any anti-gift and/or sunshine regulations, such as the provisions of Articles L. 1453-1 and L. 1453-3 et seq. of the French Public Health Code or any other such regulations, as applicable in the Territory.

Each Party shall be responsible for the implementation of the present provision by its officers, directors, employees, agents, representatives and subcontractors (hereafter referred to as "Representative(s)").

To the concerned Party's best knowledge and belief, no criminal or administrative investigation, action or enforcement proceeding is pending or threatened against it or its Representatives or any its Affiliates, relating to a violation of the applicable domestic anti-bribery legislation of any government, and more specifically the SAPIN II Law, the United Kingdom Bribery Act 2010, the FCPA, any applicable country legislation implementing the OECD Convention or, in the absence of any such implementing legislation, the OECD Convention itself.

Each Party shall promptly report to the other any request or demand which if complied with would lead to a breach of either this Agreement or the United Kingdom Bribery Act 2010 or the FCPA or SAPIN II Law or any applicable country legislation implementing the OECD Convention or the OECD Convention itself.

Each Party acknowledges it is aware of the SAPIN II Law, the United Kingdom Bribery Act 2010, the FCPA, the OECD Convention along with anti-corruption rules that must be applicable to it, and undertakes to implement all necessary measures to ensure their respect regarding the performance of the Agreement. Each Party further undertakes not to use its corporate capacity or any other individual or corporate capacity for illegal purpose as regards to the above clauses and rules as applicable either directly or indirectly.

Non-compliance by any Party or by its Representatives or by its Affiliates with the present Article and/or refusal by it or its Representatives of making required statements as required under the Agreement or applicable laws shall be deemed a material breach of this Agreement entitling the other Party to terminate it immediately.

Each Party undertakes to demonstrate to the other Party its compliance with this provision, therefore, it must (i) make and keep books, records and accounts, which accurately and fairly reflect the transactions, and dispositions of assets of the company, in order to demonstrate that its company is compliant with this Section 14.18; and (ii) devise and maintain a system of internal accounting controls.

To that extent, any Party or its designee shall have the right, at any time, to check the compliance of the other Party or its Representatives or its Affiliates with their respective obligations as provided herein, and the latter shall provide to the other Party with all necessary and relevant documents and elements. The audited Party shall grant the other, upon receipt of a commercially reasonable written request or upon request of a competent authority, access to said books, records, systems and accounts.

It is understood that the control rights of any Party do not in any way exonerate the other Party or its Representatives or its Affiliates from their responsibilities and obligations under the Agreement.

14.19 Hardship. If any unforeseen event (e.g., an evolution of the legal and/or economic framework of the Agreement), while not preventing either Party from performing any of its obligations hereunder, changes the balance of the Agreement to the detriment of such Party and therefore causes inequitable hardship to such Party in the performance of such obligations, and if such Party is able to demonstrate such hardship by competent proof, then both Parties shall attempt in good faith to negotiate an equitable way to adapt this Agreement to the new circumstances, provided neither Party is obligated to make any accommodation or agree to any amendment that is not expressly required by the terms of this Agreement.

14.20 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument.

Schedules

Schedule 1.1 - Definitions

Exhibits

Exhibit 5.1(a) – Current cost for quality release testing for Bulk Product

Exhibit 5.5 – Annual Minimum Sales

Exhibit 6.3 – Current cost for stability testing

Exhibit 8.4 – Sales Milestone Threshold

Exhibit 10.5(a) – Draft Public Announcement

Exhibit A – AcelRx Patents as of the Effective Date

Exhibit B – AcelRx Trademarks as of the Effective Date

[signature page to follow]

In Witness Whereof, the Parties by their respective authorized representatives have executed this Agreement as of the Effective Date.

AcelRx Pharmaceuticals, Inc.

By: /s/ Raffi Asadorian

Name: Raffi Asadorian

Title: CFO

Laboratoire Aguettant

By: /s/ Eric Rougemond

Name: Eric Rougemond

Title: CEO

[Signature Page to License Agreement (EU)]

Schedule 1.1

Definitions

"3PL" means a third party logistics provider selected by AcelRx from time to time.

"Accounting Standards" means, with respect to a Party or its Affiliates, U.S. generally accepted accounting principles ("**GAAP**") or International Financial Reporting Standards ("**IFRS**"), as such Party or its Affiliates uses for its financial reporting obligations, in each case.

"AcelRx Indemnitees" has the meaning set forth in Section 12.3.

"AcelRx Invention" means any Invention relating to the Product by or on behalf of and Controlled by AcelRx or any of its Affiliates as of the Effective Date or during the Term, which is necessary or reasonably useful for the Development or Commercialization of the Product in the Field in the Territory.

"AcelRx IP" means Intellectual Property, including the Core Pharmaceutical Dossier relating to the Product, the Brand Name, AcelRx Trademarks, AcelRx Patents, AcelRx Inventions and Product Improvements.

"AcelRx Know-How" means all Know-How Controlled by AcelRx or any of its Affiliates as of the Effective Date or during the Term that is necessary or reasonably useful for the Development or Commercialization of the Product in the Field in the Territory.

"AcelRx Patents" means all Patents Controlled by AcelRx or its Affiliates as of the Effective Date or during the Term that are necessary or reasonably useful for the Development or Commercialization of the Product in the Field in the Territory, including all Patents that claim Product Improvements. A list of AcelRx Patents as of the Effective Date is set forth in Exhibit A.

"AcelRx Trademarks" means all Trademarks Controlled by AcelRx or its Affiliates as of the Effective Date or during the Term that are necessary or reasonably useful for the Commercialization of the Product in the Field in the Territory. A list of AcelRx Trademarks as of the Effective Date is set forth in Exhibit B.

"Adjusted Supply Price" has the meaning set forth in Section 5.1(c).

"Affiliate" means, with respect to a Party, any Person directly or indirectly controlling, controlled by, or under common control with, such Party. For purposes of this definition only, the terms "controlled," "controlled by," and "under common control with," as used in this context, mean the direct or indirect ability or power to direct or cause the direction of management policies of a Person or otherwise direct the affairs of such Person, whether through ownership of equity, voting securities, beneficial interest, by contract or otherwise.

"Agreement" has the meaning set forth in the first paragraph hereof.

"Aguettant Indemnitees" has the meaning set forth in Section 12.4.

"Alliance Manager" has the meaning set forth in Section 7.2.

"Applicable Laws" means the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, permits (including Regulatory Approvals, Pricing Approvals and Other Approvals) of or from any court, arbitrator, Regulatory Authority or governmental agency or authority having jurisdiction over or related to the subject item.

"Background Intellectual Property" means, with respect to a Party, all Know-How, Trademarks, copyrights, Patents and other intellectual property (a) owned or Controlled by such Party or its Affiliates as of the Effective Date or (b) developed, acquired or created by or on behalf of such Party or its Affiliates after the Effective Date (i) independently of the Agreement and (ii) not directly related to the Product.

"Bankruptcy Laws" has the meaning set forth in Section 13.7.

"Brand Name" means the brand name "DZUVEO®".

"Bulk Products" means Products that are pre-packaged in labeled pouches and packed in bright stock cartons for shipment and proper handling and protection during warehousing and transportation, as set forth in the Quality Agreement. For the avoidance of doubt, Bulk Products are not labeled for final sale in any particular market in the Territory.

"Business Day" means a calendar day other than a Saturday or Sunday or any public holiday in San Francisco, California, or in Lyon, France, but excluding the nine (9) consecutive calendar days beginning on December 24 and continuing through January 1 of each Calendar Year during the Term. For the avoidance of doubt, references in this Agreement to "days" mean calendar days. For pharmacovigilance matters, Business Days shall not be applicable.

"Calendar Quarter(ly)" or "**Quarter(ly)**" means the respective periods of three (3) consecutive calendar months period ending on March 31, June 30, September 30 or December 31 for so long as the Agreement is in effect.

"Calendar Year" means a period of twelve consecutive months beginning on and including January 1.

"Change of Control" means, with respect to a Party, (a) the acquisition of beneficial ownership, directly or indirectly, by any Person of securities or other voting interest of such Party representing 50% or more of the combined voting power of such Party's then outstanding securities or other voting interests, (b) any merger, reorganization, consolidation or business combination involving such Party that results in the holders of beneficial ownership of the voting securities or other voting interests of such Party (or, if applicable, the ultimate parent of such Party) immediately prior to such merger, reorganization, consolidation or business combination ceasing to hold beneficial ownership of 50% or more of the combined voting power of the surviving entity immediately after such merger, reorganization, consolidation or business combination, (c) any sale, lease, exchange, contribution or other transfer (in one transaction or a series of related transactions) of all or substantially all of the assets of such Party to which this Agreement relates, or (d) the approval of any plan or proposal for the liquidation or dissolution of such Party (other than in circumstances to which Section 13.2(b) is applicable). Notwithstanding the foregoing, an equity sale to underwriters in a public offering of a Party or an equity sale to Third Parties solely for the purpose of financing or a transaction solely to change the domicile of a Party shall not constitute a Change of Control. For the purpose of this clause, any acquisition of additional Aguettant voting equity securities by a member of the Aguettant family who is currently an Aguettant shareholder shall not constitute a Change of Control of Aguettant.

"CMC" means chemistry, manufacturing and controls.

"Commercialization" means any and all activities relating to the preparation for sale of, offering for sale of, or sale of a product, including activities related to Launch, marketing, promoting, distributing, using, importing, pricing, reimbursement, and advertising such product, and interacting with Regulatory Authorities regarding any of the foregoing, but excluding any activities relating to Manufacturing or Development. "**Commercialize**" means to engage in Commercialization.

"Commercialization Plan" has the meaning set forth in Section 3.4(a).

"Commercialization Strategy" has the meaning set forth in Section 3.3.

"Commercialization Updates" has the meaning set forth in Section 3.4(b).

"Commercially Reasonable Efforts" means that level of efforts and resources, with respect to a particular Party, at the relevant point in time, that is consistent with the usual practice followed by that Party, in the exercise of its reasonable scientific, commercial and business judgment relating to other prescription pharmaceutical products owned or licensed by it or to which it has exclusive rights in each country in the Territory, which have market potential and are at a stage of development or product life similar to the Product, taking into account: measures of patent coverage; relative safety and efficacy; product profile; the then-current competitiveness of the marketplace and the likely competitive environment at the time of projected entry into the market; Development, Marketing Authorization, Manufacturing, and Commercialization costs; feasibility of Manufacture; the proprietary position of the compound or product, including the strength and duration of patent protection and anticipated exclusivity; the likelihood of obtaining Marketing Authorizations and the timing of such; the current guidance and requirements for Regulatory Approval and similar products and the current and projected regulatory status; labeling or anticipated labeling; and the relative profitability of the products (including pricing and reimbursement status, but excluding consideration of amounts payable under the Agreement).

"Confidential Information" has the meaning set forth in Section 10.1.

"Confidentiality Agreement" means the Mutual Confidentiality Agreement by and between the Parties effective as of August 1, 2018.

"Control" (including any variations such as "**Controlled**"), in the context of intellectual property rights, Know-How and Confidential Information, means possession (whether by ownership or license, other than pursuant to this Agreement) by a Party of the ability to grant access to, or a license or sublicense of, such rights, Know-How and Confidential Information as set forth in this Agreement without violating the terms of an agreement with a Third Party.

"Core Pharmaceutical Dossier" means a compilation of pre-clinical, clinical and CMC data necessary to support and maintain Regulatory Approvals in the Field in the Territory.

"Cure Period" has the meaning set forth in Section 5.1(d).

"Data Contact" has the meaning set forth in Section 14.17.

"DEA" means the US Drug Enforcement Administration.

"Deadline" has the meaning set forth in Section 3.3.

"Dental Field" means the dental healthcare setting.

"Development" means non-clinical and clinical development activities reasonably related to the development and submission of information to a Regulatory Authority or otherwise related to the research, identification, testing and validation, including, without limitation, toxicology, pharmacology and other discovery and pre-clinical efforts, test method development and stability testing, manufacturing process and CMC development, formulation development, quality assurance and quality control development, generation of data for regulatory filings, statistical analysis, clinical trials (including Post-Approval Commitments and Post-Marketing Studies) of a product, whether for purposes of label expansion or otherwise, but does not include Manufacturing or Commercialization. "**Develop**" means to engage in Development.

"Disclosing Party" has the meaning set forth in Section 10.1.

"Dispute Notice" has the meaning set forth in Section 7.3.

"Distributor" means a Third Party or an Affiliate of Aguettant to whom Aguettant or an Affiliate of Aguettant has granted the right to market, promote, co-promote, advertise, detail, sell or distribute the Product in the Field in the Territory without the control of Regulatory Filings for the Product in the Field in the Territory. For the avoidance of doubt, such grant of right by Aguettant to a Distributor is not subject to AcelRx's prior approval.

"Dollars" or "**USD**" means the official currency of the United States.

"Effective Date" has the meaning set forth in the first paragraph hereof.

"Effective Per Unit Transfer Price" has the meaning set forth in Section 8.3(b).

"EFPIA Code" means the European Federation of Pharmaceutical Industries and Associations Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations.

"European Union" or "**EU**" means the supra-national community consisting of, as of January 1, 2019, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden.

"Euros" or "**EUR**" means the official currency of the EU.

"Failure" means, in any MY after the Line Change MY, sales by or on behalf of Aguettant are less than [***]% of the Minimum Sales Obligations for such MY, and such failure is not justified or due to AcelRx's failure in any of its contractual obligations (e.g., failure to supply, delay in supply, etc.).

"Field" means adult use for the treatment of moderate to severe pain in a medically monitored setting. For the avoidance of doubt, the Field includes the Dental Field.

"Fill and Finish" means Manufacturing Finished Products from Bulk Products, including the secondary and tertiary packaging to EU quality packaging standards, serialization, labeling, testing, releasing, quality assurance and quality control, of Finished Products. "**Fill and Finishing**" means to engage in Fill and Finish.

"Final Artwork" has the meaning set forth in Section 4.1(b).

"Finished Products" means Products that are fully packaged, serialized, labeled and EU quality packaged, including primary, secondary and tertiary packaging, as required for sale and proper handling and protection during warehousing and transportation in a particular market in the Territory, as set forth in the Quality Agreement.

"First Commercial Sale" means the first arm's length sale of the Product to a Third Party by Aguettant, or its Affiliates, Sublicensees or Distributors, for use in the Field and in the Territory, after the respective Product has been granted Pricing Approval and Other Approvals by the Regulatory Authority in the Territory.

"Force Majeure Event" has the meaning set forth in Section 14.1.

"Good Clinical Practices" or "**GCP**" means the then-current standards, practices and procedures promulgated or endorsed by the ICH as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the EU and comparable regulatory standards, practices and procedures in other jurisdictions in the Territory, as they may be updated from time to time.

"Good Laboratory Practices" or "**GLP**" means the then-current good laboratory practice standards promulgated or endorsed by the EU, and comparable regulatory standards in other jurisdictions in the Territory, as they may be updated from time to time.

"Good Manufacturing Practices" or "**GMP**" means the then-current good manufacturing practices required by the EU for the manufacture and testing of pharmaceutical materials, and comparable laws or regulations applicable to the manufacture and testing of pharmaceutical materials in other jurisdictions in the Territory, as they may be updated from time to time.

"Good Pharmacovigilance Practices" or "**GVP**" means the then-current good pharmacovigilance practices required by the EU, and comparable regulatory standards in other jurisdictions in the Territory, as they may be updated from time to time.

"Governmental Authority" means any court, agency, department, authority or other instrumentality of any national, supranational, state, county, city or other political subdivision.

"Gross Sales" means, for the applicable period, Aguettant's ex-factory Unit gross selling price (i.e., the gross amount invoiced per Unit by Aguettant, or its Affiliates or Sublicensees) multiplied by the number of Units sold in the Territory to Third Parties (other than Aguettant's Sublicensees).

"ICC" has the meaning set forth in Section 14.14.

"ICH" means the International Conference on Harmonization (of Technical Requirements for Registration of Pharmaceuticals for Human Use).

"Indication" means the use of the Product, which is stated on the label as: "DZUVEO® is a human pharmaceutical drug indicated in moderate to severe pain in adults in a disposable single-dose applicator, to be administered by a healthcare provider."

"Initial Term" has the meaning set forth in Section 13.1.

"Intellectual Property" means any and all Know-How, Trademarks, copyrights, Patents and other intellectual property rights, which pertain to the Manufacture, use, sale or import of the Product in the Territory, owned or controlled by AcelRx or its Affiliates in the Territory as of the Effective Date or during the Term.

"Inventions" means any and all inventions, discoveries, processes and techniques, which are, or may be, patentable or otherwise protectable under Applicable Laws of any country or region, and which are conceived, discovered or reduced to practice by or on behalf of a Party (whether solely or jointly with the other Party or its Affiliates).

"IP Adversarial Action" has the meaning set forth in Section 9.3(c).

"IP Challenge" has the meaning set forth in Section 13.3(e).

"IP Expenses" means expenses relating to the preparation, filing, prosecution and maintenance of the AcelRx IP, including the use of counsel of AcelRx's choice.

"Joint Steering Committee" or "**JSC**" has the meaning set forth in Section 7.1.

"Know-How" means all tangible and intangible scientific, technical, clinical, regulatory, trade, marketing, commercial, financial or business information and materials, including compounds, solid state forms, compositions of matter, formulations, devices, techniques, processes, methods, trade secrets, formulae, procedures, tests, data, results, analyses, documentation, reports, information (including pharmacological, toxicological, non-clinical (including CMC), and clinical test design, methods, protocols, data, results, analyses, and conclusions), quality assurance and quality control information, regulatory documentation, information and submissions pertaining to, or made in association with, filings with any Regulatory Authority, knowledge, know-how, skill, and experience.

"Launch" means the commencement of the First Commercial Sale of the Product in a country within the Territory after receiving the required Marketing Authorizations. When used as a verb, to "**Launch**" means to engage in the Launch.

"Launch Date" means the date of the Launch, and is based upon regulatory and commercial preparedness requirements, including supply of the Product by AcelRx.

"Line Change MY" means the MY in which the Manufacturing Line Change Approval occurs.

"Losses" has the meaning set forth in Section 12.3.

"MAA" means an application for Marketing Authorization or for Regulatory Approval filed with a Regulatory Authority.

"Manufacture" means, as applicable to Bulk Products or Finished Products, manufacture, generate, process, prepare, make, assemble, test, label, package, store, hold, handle, receive, release, serialize, transport, and deliver a product (or any component or intermediate thereof), including any related stability testing, quality assurance and quality control. "**Manufacturing**" means to engage in Manufacture.

"Manufacturing Line Change Approval" means the approval of the MA variation relating to the switch of lines in the Manufacturing process, enabling AcelRx to Manufacture the Products on an automated line.

"Marketing Authorization" or "**MA**" means the grant or issuance of all Regulatory Approvals and all Pricing Approvals, including any technical, medical and scientific approvals, licenses, registrations or authorizations (including approvals of MAAs, supplements and amendments, pre- and post- approvals, pricing and Third Party reimbursement approvals, and labeling approvals) in a country of the Territory necessary for the Development, Manufacture or Commercialization, as applicable, of the Product in the Field in such country, but excluding Other Approvals.

"Marketing Year" or "**MY**" means the period from the first Launch of the Product in any country of the Territory until December 31 of the next Calendar Year following the Calendar Year of the Launch, and any subsequent 12-month period, except in the event that the first Launch occurs in the period from January 1, 2022 until April 30, 2022, MY 1 shall end on December 31, 2022. For the avoidance of doubt, Marketing Year is defined once for the entire Agreement, and not on a Product-by-Product or country-by-country basis.

"Minimum Batch Size" has the meaning set forth in Section 5.1(e).

"Minimum Sales Obligation(s)" has the meaning set forth in Section 5.5(a).

"Net Sales" means Gross Sales invoiced in the course of the applicable period by or on behalf of Aguettant, its Affiliates or Sublicensees for sales of the Product to Third Parties (other than Aguettant's Sublicensees), less deductions in the course of such applicable period directly relating to sales of the Product by Aguettant, its Affiliates or Sublicensees using Accounting Standards applied on a consistent basis for:

(a) credits or allowances actually given or made for rejection of or return of previously sold Product (whether as a result of Recalls, market withdrawals, other corrective actions, damaged, defective goods or otherwise), for retroactive price reductions and billing errors, or other allowances specifically identifiable as relating to the Product; and

(b) trade, cash or quantity discounts actually granted, incurred, or allowed in the ordinary course of business (including rebates, purchase charge backs and allowances calculated based on the sales amount of the Product).

"Other Approvals" means all licenses, permissions, consents and regulatory authorizations other than Marketing Authorizations and Pricing Approvals that are (a) necessary to enable the Product to be imported, marketed, sold, distributed, stored and shipped in the Territory by Aguettant, or its Affiliates or Sublicensees; or (b) necessary at each specific institution in the Territory where Aguettant, or its Affiliates or Sublicensees, plans to market, sell or promote the Product.

"Party" has the meaning set forth in the first paragraph hereof.

"Patent(s)" means (a) all patents, certificates of invention, applications for certificates of invention, priority patent filings and patent applications, and (b) any renewal, division, continuation (in whole or in part), or request for continued examination of any of such patents, certificates of invention and patent applications, and any and all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.

"Person" means any individual, corporation, partnership, limited liability company, trust, governmental entity, or other legal entity of any nature whatsoever.

"Personal Data" means any information relating to an identified or identifiable natural person, where an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

"Pharmacovigilance Agreement" has the meaning set forth in Section 6.5(a).

"Post-Approval Commitments" means all clinical studies (including pediatric studies and Post-Marketing Studies) conducted after Regulatory Approval for the Product that are requested by a Regulatory Authority or that are necessary to fulfill commitments made to any Regulatory Authority as a condition for the receipt or maintenance of such Regulatory Approval in any country.

"Post-Marketing Studies" means all non-interventional and interventional clinical trials of the Product with the main objective to collect data to increase product knowledge or for marketing and market access purposes, e.g., pricing studies, post-marketing surveillance studies, patient outcome studies, patient preference studies and investigator-initiated trials.

"Pricing Approval" means any and all permissions, excluding Regulatory Approvals, to be obtained from the relevant Regulatory Authorities that are necessary for the definition of the public price of the Product or reimbursement conditions established by such Regulatory Authorities as well as the grant of such public price or reimbursement conditions, and any variation of any such permission where applicable. Pricing Approvals will also include approvals, permissions and conditions established by such Regulatory Authorities imposed on a Party for participating in and supplying Product pursuant to tender processes in the Territory.

"Product" means 30 mcg of sufentanil formulated in a sublingual tablet in a single-dose disposable dispenser for medically supervised use, packaged within a tamper-evident laminate foil pouch, as authorized in the EU under the Brand Name.

"Product Improvement" means any and all Inventions, and any and all changes, modifications and amendments, by or on behalf of a Party, or by the Parties jointly, during the Term, which relate to the Product, or a modified form thereof (except for forms for parenteral application of sufentanil), whether patentable or not, whether in the Field or not.

“Promotional Material” has the meaning set forth in Section 3.8.

“Qualified Person” means a person appointed in compliance with applicable EU regulations, who is responsible for the release of medicinal products within the applicable territory, fully complies with Applicable Laws, and continues to be responsible for release testing and issuance of certificates.

“Quality Agreement” has the meaning set forth in Section 6.1.

“Recall” means Product recall, Product withdrawal, field correction of the Product or other related action.

“Receiving Party” has the meaning set forth in Section 10.1.

“Regulatory Approval” means, with respect to any Product in any country or regulatory jurisdiction, any and all approvals from the applicable Regulatory Authority sufficient for the import, distribution, marketing, use, offering for sale, and sale of the Product for use in the Field in such country or jurisdiction in the Territory in accordance with Applicable Laws, but excluding any applicable Pricing Approvals.

“Regulatory Authority” means any national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity: (a) whose review or approval is necessary (i) for the Manufacture, packaging, use, storage, import, export, distribution, promotion, marketing, offer for sale and sale of the Product, (ii) for reviewing Regulatory Filings for the Product (or a component thereof) or (iii) for granting Regulatory Approvals or Pricing Approvals for the Product; or (b) having authority to review and enforce GMP or other Applicable Laws relating to the Product or the Manufacture, Development, Commercialization, use or sale thereof.

“Regulatory Filings” means all applications, approvals, licenses, registrations, notifications, submissions and authorizations made to or received from a Regulatory Authority in a country necessary for the Manufacture, Development or Commercialization of the Product in such country, including any MAA or any other applications for Regulatory Approvals or Pricing Approvals.

“Regulatory Strategy” means any decision: (a) relating to the nature of an MAA; (b) that impacts the availability of market exclusivity or regulatory data protection; (c) that is reasonably likely to affect the timing of Marketing Authorization by more than a Calendar Quarter; (d) relating to the conduct of any Post-Approval Commitments or Post-Marketing Studies or the implementation or a risk management plan; or (e) that entails a material modification to an existing Marketing Authorization (e.g., type II variation or above in the EU).

“Renewal Term” has the meaning set forth in Section 13.1.

“Requested Delivery Date” has the meaning set forth in Section 5.3.

“Re-registration” means, with respect to MA, the transfer of MA in the Territory from AcelRx to Aguettant as the new MA holder, including all variations thereof at the time of such transfer.

“Sales Milestone Threshold” has the meaning set forth in Section 8.4.

"Senior Executives" has the meaning set forth in Section 14.12.

"Specification" means (a) the specifications for the Product established by inclusion in the MAA and as required by a Regulatory Authority in the Territory for approval and (b) such other specifications for the Product agreed to by the Parties pursuant to the Supply Agreement related to the packaging, storage conditions, shelf life and labeling of the Product.

"Sublicensee" has the meaning set forth in Section 2.2.

"Supply Agreement" has the meaning set forth in Section 5.1(b).

"Supply Cost Payment" has the meaning set forth in Section 8.2.

"Supply Price" has the meaning set forth in Section 5.1(b).

"Swissmedic" means the Swiss Regulatory Authority.

"Term" has the meaning set forth in Section 13.1.

"Territory" means each member state of the European Union as it is constituted as of January 1, 2021, plus Norway, Iceland, Liechtenstein, Andorra, Vatican Republic, Monaco, Switzerland and the United Kingdom. The Territory may be expanded by mutual written agreement of the Parties in accordance with Section 7.1(b)(vi).

"Third Party" means any Person other than AcelRx, Aguettant and their respective Affiliates.

"Third Party Claim" has the meaning set forth in Section 12.3.

"Trademark" means trademarks, trade names, trade dresses, domain names, logos and brandings.

"Transfer Price" has the meaning set forth in Section 8.3(b).

"Unit" means one Product.

"Unit Cost" has the meaning set forth in Section 5.1(c).

"[***]" has the meaning set forth in Section 2.2.

Exhibit 10.2

[***] = CERTAIN INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS CONFIDENTIAL, (II) IS NOT MATERIAL, AND (III) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

LICENSE AND COMMERCIALIZATION AGREEMENT (US)

BETWEEN

ACELRX PHARMACEUTICALS, INC.

AND

LABORATOIRE AGUETTANT

EFFECTIVE AS OF JULY 14, 2021

This License and Commercialization Agreement (this "**Agreement**") is entered into and effective as of July 14, 2021 (the "**Effective Date**"), by and between AcelRx Pharmaceuticals, Inc., a corporation organized and existing under the laws of the State of Delaware, 25821 Industrial Boulevard, Suite 400, Hayward, CA 94545, USA ("**AcelRx**"), and **Laboratoire Aguettant,** a corporation organized and existing under the laws of France, 1 rue Alexander Fleming, 69007 Lyon, France ("**Aguettant**"). AcelRx and Aguettant are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

Recitals

WHEREAS, Aguettant is a pharmaceutical company that develops, manufactures, and distributes injectable medications, primarily in Europe, including ephedrine and phenyl ephedrine prefilled syringe products;

WHEREAS, Aguettant owns or controls data, know-how and other intellectual property relating to such products;

WHEREAS, AcelRx is a biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute pain, primarily in the United States;

WHEREAS, AcelRx desires to obtain from Aguettant certain rights and licenses to commercialize and import such products in the United States, and Aguettant is willing to supply such products and to grant AcelRx such rights and licenses in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Aguettant and AcelRx hereby agree as follows:

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ARTICLE 1

DEFINITIONS AND USAGE

1.1 Definitions. Capitalized terms used in this Agreement shall have the meaning ascribed thereto herein, including in Schedule 1.1.

1.2 Headings, Gender and Number. All section and article titles or captions contained in this Agreement and in any exhibit, schedule or certificate referred to herein or annexed to this Agreement are for convenience only, shall not be deemed a part of this Agreement and shall not affect the meaning or interpretation of this Agreement. Words used herein, regardless of the number and gender specifically used, shall be deemed and construed to include any other number, singular or plural, and other gender, masculine, feminine, or neuter, as the context requires.

1.3 References. Unless explicitly provided for, references to articles, sections, schedules or exhibits are references to articles, sections, schedules or exhibits of this Agreement.

1.4 Usage. Unless otherwise indicated to the contrary herein by context or use hereof, words importing the singular shall also include the plural, and vice versa. All references to days in this Agreement shall mean calendar days, unless otherwise specified. The words “include,” “includes” and “including” shall be deemed to be followed by the phrase “but not limited to” unless expressly stated otherwise. The word “or” shall mean “and/or”, unless otherwise specified.

ARTICLE 2

GRANT OF LICENSE

2.1 License Grant.

(a) **Aguettant IP**. Subject to the terms and conditions set forth in the Agreement and except as set out in Section 2.1(b), Aguettant, on behalf of itself and its Affiliates, hereby grants to AcelRx for the Term an exclusive, royalty-bearing, non-transferable, non-assignable (except as set forth in Section 14.4), non-sublicensable (except as provided in Section 2.2) right and license under the Aguettant IP (other than Aguettant Inventions, and Product Improvements, which are addressed in Section 2.1(b)) to (i) Develop, solely to the extent expressly permitted by the Agreement, and (ii) Commercialize, in each case, the Products in the Territory.

(b) **Inventions and Improvements**. Subject to the terms and conditions set forth in the Agreement, Aguettant, on behalf of itself and its Affiliates, hereby grants to AcelRx for the Term an exclusive, royalty-free, non-transferable, non-assignable (except as provided in Section 14.4), non-sublicensable (except as provided in Section 2.2) right and license under the Aguettant Inventions and Product Improvements to use any such Aguettant Inventions or Product Improvements to (i) Develop, solely to the extent expressly permitted by the Agreement, and (ii) Commercialize, in each case, the Products in the Territory.

2.2 Sublicense to Affiliates or Third Parties. AcelRx shall have the right to grant sublicenses under the licenses granted in Section 2.1 to its Affiliates or, with the prior written approval of Aguettant, to Third Parties (the "**Sublicensees**"). Aguettant shall not withhold or delay such written approval unreasonably, provided that consent to a sublicense of all or substantially all rights under this Agreement to a Third Party (i.e., essentially a substitution of AcelRx) shall be at the sole discretion of Aguettant.

2.3 No Implied Licenses. No right or license under the Aguettant IP is granted or shall be granted by implication or estoppel. All rights or licenses that are or shall be granted between Aguettant and AcelRx are only those rights or licenses expressly provided in this Agreement.

ARTICLE 3

REGULATORY APPROVAL, COMMERCIALIZATION AND MARKETING

3.1 Regulatory Approval of the Products in the Territory. Within [***] after the Effective Date, Aguettant shall provide to AcelRx the current version of the Core Pharmaceutical Dossiers in eCTD format for the Products. AcelRx shall be responsible, at its sole cost and expense, for the submission of a marketing authorization application with FDA. Each and any such submission shall be at the sole discretion of AcelRx. AcelRx shall keep Aguettant reasonably informed regarding all relevant local regulatory activities relating to the Product in the Territory and shall promptly provide to Aguettant copies of all local regulatory submissions (including applications for Regulatory Approval) in the Territory and of all responses from the FDA and other competent Regulatory Authorities. AcelRx shall update Aguettant as to all progress and results of such regulatory filings. Aguettant shall have the right to comment on all draft local regulatory submissions, and AcelRx shall use reasonable efforts to accommodate all such comments. AcelRx shall not generate any pharmaceutical or technical data to be added to the M3 part of the Core Pharmaceutical Dossiers except, subject to Aguettant's prior written approval, if a Regulatory Authority requires additional information or documentation in relation to the Product in order to obtain the Marketing Approvals in the Territory.

3.2 If any documents in the Core Pharmaceutical Dossiers need to be upgraded to be FDA acceptable, then the Parties shall collaborate to complete the necessary work, provided that any substantial work shall require the prior consent of both Parties, and agree on the allocation of related costs between them. In case the Parties fail to agree on these elements, then each of them shall be entitled to end the Agreement as provided in Section 13.2(d)(iii).

3.3 Commercialization of the Products in the Territory. AcelRx, at its sole discretion, shall Commercialize the Products in the Territory, and shall fulfill responsibilities in support thereof, including the following: legal, compliance, finance, audit, human resources, regulatory, safety, market access, strategy, government affairs and stakeholder management, public affairs and any other operational requirements (excluding Development and Manufacturing performed by Aguettant). Without limiting the foregoing, AcelRx shall be responsible for Commercialization, including marketing, strategy, pricing, promotion, physician targeting, reimbursement, branding, distribution and sale of the Products in the Territory. The Commercialization of the Products in the Territory, if any, will be overseen by the Joint Steering Committee as set out in Article 7. All costs and expenses of Commercialization, including for distribution, marketing and selling, of the Products in the Territory shall be for AcelRx's account.

3.4 AcelRx's Commercialization Rights and Obligations. AcelRx, in consultation with Aguettant and the JSC, shall have the right to: (a) establish the strategy for Commercialization of the Products in the Territory (the "**Commercialization Strategy**") and (b) Commercialize the Products in the Territory. AcelRx shall use Commercially Reasonable Efforts to conduct all such activities in accordance with any Commercialization Plan, and shall use Commercially Reasonable Efforts to satisfy all diligence therein.

3.5 Commercialization Coordination.

(a) **Commercialization Plans**. For each Product, no later than [***] before the expected Launch Date, and thereafter every [***] for the first Marketing Year and every [***] after the first Marketing Year, AcelRx shall prepare and submit to the JSC for review, alteration and approval a plan setting forth: [***] (the "**Commercialization Plan**").

(b) **Commercial Updates**. For each Product, AcelRx shall consult with and provide regular updates to Aguettant including through the JSC regarding the Commercialization Strategy and Commercialization activities in the Territory ("**Commercialization Updates**"). Without limiting the generality of the foregoing, AcelRx shall provide (i) a Commercialization Update to Aguettant through the JSC at least [***] in MYs 1 and 2, and at least [***] in MY 3 and thereafter, and (ii) current sales reports to Aguettant in writing at least [***].

(c) **Commercialization Covenants**. In connection with its Commercialization of the Products in the Territory pursuant to the Commercialization Plan, AcelRx shall:

(i) maintain complete and accurate distribution records of all Products sold to customers or purchasers in the Territory by or on behalf of AcelRx;

(ii) retain, for a period of five (5) years from the date of creation, any and all training records related to the Products;

(iii) provide Aguettant and its designees with reasonable access to all premises and records relating to its activities involving the Products to the extent necessary to enable Aguettant to exercise its rights under the Agreement, provided a [***] prior notice has been provided to AcelRx and such designees of Aguettant have been previously approved by AcelRx, which approval shall not be unreasonably withheld or delayed; and

(iv) make no representations or warranties with respect to the Products other than those in the label for the Product or otherwise as specifically authorized in writing by Aguettant.

3.6 Compliance. AcelRx shall conduct, and shall ensure that all of its Affiliates, Distributors, Sublicensees and other subcontractors conduct, all Commercialization of the Products in the Territory in compliance with Applicable Laws and all ethics policies applicable in the Territory, as well as those provided by Aguettant to be mutually agreed upon by the Parties in good faith. AcelRx shall make all related disclosures with respect to and record all transfers of value to health care providers in the Territory as required by Applicable Laws and shall provide an annual summary thereof to Aguettant.

3.7 Regulatory and Pharmacovigilance Responsibilities. Upon the completion of the Marketing Approvals for an applicable Product, AcelRx shall be responsible for all regulatory and pharmacovigilance obligations, at its sole discretion and its sole cost and expense unless explicitly provided otherwise herein, including subsequent mandatory clinical trials, further Development of the Product to the extent such Development is requested by Regulatory Authorities, and obtaining and maintaining all Marketing Approvals and Other Approvals for the Products in the Territory.

3.8 Medical Affairs. AcelRx shall provide medical and scientific support for the Products in the Territory. AcelRx shall, subject to Applicable Laws, comply with Aguettant's policies on engaging and sponsoring healthcare providers.

3.9 Promotional Materials. AcelRx shall have the right to develop all written, printed, electronic or graphic material intended for use by sales representatives in promoting the Products in the Territory, including visual aids, file cards, premium items, clinical study reports, reprints, drug information updates, and any other promotional support items (collectively, the "**Promotional Materials**"); provided that (a) all Promotional Materials shall comply with Applicable Laws; (b) AcelRx shall provide a copy of all Promotional Materials to the JSC for discussion within JSC, prior to finalization thereof and at least [***] prior to use or distribution in the Territory, provided that AcelRx may repeatedly use or distribute any Promotional Materials previously approved by the JSC without any additional JSC review; (c) all Promotional Materials shall be compliant with Aguettant's global branding guidelines and core materials (including Indication), for the Product, as provided by Aguettant to AcelRx upon execution of the Agreement, as long as this is compliant with FDA requirements and regulations; and (d) no Promotional Material shall be detrimental to Aguettant's products other than the Product. Aguettant shall provide AcelRx, at Aguettant's cost and expense, all existing marketing and promotional materials (including website and digital content) regarding the Products, whether electronic (including source code thereof, if applicable) or physical copies, provided that Aguettant shall have no obligations under this Agreement to assist with the technical aspects of the creation and maintenance of such website or to provide such digital content in any particular format.

3.10 Territory Compliance. AcelRx shall not, and shall ensure its Affiliates, Distributors and Sublicensees do not: directly or indirectly promote, sell or distribute the Products for any use outside the Territory, which other territories are exclusively reserved to Aguettant or its licensees. Aguettant shall not, and shall ensure its Affiliates, distributors and sublicensees do not: actively promote, sell or distribute the Products for any use in the Territory (other than to AcelRx, its Affiliates, Distributors or Sublicensees).

ARTICLE 4

FURTHER DEVELOPMENT AND REGULATORY ACTIVITIES

4.1 Further Development.

(a) **Aguettant Responsibilities**. Aguettant shall be solely responsible for all CMC and Manufacturing activities, including the Stability Testing and Quality Reporting as set forth in Section 6.3, and provide all data related thereto, to the extent necessary to support any filings, updates or changes in Regulatory Approvals required for submission by AcelRx to the Regulatory Authorities. Aguettant shall, at its own expense, cooperate with AcelRx in connection with all regulatory filings, including all activities conducted by AcelRx related to Marketing Approval of the Products provided that AcelRx shall remain fully responsible for such approval activities and shall carry the burden of such activities, the cooperation of Aguettant being limited to reasonable support and assistance throughout the registration process, pricing and reimbursement. Aguettant shall allow any request by FDA to audit Aguettant's manufacturing and batch release facilities for Products. Aguettant shall be responsible for any variations outside the Territory, and for any variations it has decided to conduct; all costs and expenses pertaining thereto shall consequently be borne by Aguettant.

(b) **AcelRx Responsibilities**. AcelRx shall be responsible, at its sole discretion and at its sole cost and expense, for (i) all further Development activities for the Products in the Territory, including non-clinical and clinical studies, that are not expressly the responsibility of Aguettant under Section 4.1 (a), (ii) market access activities in the Territory, and shall pay related costs specific to the Territory, and (iii) any activities in support of the foregoing, including: Post-Approval Commitments required by Regulatory Authorities in the Territory; design and any approval required by Regulatory Authorities of the final artwork and packaging material, including labels, stickers, leaflets and carton boxes (collectively, the "**Final Artwork**"); commercial batch release; management of communications and interactions with the local Regulatory Authorities; each with Aguettant's reasonable support and assistance throughout the registration process, pricing and reimbursement.

(c) **Access to Development results**. Aguettant shall have, for the Term of this Agreement, the irrevocable, sublicensable right to use, worldwide and on a royalty-free basis, in connection with the Development, Manufacturing and Commercialization of products by Aguettant, its Affiliates or its or their sublicensees, all Marketing Approvals and all data (including safety and efficacy data, clinical data package, and data related to drug formulation and method of administration) that are generated by AcelRx in connection with the Development of the Products, and AcelRx shall update Aguettant of and shall provide Aguettant with any such Development results at least on an annual basis. The Parties shall determine the process for exchange of such Development results through the JSC.

4.2 Conduct of Development Activities.

(a) **Compliance**. Each Party shall conduct, and in AcelRx's case, shall ensure that all of its Affiliates, Sublicensees and other subcontractors conduct, the Development activities for which it is the responsible Party (i) in accordance with the terms and conditions of this Agreement, and (ii) in compliance in all material respects with all Applicable Laws (including ISO standards, GMP, GLP and GCP, if applicable).

(b) **Information Regarding Development Activities**. Each Party shall maintain records, in sufficient detail and in good scientific manner appropriate for patent, quality, compliance and regulatory purposes, which shall fully and properly reflect all work done and results achieved by or on behalf of such Party in the performance of its Development activities under this Agreement. Each Party shall keep the JSC appropriately informed of the status of the Development activities and other activities with respect to the Products in the Territory.

4.3 Regulatory Information; Right of Reference.

(a) **Dossier Information**. Upon AcelRx's reasonable request, Aguettant shall provide to AcelRx any previously generated bibliographic and CMC data within the Aguettant Know-How necessary to any new filing or to support and maintain Regulatory Approvals in the Territory and to Commercialize the Products in the Territory, provided that CMC data from the closed part of the drug master file shall be provided to AcelRx through a letter of access by which Regulatory Authorities may directly rely on such CMC data that shall remain at Aguettant or any of its subcontractors.

(b) **Right of Reference**. To the extent Controlled by a Party, the other Party shall have the right to (i) cross-reference the Regulatory Approvals and other regulatory documentation specifically related to the Products, (ii) access such Regulatory Approvals and regulatory documentation and any information therein, and (iii) use such information, in each case in connection with the performance of its obligations and exercise of its rights under this Agreement or, in the case of Aguettant, its development and commercialization of products outside the Territory. Each Party hereby grants to the other Party a "right of reference" (as that term is defined in 21 C.F.R. § 314.3(b) in the United States) to any data Controlled by such Party, including any Party's Regulatory Approvals and regulatory documentation, that specifically relate to a Product for use by the other Party as may be necessary to Develop Products for Commercialization by AcelRx in the Territory pursuant to this Agreement or, in the case of Aguettant, outside the Territory. Each Party shall, or shall cause its Affiliates to, provide a signed statement to this effect, if requested by the other Party, in accordance with 21 C.F.R. § 314.50(g)(3) or the equivalent as required in any other jurisdiction or otherwise provide appropriate notification of such right to the applicable Regulatory Authority. For clarity, access to and copies and use of any of the Regulatory Approvals, regulatory documentation and any information therein shall be subject to the terms and conditions of any agreement with a AcelRx or sublicensee of a Party providing access or right of reference pursuant to this Section 4.3; provided that AcelRx shall ensure that each Sublicensee provides the applicable rights to AcelRx so that AcelRx may grant such rights to Aguettant under this Section 4.3.

4.4 Global Dossier. As between the Parties and notwithstanding anything to the contrary provided in this Agreement, Aguettant shall retain the full unfettered ownership of the Core Pharmaceutical Dossiers.

ARTICLE 5

MANUFACTURE AND SUPPLY; QUALITY

5.1 Supply and Purchase of the Products.

(a) **Responsibility for Manufacturing**. Except as may otherwise be agreed in writing by the Parties or in the Supply Agreement, Aguettant shall Manufacture and supply Products in the form of Finished Products to AcelRx, or its Affiliates or Sublicensees or Distributors, for Commercialization in the Territory. Aguettant shall conduct quality control testing and quality assurance release for Finished Product at Aguettant's sole cost and expense. Aguettant, or its designated vendors, shall conduct final testing and quality control release for Finished Products for the placing of the Finished Products on the market in the Territory.

(b) **Commercial Supply**. Within [***] after the Effective Date, and in any event no later than [***] before the expected Launch Date of a Product, the Parties shall enter into a supply agreement for the commercial supply by Aguettant of such Product to AcelRx (such agreement, the "**Supply Agreement**"), which shall be consistent with the terms and conditions of the Agreement. Aguettant shall supply the Products in the Territory exclusively to AcelRx. AcelRx shall purchase the Products exclusively from Aguettant. Aguettant shall supply the Finished Products to AcelRx at a price of [***]€ per Unit of Phenylephrine and [***]€ per Unit of Ephedrine, FCA St Fons (France) Incoterms ICC 2020 (each, a "**Supply Price**"), provided that the Products are manufactured in Aguettant capacities.

(c) **Adjustment of Supply Price**.

(i) Provided that Aguettant can provide written documentation that the average variable cost per Unit charged to Aguettant by its suppliers, including raw materials and components costs, (the "**Unit Cost**") exceeds the applicable Supply Price in any Calendar Quarter, the Supply Price shall be adjusted to be the Unit Cost (the "**Adjusted Supply Price**") effective as of the acceptance by Aguettant of the next order of AcelRx delivered to Aguettant after the date that such written documentation is delivered to AcelRx. Notwithstanding the foregoing, [***]. The Parties shall have [***] upon such notice by Aguettant (the "**Cure Period**") to work together diligently and in good faith to cure the situation in such a way as to make continuing performance under the Agreement economically feasible for both Parties. During the Cure Period, the Adjusted Supply Price shall be [***].

(ii) In the event that Aguettant decides to no longer manufacture and release Finished Product in its own capacities then the Parties shall discuss in good faith on prices applicable to the concerned Products (also called "**New Supply Price**"), the New Supply Price being effective as of the acceptance by Aguettant of the next order of AcelRx delivered to Aguettant after the agreement between the Parties on the New Supply Price. In case the Parties fail to agree on such New Supply Price, then each of them shall be entitled to terminate the Agreement in the conditions of Section 13.2(d)(ii).

(d) Minimum Batch Size. The minimum batch size shall be the following (the "**Minimum Batch Size**"):

	If the Products are manufactured in [***] site (France)	If the Products are manufactured in [***] site (France)
EPHEDRINE	[***]	[***]
PHENYLEPHRINE	[***]	[***]

(e) Each order of the Product by AcelRx shall respect the following minimum order quantity:

	If the Products are manufactured in [***] site (France)	If the Products are manufactured in [***] site (France)
EPHEDRINE	[***]	[***]
PHENYLEPHRINE	[***]	[***]

5.2 Forecast and Orders.

(a) **Initial Forecast**. No later than [***] before the expected Launch Date of a Product, AcelRx shall provide to Aguettant a written [***] forecast of its expected orders of Products in the Territory (the "**Initial Forecast**").

(b) **Rolling Forecast**. Within the first [***] of every calendar month following the Initial Forecast, AcelRx shall provide a rolling non-binding forecast. Such forecast shall specify quantities of Products for which AcelRx reasonably expects to submit orders in each calendar month during the following [***] months.

(c) **Orders**. The first [***] of each rolling forecast shall be binding and the balance of each forecast will constitute a non-binding good faith estimate of expected orders for Products, provided that for the further [***] of each rolling forecast (i.e., months [***]), AcelRx shall place at the minimum binding purchase orders with Aguettant for quantities of Products of [***]% of the non-binding forecasts. The first non-binding forecast for a specific calendar month shall be decisive for this threshold for the applicable month. Aguettant shall use Commercially Reasonable Efforts to meet demand by AcelRx up to [***]% of the forecasted quantity for the applicable calendar month following the binding [***] period.

5.3 Delivery. Aguettant shall deliver Products to AcelRx by making them available for pick-up FCA St Fons: (a) for the first order no later than [***] after both a delivery date is agreed upon between the Parties and there is an order confirmation by Aguettant, provided that the Parties have mutually approved the Final Artwork; and (b) for orders following the first order no later than [***] after both a delivery date is agreed upon between the Parties and there is an order confirmation by Aguettant (the respective agreed date for such [***] or [***] period, a "**Requested Delivery Date**"). Aguettant may deliver the Product [***] in advance of standard lead time, provided that AcelRx accepts such early delivery before any shipping from Aguettant. Aguettant shall not deliver later than the Requested Delivery Date. Aguettant shall deliver to AcelRx Products with, at minimum, [***] remaining of the shelf life.

5.4 Annual Minimum Sales.

(a) **Minimum Sales Obligations**. AcelRx and Aguettant shall agree via the JSC [***] prior to Launch of each Product on minimum sales obligations for MY 2 through MY 5 (the "**Minimum Sales Obligations**"). Subject to Aguettant's ability to supply Products in conformity with the Requested Delivery Date, AcelRx shall make Commercially Reasonable Efforts, throughout the Launch and Commercialization phases in which it chooses to participate, to create the markets for the Products in the Territory so as to reach the Minimum Sales Obligation for MY 2 through MY 5 as to be agreed between the Parties accordingly.

(b) **Failure to Meet Obligations**. In the event of any Failure by AcelRx in any MY after MY 2, the Parties shall meet in order to assess the reasons for such Failure and decide a recovery plan. [***] AcelRx shall apply such recovery plan and deploy it within the timeline agreed in such recovery plan. The Parties may decide in JSC, or after a decision regarding a recovery plan, to amend the Minimum Sales Obligations retroactively. In the event of Failure by AcelRx in two consecutive MYs after MY 2, or in the event that AcelRx fails to apply the agreed recovery plan, Aguettant has the right to terminate the Agreement as set forth in Section 13.3(c).

ARTICLE 6

QUALITY AND PHARMACOVIGILANCE

6.1 Quality Agreement. The Parties shall use best efforts to sign a quality agreement (the "**Quality Agreement**") at the latest [***] before the anticipated Launch for the first Product to comply with the requirements of Regulatory Authorities in the Territory affecting each Party. The Quality Agreement shall set forth in detail the Specifications and customary representations and warranties with respect to the Products, including quality assurance arrangements and procedures with respect to the Manufacturing and supply of the Products, reporting customer complaints, conducting timely investigations, Recalls, logistics (including warehousing and shipping requirements) and testing requirements, which Quality Agreement shall be incorporated herein by reference following execution by both Parties. In the event of a conflict between any of the provisions of this Agreement or the Supply Agreement and the Quality Agreement, this Agreement or the Supply Agreement, as applicable, shall govern.

6.2 Record retention. AcelRx shall establish and maintain a written records retention policy with respect to the Products, including maintaining quality system documents in a central, controlled location and using Commercially Reasonable Efforts to prevent any loss, destruction, deterioration or unauthorized access to such documents. AcelRx shall, for a period of the Term and [***] years thereafter (or such longer period as required by Applicable Laws) retain original documents with original signatures in a central file within AcelRx's quality assurance or document control records.

6.3 Stability Testing and Quality Reports. Upon execution of the Agreement, Aguettant shall conduct [***] stability testing [***] and provide to AcelRx [***] quality review reports of the Products and the stability data thereof as required for Regulatory Approval in the Territory. In case AcelRx or a Regulatory Authority requires any additional stability testing for the Products, all costs related to such additional stability testing shall be borne by AcelRx.

6.4 Pharmacovigilance; Safety Data.

AcelRx, as Applicant having approved applications, is solely responsible for Pharmacovigilance of the Products in the Territory and all related duties in accordance with the applicable regulations. The Parties shall use best efforts to sign a pharmacovigilance agreement (the "**Pharmacovigilance Agreement**") at the latest [***] before the anticipated Launch for the first Product to comply with the requirements of Regulatory Authorities in the Territory affecting each Party.

If a Party becomes aware of a major safety concern relating to the Products relevant to the Agreement, this Party shall inform the other Party without delay. For this purpose, at any time, AcelRx and Aguettant agree to exchange data that may meaningfully contribute to the safety analysis of the Product, such as safety signals and/or information which may directly impact the risk-benefit assessment of the Product and/or which may require immediate action such as urgent safety restriction. This information should reach the other Party within [***] days from identification.

6.5 Complaints Handling and Reporting.

(a) Notifications, communications, handling and reporting of the Products complaints and adverse events shall be addressed by the Pharmacovigilance Agreement, provided that such Pharmacovigilance Agreement shall provide that AcelRx must: (i) investigate any complaints or issues relating to the Products and notify Aguettant thereof; (ii) not admit liability or settle any dispute or complaint without Aguettant's prior written consent; and (iii) provide Aguettant and its designees access to all premises and records relating to AcelRx's activities involving the Products with a [***] prior notice and provided such designees of Aguettant have been previously approved by AcelRx, which approval shall not be unreasonably withheld or delayed.

(b) Notifications, communications, handling and reporting of Product complaints that relate to the Manufacturing of a Product shall be addressed by the Quality Agreement. The Quality Agreement shall provide a right for AcelRx to access Aguettant's premises and to audit the Manufacturing facilities in order to conduct research and investigation to determine causes.

6.6 Returns and Recalls.

(a) **Returns**. AcelRx shall handle all returns, at its sole cost and expense, as needed. Unless the Parties agree otherwise, AcelRx shall only allow returns in customary conditions (e.g., a defect in a Product, Product not produced as specified) or due to a safety regulatory decision in the Territory. Further processing of returns by AcelRx shall be governed by the Quality Agreement.

(b) **Recalls**. Each Party agrees to notify the other Party within [***] if it discovers any issue that it reasonably believes could lead to a Recall. If practicable, the Parties shall promptly, following notification, discuss the plans for a Recall, provided that the Parties shall have joint responsibility for determining whether a Recall in the Territory is necessary. If the Parties, through the JSC, decide that a Recall is necessary, the Parties shall work together to develop and implement a Recall plan, which, unless agreed otherwise, shall be implemented by AcelRx. All costs and expenses associated with implementing a Recall in the Territory shall be borne by AcelRx, except to the extent it arises from Aguettant's failure to supply the Products in accordance with the Specifications or to transport the Products in accordance with Section 5.3. The Parties shall jointly determine the cause of a Recall, or in the event of disagreement between the Parties regarding such cause, an independent laboratory mutually agreed upon by the Parties shall determine such cause.

(c) **Costs**. For clarity, if a return or a Recall is due to Aguettant's failure to supply the Products in accordance with Specifications or to transport the Products in accordance with Section 5.3, Aguettant shall bear all costs and expenses which directly result from such return, Recall, or potential destruction of Products.

ARTICLE 7

GOVERNANCE

7.1 Joint Steering Committee. Within [***] following the Effective Date, the Parties shall establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**") to oversee matters related to the Development, Manufacturing and Commercialization of the Products in the Territory, including Regulatory Strategy, marketing, reimbursement, sales and revenue targets, and scientific and market access matters.

(a) **Composition**. The JSC shall consist of individuals appropriately qualified and of appropriate seniority and having decision-making authority to discuss and make decisions with respect to the Development, Manufacturing and Commercialization of Products in the Territory and shall be responsible for coordinating communications and managing the roles, responsibilities and timelines for such activities. The Joint Steering Committee shall be composed of four (4) members, two (2) of whom shall be nominated by Aguettant and two (2) of whom shall be nominated by AcelRx. Any member of the Joint Steering Committee may designate an appropriately qualified substitute to attend and perform the functions of that member at any meeting of the JSC. Each Party may, with the consent of the other Party, which consent shall not be unreasonably withheld or delayed, invite non-member representatives of such Party to attend meetings of the Joint Steering Committee.

(b) **Duties**. The Joint Steering Committee shall:

(i) discuss and align on Regulatory Strategy for Products;

(ii) review each Commercialization Plan and Commercialization Strategy in the Territory, including all updates and amendments thereto, including for the purpose of alignment with Aguettant's global commercialization strategy for Products, including any modification of branding of the Products in the Territory;

(iii) discuss and approve all Development of the Products in the Territory, including all Post-Approval Commitments and Post-Marketing Studies, including any investigator-sponsored trials, and approve the protocol, enrollment criteria and endpoints of each such study;

(iv) exchange information with regard to Development results achieved by either Party relating to the Products;

(v) exchange information with respect to pre-Launch, Launch and subsequent Commercialization activities with respect to the Products in the Territory;

(vi) recommend to the Parties for approval any extension of the Territory, which extension would be implemented by amendment to this Agreement;

(vii) discuss pricing in the Territory relative to outside the Territory;

(viii) approve any Recall or termination of Commercialization of any Product in any country in the Territory, and discuss any cause for Product defects or any complaints;

(ix) perform such other duties as are specifically assigned by the Parties to the Joint Steering Committee pursuant to this Agreement or otherwise in writing;

(x) discuss any litigation in relation to the Aguettant IP in the Territory; and

(xi) be the first forum for resolution of material disputes between the Parties under this Agreement.

The JSC shall have only the powers expressly assigned to it in this Section 7.1(b) and elsewhere in this Agreement, and shall have no power to amend, modify, or waive compliance with this Agreement. For clarity, (A) the JSC is not responsible for tactical and operational matters relating to the Commercialization of the Products in the Territory, which are AcelRx's responsibility, and (B) each Party shall maintain final decision-making authority over specific areas related to the Products as set forth expressly herein.

(c) **JSC Decision-Making**. The JSC shall act by consensus, and shall use reasonable efforts to reach consensus on all matters within its scope of responsibility. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party. If the JSC cannot reach consensus on an issue that comes before the JSC and over which the JSC has oversight, then the issue will be determined in accordance with Section 7.3.

(d) **JSC Meetings**. Joint Steering Committee meetings will be held as often as the members may determine, but at least twice per Calendar Year. Such meetings may be held in person, or by any means of telecommunications or video conference, as the members deem necessary or appropriate.

(e) **Minutes**. Minutes for each Joint Steering Committee meeting shall be prepared by an AcelRx or an Aguettant member of the Joint Steering Committee on an alternating basis. The draft minutes shall be sent to all members of the Joint Steering Committee for comment promptly after each such meeting (but in no event more than [***] days after each such meeting). All actions noted in the minutes shall be reviewed and approved at subsequent meetings of the Joint Steering Committee; provided that if the Parties cannot agree as to the content of the minutes by the time the Joint Steering Committee next meets, such minutes shall be finalized to reflect any areas of disagreement.

(f) **Expenses**. Each Party shall bear its own costs and expenses incurred by its members in connection with their activities as members of the Joint Steering Committee.

(g) **Subcommittees**. From time to time, the Joint Steering Committee may establish subcommittees to oversee particular projects or activities within the scope of authority of the Joint Steering Committee, as it deems necessary or advisable. Each subcommittee shall consist of such number of representatives of each Party as the Joint Steering Committee determines is appropriate from time to time and shall meet with such frequency as the Joint Steering Committee shall determine.

7.2 Alliance Managers. Each of Aguettant and AcelRx shall appoint one senior representative who possesses a general understanding of clinical, regulatory, manufacturing and marketing issues to act as its respective alliance manager for this relationship (each, an "**Alliance Manager**"). Each Party may appoint and replace its respective Alliance Manager at any time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment between the Parties. Each Alliance Manager will also be responsible for: (a) coordinating the relevant functional representatives of the Parties, in developing and executing strategies and plans for the Products; (b) providing a single point of communication for seeking consensus both internally within the respective Party's organization and together regarding key strategy and plan issues, including where all questions coming up will be channeled, where joint timelines, budget and capacity requirement are aligned; and (c) planning and coordinating: (i) collaboration efforts, (ii) the establishment of new work streams proactively at each Party, and (iii) internal and external communications. The Alliance Managers shall be entitled to attend meetings of the JSC and of any subcommittee, but shall not have, or be deemed to have, any rights or responsibilities of a member of the JSC or subcommittee unless formally appointed to such committees. Each Alliance Manager may bring any matter to the attention of the JSC or subcommittee when such Alliance Manager reasonably believes that such matter requires such attention.

7.3 Dispute Resolution. In the event that any subcommittee or the JSC is unable to reach a consensus or a dispute otherwise arises in such subcommittee or the JSC, then either Party may initiate the initial dispute resolution process in this Section 7.3 by providing written notice to the other Party identifying the particular dispute (the "**Dispute Notice**"). If any subcommittee is unable to resolve the dispute at the subcommittee level within [***] following the receipt of the Dispute Notice, then the dispute shall be referred to the Joint Steering Committee for resolution. If the Joint Steering Committee is unable to resolve any dispute that either (a) arises at the JSC level and is identified by a Party by a Dispute Notice or (b) is referred to it by a subcommittee pursuant to the preceding sentence, in each case, within [***] after a Party's receipt of written notice or the date of the referral, as applicable, then either Party may, by written notice to the other Party, have such dispute referred to the Senior Executives in accordance with Section 14.12, and such dispute shall thereafter be handled in accordance with Section 14.12.

7.4 Discontinuation of Participation. The Joint Steering Committee (and any subcommittee established under this Article 7) shall continue to exist until the first to occur of: (a) the Parties mutually agreeing to disband the committee; or (b) Aguettant providing to AcelRx written notice of its intention to disband and no longer participate in such committee at any time during the Term. Once Aguettant has provided such written notice, Aguettant shall have no further obligations under this Agreement with respect to any such committee or subcommittee, and (i) any matters that would previously have been addressed by a subcommittee will be handled by the JSC, and (ii) any matters that would previously have been addressed by the JSC will be handled by the Parties in accordance with the terms of this Agreement, except that AcelRx will have the right to decide all matters previously decided by the JSC.

ARTICLE 8

PAYMENTS AND RECORDS

8.1 In consideration of the rights and licenses granted to AcelRx by Aguettant hereunder, AcelRx shall pay to Aguettant the amounts set forth in this Article 8.

8.2 Supply Cost Payment. AcelRx shall place its Product purchase orders, which orders shall not be cancelled or modified once placed, to Aguettant and, within [***] upon receipt of invoice, pay to Aguettant an amount equal to the total number of Units Aguettant supplied to AcelRx, in the course of the applicable period, multiplied by the applicable Supply Price or the Adjusted Supply Price, if applicable, that is effective on the date the purchase order is accepted by Aguettant ("**Supply Cost Payment**"). For clarity, the applicable Supply Price or the Adjusted Supply Price, if applicable, shall be the minimum price to be paid by AcelRx to Aguettant for any Unit of a Product. Aguettant shall only provide an invoice to AcelRx after Aguettant makes Products available in accordance with Section 5.3.

8.3 Transfer Price Adjustment Payment.

(a) **Quarterly Sales Report**. No later than [***] after each Calendar Quarter, AcelRx shall send Aguettant an aggregated report of Net Sales in such Calendar Quarter, on a Product-by-Product basis, at AcelRx's cost.

(b) **Transfer Price**. On a product-by-product basis, for (i) [***], the transfer price shall be, an amount equal to forty percent (40%) of Net Sales in the applicable period (the "**Transfer Price**") and (ii) from [***] and thereafter, the Transfer Price shall be an amount equal to forty-five percent (45%) of Net Sales in the applicable period. Without limiting the foregoing, the effective applicable per Unit Transfer Price shall be the quotient obtained by dividing the Transfer Price (the Euro amount being converted, for purposes of the comparison and calculation, to USD in accordance with Section 8.5) by the total number of Units used to calculate the Net Sales applicable to such Transfer Price (the "**Effective Per Unit Transfer Price**").

(c) **Adjustment Payment**. After the end of each Calendar Quarter within a MY, if [***] then within [***] after AcelRx has received a corresponding invoice from Aguettant, AcelRx shall pay to Aguettant an adjustment calculated based on the quantity of Units as used to calculate the Net Sales in such Calendar Quarter multiplied by [***], which shall apply to the quantity of Units supplied by Aguettant to AcelRx thereunder on a first-in first-out basis, [***] which shall apply to Units beyond the quantity of Units supplied by Aguettant to AcelRx under the immediately preceding Supply Price or Adjusted Supply Price (as applicable) on a first-in first-out basis.

8.4 Milestone Payments. AcelRx shall pay to Aguettant one-time, non-refundable (except as otherwise provided in this Agreement), and non-creditable milestone payments not subject to set-off, the first time that Net Sales in a MY reach the sales milestone threshold levels set forth in Exhibit 8.4 (the "**Sales Milestone Threshold**"), within [***] after the end of such MY. For the avoidance of doubt, should more than one Sales Milestone Threshold be met within the same MY, all related Sales Milestones become due cumulatively, but only once. The applicable currency conversion rate mentioned in Section 8.5 shall be the one prevailing on December 31 of such MY.

8.5 Mode of Payment. All payments under the Agreement shall be made in Euros by bank wire transfer in immediately available funds to an account in the name of Aguettant as Aguettant may designate from time to time by written notice to AcelRx, or in the name of AcelRx as AcelRx may designate from time to time by written notice to Aguettant. Except as otherwise provided in Section 8.4, if any currency conversion shall be required in connection with the amounts hereunder, such conversion shall be made by using the currency conversion rate prevailing at the European Central Bank on the last Business Day of the Calendar Quarter reporting period to which such payments relate.

8.6 Taxes.

(a) **Cooperation and Coordination**. The Parties acknowledge and agree that they shall use their reasonable efforts to cooperate and inform each other for the purpose of facilitating income and other tax payments in relation to their activities under the Agreement.

(b) **Payment of Tax**. A Party receiving a payment shall pay any and all taxes levied on such payment. If the fiscal or taxing authorities of any relevant jurisdiction assert that amounts are required to be withheld from the payments due to a Party hereunder, or the tax laws in one or more jurisdictions have changed so as to explicitly require such treatment, the Party made aware of such assertion or change in law shall inform the other Party within [***] and shall consult with the other Party regarding the consequences of such assertion or change. If Applicable Laws require that taxes be deducted and withheld from a payment, the remitting Party shall (i) deduct those taxes from the payment, (ii) pay the taxes to the proper taxing authority, (iii) send evidence of the obligation together with proof of payment to the other Party within [***] following that payment, and (iv) provide such assistance as the other Party may reasonably require in obtaining any refund of such amounts to which the other Party may be entitled, to the extent that such assistance does not cause the remitting Party to incur any liability in respect of the taxes asserted to be due. Notwithstanding the foregoing, if AcelRx takes any action (including sublicensing its rights hereunder) that would create or cause an increase in withholding liability, above the withholding required prior to such action, then AcelRx will be responsible for paying any amounts resulting from such increase. All payments made under this Agreement are net prices and shall be free and clear of any and all taxes (like sales and use taxes, consumption taxes, goods and sale taxes or value-added taxes or comparable taxes), duties, levies, fees or other charges, applicable to the concerned Party under Applicable Laws, except for withholding taxes.

8.7 Records. AcelRx shall keep, and require its Affiliates, Sublicensees and Distributors to keep, complete, true and accurate books of accounts and records for the purpose of determining the amounts payable to Aguettant pursuant to this Agreement. Such books and records shall be kept for such period of time as required by law, but no less than [***] following the end of the Calendar Quarter to which they pertain. Such records shall be subject to audit by Aguettant in accordance with Section 8.8.

8.8 Audits. Aguettant, at its expense, through an independent, internationally recognized certified public accountant reasonably acceptable to AcelRx, shall have the right to access AcelRx's relevant books and records in relation to the sales of Products in the Territory for the sole purpose of verifying AcelRx's payments to Aguettant hereunder during any portion of the Term; such access shall be conducted after [***] prior notice by Aguettant to AcelRx during AcelRx's ordinary business hours, shall not be more frequent than [***] during any Calendar Year and shall not include any books and records that were previously accessed pursuant to this Section 8.8. Such accountant shall execute a confidentiality agreement with AcelRx in customary form and shall only disclose to Aguettant whether AcelRx paid Aguettant the correct amounts during the audit period and if not, any information necessary to explain the source of the discrepancy. If such audit determines that AcelRx paid Aguettant less than the amount properly due, then AcelRx shall pay Aguettant within [***] after conclusion of the audit an amount equal to such underpayment, along with interest under Section 8.9, and if the amount underpaid exceeds [***] of the amount due over the audited period, AcelRx shall also reimburse Aguettant for the reasonable costs of such audit (including the fees and expenses of the certified public accountant). If such audit determines that AcelRx paid Aguettant more than the amount properly due, then AcelRx shall be entitled to credit such overpayment against future payments due to Aguettant; provided, however, that if no future payments to Aguettant hereunder are reasonably anticipated, then Aguettant shall promptly issue a refund to AcelRx of such overpayment.

8.9 Late Payment. Any amounts not paid by the date due under the Agreement shall be subject to interest of [***] from the due date through and including the date upon which payment is received.

ARTICLE 9

INTELLECTUAL PROPERTY

9.1 Ownership of Intellectual Property.

(a) **Background IP**. Subject to the licenses and other rights expressly granted herein, each Party shall retain all right, title and interest in and to its Background Intellectual Property.

(b) **Product Improvements**. Aguettant shall solely own all right, title, and interest in and to the Product Improvements. AcelRx agrees to assign and hereby assigns and transfers to Aguettant all of its right, title and interest in and to the Product Improvements and agrees to take, and to cause its Affiliates, Sublicensees and its or their employees and agents to take, all further acts reasonably required to evidence such assignment and transfer to Aguettant, at Aguettant's reasonable expense. AcelRx hereby appoints Aguettant as its attorney-in-fact to sign such documents as Aguettant deems necessary for Aguettant to obtain ownership and to apply for, secure, and maintain patent or other proprietary protection of the Product Improvements if Aguettant is unable, after reasonable inquiry, to obtain AcelRx's (or its employee's or agent's) signature on such a document. AcelRx shall notify Aguettant in writing of any and all Product Improvements generated or reduced to practice by or on behalf of AcelRx or its Affiliates, promptly after each such Product Improvement is made or generated. For clarity, the Product Improvements shall be automatically incorporated in the definition of the Aguettant Patents and Aguettant Know-How. AcelRx shall ensure that each individual and entity conducting any activities under this Agreement on its behalf is under written obligation to assign all right, title and interest in and to the Product Improvements to AcelRx.

9.2 Prosecution and Maintenance. Aguettant shall be solely responsible for the preparation, filing, prosecution and maintenance of the Aguettant IP using counsel of its choice. Aguettant shall keep AcelRx informed of any material events or progress with regard to the preparation, filing, prosecution and maintenance of the Aguettant IP.

9.3 Infringement by Third Parties and Defense.

(a) **Monitoring**. AcelRx shall use Commercially Reasonable Efforts to monitor Third Party infringement of the Aguettant Patents in the Territory. AcelRx shall keep Aguettant timely informed of any activities by AcelRx in regard thereto.

(b) **Notice**. In the event that either Aguettant or AcelRx becomes aware of any infringement or threatened infringement by a Third Party of any Aguettant IP, it will notify the other Party in writing to that effect. Any such notice shall include evidence to support an allegation of infringement or threatened infringement by such Third Party.

(c) **Enforcement and Defense of Aguettant IP**. As between the Parties, Aguettant shall have the sole right to enforce and defend the Aguettant IP, including initiating, conducting, defending and managing any declaratory judgment action or infringement action (collectively, "**IP Adversarial Actions**") during the Term. AcelRx shall provide Aguettant with all reasonable assistance and cooperation in initiating, conducting or defending against any such IP Adversarial Action, including joining in any such IP Adversarial Action, at Aguettant's reasonable request and reasonable expense, provided that Aguettant shall at all times have full control over such IP Adversarial Action. Except as otherwise agreed to by the Parties in writing as part of a cost-sharing arrangement, any sums recovered or obtained in connection with a IP Adversarial Action shall be used first to reimburse the Parties' documented out-of-pocket legal expenses relating to such IP Adversarial Action on a pro-rata basis, and any remaining sums shall be retained by Aguettant, provided that if AcelRx joins in such IP Adversarial Action at its sole cost and expense, any remaining sums shall be divided between the Parties on such pro-rata basis.

9.4 Third Party Rights. Each Party shall promptly notify the other in writing of any allegation by a Third Party that the activity of either Party pursuant to this Agreement infringes or may infringe the intellectual property rights of such Third Party. Article 12 applies to the defense against such allegations.

ARTICLE 10

CONFIDENTIALITY

10.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, during the Term and for [***] years thereafter, the receiving Party (the "**Receiving Party**") shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any confidential or proprietary information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, visual or otherwise) which are disclosed to it by the other Party (the "**Disclosing Party**"), including all information concerning the Products and all information disclosed by one Party to the other pursuant to the Confidentiality Agreement and any other technical or business information of whatever nature (collectively, "**Confidential Information**").

10.2 Exceptions. Notwithstanding Section 10.1 above, the Receiving Party's obligations of confidentiality and non-use shall not apply to Confidential Information of the Disclosing Party that, in each case, the Receiving Party can demonstrate by competent evidence:

(a) was already known to the Receiving Party or any of its Affiliates, other than under an obligation of confidentiality, at the time of disclosure;

(b) was generally available to the public or was otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure by the Disclosing Party and other than through any act or omission of the Receiving Party or any of its Affiliates in breach of this Agreement;

(d) was subsequently lawfully disclosed to the Receiving Party or any of its Affiliates by a Person other than the Disclosing Party, and who, to the knowledge of the Receiving Party, did not receive such information directly or indirectly from the Disclosing Party under an obligation of confidence; or

(e) was independently developed by the Receiving Party or any of its Affiliates without use of or reference to the Confidential Information of the Disclosing Party.

Specific aspects or details of the Disclosing Party's Confidential Information shall not be deemed to be within the public domain or known to the Receiving Party merely because such Confidential Information is embraced by more general information in the public domain or known to the Receiving Party. Further, any combination of the Disclosing Party's Confidential Information shall not be considered in the public domain or known to the Receiving Party merely because individual elements of such Confidential Information are in the public domain or known to the Receiving Party unless the combination and its principles are in the public domain or known to the Receiving Party.

10.3 Permitted Disclosures. Notwithstanding the provisions of Section 10.1, each Party may disclose Confidential Information belonging to the other Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) filing or prosecuting Patents as permitted by this Agreement;

(b) prosecuting or defending litigation as permitted by this Agreement;

(c) complying with applicable court orders or governmental regulations;

(d) disclosing to its Affiliates, employees, directors, consultants, attorneys, and other professional advisors, and in AcelRx's case, to its Sublicensees, in each case who have a legitimate need to know such information, data, or materials and who are bound by written confidentiality obligations at least as restrictive as those set forth herein; and

(e) disclosure to Third Parties in connection with due diligence or similar investigations by or on behalf of a Third Party in connection with a potential license to, distribution agreement with or collaboration with such Third Party (including entry into any such agreement), or a potential merger or acquisition by such Third Party, and disclosure to potential or actual Third Party investors in confidential financing documents, provided, in each case, that any such Third Party agrees to be bound by similar terms of confidentiality and non-use at least as stringent as those set forth in this Article 10 (provided that the term may be shorter, but at least [***].

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 10.3(b) or (c), it shall, to the extent permitted by Applicable Laws, give reasonable advance notice to the other Party of such disclosure and use efforts to secure confidential treatment of such information at least as diligent as such Party would use to protect its own confidential information, but in no event less than reasonable efforts; provided that any Confidential Information so disclosed shall still be subject to the restrictions on use set forth in this Article 10. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder.

10.4 Confidentiality of this Agreement and its Terms. Except as otherwise provided in this Article 10, each Party agrees not to disclose to any Third Party the existence of this Agreement or the terms of this Agreement without the prior written consent of the other Party hereto, except that each Party may disclose the terms of this Agreement that are not otherwise made public as contemplated by Section 10.5 and as permitted under Section 10.3.

10.5 Public Announcements.

(a) As soon as practicable following the Effective Date, the Parties shall issue a joint press release announcing the existence of this Agreement substantially in the form attached hereto as Exhibit 10.5(a). Except as required by law (including disclosure requirements of the U.S. Securities and Exchange Commission ("SEC"), the Nasdaq stock market or any other stock exchange on which securities issued by a Party or its Affiliates are traded), neither Party shall make any other public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed; provided that it shall not be unreasonable for a Party to withhold consent with respect to any public announcement containing any of such Party's Confidential Information. In the event of a required public announcement, to the extent practicable under the circumstances, the Party making such announcement shall provide the other Party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other Party a reasonable opportunity to review and comment upon the proposed text.

(b) The Parties shall coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the SEC, the Nasdaq stock market or any other stock exchange or governmental agency on which securities issued by a Party or its Affiliate are traded, and each Party shall use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; provided that each Party shall ultimately retain control over what information to disclose to the SEC, the Nasdaq stock exchange or any other stock exchange or governmental agency, as the case may be, and provided further that the Parties shall use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither Party (nor its Affiliates) shall be obligated to consult with or obtain approval from the other Party with respect to any filings to the SEC, the Nasdaq stock market or any other stock exchange or governmental agency.

10.6 Publication of the Product Information. Without limiting the foregoing, AcelRx shall not, and shall ensure its Affiliates and Sublicensees do not, publish or publicly present any non-public scientific or technical information with respect to the Products without Aguettant's prior written consent.

10.7 Prior Non-Disclosure Agreements. As of the Effective Date, the terms of this Article 10 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) dealing with the subject of this Agreement, including the Confidentiality Agreement; provided that the existing Confidentiality Agreement between the Parties is hereby terminated and any and all Confidential Information pursuant to the Confidentiality Agreement shall be deemed "Confidential Information" of a Party pursuant to this Article 10.

ARTICLE 11

REPRESENTATIONS, WARRANTIES AND COVENANTS

11.1 Mutual Representations, Warranties and Covenants. Each Party hereby represents and warrants to the other Party, as of the Effective Date, as follows:

(a) **Duly Organized**. Such Party is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, and is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent such Party from performing its obligations under this Agreement.

(b) **Due Authorization; Binding Agreement**. The execution, delivery and performance of this Agreement by such Party have been duly authorized by all necessary corporate or organizational action. This Agreement is a legal and valid obligation binding on such Party and enforceable in accordance with its terms and does not (i) to such Party's knowledge and belief, violate any law, rule, regulation, order, writ, judgment, decree, determination or award of any court, governmental body or administrative or other agency having jurisdiction over such Party, or (ii) conflict with, or constitute a default under, any agreement, instrument or understanding, oral or written, to which such Party is a party or by which it is bound.

(c) **Consents**. Such Party has obtained, will obtain following the Effective Date before Commercialization in the Territory, or is not required to obtain, the consent, approval, order or authorization of any Third Party, and has completed, or is not required to complete, any registration, qualification, designation, declaration, or filing with any Regulatory Authority or Governmental Authority, in connection with the execution and delivery of this Agreement and the performance by such Party of its obligations under this Agreement (except for any Marketing Authorizations to be obtained in accordance with the terms of this Agreement).

(d) **Debarment**. Such Party is not debarred under the United States Federal Food, Drug and Cosmetic Act or similar Applicable Laws outside the U.S. and it does not, and will not during the Term, employ or use the services of any Person who is debarred, in connection with the Development, Manufacturing or Commercialization of the Products under this Agreement.

11.2 Representations, Warranties and Covenants of Aguettant. As used in this Section 11.2, "Knowledge" means, as applied to Aguettant, that any of Aguettant's executive officers knows of a particular fact or other matter, without any duty to perform diligence or due inquiry. Aguettant represents and warrants to AcelRx that as of the Effective Date:

(a) **Right to Grant License**. (i) Aguettant owns all right, title and interest in and to, or has a license, sublicense or otherwise permission to use and license, all of the Aguettant IP, free and clear of all encumbrances; (ii) Aguettant has not previously assigned, transferred, conveyed or otherwise encumbered or granted, and will not during the Term assign, transfer, convey or otherwise encumber its right, title and interest in any of the Aguettant IP or any rights granted to AcelRx hereunder, in each case (i) and (ii), that would adversely affect AcelRx's rights under this Agreement.

(b) **Scope of License**. To the Knowledge of Aguettant as of the Effective Date, Exhibit A sets forth all Patents included in the Aguettant Patents, as of the Effective Date, and Exhibit B sets forth all Trademarks included in the Aguettant IP, as of the Effective Date.

(c) **Patent and Trademark Status**. To Aguettant's Knowledge, (i) all issued Patents listed in Exhibit A and Trademarks listed on Exhibit B are in full force and effect, valid, subsisting and enforceable; (ii) none of the Patents listed in Exhibit A and Trademarks listed in Exhibit B is currently involved in any interference, reissue, reexamination, or opposition proceeding; (iii) neither Aguettant nor any of its Affiliates has received any written notice from any Person, or has knowledge, of any such actual or threatened proceeding; and (iv) all official fees, maintenance fees and annuities for the Aguettant Patents and the Trademarks listed in Exhibit B that are required to be paid to prevent abandonment or other loss of rights have been paid through the Effective Date to the extent due on or before the Effective Date.

(d) **Non-Infringement by Third Parties**. To Aguettant's Knowledge, there are no activities by Third Parties that would constitute infringement of the Aguettant IP or misappropriation of the Aguettant Know-How in the Territory.

(e) **Non-Infringement of Third Party Rights**. To Aguettant's Knowledge, the sale or importation of the Products, as in existence as of the Effective Date, in the Territory does not infringe or misappropriate any Patent, Trademark or other intellectual property right of a Third Party. Neither Aguettant nor any of its Affiliates has received any written notice from any Person, or has knowledge of, any actual or threatened claim or assertion that the use of the Aguettant Patents or Aguettant Trademarks in the Territory infringes or misappropriates the intellectual property rights of a Third Party.

(f) **Additional Legal Compliance**.

(i) To Aguettant's Knowledge, Aguettant and its Affiliates have complied in all material respects with all Applicable Laws in conducting Development and Manufacturing of the Products prior to the Effective Date, and neither Aguettant nor any of its Affiliates has received any written notice from any Governmental Authority in the Territory claiming that any such activities as conducted by them are not in such compliance.

(ii) No Governmental Authority in the Territory has commenced or, to Aguettant's Knowledge, threatened to initiate any action to enjoin production of the Products at any facility, nor has Aguettant or any of its Affiliates or, to the Knowledge of Aguettant, any of its contractor manufacturers, received any notice to such effect, nor has Aguettant received any order not to import the Products into the Territory.

ARTICLE 12

DISCLAIMER, LIMITATION OF LIABILITY AND INDEMNIFICATION

12.1 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, OR ANY OTHER AGREEMENT CONTEMPLATED HEREUNDER, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AND EACH PARTY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE OR USE, NON-INFRINGEMENT, VALIDITY AND ENFORCEABILITY OF PATENTS, OR THE PROSPECTS OR LIKELIHOOD OF DEVELOPMENT OR COMMERCIAL SUCCESS OF THE LICENSED PRODUCT.

12.2 Limitation of Liability. THE LIABILITY OF EITHER PARTY SHALL NOT EXCEED [***] IN THE AGGREGATE. FOR THE AVOIDANCE OF DOUBT, THIS DOES NOT APPLY TO PAYMENT OBLIGATIONS EXPLICITLY ORIGINATING FROM THE AGREEMENT. IN ANY EVENT, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; PROVIDED, HOWEVER, THAT THIS SECTION 12.2 SHALL NOT BE CONSTRUED TO LIMIT (A) EITHER PARTY'S INDEMNIFICATION OBLIGATIONS UNDER THIS ARTICLE 12 (B) EITHER PARTY'S REMEDIES FOR BREACH OF ARTICLE 10 BY THE OTHER PARTY, (C) EITHER PARTY'S REMEDIES FOR INFRINGEMENT OR MISAPPROPRIATION OF SUCH PARTY'S INTELLECTUAL PROPERTY RIGHTS BY THE OTHER PARTY, OR (D) EITHER PARTY'S LIABILITY FOR WILLFUL INTENT.

12.3 Indemnification of Aguettant. AcelRx shall indemnify, defend and hold harmless each of Aguettant and its Affiliates, and the directors, officers, shareholders, employees and agents of such entities and the successors and assigns of any of the foregoing (the "**Aguettant Indemnitees**"), from and against any and all losses, liabilities, damages, penalties, fines, costs and expenses (including reasonable attorneys' fees and other expenses of litigation) ("**Losses**") resulting from any claims, actions, suits or proceedings brought by a Third Party (a "**Third Party Claim**") incurred by any Aguettant Indemnitee, to the extent arising from (a) the negligence or willful misconduct of any AcelRx Indemnitees or any Sublicensees, Distributors or other subcontractors of AcelRx; (b) the Development, regulatory and Commercialization activities relating to a Product conducted by or on behalf of AcelRx, its Affiliates, Sublicensees, subcontractors and Distributors (other than AcelRx and its Affiliates and licensees) in connection with this Agreement, other than the Development and regulatory activities relating to a Product conducted by or on behalf of Aguettant and its Affiliates (other than AcelRx and its Affiliates and Sublicensees) in connection with this Agreement; or (c) any breach of any representations, warranties or covenants by AcelRx under this Agreement or the Supply Agreement; except in each case (a)-(c) to the extent such Third Party Claims fall within the scope of the indemnification obligations of Aguettant set forth in Section 12.4(a) or (c).

12.4 Indemnification of AcelRx. Aguettant shall indemnify, defend and hold harmless each of AcelRx and its Affiliates, and the directors, officers, shareholders, employees and agents of such entities and the successors and assigns of any of the foregoing (the "**AcelRx Indemnitees**"), from and against any and all Losses resulting from any Third Party Claims incurred by any AcelRx Indemnitee, to the extent arising from (a) the negligence or willful misconduct of any Aguettant Indemnitee; (b) the Development and regulatory activities relating to a Product conducted by or on behalf of Aguettant and its Affiliates (other than AcelRx and its Affiliates and Sublicensees) in connection with this Agreement; or (c) any breach of any representations, warranties or covenants by Aguettant under this Agreement or the Supply Agreement; except in each case (a)-(c) to the extent such Third Party Claims fall within the scope of the indemnification obligations of AcelRx set forth in Section 12.3(a) or (c).

12.5 Procedure. A Party that intends to claim indemnification under this Article 12 shall promptly notify the indemnifying Party in writing of any Third Party Claim, in respect of which the indemnitee intends to claim such indemnification. The indemnified Party shall provide the indemnifying Party with reasonable assistance, at the indemnifying Party's expense, in connection with the defense of the Third Party Claim for which indemnity is being sought. The indemnitee may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the indemnitor shall have the right to assume and conduct the defense of the Third Party Claim with counsel of its choice. The indemnitor shall not settle any Third Party Claim without the prior written consent of the indemnified Party, which consent shall not be unreasonably withheld, unless the settlement involves only the payment of money. So long as the indemnitor is actively defending the Third Party Claim in good faith, the indemnitee shall not settle any such Third Party Claim without the prior written consent of the indemnifying Party. If the indemnitor does not assume and conduct the defense of the Third Party Claim as provided above, (a) the indemnitee may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Third Party Claim in any manner the indemnitee may deem reasonably appropriate (and the indemnitee need not consult with, or obtain any consent from, the indemnitor in connection therewith), and (b) the indemnitor will remain responsible to indemnify the indemnitee as provided in this Article 12. The failure to deliver written notice to the indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the indemnitor of its indemnification obligations under this Article 12 if and to the extent the indemnitor is actually prejudiced thereby.

ARTICLE 13

TERM AND TERMINATION

13.1 Term. This Agreement shall commence on the Effective Date and shall continue for an initial term of ten (10) Marketing Years (the "**Initial Term**") and shall automatically renew for successive five (5) Marketing Year periods (each, a "**Renewal Term**", the Initial Term and each Renewal Term collectively the "**Term**"), unless either Party notifies the other Party of its intention to not renew at least six (6) months prior to the expiration of the then-current Term.

13.2 Termination for Cause.

(a) Each Party shall have the right to terminate this Agreement upon written notice if the other Party is in material breach of this Agreement and has not cured such breach within [***] days ([***] days with respect to any payment breach) after notice from the terminating Party requesting cure of the breach. Any such termination shall become effective at the end of such [***] day ([***] day with respect to any payment breach) period unless the breaching Party has cured any such breach or default prior to the end of such period.

(b) Each Party shall have the right to terminate this Agreement upon written notice upon the bankruptcy or insolvency of, or the filing of an action to commence insolvency proceedings against, the other Party, or the making or seeking to make or arrange an assignment for the benefit of creditors of the other Party, or the initiation of proceedings in voluntary or involuntary bankruptcy, or the appointment of a receiver or trustee of such Party's property, in each case that is not discharged within [***] days.

(c) Each Party shall have the right to terminate this Agreement upon written notice if the other Party claims the benefit of a Force Majeure Event for a period of more than [***] consecutive days, as set forth in Section 14.1.

(d) Each Party shall have the right to terminate this Agreement:

(i) after the Cure Period as set forth in Section 5.1(c)(i) upon [***] days written notice, if the Parties are unable, after diligent and good faith efforts, to cure the situation in such a way as to make continuing performance under the Agreement economically feasible for both Parties; and

(ii) In case the Parties fail to agree, after diligent and good faith efforts, on a New Supply Price within [***] days from the first negotiation of the New Supply Price between the Parties, in application of Section 5.1(c)(ii) of the Agreement.

(iii) In case the Parties fail to agree, after diligent and good faith efforts, in application of Section 3.2 of the Agreement.

13.3 Aguettant shall have the right to terminate this Agreement on a Product by Product basis, as applicable, with immediate effect by giving written notice to AcelRx:

(a) If the FDA refuses to grant, suspend or revoke a Marketing Approval for a Product. For the avoidance of doubt, the receipt of a Complete Response Letter (CRL) or a Refuse to File Letter does not constitute a refusal to grant, suspend or revoke a Marketing Approval for a Product;

(b) If AcelRx does not Launch a Product in the Territory within the Deadline, and this is not justified or due to Aguettant's failure in any of its contractual obligations;

(c) if AcelRx has a Failure in two consecutive MYs after MY 2;

(d) if AcelRx fails to apply the agreed recovery plan, as set forth in Section 5.4(b);

(e) in the event of a Change of Control in AcelRx; or

(f) if AcelRx or its Affiliates or Sublicensees bring or join any challenge to the validity or enforceability of any Aguettant IP (an "**IP Challenge**"); provided that (i) an IP Challenge does not include AcelRx's or its Affiliates' or its Sublicensees (A) responding to compulsory discovery, subpoenas or other requests for information in a judicial or arbitration proceeding or (B) complying with any Applicable Law or a court order; and (ii) the foregoing right of termination shall not apply with respect to any IP Challenge where the IP Challenge is based solely on the scope of a Patent or whether a claim therein qualifies as a valid claim and is made in defense of a claim first brought by Aguettant or its Affiliates.

13.4 AcelRx shall have the right to terminate this Agreement:

(a) in its entirety, upon [***] days prior written notice, in the event of any failure of supply by Aguettant or delayed supply of Products by Aguettant for more than [***] months beyond the Requested Delivery Date for [***] consecutive confirmed orders, if, after AcelRx provides written notice to Aguettant of such failure or delay, Aguettant and AcelRx fail to reach a resolution on the issues causing such failure or delay within [***] days after such written notice; or

(b) in its entirety or partially, if Aguettant and/or one of its manufacturers have lost its certificate to Manufacture a Product.

(c) in its entirety, upon [***] days prior written notice, at any time before the grant of the first Marketing Approval for a Product in the Territory.

13.5 Accrued Obligations. The termination of this Agreement for any reason shall not release either Party from any liability which, at the time of such termination, has already accrued to such Party or which is attributable to a period prior to such termination, nor will any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement.

13.6 Effects of Termination. Upon the termination of this Agreement, the following will apply:

(a) **Termination of Licenses**. All rights and licenses granted to AcelRx with respect to Products, and all sublicenses granted by AcelRx and its Affiliates, will terminate. AcelRx shall transfer to Aguettant, free of charge and without delay, all documents, data (including Development data and results), information, evaluation and work realized in application of Sections 3.1 and 3.2, exchanges with the FDA etc. related to this Agreement and the Products and that Aguettant, as sole owner, shall be free to use inside and/or outside the Territory.

(b) **Winding Down of Development Activities**. In the event there are any on-going clinical trials of a Product being conducted by or on behalf of AcelRx in the Territory, the Parties shall work together in good faith to adopt, and Aguettant shall have the final decisional power with respect to, a plan to wind down such Development activities in an orderly fashion, with due regard for patient safety and the rights of any subjects that are participants in any clinical trials of a Product, and take any actions it deems reasonably necessary or appropriate to avoid any human health or safety problems, in compliance with all Applicable Laws.

(c) **Inventory**. Aguettant shall have the right to purchase from AcelRx, at the cost incurred by AcelRx for purchase, all of AcelRx's and its Affiliates' then-current inventory of Product, provided that in the event the Parties agree before the effective date of the termination of the Agreement upon a period for AcelRx to sell and Commercialize such inventory after the Term of the Agreement, AcelRx may sell or Commercialize such inventory within such period. Except otherwise provided for in this Agreement and except in cases of termination for cause (Sections 13.2 and 13.3), any binding orders placed by AcelRx prior to termination of the Agreement will need to be paid for by AcelRx.

(d) **Transfer of Regulatory Filings or Regulatory Approvals**. To the extent permitted under Applicable Laws, AcelRx shall arrange for the transfer to Aguettant or its designee (or to the extent not so re-registrable, AcelRx shall take all reasonable actions to make available to Aguettant or its designee the benefits thereof) of all Regulatory Filings and Regulatory Approvals for the Products in the Territory, including any such Regulatory Filings and Regulatory Approvals made by or registered to its Affiliates or Sublicensees; all such re-registration or transfer shall be at Aguettant's sole cost and expense, unless Aguettant is the terminating Party under Section 13.2(a), 13.2(c) or 13.3, in which case all such re-registration or transfer shall be at AcelRx's sole cost and expense. Aguettant shall notify AcelRx before the effective date of termination, whether the foregoing should be re-registered or transferred to Aguettant or its designee, and if the latter, identify the designee, and provide AcelRx with all necessary details to enable AcelRx to effect the re-registration (or availability of the benefit thereof).

(e) **License Grant by AcelRx to Aguettant**. AcelRx hereby grants Aguettant, effective upon the effective date of such termination, a fully-paid, royalty-free, non-exclusive license, with the right to grant sublicenses through multiple tiers, under any and all Patents (to the extent not previously assigned) and Know-How Controlled by AcelRx or its Affiliates and incorporated into the Products at the time of such termination for Aguettant to use and Commercialize the Products or any other products with substantially the same chemical composition or active pharmaceutical ingredient as the Products anywhere in the world.

(f) **Ancillary Agreements**. The Supply Agreement, the Quality Agreement and the Pharmacovigilance Agreement shall terminate effective upon the effective date of termination of this Agreement, except as provided otherwise in the Quality Agreement and the Pharmacovigilance Agreement in conformity with Applicable Laws.

(g) **Transition**. Each Party shall use Commercially Reasonable Efforts to cooperate with the other Party to effect a smooth and orderly transition in the Development and Commercialization of the Products in the Territory during the notice and wind-down periods. AcelRx shall provide reasonable transition support to enable Aguettant to assume all Commercialization responsibility. AcelRx shall, at Aguettant's request, assign to Aguettant all Third Party contracts, including contracts with Distributors, to the extent related to the Products, and if any such contract is not assignable, and if such Third Party agrees to it, AcelRx shall introduce Aguettant to such Third Party, and shall ensure that Aguettant and such Third Party are in contact, to facilitate the discussions regarding the relationship between Aguettant and such Third Party after the Term of the Agreement.

(h) **Return of Confidential Information**. Except to the extent necessary or reasonably useful for a Party to exercise its rights surviving such termination, each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that such Party may keep one copy of such materials to ensure compliance obligations of such Party are met.

(i) **Survival**. All rights and obligations of the Parties under this Agreement shall terminate, except those described in the following Articles and Sections: Sections 1.1, 8.6, 8.7, 8.8, 8.9, 9.1, 13.5, 13.6, and 13.7, and Article 10, Article 12, and Article 14.

13.7 Rights Upon Bankruptcy. All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar laws in any jurisdiction in the Territory or where a Party is situated (collectively, the "**Bankruptcy Laws**"), licenses of rights to "intellectual property" as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under Bankruptcy Laws then, unless and until this Agreement is rejected as provided in such Bankruptcy Laws, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall perform all of the obligations provided in this Agreement to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws, this Agreement is rejected as provided in the Bankruptcy Laws and the other Party elects to retain its rights hereunder as provided in the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee) shall provide to the other Party copies of all information necessary for such other Party to prosecute, maintain and enjoy its rights under the terms of this Agreement promptly upon such other Party's written request therefor. All rights, powers and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws. In particular, it is the intention and understanding of the Parties that the rights granted to the Parties under this Section 13.7 are essential to the Parties' respective businesses and the Parties acknowledge that damages are not an adequate remedy.

ARTICLE 14

MISCELLANEOUS

14.1 Force Majeure. If the performance of any part of this Agreement by either Party is prevented, restricted, interfered with or delayed by any reason or cause beyond the reasonable control of such Party (including fire, flood, embargo, power shortage or failure, acts of war, insurrection, riot, terrorism, strike, lockout or other labor disturbance, shortage of raw materials, epidemic, pandemic, actions by Government Authorities to address epidemics or pandemics, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, or storm or like catastrophe, acts of God or any acts, omissions or delays in acting of the other Party) (each, a "**Force Majeure Event**"), the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such Force Majeure Event, provided that the affected Party shall use its substantial efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed. The Parties agree the effects of the COVID-19 pandemic that is ongoing as of the Effective Date (including related government orders) may be invoked as a Force Majeure Event for the purposes of this Agreement even though the pandemic is ongoing and those effects may be reasonably foreseeable as of the Effective Date. In addition, a Force Majeure Event may include reasonable measures affirmatively taken by a Party or its Affiliates to respond to any epidemic, pandemic, or spread of infectious disease (including the COVID-19 pandemic), or other Force Majeure Event, such as requiring employees to stay home, closures of facilities, delays of Development, or cessation of activities in response to an epidemic or pandemic or other Force Majeure Event.

(a) **Notification**. If either Party becomes aware that such a Force Majeure Event has occurred or is imminent or likely, it shall immediately notify the other.

(b) **Efforts to Overcome**. The Party which is subject to such Force Majeure Event shall exert all reasonable efforts to overcome it; provided that if the Force Majeure Event continues unabated for a period of [***] days, the other Party may terminate the Agreement upon [***] days written notice to the affected Party.

(c) **Keeping the Other Informed**. Such Party shall keep the other informed as to the progress of overcoming such Force Majeure Event.

14.2 Waiver of Breach. No delay or waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

14.3 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to perform all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

14.4 Affiliates; Continuing Responsibility. Either Party shall have the right to assign, sublicense, subcontract or delegate this Agreement or any or all of its obligations or rights hereunder to an Affiliate upon written notice to the other Party; *provided*, however, the assigning, sublicensing, subcontracting or delegating Party hereby guarantees and shall remain fully and unconditionally obligated and responsible for the full and complete performance of this Agreement by such Affiliate and in no event shall such assignment, sublicensing, subcontracting or delegation be deemed to relieve such Party's liabilities or obligations to the other Party under this Agreement. The other Party shall, at the request of the assigning, sublicensing, subcontracting or delegating Party, enter into such supplemental agreements with the applicable Affiliates as may be necessary or advisable to permit such Affiliates to avail itself of any rights or perform any obligations of the assigning, sublicensing, subcontracting or delegating Party hereunder.

14.5 Modification. No amendment or modification of any provision of this Agreement shall be effective unless in a prior writing signed by both Parties hereto. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by both Parties hereto.

14.6 Severability. In the event any provision of this Agreement should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate in good faith and enter into a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties. All other provisions of this Agreement shall remain in full force and effect in such jurisdiction. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

14.7 Entire Agreement. This Agreement (including the schedules and exhibits attached hereto) constitutes the entire agreement between the Parties relating to the subject matter hereof and supersedes and cancels all previous express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect of the subject matter hereof, including the Confidentiality Agreement. Each of the Parties acknowledges and agrees that in entering into this Agreement, and the documents referred to in it, it does not rely on, and shall have no remedy in respect of, any statement, representation, warranty or understanding (whether negligently or innocently made) of any person (whether party to this Agreement or not) other than as expressly set out in this Agreement. Nothing in this clause shall, however, operate to limit or exclude any liability for fraud.

14.8 Language. The language of this Agreement and all activities to be pursued under this Agreement is English. Any and all documents proffered by one Party to the other in fulfillment of any provision of this Agreement shall only be in compliance if in English. Any translation of this Agreement in another language shall be deemed for convenience only and shall never prevail over the original English version. This Agreement is established in the English language.

14.9 Notices. Any notice, request, or other communication required or permitted under this Agreement shall be in writing in the English language, delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by internationally-recognized courier, sent by registered or certified mail, postage prepaid to the following addresses of the Parties (or such other address for a Party as may be at any time thereafter specified by like notice), or sent by email:

To AcelRx:	**To Aguettant:**
AcelRx Pharmaceuticals, Inc. 25821 Industrial Boulevard, Suite 400, Hayward, CA 94545 Attention: Chief Executive Officer Email: [***]	Laboratoire Aguettant SAS 1 rue Alexander Fleming 69007 Lyon, France Attention: Chief Executive Officer Email: [***]
with a copy to:	**with a copy to:**
AcelRx Pharmaceuticals, Inc. 25821 Industrial Boulevard, Suite 400, Hayward, CA 94545 Attention: Legal Department Email: [***]	Laboratoire Aguettant SAS 1 rue Alexander Fleming 69007 Lyon, France Attention: Legal Department Email: [***]

Any such notice shall be deemed to have been given (a) when delivered if personally delivered; (b) on the next Business Day after dispatch if sent by confirmed facsimile or by internationally-recognized overnight courier; (c) on the fifth (5th) Business Day following the date of mailing if sent by mail; or (d) upon confirmation of receipt if sent by email. Notices hereunder will not be deemed sufficient if provided only between or among each Party's representatives on the Joint Steering Committee.

14.10 Assignment. Subject to Sections 2.2 and 14.4, this Agreement shall not be assignable or otherwise transferred, nor may any rights or obligations hereunder be assigned or transferred, by either Party to any Third Party without the prior written consent of the other Party; except that either Party may assign or otherwise transfer this Agreement without the consent of the other Party to an entity that acquires all or substantially all of the business or assets of the assigning Party relating to the subject matter of this Agreement, whether by merger, acquisition or otherwise. Subject to the foregoing, this Agreement shall inure to the benefit of each Party, its successors and permitted assigns. Any assignment of this Agreement in contravention of this Section 14.10 shall be null and void.

14.11 No Partnership or Joint Venture. Nothing in this Agreement or any action which may be taken pursuant to its terms is intended, or shall be deemed, to establish a joint venture or partnership between Aguettant and AcelRx. Except as set forth in this Agreement, neither Party to this Agreement shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, or to bind the other Party to any contract, agreement or undertaking with any Third Party.

14.12 Dispute Resolution Process. The Parties recognize that disputes as to certain matters may from time to time arise during the Term that relate to (i) interpretation of a Party's rights or obligations hereunder, (ii) any alleged breach of this Agreement, or (iii) any issue that is unable to be resolved pursuant to informal channels of resolution. If the Parties cannot resolve any such dispute within [***] days after written notice of a dispute from one Party to another, either Party may, by written notice to the other Party, have such dispute referred to the JSC. If the JSC cannot resolve such dispute within [***] days after such dispute is referred thereto, either Party may, by written notice to the other Party, have such dispute referred to the Chief Executive Officer of AcelRx and the Chief Executive Officer of Aguettant (collectively, the "**Senior Executives**"). The Senior Executives shall negotiate in good faith to resolve the dispute within [***] days. If the Senior Executives are unable to resolve the dispute within such time period, the parties shall submit the dispute for arbitration in accordance with Section 14.14. Notwithstanding anything in this Article 14 to the contrary, AcelRx and Aguettant shall each have the right at all times to apply to any court of competent jurisdiction for appropriate interim or provisional relief, as necessary to protect the rights or property of that Party.

14.13 Governing Law. This Agreement and all questions regarding the existence, validity, interpretation, breach or performance of this Agreement, shall be exclusively governed by, and construed and enforced in accordance with, the laws of the State of New York, United States, without reference to its conflicts of law principles**.**

14.14 Arbitration. Any disputes arising in connection with this Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce ("**ICC**") as amended herein, and judgment on the arbitration award may be entered in any court having jurisdiction thereof. The Parties agree that:

(a) The arbitration shall be conducted by a panel of three (3) arbitrators, or such lesser number as the Parties may agree. Each of the Parties shall nominate an arbitrator and these two arbitrators shall endeavor to agree on the third arbitrator, who shall act as chairman of the arbitral tribunal, within [***] days from the date when both Parties have received from the ICC confirmation of the second arbitrator by the ICC court. All arbitrators shall have a legal qualification. The chairman shall have chaired at least one ICC arbitration before, and the arbitrators nominated by the Parties shall have at the minimum ten (10) years working experience in the pharmaceutical industry. The seat, or legal place, of arbitration shall be New York City, New York, U.S., and the Parties consent to the personal jurisdiction of the U.S. federal courts for any case arising out of or otherwise related to this arbitration, its conduct and its enforcement. The language of the arbitration proceedings shall be English. The decision and award of the arbitral tribunal shall be final and binding on the Parties. The Parties acknowledge that this Agreement evidences a transaction involving interstate commerce.

(b) Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect its rights hereunder. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees of arbitration.

(c) Any award shall be promptly paid, free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by Applicable Laws, be charged against the Party resisting enforcement. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Section 14.14, and agrees that judgment may be entered upon the final award in the Federal District Court in the Southern District of New York and that other courts may award full faith and credit to such judgment in order to enforce such award. Judgment on the award may also be entered in any other court of competent jurisdiction. The award shall include interest from the date of any damages incurred for breach of this Agreement, and from the date of the award until paid in full, at a rate fixed by the arbitrators.

(d) The existence and content of the arbitral proceeding, including any rulings or award, shall be kept confidential by the Parties and the arbitrator except to the extent (i) required by Applicable Laws; (ii) required to protect or pursue a legal right; (iii) required to enforce or challenge an award; or (iv) approved by written consent of the Parties. Notwithstanding anything to the contrary herein, either Party may disclose matters relating to the arbitration or the arbitral proceedings where necessary for the preparation or presentation of a claim or defense in such arbitration. The arbitrator shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by Applicable Laws, no Party shall make (or instruct the arbitrator to make) any public announcement with respect to the proceedings, rulings or award without prior written consent of the other Party.

(e) Any duty to arbitrate under this Agreement shall remain in effect and be enforceable after termination of this Agreement for any reason.

14.15 Fees and Expenses. Each Party shall bear its own attorneys' fees and fees and expenses associated with all aspects of the negotiation and diligence of the transaction contemplated hereunder.

14.16 Cessation of EU Commercialization. In the event that Aguettant makes a binding decision to cease the Commercialization of the EU counterpart of a Product in the European Union, it shall inform AcelRx without undue delay and shall permit interactions between AcelRx and Aguettant's subcontractors for the purpose of continuation of execution of the Agreement. Aguettant shall maintain or arrange for the manufacturing of the Products for as long as AcelRx Commercializes the Products in the Territory.

14.17 Data privacy. AcelRx is informed and accepts that Aguettant, acting as "data controller," as defined in Article 4 of the EU General Data Protection Regulation, collects and processes Personal Data concerning its contact persons within AcelRx (the "**Data Contacts**") in the context of the management of its relations with AcelRx as follows:

(a) performance of the Agreement;

(b) ensure the security of information systems;

(c) ensure the follow-up and management of its commercial relations and communication with AcelRx;

(d) conduct audits (if applicable);

(e) administer, manage and defend against legal claims or actions (if applicable); and

(f) comply with its legal, regulatory and contractual obligations.

Aguettant shall retain Personal Data of such Data Contacts for the period necessary to fulfil the purposes specified above in this Section 14.7, and shall retain such Personal Data in compliance with applicable laws and regulations. In accordance with applicable laws and regulations, AcelRx's Data Contacts have a right of access and rectification of Personal Data concerning such Data Contacts, limitation of processing of such Personal Data, and opposition to such processing for legitimate reasons. Such rights can be exercised by written notice to personaldata@aguettant.fr. AcelRx undertakes to inform concerned Data Contacts of the existence of these rights and shall obtain the necessary consent from concerned Data Contacts for the processing of their Personal Data. Each Party undertakes to comply with all obligations prescribed by laws and regulations relating to the protection of personal data.

14.18 Anti-Bribery, Anti-Gift and Sunshine Obligations.

In connection with this Agreement, any Products and any performance, activity, act or omission under, each Party undertakes not to make, give, provide, offer, or promise, directly or indirectly, any payment, benefit, or other incentive to:

(a) any governmental officials, political parties, party officials, candidates for public or political party office,

(b) any other person acting in an official capacity for or on behalf of any government, government-owned corporation, organization or entity, or any department, agency, or instrumentality thereof, or a public international organization,

(c) any director, officer, manager, employee, subcontractor, and/or agent of any partner or potential partner, or

(d) any other person, individual or entity,

at the suggestion, request or direction, or engage in acts or transactions, in order to influence the acts of the above-described persons and/or entities in their official capacity or to induce them to use their influence with a government to obtain or retain business or gain an improper advantage in connection with the Agreement in manner that would be in violation of the applicable domestic anti-bribery legislation of any government, and more specifically the French law of December 9th, 2016 on transparency, fight against corruption and modernization of economic life (and known as "SAPIN II Law"), the United Kingdom Bribery Act 2010, the United States Foreign Corrupt Practices Act (“FCPA”), any applicable country legislation implementing the OECD Convention on Combating Bribery of Foreign Officials (the “OECD Convention”) or, in the absence of any such implementing legislation, the OECD Convention itself.

Each Party also undertakes not to solicit or accept illegally, at any time, directly or indirectly, offers, promises, donations, gifts or incentives, for itself or for anybody, so as to, accomplish or for having accomplished, refrain from accomplishing or from having accomplished, an action related to its activity or function, or in order to facilitate or having facilitated an action through its activity or function, within the framework of the Agreement.

Each Party shall be responsible for the implementation of the present provision by its officers, directors, employees, agents, representatives and subcontractors (hereafter referred to as “**Representative(s)**”).

To the concerned Party’s best knowledge and belief, no criminal or administrative investigation, action or enforcement proceeding is pending or threatened against it or its Representatives or any its Affiliates, relating to a violation of the applicable domestic anti-bribery legislation of any government, and more specifically the SAPIN II Law, the United Kingdom Bribery Act 2010, the FCPA, any applicable country legislation implementing the OECD Convention or, in the absence of any such implementing legislation, the OECD Convention itself.

Each Party shall promptly report to the other any request or demand which if complied with would lead to a breach of either this Agreement or the United Kingdom Bribery Act 2010 or the FCPA or SAPIN II Law or any applicable country legislation implementing the OECD Convention or the OECD Convention itself.

Each Party acknowledges it is aware of the SAPIN II Law, the United Kingdom Bribery Act 2010, the FCPA, the OECD Convention along with anti-corruption rules that must be applicable to it, and undertakes to implement all necessary measures to ensure their respect regarding the performance of the Agreement. Each Party further undertakes not to use its corporate capacity or any other individual or corporate capacity for illegal purpose as regards to the above clauses and rules as applicable either directly or indirectly.

Non-compliance by any Party or by its Representatives or by its Affiliates with the present Article and/or refusal by it or its Representatives of making required statements as required under the Agreement or applicable laws shall be deemed a material breach of this Agreement entitling the other Party to terminate it immediately.

Each Party undertakes to demonstrate to the other Party its compliance with this provision, therefore, it must (i) make and keep books, records and accounts, which accurately and fairly reflect the transactions, and dispositions of assets of the company, in order to demonstrate that its company is compliant with this Section 14.18; and (ii) devise and maintain a system of internal accounting controls.

To that extent, any Party or its designee shall have the right, at any time, to check the compliance of the other Party or its Representatives or its Affiliates with their respective obligations as provided herein, and the latter shall provide to the other Party with all necessary and relevant documents and elements. The audited Party shall grant the other, upon receipt of a commercially reasonable written request or upon request of a competent authority, access to said books, records, systems and accounts.

It is understood that the control rights of any Party do not in any way exonerate the other Party or its Representatives or its Affiliates from their responsibilities and obligations under the Agreement.

14.19 Hardship. If any unforeseen event (e.g., an evolution of the legal and/or economic framework of the Agreement), while not preventing either Party from performing any of its obligations hereunder, changes the balance of the Agreement to the detriment of such Party and therefore causes inequitable hardship to such Party in the performance of such obligations, and if such Party is able to demonstrate such hardship by competent proof, then both Parties shall attempt in good faith to negotiate an equitable way to adapt this Agreement to the new circumstances, provided neither Party is obligated to make any accommodation or agree to any amendment that is not expressly required by the terms of this Agreement.

14.20 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument.

Schedules

Schedule 1.1 - Definitions

Exhibits

Exhibit 8.4 – Sales Milestone Threshold

Exhibit 10.5(a) – Draft Public Announcement

Exhibit A – Aguettant Patents as of the Effective Date

Exhibit B – Aguettant Trademarks as of the Effective Date

[signature page to follow]

In Witness Whereof, the Parties by their respective authorized representatives have executed this Agreement as of the Effective Date.

AcelRx Pharmaceuticals, Inc.

By: /s/ Raffi Asadorian

Name: Raffi Asadorian

Title: CFO

Laboratoire Aguettant

By: /s/ Eric Rougemond

Name: Eric Rougemond

Title: CEO

[Signature Page to License Agreement (US)]

Schedule 1.1

Definitions

"Accounting Standards" means, with respect to a Party or its Affiliates, U.S. generally accepted accounting principles ("**GAAP**") or International Financial Reporting Standards ("**IFRS**"), as such Party or its Affiliates uses for its financial reporting obligations, in each case.

"AcelRx Indemnitees" has the meaning set forth in Section 12.4.

"Affiliate" means, with respect to a Party, any Person directly or indirectly controlling, controlled by, or under common control with, such Party. For purposes of this definition only, the terms "controlled," "controlled by," and "under common control with," as used in this context, mean the direct or indirect ability or power to direct or cause the direction of management policies of a Person or otherwise direct the affairs of such Person, whether through ownership of equity, voting securities, beneficial interest, by contract or otherwise.

"Agreement" has the meaning set forth in the first paragraph hereof.

"Aguettant Indemnitees" has the meaning set forth in Section 12.3.

"Aguettant Invention" means any Invention relating to a Product by or on behalf of and Controlled by Aguettant or any of its Affiliates as of the Effective Date or during the Term, which is necessary or reasonably useful for the Development or Commercialization of the respective Product in the Territory.

"Aguettant IP" means Intellectual Property, including the dossier relating to the Products, Aguettant Trademarks, Aguettant Patents, Aguettant Inventions and Product Improvements.

"Aguettant Know-How" means all Know-How Controlled by Aguettant or any of its Affiliates as of the Effective Date or during the Term that is necessary or reasonably useful for the Development or Commercialization of the Products in the Territory.

"Aguettant Patents" means all Patents Controlled by Aguettant or its Affiliates as of the Effective Date or during the Term that are necessary or reasonably useful for the Development or Commercialization of the Products in the Territory, including all Patents that claim Product Improvements. A list of Aguettant Patents as of the Effective Date is set forth in Exhibit A.

"Aguettant Trademarks" means all Trademarks Controlled by Aguettant or its Affiliates as of the Effective Date or during the Term that are necessary or reasonably useful for the Commercialization of the Products in the Territory. A list of Aguettant Trademarks as of the Effective Date is set forth in Exhibit B.

"Adjusted Supply Price" has the meaning set forth in Section 5.1(c).

"Alliance Manager" has the meaning set forth in Section 7.2.

"Applicable Laws" means the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, permits (including Regulatory Approvals and Other Approvals) of or from any court, arbitrator, Regulatory Authority or governmental agency or authority having jurisdiction over or related to the subject item.

"Applicant" means the applicant having the approved applications in the Territory for the Products, and consequently endorsing all Pharmacovigilance responsibility and activities in the Territory for the Products, being AcelRx.

"Background Intellectual Property" means, with respect to a Party, all Know-How, Trademarks, copyrights, Patents and other intellectual property (a) owned or Controlled by such Party or its Affiliates as of the Effective Date or (b) developed, acquired or created by or on behalf of such Party or its Affiliates after the Effective Date (i) independently of the Agreement and (ii) not directly related to the Products.

"Bankruptcy Laws" has the meaning set forth in Section 13.7.

"Business Day" means a calendar day other than a Saturday or Sunday or any public holiday in San Francisco, California, or in Lyon, France, but excluding the nine (9) consecutive calendar days beginning on December 24 and continuing through January 1 of each Calendar Year during the Term. For the avoidance of doubt, references in this Agreement to "days" mean calendar days. For pharmacovigilance matters, Business Days shall not be applicable.

"Calendar Quarter(ly)" or "**Quarter(ly)**" means the respective periods of three (3) consecutive calendar months period ending on March 31, June 30, September 30 or December 31 for so long as the Agreement is in effect.

"Calendar Year" means a period of twelve consecutive months beginning on and including January 1.

"Change of Control" means, with respect to a Party, (a) the acquisition of beneficial ownership, directly or indirectly, by any Person of securities or other voting interest of such Party representing 50% or more of the combined voting power of such Party's then outstanding securities or other voting interests, (b) any merger, reorganization, consolidation or business combination involving such Party that results in the holders of beneficial ownership of the voting securities or other voting interests of such Party (or, if applicable, the ultimate parent of such Party) immediately prior to such merger, reorganization, consolidation or business combination ceasing to hold beneficial ownership of 50% or more of the combined voting power of the surviving entity immediately after such merger, reorganization, consolidation or business combination, (c) any sale, lease, exchange, contribution or other transfer (in one transaction or a series of related transactions) of all or substantially all of the assets of such Party to which this Agreement relates, or (d) the approval of any plan or proposal for the liquidation or dissolution of such Party (other than in circumstances to which Section 13.2(b) is applicable). Notwithstanding the foregoing, an equity sale to underwriters in a public offering of a Party or an equity sale to Third Parties solely for the purpose of financing or a transaction solely to change the domicile of a Party shall not constitute a Change of Control. For the purpose of this clause, any acquisition of additional AcelRx voting equity securities by a member of the AcelRx family who is currently an AcelRx shareholder shall not constitute a Change of Control of AcelRx.

"CMC" means chemistry, manufacturing and controls.

"Commercialization" means any and all activities relating to the preparation for sale of, offering for sale of, or sale of a product, including activities related to Launch, marketing, promoting, distributing, using, importing, pricing, reimbursement, and advertising such product, and interacting with Regulatory Authorities regarding any of the foregoing, but excluding any activities relating to Manufacturing or Development. "**Commercialize**" means to engage in Commercialization.

"Commercialization Plan" has the meaning set forth in Section 3.5(a).

"Commercialization Strategy" has the meaning set forth in Section 3.4.

"Commercialization Updates" has the meaning set forth in Section 3.5(b).

"Commercially Reasonable Efforts" means that level of efforts and resources, with respect to a particular Party, at the relevant point in time, that is consistent with the usual practice followed by that Party, in the exercise of its reasonable scientific, commercial and business judgment relating to other prescription pharmaceutical products owned or licensed by it or to which it has exclusive rights in the Territory, which have market potential and are at a stage of development or product life similar to the Products, taking into account: measures of patent coverage; relative safety and efficacy; product profile; the then-current competitiveness of the marketplace and the likely competitive environment at the time of projected entry into the market; Development, Marketing Authorization, Manufacturing, and Commercialization costs; feasibility of Manufacture; the proprietary position of the compound or product, including the strength and duration of patent protection and anticipated exclusivity; the likelihood of obtaining Marketing Authorizations and the timing of such; the current guidance and requirements for Regulatory Approval and similar products and the current and projected regulatory status; labeling or anticipated labeling; and the relative profitability of the Products (including pricing and reimbursement status, but excluding consideration of amounts payable under the Agreement).

"Confidential Information" has the meaning set forth in Section 10.1.

"Confidentiality Agreement" means the Mutual Confidentiality Agreement by and between the Parties effective as of August 1, 2018.

"Control" (including any variations such as "**Controlled**"), in the context of intellectual property rights, Know-How and Confidential Information, means possession (whether by ownership or license, other than pursuant to this Agreement) by a Party of the ability to grant access to, or a license or sublicense of, such rights, Know-How and Confidential Information as set forth in this Agreement without violating the terms of an agreement with a Third Party.

"Core Pharmaceutical Dossier" means a compilation of pre-clinical, clinical and CMC data necessary to support and maintain Regulatory Approvals in the Field in the Territory, as audited by AcelRx. The Core Pharmaceutical Dossiers do not include the Module 1.

"Cure Period" has the meaning set forth in Section 5.1(c)(i).

"Data Contact" has the meaning set forth in Section 14.17.

"Deadline" means, with respect to each Product, the twelve (12)-month period beginning on the date that Marketing Approval is received for such Product.

"Development" means non-clinical and clinical development activities reasonably related to the development and submission of information to a Regulatory Authority or otherwise related to the research, identification, testing and validation, including, without limitation, toxicology, pharmacology and other discovery and pre-clinical efforts, test method development and stability testing, manufacturing process and CMC development, formulation development, quality assurance and quality control development, generation of data for regulatory filings, statistical analysis, clinical trials (including Post-Approval Commitments and Post-Marketing Studies) of a product, whether for purposes of label expansion or otherwise, but does not include Manufacturing or Commercialization. "**Develop**" means to engage in Development.

"Disclosing Party" has the meaning set forth in Section 10.1.

"Dispute Notice" has the meaning set forth in Section 7.3.

"Distributor" means a Third Party or an Affiliate of AcelRx to whom AcelRx or an Affiliate of AcelRx has granted the right to market, promote, co-promote, advertise, detail, sell or distribute a Product in the Territory without the control of Regulatory Filings for such Product in the Territory. For the avoidance of doubt, such grant of right by AcelRx to a Distributor is not subject to Aguettant's prior approval.

"Dollars" or "**USD**" means the official currency of the United States.

"Effective Date" has the meaning set forth in the first paragraph hereof.

"Effective Per Unit Transfer Price" has the meaning set forth in Section 8.3(b).

"Ephedrine" means an ephedrine pre-filled syringe containing 10 ml of a solution of 3 mg / ml ephedrine hydrochloride for injection.

"Euros" or "**EUR**" means the official currency of the EU.

"Failure" means sales by or on behalf of AcelRx are less than [***]% of the Minimum Sales Obligations for such MY, and such failure is not justified or due to Aguettant's failure in any of its contractual obligations (e.g., failure to supply, delay in supply, etc.).

"FDA" means the United States Food and Drug Administration and any successor agency thereto.

"Fill and Finish" means Manufacturing Finished Products from Bulk Products, including the secondary and tertiary packaging to EU quality packaging standards, serialization, labeling, testing, releasing, quality assurance and quality control, of Finished Products. "Fill and Finishing" means to engage in Fill and Finish.

"Final Artwork" has the meaning set forth in Section 4.1(b).

"Finished Products" means Products that are fully packaged, serialized, labeled and FDA quality packaged, including primary, secondary and tertiary packaging, as required for sale and proper handling and protection during warehousing and transportation in the Territory, as set forth in the Quality Agreement.

"First Commercial Sale" means the first arm's length sale of a Product to a Third Party by AcelRx, or its Affiliates, Sublicensees or Distributors, for use and in the Territory, after the respective Product has been granted Other Approvals by the Regulatory Authority in the Territory.

"Force Majeure Event" has the meaning set forth in Section 14.1.

"Good Clinical Practices" or "**GCP**" means the then-current standards, practices and procedures promulgated or endorsed by ICH as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the EU and comparable regulatory standards, practices and procedures in other jurisdictions in the Territory., as they may be updated from time to time.

"Good Manufacturing Practices" or "**GMP**" means the then-current good manufacturing practices required by the EU for the manufacture and testing of pharmaceutical materials, as they may be updated from time to time.

"Good Pharmacovigilance Practices" or "**GVP**" means the then-current good pharmacovigilance practices required by the US, and comparable regulatory standards in other jurisdictions in the Territory, as they may be updated from time to time.

"Governmental Authority" means any court, agency, department, authority or other instrumentality of any national, supranational, state, county, city or other political subdivision.

"Gross Sales" means, for the applicable period, AcelRx's ex-factory Unit gross selling price (i.e., the gross amount invoiced per Unit by AcelRx, or its Affiliates or Sublicensees) multiplied by the number of Units sold in the Territory to Third Parties (other than AcelRx's Sublicensees).

"ICC" has the meaning set forth in Section 14.14.

"ICH" means the International Conference on Harmonization (of Technical Requirements for Registration of Pharmaceuticals for Human Use).

"Indication" means the use of the Products, which is stated on each label.

"Initial Forecast" has the meaning set forth in Section 5.2(a).

"Initial Term" has the meaning set forth in Section 13.1.

"Intellectual Property" means any and all Know-How, Trademarks, copyrights, Patents and other intellectual property rights, which pertain to the Manufacture, use, sale or import of the Products in the Territory, owned or controlled by Aguettant or its Affiliates in the Territory as of the Effective Date or during the Term.

"Inventions" means any and all inventions, discoveries, processes and techniques, which are, or may be, patentable or otherwise protectable under Applicable Laws of any country or region, and which are conceived, discovered or reduced to practice by or on behalf of a Party (whether solely or jointly with the other Party or its Affiliates).

"IP Adversarial Action" has the meaning set forth in Section 9.3(c).

"IP Challenge" has the meaning set forth in Section 13.3(f).

"IP Expenses" means expenses relating to the preparation, filing, prosecution and maintenance of the Aguettant IP, including the use of counsel of Aguettant's choice.

"Joint Steering Committee" or "**JSC**" has the meaning set forth in Section 7.1.

"Know-How" means all tangible and intangible scientific, technical, clinical, regulatory, trade, marketing, commercial, financial or business information and materials, including compounds, solid state forms, compositions of matter, formulations, devices, techniques, processes, methods, trade secrets, formulae, procedures, tests, data, results, analyses, documentation, reports, information (including pharmacological, toxicological, non-clinical (including CMC), and clinical test design, methods, protocols, data, results, analyses, and conclusions), quality assurance and quality control information, regulatory documentation, information and submissions pertaining to, or made in association with, filings with any Regulatory Authority, knowledge, know-how, skill, and experience.

"Launch" means the commencement of the First Commercial Sale. When used as a verb, to "**Launch**" means to engage in the Launch.

"Launch Date" means the date of the Launch, and is based upon regulatory and commercial preparedness requirements, including supply of the Products by Aguettant.

"Losses" has the meaning set forth in Section 12.3.

"Manufacture" means, as applicable to Finished Products, manufacture, generate, process, prepare, make, assemble, test, label, package, store, hold, handle, receive, release, serialize, transport, and deliver a product (or any component or intermediate thereof), including any related stability testing, quality assurance and quality control. "**Manufacturing**" means to engage in Manufacture.

"Marketing Approval" means the grant or issuance of all Regulatory Approvals, approvals, licenses, registrations or authorizations of any federal, state or local regulatory agency, department, bureau or other governmental entity, in the Territory necessary for the Development, Manufacture or Commercialization, as applicable, of a Product, but excluding Other Approvals.

"Marketing Year" or "**MY**" means the period from the first Launch of a Product in the Territory until December 31 of the next Calendar Year following the Calendar Year of the Launch, and any subsequent 12-month period, except in the event that the first Launch occurs in the period from January 1 until April 30 of the concerned year, MY 1 shall end on December 31 of such year. For the avoidance of doubt, Marketing Year is defined once for the entire Agreement, and not on a Product-by-Product basis.

"Minimum Sales Obligation(s)" has the meaning set forth in Section 5.4(a).

"Net Sales" means Gross Sales invoiced in the course of the applicable period by or on behalf of AcelRx, its Affiliates or Sublicensees for sales of the Products to Third Parties (other than AcelRx's Sublicensees), less deductions in the course of such applicable period directly relating to sales of the Products by AcelRx, its Affiliates or Sublicensees using Accounting Standards applied on a consistent basis for:

(a) credits or allowances actually given or made for rejection of or return of previously sold Product (whether as a result of Recalls, market withdrawals, other corrective actions, damaged, defective goods or otherwise), for retroactive price reductions and billing errors, or other allowances specifically identifiable as relating to the Products; and

(b) trade, cash or quantity discounts actually granted, incurred, or allowed in the ordinary course of business (including rebates, purchase charge backs and allowances calculated based on the sales amount of the Products).

"New Supply Price" has the meaning set forth in Section 5.1(c)(ii).

"Other Approvals" means all licenses, permissions, consents and regulatory authorizations other than Marketing Approvals that are (a) necessary to enable the Products to be imported, marketed, sold, distributed, stored and shipped in the Territory by AcelRx, or its Affiliates or Sublicensees; or (b) necessary at each specific institution in the Territory where AcelRx, or its Affiliates or Sublicensees, plans to market, sell or promote the Products.

"Party" has the meaning set forth in the first paragraph hereof.

"Patent(s)" means (a) all patents, certificates of invention, applications for certificates of invention, priority patent filings and patent applications, and (b) any renewal, division, continuation (in whole or in part), or request for continued examination of any of such patents, certificates of invention and patent applications, and any and all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.

"Person" means any individual, corporation, partnership, limited liability company, trust, governmental entity, or other legal entity of any nature whatsoever.

"Personal Data" means any information relating to an identified or identifiable natural person, where an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

"Pharmacovigilance Agreement" has the meaning set forth in Section 6.4.

"Phenylephrine" means a phenylephrine prefilled syringe containing 10 ml of a solution of 50 micrograms / ml phenylephrine hydrochloride for injection.

"Post-Approval Commitments" means all clinical studies (including pediatric studies and Post-Marketing Studies) conducted after Regulatory Approval for a Product that are requested by a Regulatory Authority or that are necessary to fulfill commitments made to any Regulatory Authority as a condition for the receipt or maintenance of such Regulatory Approval in any country.

"Post-Marketing Studies" means all non-interventional and interventional clinical trials of a Product with the main objective to collect data to increase product knowledge or for marketing and market access purposes, e.g., pricing studies, post-marketing surveillance studies, patient outcome studies, patient preference studies and investigator-initiated trials.

"Product" means each Ephedrine and Phenylephrine.

"Product Improvement" means any and all Inventions, and any and all changes, modifications and amendments, by or on behalf of a Party, or by the Parties jointly, during the Term, which relate to a Product in the same dosage, formulation and injectable form, whether patentable or not.

"Promotional Material" has the meaning set forth in Section 3.9.

"Quality Agreement" has the meaning set forth in Section 6.1.

"Recall" means Product recall, Product withdrawal, field correction of a Product or other related action.

"Receiving Party" has the meaning set forth in Section 10.1.

"Regulatory Approval" means, with respect to any Product, any and all approvals from the applicable Regulatory Authority sufficient for the import, distribution, marketing, use, offering for sale, and sale of a Product for use in the Territory in accordance with Applicable Laws.

"Regulatory Authority" means any national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity: (a) whose review or approval is necessary (i) for the Manufacture, packaging, use, storage, import, export, distribution, promotion, marketing, offer for sale and sale of a Product, (ii) for reviewing Regulatory Filings for a Product (or a component thereof) or (iii) for granting Regulatory Approvals for a Product; or (b) having authority to review and enforce GMP or other Applicable Laws relating to a Product or the Manufacture, Development, Commercialization, use or sale thereof.

"Regulatory Filings" means all applications, approvals, licenses, registrations, notifications, submissions and authorizations made to or received from a Regulatory Authority in a country necessary for the Manufacture, Development or Commercialization of a Product in such country, including any applications for any Marketing Approval, including all applications for Regulatory Approvals.

"Regulatory Strategy" means any decision: (a) relating to the nature of an application for any Marketing Approval, including all applications for Regulatory Approvals ; (b) that impacts the availability of market exclusivity or regulatory data protection; (c) that is reasonably likely to affect the timing of Marketing Approval by more than a Calendar Quarter; (d) relating to the conduct of any Post-Approval Commitments or Post-Marketing Studies or the implementation or a risk management plan; or (e) that entails a material modification to an existing Marketing Approval.

"Renewal Term" has the meaning set forth in Section 13.1.

"Requested Delivery Date" has the meaning set forth in Section 5.3.

"Sales Milestone Threshold" has the meaning set forth in Section 8.4.

“Senior Executives” has the meaning set forth in Section 14.12.

“Specification” means (a) the specifications for a Product established by inclusion in an application for any Marketing Approval, including all applications for Regulatory Approvals and as required by a Regulatory Authority in the Territory for approval and (b) such other specifications for a Product agreed to by the Parties pursuant to the Supply Agreement related to the packaging, storage conditions, shelf life and labeling of a Product.

“Sublicensee” has the meaning set forth in Section 2.2.

“Supply Agreement” has the meaning set forth in Section 5.1(b).

“Supply Cost Payment” has the meaning set forth in Section 8.2.

“Supply Price” has the meaning set forth in Section 5.1(b).

“Term” has the meaning set forth in Section 13.1.

“Territory” means the United States of America.

“Third Party” means any Person other than AcelRx, Aguettant and their respective Affiliates.

“Third Party Claim” has the meaning set forth in Section 12.3.

“Trademark” means trademarks, trade names, trade dresses, domain names, logos and brandings.

“Transfer Price” has the meaning set forth in Section 8.3(b).

“Unit” means one Product.

Exhibit 10.3

Form of Contingent Value Rights Agreement

This Contingent Value Rights Agreement, dated as of [●], 2021 (this "**Agreement**"), is entered into by and among AcelRx Pharmaceuticals, Inc., a Delaware corporation ("**Parent**"), James Wilkie (the "**Stockholder Representative**"), solely in his capacity as the representative of the Holders and [●], as Rights Agent (the "**Rights Agent**").

RECITALS

Whereas, Parent, AcelRx Intermediate Sub, Inc., a Delaware corporation and a direct wholly owned subsidiary of Parent ("**Merger Sub 1**"), AcelRx Consolidation Sub, LLC , a Delaware limited liability company and a direct wholly owned subsidiary of Parent ("**Merger Sub 2**"), Lowell Therapeutics, Inc., a Delaware corporation (the "**Company**"), and the Stockholder Representative, solely in his capacity as the representative of the Stockholders and the Company Option Holders, have entered into an Agreement and Plan of Merger dated as of November 14, 2021 (as it may be amended or supplemented from time to time pursuant to the terms thereof, the "**Merger Agreement**"), pursuant to which, at the First Effective Time, Merger Sub 1 will merge with and into Company, with the Company continuing as the Initial Surviving Company and as a direct wholly owned subsidiary of Parent and at the Second Effective Time, the Initial Surviving Company shall merge with and into Merger Sub 2, the separate corporate existence of the Initial Surviving Company shall cease and Merger Sub 2 shall continue as the surviving company, shall remain a wholly owned subsidiary of Parent and shall be referred to herein as the "**Surviving Company**".

Whereas, pursuant to the Merger Agreement, Parent has agreed to provide to the Stockholders the right to receive contingent value rights as hereinafter described in accordance with the terms hereof and the Merger Agreement; and

Whereas, the Rights Agent is willing to act in connection with the issuance, transfer, exchange and payment of such contingent value rights as provided herein.

Now, **Therefore**, in consideration of the premises and mutual agreements herein, Parent, the Stockholder Representative and the Rights Agent hereby agree as follows:

ARTICLE I
DEFINITIONS

Section 1.1 Definitions. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Merger Agreement. As used in this Agreement, the following terms shall have the following meanings:

"Affiliate" of any Person means another Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such first Person.

"Annual Revenues" means, for any Calendar Year, without duplication, the aggregate net sales of NIYAD and LTX-608 by all Selling Parties, in each case as determined in accordance with GAAP.

"Calendar Quarter" means each period of three consecutive months commencing on January 1, April 1, July 1 and October 1 of each calendar year.

"Calendar Year" means the period of four consecutive Calendar Quarters beginning on January 1 and ending on December 31 of each calendar year.

"Change of Control" means (i) a sale or other disposition of all or substantially all of the assets of either Parent or the Surviving Company on a consolidated basis (other than to any direct or indirect wholly owned subsidiary of Parent), (ii) a merger or consolidation involving either Parent or the Surviving Company in which Parent or the Surviving Company, respectively, is not the surviving entity, and (iii) any other transaction involving either Parent or the Surviving Company in which Parent or the Surviving Company, respectively, is the surviving entity but in which the stockholders of Parent or the Surviving Company, respectively, immediately prior to such transaction own less than fifty percent (50%) of the surviving entity's voting power immediately after the transaction, other than any equity financing transaction solely related to the continued financing of the operations of Parent and its subsidiaries; provided neither of the Mergers shall be considered a Change of Control.

"control" (including the terms "**controlled by**" and "**under common control with**"), with respect to the relationship between or among two or more Persons, means the possession, directly or indirectly or as trustee, personal representative or executor, of the power to direct or cause the direction of the affairs or management of a Person, whether through the ownership of voting securities, as trustee, personal representative or executor, by Contract, credit arrangement or otherwise.

"CVRs" means the rights of Holders to receive contingent payments of cash or Parent Common Stock pursuant to the Merger Agreement and this Agreement.

"CVR Register" has the meaning set forth in Section 2.3(b).

"Date of Determination of Value" shall mean, if for Milestone 1, 2, 3 or 4, the day on which Parent receives written notification from the FDA or CMS of the achievement of the subject matter in the respective Milestone, or, if for a revenue milestone, the day before public release of quarterly financials for the respective period. If quarterly financials are not publicly released, then a date no later than 15 days after the end of the respective period as set forth the in the notice from Parent to the Stockholder Representative.

"Diligent Efforts" means, with respect to a task related to a Company Product, using such efforts and resources normally used by Persons of comparable size within the pharmaceutical industry for the development and seeking of regulatory approval for a pharmaceutical product having similar limited market potential as a Company Product at a similar stage of its development or product life, taking into account all relevant factors, including issues of market exclusivity (including patent coverage, regulatory and other exclusivity), product profile, including efficacy, safety, tolerability, methods of administration and convenience, cost of developing, manufacturing and commercializing such product, product labeling (including anticipated product labeling), other product candidates, the competitiveness of alternative products in the marketplace or under development, the launch or sale of a generic or biosimilar product, the regulatory structure involved, the regulatory environment and the expected profitability of the applicable product (including development costs, pricing and reimbursement, cost of goods and all other costs associated with the applicable product), and relevant technical, commercial, legal, scientific medical factors; *provided* that Diligent Efforts will not require Parent to (i) exercise any effort beyond what it uses for Parent Products or (ii) take any actions that are not commercially reasonable in relation to Parent's resources, business plan or development of Parent Products.

"Event of Default" has the meaning set forth in Section 6.1(a).

"FDA" means the United States Food and Drug Administration.

"Funds" has the meaning set forth in Section 2.11.

"Holder" means a Person in whose name a CVR is registered in the CVR Register at the applicable time.

"Indemnification Off-Set Amount" has the meaning set forth in Section 2.6.

"Licensee" means any non-Affiliate third party granted a license by, or otherwise acquiring rights from, Parent, its Affiliates (and their respective successors and assigns) to make, have made, use, sell, offer for sale, or import Company Products in any territory worldwide, but shall exclude (i) any third party distributor of Company Products that has no royalty or other payment obligations to any Parent or any of its Affiliates that are calculated based on amounts invoiced or received by such third party for sales of Company Products or (ii) a third party distributor of Company Products that (x) does not take title to Company Products, (y) does not invoice Company Products sales to third party customers and (z) is responsible only for inventory management and distribution with respect to Company Products on behalf of Selling Parties.

"Losses" has the meaning set forth in Section 3.2(h).

"LTX-608" means the drug product candidate of the name "LTX-608" developed by the Company with an indication other than anticoagulation of the extracorporeal circuit.

"Milestone" means each of Milestone 1, Milestone 2, Milestone 3, Milestone 4, Milestone 5, Milestone 6 and Milestone 7.

"Milestone 1" means obtaining approval from the FDA, which may be via a PMA or NDA (as defined below), for NIYAD with a label indication for use for patients in the in-patient setting for continuous renal replacement therapy (CRRT).

"Milestone 2" means obtaining (i) approval from the FDA, via a PMA or NDA, for NIYAD with a label indication for use for patients undergoing intermittent hemodialysis (IHD) in the outpatient setting and (ii) the receipt of approval from CMS of NIYAD to be included in the End-Stage Renal Dialysis (ESRD) Prospective Payment System (PPS), as a qualified device under the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES), if approved by the FDA as a device, or the Transitional Drug Add-on Payment Adjustment (TDAPA), if approved by the FDA as a drug.

"Milestone 3" means obtaining the approval by the FDA of a New Drug Application for LTX-608 with a label indication for use for patients with Acute Respiratory Distress Syndrome (ARDS), Disseminated Intravascular Coagulation (DIC), or as an antiviral.

"Milestone 4" means obtaining ownership of an issued patent in the United States in favor of Parent or its Affiliates that covers LTX-608, whereby the corresponding patent information is also published in the Orange Book prior to losing exclusivity.

"Milestone 5" means achievement of aggregate Annual Revenues by all Selling Parties of at least $12,000,000 during any Calendar Year ending on or before December 31, 2026.

"Milestone 6" means achievement of aggregate Annual Revenues by all Selling Parties of at least $25,000,000 during any Calendar Year ending on or before December 31, 2027.

"Milestone 7" means achievement of aggregate Annual Revenues by all Selling Parties of at least $100,000,000 during any Calendar Year ending on or before December 31, 2030.

"Milestone Amount" means each of Milestone 1 Amount, Milestone 2 Amount, Milestone 3 Amount, Milestone 4 Amount, Milestone 5 Amount, Milestone 6 Amount and Milestone 7 Amount.

"Milestone 1 Amount" means, with respect to the achievement of Milestone 1, an amount per CVR equal to the quotient of $3,000,000 divided by the aggregate number of CVRs issued pursuant to the Merger Agreement and this Agreement, without interest, *less* the Indemnification Off-Set Amount pursuant to Section 2.6.

"Milestone 2 Amount" means, with respect to the achievement of Milestone 2, an amount per CVR equal to the quotient of $2,000,000 divided by the aggregate number of CVRs issued pursuant to the Merger Agreement and this Agreement, without interest, *less* the Indemnification Off-Set Amount pursuant to Section 2.6.

"Milestone 3 Amount" means, with respect to the achievement of Milestone 3, an amount per CVR equal to the quotient of $2,000,000 divided by the aggregate number of CVRs issued pursuant to the Merger Agreement and this Agreement, without interest, *less* the Indemnification Off-Set Amount pursuant to Section 2.6.

"Milestone 4 Amount" means, with respect to the achievement of Milestone 4, an amount per CVR equal to the quotient of $2,000,000 divided by the aggregate number of CVRs issued pursuant to the Merger Agreement and this Agreement, without interest, *less* the Indemnification Off-Set Amount pursuant to Section 2.6.

"Milestone 5 Amount" means, with respect to the achievement of Milestone 5, an amount per CVR equal to the quotient of $3,500,000 divided by the aggregate number of CVRs issued pursuant to the Merger Agreement and this Agreement, without interest, *less* the Indemnification Off-Set Amount pursuant to Section 2.6.

"Milestone 6 Amount" means, with respect to the achievement of Milestone 6, an amount per CVR equal to the quotient of $3,500,000 divided by the aggregate number of CVRs issued pursuant to the Merger Agreement and this Agreement, without interest, *less* the Indemnification Off-Set Amount pursuant to Section 2.6.

"Milestone 7 Amount" means, with respect to the achievement of Milestone 7, an amount per CVR equal to the quotient of $10,000,000 divided by the aggregate number of CVRs issued pursuant to the Merger Agreement and this Agreement, without interest, *less* the Indemnification Off-Set Amount pursuant to Section 2.6.

"Milestone Cash Amount" has the meaning set forth in Section 2.4(a)(i).

"Milestone Non-Achievement Certificate" has the meaning set forth in Section 2.4(g).

"Milestone Notice" has the meaning set forth in Section 2.4(a)(i).

"Milestone Payment Date" has the meaning set forth in Section 2.4(a).

"Milestone Stock Amount" has the meaning set forth in Section 2.4(a)(i).

"Milestone Stock Price" means : (i) if Parent Common Stock is not publicly traded or quoted on a national securities exchange or automated quotation system, the fair market value as determined in good faith by Parent's Board of Directors as of the Date of Determination of Value and (ii) if Parent Common Stock is publicly traded or quoted on a national securities exchange or automated quotation system, the arithmetic average of the daily volume weighted average price per share of the Parent Common Stock during the five (5) consecutive full trading days ending on and including the last full trading day immediately prior to the Date of Determination of Value as reported by such national securities exchange.

"NDA" means New Drug Application approved via any route.

"NIYAD" means the product of the name "NIYAD" developed by the Company intended for use as a regional anticoagulant of the extracorporeal circuit.

"Officer's Certificate" means a certificate signed by the chief executive officer, president, chief financial officer, any vice president, the controller, the treasurer or the secretary, in each case of Parent, in his or her capacity as such an officer, and delivered to the Rights Agent.

"Orange Book" means the publication *Approved Drug Products with Therapeutic Equivalence Evaluations* published by the FDA.

"Parent Product" means any product or Parent Product Candidate that is being researched, tested, developed, commercialized, manufactured, sold or distributed by or on behalf of Parent (whether or not in collaboration with another Person), other than any Company Products.

"Parent Product Candidate" means any drug or biological product candidates being researched, developed, tested, labeled, manufactured or stored by Parent.

"Parent Share Cap" means, absent stockholder approval under Nasdaq Marketplace Rule 5635, a number of shares of Parent Common Stock (rounded down to the nearest whole share) equal to 19.9% of the total number of shares of Parent Common Stock that are issued and outstanding immediately prior to the First Effective Time; *provided* that there shall be excluded from the shares of Parent Common Stock issued and outstanding immediately prior to the First Effective Time, any shares of Parent Common Stock that have been issued prior to such First Effective Time and which are aggregable with the issuance of Parent Common Stock pursuant to the Merger Agreement, to determine whether the 19.9% limit has been reached. In the case of stockholder approval under Nasdaq Marketplace Rule 5635, the Parent Share Cap shall be disregarded.

"Permitted Transfer" means a transfer of CVRs: (i) upon death of a Holder by will or intestacy; (ii) by instrument to an *inter vivos* or testamentary trust in which the CVRs are to be passed to beneficiaries upon the death of the trustee; (iii) pursuant to a court order of a court of competent jurisdiction (such as in connection with divorce, bankruptcy or liquidation); or (iv) by operation of law (including by consolidation or merger) or without consideration in connection with the dissolution, liquidation or termination of any corporation, limited liability company, partnership or other entity to Persons who control such Person as of the date hereof; *provided* that any such transferred CVR shall remain subject to the terms and conditions of this Agreement, including Section 2.2.

"Person" means any individual, corporation, partnership, limited liability company, estate, trust, association, joint stock company, joint venture, organization or other entity, including any Governmental Entity (or any department, agency, or political subdivision thereof).

"PMA" means a Pre-Market Approval Application filed with the FDA.

"Reorganization" has the meaning set forth in Section 2.8(a).

"Rights Agent" means the Rights Agent named in the first paragraph of this Agreement, until a successor Rights Agent becomes such pursuant to the applicable provisions of this Agreement, and thereafter "Rights Agent" means such successor Rights Agent. Parent shall be solely responsible for all contractual payment obligations to Rights Agent for its services under this Agreement and the Merger Agreement pursuant to any other agreement between Rights Agent and Parent.

"Selling Party" means, with respect to Annual Revenues, Parent, any of its Affiliates (including the Surviving Company) or any of their respective Licensees and each of their respective successors or assigns.

"Share" means each share of Company Capital Stock outstanding immediately prior to the First Effective Time, except any (i) Cancelled Shares or (ii) Dissenting Shares.

"Transfer Agent" has the meaning set forth in Section 2.7(a).

"U.S." means the United States of America and its territories, districts and possessions.

Section 1.2 Rules of Construction. When a reference is made in this Agreement to an Article or a Section, such reference shall be to an Article or a Section of this Agreement unless otherwise indicated. The use of "or" is not intended to be exclusive unless expressly indicated otherwise. The words "include," "includes" and "including" when used herein shall be deemed in each case to be followed by the words "without limitation." All references in this Agreement to "$" or dollars shall mean U.S. denominated dollars. The table of contents and headings set forth in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement. The terms defined in the singular have a comparable meaning when used in the plural, and vice versa. The words "hereof," "herein," "hereto" and "hereunder" and words of similar import refer to this Agreement as a whole and not to any particular provision of this Agreement, and the words "date herein" refer to the date of this Agreement. The parties hereto agree that they have been represented by counsel during the negotiation and execution of this Agreement and, therefore, waive the application of any Law holding or rule of construction providing that ambiguities in an agreement or other document will be construed against the party drafting such agreement or document. All references to "day" or "days" are to calendar days. When calculating the period of time before which, within which or following which any act is to be done or step taken pursuant to this Agreement, the date that is the reference date in calculating such period shall be excluded and if the last day of such period is a non-Business Day, the period in question shall end on the next succeeding Business Day.

ARTICLE II
CONTINGENT VALUE RIGHTS

Section 2.1 CVRs. As provided in the Merger Agreement, effective as of the First Effective Time, (i) each Share of Company Capital Stock (except for Cancelled Shares and Dissenting Shares) shall be converted into the right to receive the Merger Consideration, which includes one CVR, (ii) each Company Option that is converted pursuant to Section 1.6(c) of the Merger Agreement shall be treated in accordance with Section 1.6(c) of the Merger Agreement and (iii) each Company Warrant shall be treated in accordance with Section 1.6(c) of the Merger Agreement. The initial Holders shall be determined pursuant to the terms of the Merger Agreement and this Agreement, and a list of the initial Holders shall be furnished to the Rights Agent by or on behalf of Parent in accordance with Section 4.1 hereof.

Section 2.2 Non-transferable. The CVRs may not be directly or indirectly sold, assigned, transferred, pledged, encumbered or in any other manner transferred or disposed of, in whole or in part, other than through a Permitted Transfer, and, in the case of a Permitted Transfer, only in accordance with Section 2.3(c) hereof and in compliance with applicable United States federal and state securities laws and the terms and conditions hereto. Any such sale, assignment, transfer, pledge, encumbrance or disposal of CVRs, in whole or in part, in violation of this Section 2.2, shall be null and *void ab initio* and of no effect. In addition, each Holder, by virtue of its acceptance of a CVR, shall be deemed to have agreed to not facilitate or recognize any attempt by any beneficial owner of such CVR to sell, assign, transfer, pledge, encumber or in any other manner transfer or dispose of, in whole or in part, directly or indirectly, an interest in such CVR other than through a Permitted Transfer.

Section 2.3 No Certificate; Registration; Registration of Transfer; Change of Address.

(a) The CVRs shall not be evidenced by a certificate or other instrument.

(b) The Rights Agent shall keep a register (the "**CVR Register**") for the purpose of identifying the Holders and registering CVRs and transfers of CVRs as herein provided. The Rights Agent shall provide for the registration of CVRs and of transfers of CVRs on its books and records in book-entry form. The Stockholder Representative shall have reasonable access to the CVR Register and the Rights Agent shall provide access to such records in electronic form upon the reasonable written request by the Stockholders Representative. The Holders shall be entitled to request confirmation of their respective CVR interest by submitting a request to the Stockholders Representative.

(c) Subject to the restrictions on transferability set forth in Section 2.2, every request made to transfer a CVR must be in writing and accompanied by a written instrument of transfer in form reasonably satisfactory to the Rights Agent pursuant to its written guidelines, duly executed by the Holder thereof, the Holder's attorney duly authorized in writing, the Holder's personal representative or the Holder's survivor, as applicable, and setting forth in reasonable detail the circumstances relating to the transfer. Upon receipt of such written notice, the Rights Agent shall, subject to its reasonable determination that the transfer instrument is in proper form and the transfer otherwise complies with the other terms and conditions of this Agreement (including the provisions of Section 2.2), register the transfer of the CVRs in the CVR Register and notify Parent of the same. Any registration, transfer or assignment of the CVRs shall be without charge to the Holder (other than payment of a sum to the extent necessary to cover any stamp or other Tax or other governmental charge that is imposed in connection with any such registration, transfer or assignment). All duly transferred CVRs registered in the CVR Register shall be the valid obligations of Parent and shall entitle the transferee to the same benefits and rights under this Agreement as those held immediately prior to the transfer by the transferor. No transfer of a CVR shall be valid unless and until registered in the CVR Register.

(d) A Holder may make a written request to the Rights Agent to change such Holder's address of record in the CVR Register. The written request must be duly executed by the Holder. Upon receipt of such written request, the Rights Agent is hereby authorized to, and shall promptly, record the change of address in the CVR Register.

Section 2.4 Payment Procedures.

(a) If any Milestone is achieved as set forth in this Agreement, then, in each case, on a date (a "**Milestone Payment Date**") that is within 60 days following the last day of such Calendar Quarter in which such Milestone is achieved:

(i) Parent will deliver to the Rights Agent (A) a notice (a "**Milestone Notice**") indicating (1) the achievement of such Milestone and that the Holders are entitled to receive the applicable Milestone Amount, and (2) Parent's election, in its sole discretion, as to which portion of such Milestone Amount shall be settled by payment of cash (the "**Milestone Cash Amount**") pursuant to Section 2.4(b) or by credit of Parent Common Stock (the "**Milestone Stock Amount**") pursuant to Section 2.4(c), and (B) in the event that Parent, in its sole discretion, elects to pay a portion of the Milestone Amount in cash, cash in the aggregate amount of the Milestone Cash Amount.

(ii) Subject to the terms of this Agreement, including Section 2.4(d), each CVR shall entitle the Holder thereof to receive from Parent the number of fully paid and nonassessable shares of Parent Common Stock equal to the applicable Milestone Stock Amount (determined by dividing the applicable Milestone Amount, *less* the Milestone Cash Amount, *by* the Milestone Stock Price), together, if applicable, with any Milestone Cash Amount, any cash payable in lieu of fractional shares as provided in Section 2.9 or any dividends or distributions payable as provided in Section 2.10, in each case subject to any applicable withholding Tax.

(b) The Rights Agent shall promptly, and in any event within 10 Business Days of receipt of a Milestone Notice, as well as any letter of instruction reasonably required by the Rights Agent, send each Holder at its registered address a copy of such Milestone Notice. If any Milestone Cash Amount is payable to the Holders, then at the time the Rights Agent sends a copy of such Milestone Notice to the Holders, the Rights Agent shall also pay to each Holder, subject to any applicable withholding Tax, the applicable Milestone Cash Amount (the amount of which each Holder is entitled to receive shall be based on the applicable Milestone Cash Amount multiplied by the number of CVRs held by such Holder as reflected in the CVR Register), in accordance with the corresponding letter of instruction (i) by check mailed to the address of such Holder reflected in the CVR Register as of 5:00 p.m. New York City time on the date of the applicable Milestone Notice or (ii) with respect to any such Holder that is due an amount in excess of $10,000 in the aggregate who has provided the Rights Agent wiring instructions in writing as of the close of business on the date of the Milestone Notice, by wire transfer of immediately available funds to the account specified on such instruction.

(c) Promptly following a Milestone Payment Date, and in any event within 10 Business Days of an applicable Milestone Payment Date, subject to any withholding Tax, Parent shall (i) pay the applicable Milestone Stock Amount by crediting (or shall cause its Transfer Agent to credit) the appropriate number of book-entry shares of Parent Common Stock (as determined in accordance with Section 2.4(a)(ii)) to each Holder in the name of such Holder as recorded in the CVR Register, and such book-entry shares of Parent Common Stock shall be deemed to have been issued and any person so named therein shall be deemed to have become a holder of record of such shares of Parent Common Stock as of the applicable Milestone Payment Date, and (ii) deliver to the Rights Agent any cash necessary to be paid to Holders in lieu of fractional shares as provided in Section 2.9 hereof, and the Rights Agent shall deliver to each Holder at his, her or its address appearing on the CVR Register, (x) a written notice specifying the number of shares of Parent Common Stock (if any) paid for each CVR and to whom the shares of Parent Common Stock were issued and the Rights Agent shall promptly record such issuance in the CVR Register and (y) a check reflecting the amount of any cash payable pursuant to Section 2.7(c) or cash in lieu of fractional shares to be provided to such Holder as provided in Section 2.9 hereof and, if applicable, amounts payable pursuant to Section 2.10.

(d) Notwithstanding anything to the contrary herein, in no event shall Parent credit or issue (or have any obligation to credit or issue) pursuant to, or in connection with, the CVRs a number of shares of Parent Common Stock that, together with the shares of Parent Common Stock issuable pursuant to the Merger Agreement (including Holdback Shares) plus any other shares of Parent Common Stock aggregable for purposes of determining whether the Nasdaq Stock Market would require a stockholder vote in connection with any such issuances, that exceeds the Parent Share Cap, unless Parent, in its sole discretion, obtains the approval of its stockholders as required by Nasdaq Marketplace Rules for issuances of shares of Parent Common Stock in excess of the Parent Share Cap; *provided* that (i) this Section 2.4(d) shall not be deemed to limit any Holder's right to receive any Milestone Amount in full (it being understood that any portion of a Milestone Amount that would otherwise exceed the Parent Share Cap shall be paid as a Milestone Cash Amount) and (ii) Parent shall use reasonable efforts to issue Parent Shares rather than cash for any Milestone Amounts payable up to an amount equal to the Parent Share Cap.

(e) Notwithstanding any other provisions of this Agreement, any portion of the cash provided by Parent to the Rights Agent as a reserve for purposes of payments to Holders of cash pursuant to Section 2.7(c) or cash in lieu of fractional shares pursuant to Section 2.9 hereof and, if applicable, amounts payable pursuant to Section 2.4(b) or Section 2.10 that remains unclaimed as of the first anniversary of the applicable Milestone Payment Date (including by means of uncashed checks or invalid addresses on the CVR Register) shall be delivered to Parent or its designee (concurrently with notification to the Stockholder Representative) and not disbursed to the Holders, and, thereafter, such Holders shall be entitled to look to Parent (subject to abandoned property, escheat and other similar Laws) only as general creditors thereof with respect to such cash that may be payable.

(f) Neither Parent, the Rights Agent nor any of their Affiliates shall be liable to any Holder for any payments delivered to a public official pursuant to any abandoned property, escheat law or other similar Laws.

(g) For calculation of all payments to be made in respect of Milestones, any CVRs issuable pursuant to the Merger Agreement but not issued because they are represented by Dissenting Shares shall nevertheless be included in the number of CVRs outstanding and any payments thereon shall be paid to the Parent.

(h) If a Milestone is not achieved in connection with the terms and conditions of this Agreement during the applicable Calendar Year period as defined in each Milestone, then on or before the date that is 60 days after the expiration of each such applicable Calendar Year period, Parent shall deliver to the Rights Agent a certificate certifying that such Milestone has not occurred, accompanied by a statement setting forth, in reasonable detail, and if applicable, a calculation of Annual Revenues for the applicable period (each, a "**Milestone Non-Achievement Certificate**"). The Rights Agent shall promptly, and in any event within 10 Business Days of receipt of a Milestone Non-Achievement Certificate, send each Holder at its registered address a copy of such Milestone Non-Achievement Certificate, including detail regarding the ability of the Stockholder Representative to dispute or contest such determination of non-achievement of a Milestone pursuant to this Agreement. If the Rights Agent does not receive from the Stockholder Representative a written objection to a Milestone Non-Achievement Certificate, if any, within 180 days of the delivery by the Rights Agent of such Milestone Non-Achievement Certificate to the Holders in accordance with this Section 2.4(g), the Stockholder Representative shall be deemed to have accepted such Milestone Non-Achievement Certificate and Parent and its Affiliates shall have no further obligation with respect to each such Milestone and the applicable Milestone Amount.

(i) All Milestones or a combination of Milestones may be earned in the same Calendar Year, in which case all applicable Milestone Amounts shall be payable. Notwithstanding anything to the contrary in the Merger Agreement or this Agreement, each Milestone Amount is only payable once.

Section 2.5 Withholding. Each of Parent, the Rights Agent, the Exchange Agent, the Surviving Company, their respective Affiliates, and any other Person who has any obligation to deduct or withhold from any consideration payable pursuant to this Agreement shall be entitled to deduct and withhold from the amounts otherwise payable pursuant to this Agreement such amounts as are required by any law to be deducted and withheld, as may be reasonably determined by such Person. To the extent that amounts are so withheld and remitted to the appropriate governmental body in accordance with applicable Laws, such withheld amounts shall be treated for all purposes of this Agreement as having been paid to the Person in respect of which such deduction and withholding was made.

Section 2.6 Right to Set-Off. Parent has the right (but not the obligation) to withhold or deduct from, or off-set or set-off against, any and all amounts otherwise payable hereunder to a Holder in order to satisfy the indemnification obligations pursuant to and under Article VIII of the Merger Agreement (such amount off-set or set-off, the "**Indemnification Set-Off Amount**").

Section 2.7 Transfer Agent and Parent Common Stock.

(a) Parent will keep a copy of this Agreement on file with the transfer agent for Parent Common Stock (the "**Transfer Agent**") and with every subsequent transfer agent for any shares of Parent Common Stock issuable to Holders of the CVRs. Parent will provide or otherwise make available any cash which may be payable as provided in to Section 2.7(c), Section 2.9 and Section 2.10 hereof. Parent will furnish such Transfer Agent a copy of all notices of adjustments and certificates related thereto transmitted to each Holder pursuant to Section 2.7(a) hereof.

(b) Parent covenants that all shares of Parent Common Stock which may be issued upon payment of CVRs in connection with the terms and conditions of this Agreement will, upon issue, be validly authorized and issued, fully paid, nonassessable, free of preemptive rights and free from all liens, charges and security interests with respect to the issuance thereof (other than those imposed by applicable securities laws).

(c) ***Cash-Only Consideration***. Notwithstanding anything to the contrary in this Agreement, in no event shall Parent be required to issue any shares of Parent Common Stock to any Person that (A) does not provide a duly completed and executed Accredited Investor Questionnaire establishing that such shares may be issued to such Person in connection with the Mergers and the other Transactions pursuant to an exemption from the registration and prospectus delivery requirements of the Securities Act pursuant to Regulation D and the equivalent state "blue sky" Laws, or (B) in its sole discretion, Parent has determined is an Unaccredited Investor. To the extent any such Person would otherwise have been entitled to be issued shares of Parent Common Stock as consideration or otherwise under this Agreement, Parent shall be entitled (but not required) to pay such amounts in cash, rather than issuing such shares.

(d) The shares of Parent Common Stock issued by Parent pursuant to this Agreement shall be reflected in Parent's books and records in book entry only with appropriate notations reflecting the following restrictive legend until such Parent Common Stock is registered for resale pursuant to Section 2.7(e):

"THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR UNDER THE SECURITIES LAWS OF ANY STATE. WITHOUT SUCH REGISTRATION, SUCH SECURITIES MAY NOT BE SOLD OR OTHERWISE TRANSFERRED AT ANY TIME UNLESS IN THE OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE COMPANY REGISTRATION IS NOT REQUIRED FOR SUCH TRANSFER."

(e) Parent shall use reasonable efforts to, within 45 calendar days of any issuance or crediting of Parent Common Stock under this Agreement, file a registration statement on Form S-3 (or other appropriate form if Parent is not then S-3 eligible) (including any amendments or supplements, the "**Registration Statement**") providing for the resale of all such issued Parent Common Stock. Parent shall use reasonable efforts to cause such Registration Statement to be declared effective as soon as practicable following the initial filing of such Registration Statement, subject to any comments from the SEC.)

(f) As a condition to its obligations under Section 2.7(e) of this Agreement, Parent may require each Holder of Registrable Securities as to which any registration is being effected to (A) furnish Parent with such information regarding such Person that is necessary to satisfy the disclosure requirements relating to the registration and the distribution of such securities under the Securities Act and the rules and regulations promulgated thereunder as Parent may from time to time reasonably request in writing, including the properly completed and executed Accredited Investor Questionnaire and (B) promptly notify Parent in writing of any changes in the information set forth in the applicable Registration Statement after it is prepared regarding the Holder of Registrable Securities; provided, that any delay in providing or failing to provide such information by any Holder of Registrable Securities shall not delay, eliminate or condition Parent's obligations under Section 2.7(e) with respect to any other Holder of Registrable Securities. The Registration Statement and Prospectus shall only include the Registrable Securities of all Accredited Investors for whom Parent has received properly completed Accredited Investor Questionnaire on or before the Closing Date. For the purposes of this Section 2.7, a "**Holder of Registrable Securities**" refers solely to an Accredited Investor that is a holder of Registrable Securities as of or following the Closing Date.

Section 2.8 Adjustment of CVRs.

(a) In case of any capital reorganization, other than any capital reorganization that does not result in any reclassification of the outstanding shares of Parent Common Stock into shares of other stock or other securities or property (collectively any such actions being hereinafter referred to as "**Reorganizations**") or any Change of Control, appropriate adjustment shall be made in the application of the provisions herein set forth with respect to the rights and interests of Holders so that the provisions set forth herein shall thereafter be applicable, as nearly as possible, in relation to any such shares or other securities, property or cash thereafter deliverable upon payment of CVRs.

(b) Whenever an adjustment is made to the terms of the CVRs pursuant to this Section 2.8, Parent will deliver to the Rights Agent a notice of such Reorganization or Change of Control within five (5) Business Days of the closing of such Reorganization or Change of Control, setting forth in reasonable detail the terms of such Reorganization or Change of Control and any adjustments made pursuant to this Section 2.8. Parent shall cause the Rights Agent, on behalf of and at the expense of Parent, within ten (10) Business Days after notification is received by the Rights Agent of such adjustment, to mail by first class mail, postage prepaid, to each Holder a notice of such adjustment(s) and shall deliver to the Rights Agent a certificate of the Chief Financial Officer of Parent, setting forth in reasonable detail (i) the terms of such adjustment(s), (ii) a brief statement of the facts requiring such adjustment(s) and (iii) the computation by which such adjustment(s) was made. Where appropriate, such notice by Parent may be given in advance and included as a part of the notice to the Holders required under the other provisions of this Section 2.8(b).

(c) The Rights Agent shall promptly, and in any event within ten (10) Business Days of receipt of such a notice, send each Holder a copy of such notice in accordance with Section 7.2.

(d) The Rights Agent has no duty to determine when an adjustment under this Section 2.8 should be made, how it should be made or what it should be. The Rights Agent makes no representation as to the validity or value of any securities or assets issuable upon payment of CVRs. The Rights Agent shall not be responsible for Parent's failure to comply with this Section 2.8.

(e) For purpose of this Section 2.8, the term "shares of Parent Common Stock" means (i) shares of the class of stock designated as Common Stock, par value $0.001 per share, of Parent as of the date of this Agreement, and (ii) shares of any other class of stock resulting from successive changes or reclassification of such shares consisting solely of changes in par value, or from par value to no par value, or from no par value to par value. In the event that at any time, as a result of an adjustment made pursuant to this Section 2.8, the Holders of CVRs shall become entitled to receive any securities other than, or in addition to, shares of Parent Common Stock, thereafter the number or amount of such other securities so issuable upon payment of each CVR shall be subject to terms as nearly equivalent as practicable to the provisions with respect to the shares of Parent Common Stock issuable hereunder.

(f) This Agreement shall not restrict Parent's or any successor's ability to sell, transfer or license the Company Products to any Person; *provided*, that such Person assumes Parent's obligations, duties and covenants under this Agreement in which case the obligation to issue Parent Common Stock set forth herein shall be assumed by such Person and the equity issuable hereunder shall be the equity of such Person or Affiliate thereof; *provided, further*, that in the event that none of the chief executive officer, chief financial officer or chief marketing officer of Parent remain employees of or consultants to the successor entity more than one year after a Change of Control or sale of the Company Products to another Person, then the obligation to issue equity of such Person shall thereafter be replaced with cash issued by such Person.

Section 2.9 No Fractional Shares. Parent shall not be required to issue fractional shares of Parent Common Stock upon payment of CVRs, and no certificates or scrip for any such fractional shares shall be issued. If more than one CVR shall be payable at the same time with respect to the same Holder, the number of full shares of Parent Common Stock which shall be issuable upon the payment thereof shall be computed on the basis of the aggregate number of shares of Parent Common Stock issuable upon the payment of such CVRs. If any fraction of a share of Parent Common Stock would, except for the provisions of this Section 2.9, be issuable on the payment of any CVRs, Parent shall pay in cash to the Holder thereof the dollar amount (rounded to the nearest whole cent, with numbers ending with .5 or more being rounded up to the nearest whole cent), without interest, determined by multiplying such fraction by the Milestone Stock Price.

Section 2.10 Dividends or Other Distributions. No dividend or other distribution declared with respect to Parent Common Stock with a record date prior to the applicable Milestone Payment Date shall be paid to Holders of CVRs. To the extent any shares of Parent Common Stock are issued to Holders pursuant to Section 2.4(a)(ii), there shall be paid to such Holders the amount of dividends or other distributions, without interest, declared with a record date after the applicable Milestone Payment Date.

Section 2.11 Holding of Funds. All funds received by the Rights Agent under this Agreement that are to be distributed or applied by the Rights Agent in the performance of services hereunder (the "**Funds**") shall be held by the Rights Agent as agent for Parent and deposited in one or more bank accounts to be maintained by the Rights Agent in its name as agent for Parent. Until paid pursuant to the terms of this Agreement, the Rights Agent will hold the Funds through such accounts in: deposit accounts of commercial banks with Tier 1 capital exceeding $1 billion or with an average rating above investment grade by S&P (LT Local Issuer Credit Rating), Moody's (Long Term Rating) and Fitch Ratings, Inc. (LT Issuer Default Rating) (each as reported by Bloomberg Finance L.P.). The Rights Agent shall have no responsibility or liability for any diminution of the Funds that may result from any deposit made by the Rights Agent in accordance with this paragraph, including any losses resulting from a default by any bank, financial institution or other third party; *provided* that in the event the Funds are diminished below the level required for the Rights Agent to make cash payments as required under this Agreement, including any such diminishment as a result of investment losses, Parent shall promptly transfer additional cash to the Rights Agent in an amount equal to such deficiency. The Rights Agent may from time to time receive interest, dividends or other earnings in connection with such deposits. The Rights Agent shall pay such interest, dividends or earnings to Parent, unless there is a diminution of the Funds due to a deposit or investment made by the Rights Agent, in which case, such interest, dividends or earnings shall accrue to the benefit of Parent to the extent of such diminution of the Funds.

Section 2.12 No Voting, Dividends or Interest; No Equity or Ownership Interest.

(a) Nothing contained in this Agreement shall be construed as conferring upon any Holder, by virtue of being a Holder of a CVR, the right to receive dividends other than as provided in Section 2.10, or the right to vote or to consent or to receive notice as stockholders in respect of the meetings of stockholders or the election of directors of Parent or any or any other matter, or any other rights of any kind or nature whatsoever as a stockholder of Parent, either at law or in equity.

(b) The CVRs shall not represent any equity or ownership interest in Parent or in any constituent company to the Mergers or any of their respective Subsidiaries or Affiliates. The rights of a Holder in respect of the CVRs are limited to those expressed in this Agreement and the Merger Agreement.

(c) Notwithstanding anything herein or in the Merger Agreement to the contrary, none of Parent, the Surviving Company or any of their respective Subsidiaries or Representatives shall have any liability, responsibility or obligation of any kind to any Holder in their capacity as such on any basis (including in contract, tort, under federal or state securities law or otherwise) with respect to, arising out of, or relating to, this Agreement or the CVRs, except to the extent this Agreement expressly requires the payment of any Milestone Amount to the Holders and except to the extent otherwise expressly provided for in this Agreement

Section 2.13 Ability to Abandon CVR. A Holder may at any time, at such Holder's option, abandon all of such Holder's remaining rights in a CVR by transferring such CVR to Parent or any of its Affiliates without consideration therefor. Such Holder shall notify the Stockholder Representative of such abandonment by providing written notice with respect thereto, which notice shall include the name of such Holder and the number of CVRs such Holder is entitled to and abandoning at such time. The Stockholder Representative shall notify Parent and the Rights Agent of such abandonment. Nothing in this Agreement shall prohibit Parent or any of its Affiliates from offering to acquire or acquiring any CVRs for consideration from the Holders, in private transactions or otherwise, in its sole discretion. Any CVRs acquired by Parent or any of its Affiliates shall be automatically deemed extinguished and no longer outstanding for purposes of Article V and Article VI and any Holder from whom the Parent or any of its Affiliates acquired such CVRs shall have no rights hereunder with respect to such CVRs.

ARTICLE III
THE RIGHTS AGENT

Section 3.1 Certain Duties and Responsibilities. Parent hereby appoints the Rights Agent to act as rights agent for Parent in accordance with the express terms and conditions set forth in this Agreement (and no implied terms and conditions), and the Rights Agent hereby accepts such appointment. The Rights Agent shall not have any liability for any actions taken, suffered or omitted to be taken in connection with this Agreement, except for fraud, gross negligence, bad faith or intentional misconduct on the part of the Rights Agent.

Section 3.2 Certain Rights of the Rights Agent. The Rights Agent undertakes to perform such duties and only such duties as are specifically set forth in this Agreement, and no implied covenants or obligations shall be read into this Agreement against the Rights Agent. In addition:

(a) the Rights Agent may rely and shall be protected and held harmless by Parent in acting or refraining from acting upon any resolution, certificate, statement, instrument, opinion, report, notice, request, direction, consent, order or other paper or document believed by it in good faith to be genuine and to have been signed or presented by the proper party or parties;

(b) whenever the Rights Agent shall deem it desirable that a matter be proved or established prior to taking, suffering or omitting any action hereunder, the Rights Agent may rely upon an Officer's Certificate, which certificate shall be full authorization and protection to the Rights Agent, and the Rights Agent shall, in the absence of fraud, gross negligence, bad faith or intentional misconduct on its part, incur no liability and be held harmless by Parent for or in respect of any action taken, suffered or omitted to be taken by it under the provisions of this Agreement in reliance upon such certificate;

(c) the Rights Agent may, at its own expense, engage and consult with counsel of its selection and the written advice of such counsel or any opinion of counsel shall be full and complete authorization and protection and shall be held harmless by Parent in respect of any action taken, suffered or omitted by it hereunder in good faith and in reliance thereon;

(d) the permissive rights of the Rights Agent to do things enumerated in this Agreement shall not be construed as a duty;

(e) the Rights Agent shall not be required to give any note or surety in respect of the execution of such powers or otherwise in respect of the premises;

(f) the Rights Agent shall not be liable for or by reason of, and shall be held harmless by Parent with respect to any of the statements of fact or recitals contained in this Agreement or be required to verify the same, but all such statements and recitals are and shall be deemed to have been made by Parent only;

(g) the Rights Agent shall have no liability and shall be held harmless by Parent in respect of the validity of this Agreement or the execution and delivery hereof (except the due authorization, execution and delivery hereof by the Rights Agent and the enforceability of this Agreement against the Rights Agent assuming the due execution and delivery hereof by Parent); nor shall it be responsible for any breach by Parent of any covenant or condition contained in this Agreement;

(h) Parent agrees to indemnify the Rights Agent for, and hold the Rights Agent harmless against, any loss, liability, damage, judgement, fine, penalty, claim, suits or expense ("**Losses**") arising out of or in connection with Rights Agent's duties under this Agreement, including the reasonable out-of-pocket costs and expenses of counsel in defending Rights Agent against any Losses, unless such losses have been determined by a court of competent jurisdiction to be a result of fraud, gross negligence, bad faith or intentional misconduct on the part of the Rights Agent;

(i) Anything to the contrary notwithstanding, in the absence of fraud, gross negligence, bad faith or intentional misconduct on the part of the Rights Agent, (i) the Rights Agent shall not be liable for any special, punitive or indirect loss or damage of any kind whatsoever (including but not limited to lost profits) arising out of any act or failure to act hereunder and (ii) the aggregate liability of the Rights Agent arising in connection with this Agreement, whether in contract, or in tort, or otherwise, is limited to, and shall not exceed, the amounts paid or payable hereunder by Parent to the Rights Agent as fees and charges;

(j) Parent agrees to pay the fees and expenses of the Rights Agent in connection with this Agreement agreed upon in writing by the Rights Agent and Parent prior to the date hereof; and

(k) No provision of this Agreement shall require the Rights Agent to expend or risk its own funds or otherwise incur any financial liability in the performance of any of its duties hereunder or in the exercise of its rights if there shall be reasonable grounds for believing that repayment of such funds or adequate indemnification against such risk or liability is not reasonably assured to it.

Section 3.3 Resignation and Removal; Appointment of Successor.

(a) The Rights Agent may resign at any time by giving written notice thereof to Parent specifying a date when such resignation shall take effect, which notice shall be sent at least 60 days prior to the date so specified but in no event shall such resignation become effective until a successor Rights Agent has been appointed and accepted such appointment in accordance with Section 3.4. Parent has the right to remove the Rights Agent at any time by specifying a date when such removal shall take effect but no such removal shall become effective until a successor Rights Agent has been appointed and accepted such appointment in accordance with Section 3.4. Notice of such removal shall be given by Parent to the Rights Agent, which notice shall be sent at least 60 days prior to the date so specified.

(b) If the Rights Agent provides notice of its intent to resign, is removed or becomes incapable of acting, Parent shall, as soon as is reasonably practicable, appoint a qualified successor Rights Agent who shall be a stock transfer agent of national reputation or the corporate trust department of a commercial bank. Notwithstanding the foregoing, if Parent shall fail to make such appointment within a period of sixty (60) days after giving notice of such removal or after it has been notified in writing of such resignation or incapacity by the resigning or incapacitated Rights Agent, then the incumbent Rights Agent may apply to any court of competent jurisdiction for the appointment of a new Rights Agent. The successor Rights Agent so appointed shall, forthwith upon its acceptance of such appointment in accordance with Section 3.4, become the successor Rights Agent.

(c) Parent shall give notice of each resignation and each removal of a Rights Agent and each appointment of a successor Rights Agent by mailing written notice of such event to the Stockholder Representative. Each notice shall include the name and address of the successor Rights Agent. If Parent fails to send such notice within 10 Business Days after acceptance of appointment by a successor Rights Agent, the successor Rights Agent shall cause the notice to be transmitted at the expense of Parent. Failure to give any notice provided for in this Section 3.3, however, shall not affect the legality or validity of the resignation or removal of the Rights Agent or the appointment of the successor Rights Agent, as the case may be.

(d) Notwithstanding anything else in this Section 3.3, unless consented to in writing by the Stockholder Representative, Parent shall not appoint as a successor Rights Agent any Person that is not a stock transfer agent of national reputation or the corporate trust department of an international commercial bank.

Section 3.4 Acceptance of Appointment by Successor. Every successor Rights Agent appointed hereunder shall, at or prior to such appointment, execute, acknowledge and deliver to Parent and to the retiring Rights Agent an instrument accepting such appointment and a counterpart of this Agreement, and thereupon such successor Rights Agent, without any further act, deed or conveyance, shall become vested with all the rights, powers, trusts and duties of the retiring Rights Agent. On request of Parent or the successor Rights Agent, the retiring Rights Agent shall execute and deliver an instrument transferring to the successor Rights Agent all the rights, powers, trusts and duties of the retiring Rights Agent.

ARTICLE IV
COVENANTS

Section 4.1 List of Holders. Parent shall furnish or cause to be furnished to the Rights Agent, in such form as received from Parent's Transfer Agent, the names and addresses of the Holders within 10 days of the First Effective Time. The Rights Agent shall reflect such names and addresses on the CVR Register and confirm the write up of the CVR Register and list of initial Holders to Parent promptly thereafter and in any event, within seven (7) calendar days of the receipt of such names and addresses from Parent.

Section 4.2 Further Assurances. Parent agrees that it will perform, execute, acknowledge and deliver or cause to be performed, executed, acknowledged and delivered, all such further and other acts, instruments and assurances as may reasonably be required by the Rights Agent for the carrying out or performing by the Rights Agent of the provisions of this Agreement.

Section 4.3 Diligent Efforts. Commencing upon the Closing Date and continuing until the earlier of December 31, 2030 or the achievement of all Milestones, Parent shall, and shall cause the Surviving Company to, use Diligent Efforts to achieve the Milestones; *provided*, *however* that with respect to Milestone 3, Milestone 4 or the development, marketing or sale of LTX-608, Parent shall not be obligated, and shall not be obligated to cause the Surviving Company, to use Diligent Efforts. For the avoidance of doubt, Parent is not obligated to prioritize the achievement of a Milestone over any Parent Product or take any action that would or would reasonably be expected to adversely affect any Parent Product or take any action that is not commercially reasonable as determined by Parent in its sole discretion.

Section 4.4 Audit Rights. Until one year following the earlier of December 31, 2030 or the achievement of all Milestones, upon reasonable advance written notice from the Stockholder Representative, Parent shall permit an independent certified public accounting firm of nationally recognized standing selected by such Stockholder Representative and reasonably acceptable to Parent (the "**Independent Accountant**") to have access at reasonable times during normal business hours to the books and records of Parent and its Affiliates as may be reasonably necessary to evaluate and verify Parent's calculation of Annual Revenues hereunder; *provided* that (x) such Stockholder Representative (and the Independent Accountant) enter into customary confidentiality agreements reasonably satisfactory to Parent with respect to the confidential information of Parent or its Affiliates to be furnished pursuant to this Section 4.4 and (y) such access does not unreasonably interfere with the conduct of the business of Parent or any of its Affiliates. The fees charged by such accounting firm shall be borne by the Stockholder Representative, unless the audit reveals an underpayment of 5% or more, in which case the fees shall be borne by Parent. The Independent Accountant shall provide Parent with a copy of all disclosures made to the Stockholder Representative. The audit rights set forth in this Section 4.4 may not be exercised by the Stockholder Representative more than once in any given twelve (12)-month period.

Section 4.5 Stockholder Representative.

(a) To facilitate the administration of the transactions contemplated by this Agreement and any other actions required or permitted to be taken by the Stockholder Representative under this Agreement, each Holder, by virtue of the execution and delivery of a Joinder (as applicable), and the adoption of this Agreement, and approval of the Transactions, including the Mergers, hereby agrees to appoint, authorize and empower James Wilkie as its agent and attorney-in-fact, with full power of substitution: (i) as the Stockholder Representative for and on behalf of the Holder to give and receive notices and communications in respect of this Agreement, to authorize payment to any Holder, to object to such payments, to agree to, negotiate, enter into settlements and compromises of, and demand arbitration and comply with orders of courts and awards of arbitrators with respect to, to assert, negotiate, enter into settlements and compromises of, any claims or any disputes, in each case relating to this Agreement or the Transactions, and to take all other actions that are either (x) necessary or appropriate in the judgment of the Stockholder Representative for the accomplishment of the foregoing or (y) specifically mandated by the terms of this Agreement; (ii) to make all decisions and determinations and to act (or not act) and execute, deliver and receive all agreements, documents, instruments and consents on behalf of and as agent for each Holder at any time in connection with, and that may be necessary or appropriate to accomplish the intent and implement the provisions of this Agreement and to facilitate the consummation of the transactions contemplated hereby, including without limitation for purposes of (x) negotiating and settling, on behalf of the Holders, any dispute that arises under this Agreement after the First Effective Time and (y) negotiating and settling matters with respect to the amounts to be paid to the Holders pursuant to this Agreement; and (iii) to take any and all additional action as is contemplated to be taken by or on its behalf or by the Stockholder Representative by the terms of this Agreement. All such actions shall be deemed to be facts ascertainable outside this Agreement and shall be binding on the Holders. Such agency may be changed by the Holders from time to time upon not less than thirty (30) days prior written notice to Parent; *provided*, *however*, that the Stockholder Representative may not be removed unless holders of a majority interest of the CVRs agree to such removal and to the identity of the substituted agent. Notwithstanding the foregoing, in the event of a resignation of the Stockholder Representative or other vacancy in the position of Stockholder Representative, such vacancy may be filled by the holders of a majority in interest of the CVRs. No bond shall be required of the Stockholder Representative.

(b) Notices or communications to or from the Stockholder Representative shall constitute notice to or from the Holders.

(c) The Stockholder Representative shall not be liable for any act done or omitted hereunder as Stockholder Representative while acting in good faith and in the exercise of reasonable judgment. The Holders shall indemnify the Stockholder Representative and hold the Stockholder Representative harmless against any and all Losses arising out of or in connection with the acceptance or administration of the Stockholder Representative's duties hereunder, including the reasonable fees and expenses of any legal counsel, financial advisors, auditors or other agents retained by the Stockholder Representative. Any decision, act, consent or instruction of the Stockholder Representative in connection with this Agreement, including an amendment, extension or waiver of this Agreement pursuant to Section 5.1 or Section 6.1(b), shall constitute a decision of all the Holders and shall be final, binding and conclusive upon each Holder, and no Holder shall have the right to object, dissent, protest or otherwise contest the same. Parent may rely upon any such decision, act, consent or instruction of the Stockholder Representative as being the decision, act, consent or instruction of all the Holders. Parent is hereby relieved from any liability to any Person for any acts done by them in accordance with such decision, act, consent or instruction of the Stockholder Representative.

(d) Parent and its Affiliates shall be entitled to rely conclusively on the decisions, acts, consents, waivers and instructions of the Stockholder Representative as to any determination relating to the transactions contemplated by this Agreement as being the decision, act, consent, waiver or instruction of every Holder, and any other actions required or permitted to be taken by the Stockholder Representative under this Agreement. No Person shall have any cause of action against Parent, its Affiliates, or any of their respective directors, officers, employees or agents or for any action taken by Parent in reliance upon any decision, act, consent, waiver or instruction of the Stockholder Representative; and Parent and its Affiliates are each hereby relieved from any liability to any Person for any acts done by it in accordance with such decision, act, consent, waiver or instruction of the Stockholder Representative.

(e) No Holder shall have any cause of action against the Stockholder Representative for any action taken, decision made or instruction given by the Stockholder Representative under this Agreement in its capacity as such, except for fraud or intentional breach of this Agreement by the Stockholder Representative.

(f) The Holders recognize and intend that the power of attorney granted in this Section 4.5 is coupled with an interest and is irrevocable and will survive the death, incapacity, dissolution, liquidation or winding up of each of the Holders.

(g) Notwithstanding anything to the contrary contained in this Agreement: (i) Parent, its Affiliates and the Rights Agent will be entitled to deal exclusively with the Stockholder Representative on all matters relating to this Agreement and (ii) Parent, its Affiliates and the Rights Agent will be entitled to rely conclusively (without further evidence of any kind whatsoever) on any document executed or purported to be executed on behalf of any Holder by the Stockholder Representative and on any other action taken or purported to be taken on behalf of any Holder by the Stockholder Representative as fully binding upon such Holder and none of Parent, its Affiliates and the Rights Agent will be liable to any Holder for any act taken or omitted by Parent, its Affiliates and the Rights Agent in such reliance. The provisions of this Section 4.5 are independent and severable, are irrevocable and coupled with an interest, and shall be enforceable notwithstanding any rights or remedies that Parent or any Holder may have in connection with the transactions contemplated by this Agreement.

ARTICLE V
AMENDMENTS

Section 5.1 Amendments without Consent of Holders.

(a) Without the consent of any Holders or the Stockholder Representative, Parent, at any time and from time to time, may enter into one or more amendments hereto, for any of the following purposes:

(i) to evidence the succession of another person to Parent and the assumption by any such successor of the covenants of Parent herein; *provided* that such succession and assumption is in accordance with the terms of this Agreement;

(ii) to evidence the succession of another Person as a successor Rights Agent and the assumption by any such successor of the covenants and obligations of the Rights Agent herein; *provided* that such succession and assumption is in accordance with the terms of this Agreement;

(iii) to add to the covenants of Parent such further covenants, restrictions, conditions or provisions as Parent shall consider to be for the protection of the Holders; *provided* that, in each case, such provisions do not adversely affect the interests of the Holders;

(iv) to cure any ambiguity, to correct or supplement any provision herein that may be defective or inconsistent with any other provision herein or in the Merger Agreement, or to make any other provisions with respect to matters or questions arising under this Agreement; *provided* that, in each case, such provisions do not adversely affect the interests of the Holders;

(v) as may be necessary or appropriate to ensure that the CVRs are not subject to registration under the Securities Act, the Exchange Act or any applicable state securities or "blue sky" laws;

(vi) to evidence the assignment of this Agreement by Parent as provided in Section 7.3; or

(vii) as may be necessary or appropriate to ensure that the Surviving Company complies with applicable Law.

In addition to the foregoing, upon the request of Parent, the Rights Agent hereby agrees to enter into one or more amendments hereto to evidence the succession of another person as a successor Rights Agent in accordance with the terms of this Agreement and the assumption by any successor of the covenants and obligations of such Rights Agent herein, without modification of such covenants or obligations other than as permitted by this Section 5.1.

(b) Without the consent of any Holders, Parent and the Rights Agent, at any time and from time to time, may enter into one or more amendments hereto to reduce the number of CVRs, in the event any Holder agrees to renounce such Holder's rights under this Agreement in accordance with Section 7.4 or to abandon or transfer CVRs to Parent pursuant to Section 2.13.

(c) Promptly after the execution by Parent and the Rights Agent of any amendment pursuant to the provisions of this Section 5.1, Parent shall mail (or cause the Rights Agent to mail) a notice to the Stockholder Representative, setting forth such amendment.

Section 5.2 Amendments with Consent of the Stockholder Representative.

(a) Subject to Section 5.1 (which amendments pursuant to Section 5.1 may be made without the consent of any Holder), with the written consent of the Stockholder Representative, Parent and the Rights Agent may enter into one or more amendments hereto for the purpose of adding, eliminating or changing any provisions of this Agreement, even if such addition, elimination or change is adverse to the interest of the Holders.

(b) Promptly after the execution by Parent and the Rights Agent of any amendment pursuant to the provisions of this Section 5.2, Parent shall mail (or cause the Rights Agent to mail) a notice thereof to the Stockholder Representative, setting forth such amendment.

Section 5.3 Execution of Amendments. Prior to executing any amendment permitted by this Article V, the Rights Agent shall be entitled to receive, and shall be fully protected in relying upon, an opinion of counsel selected by Parent and reasonably acceptable to Rights Agent stating that the execution of such amendment is authorized or permitted by this Agreement.

Section 5.4 Effect of Amendments. Upon the execution of any amendment under this Article V, this Agreement shall be modified in accordance therewith, such amendment shall form a part of this Agreement for all purposes and every Holder shall be bound thereby.

ARTICLE VI
REMEDIES OF THE HOLDERS

Section 6.1 Event of Default.

(a)" **Event of Default**" with respect to the CVRs, means the following events which shall have occurred and be continuing (whatever the reason for such Event of Default and whether it shall be voluntary or involuntary or be effected by operation of Legal Requirements, pursuant to any judgment, decree or order of any court or any order, rule or regulation of any governmental body or otherwise): (i) default in the payment by Parent pursuant to the terms of this Agreement of all or any part of a Milestone Amount after a period of thirty (30) Business Days after the Milestone Amount shall have become due and payable and (ii) material default in the performance, or breach in any material respect, of any other covenant of Parent hereunder, and continuance of such default or breach for a period of sixty (60) days after a written notice specifying such default or breach and requiring it to be remedied is given, which written notice states that it is a "Notice of Default" hereunder and is sent by registered, certified or electronic mail to Parent and the Rights Agent by the Stockholder Representative.

(b) If an Event of Default described above occurs and is continuing (and has not been cured or waived), then, and in each and every such case, the Stockholder Representative by notice in writing to Parent and the Rights Agent, may, in its discretion, commence a suit to protect the rights of the Holders, including to obtain payment for any amounts then due and payable.

Section 6.2 Suits by Holders. Except for the rights of the Rights Agent set forth herein, the Stockholder Representative will have the sole and exclusive right, on behalf of all Holders, by virtue of or under any provision of this Agreement, to institute any action or proceeding with respect to this Agreement, and no individual Holder or other group of Holders will be entitled to exercise such rights. Notwithstanding the foregoing, (a) the right of any Holder of any CVR to receive payment of the amounts that a Milestone Notice indicates are payable in respect of such CVR on or after the applicable due date, or to institute any action or proceeding for the enforcement of any such payment on or after such due date, shall not be impaired or affected without the consent of such Holder and (b) in the event of an insolvency proceeding of Parent, individual Holders shall be entitled to assert claims in such insolvency proceeding and take related actions in pursuit of such claims with respect to any payment that may be claimed by or on behalf of Parent or by any creditor of Parent.

ARTICLE VII
OTHER PROVISIONS OF GENERAL APPLICATION

Section 7.1 Notices to the Rights Agent and Parent. All notices, requests, claims, demands and other communications hereunder shall be in writing and shall be given or made (and shall be deemed to have been duly given or made upon receipt) by delivery in person, by an internationally recognized overnight courier service, by registered or certified mail (postage prepaid, return receipt requested) or by electronic mail (so long as confirmation of transmission is electronically or mechanically generated and kept on file by the sending party) to the respective parties hereto at the following addresses (or at such other address for a party as shall be specified in a notice given in accordance with this Section 7.1):

If to the Rights Agent, to it at:

[●]
[Address]
Attention: [●]
Phone: [●]
Email: [●]

If to Parent, to it at:

AcelRx Pharmaceuticals, Inc.
25821 Industrial Boulevard, Suite 400
Hayward, California 94545
Attention: General Counsel
Phone: 650.216.3500
Email: legal@acelrx.com

with a copy (which shall not constitute notice) to:

Shearman & Sterling LLP
New York, NY 10022-6069
Attention: Robert Masella
Email: robert.masella@shearman.com

If to the Stockholder Representative, to it at:

Burns & Levinson LLP
125 High Street
Boston, MA 02110
Attention: Gil Breiman

The Rights Agent, Parent or Stockholder Representative may specify a different address, or email address by giving notice in accordance with this Section 7.1.

Section 7.2 Notice to Holders. Where this Agreement provides for notice to Holders, such notice shall be sufficiently given (unless otherwise herein expressly provided) if in writing and mailed, first-class postage prepaid, to each Holder affected by such event, at the Holder's address as it appears in the CVR Register, not later than the latest date, and not earlier than the earliest date, if any, prescribed for the giving of such notice. Neither the failure to mail such notice, nor any defect in any notice so mailed, to any particular Holder shall affect the sufficiency of such notice with respect to other Holders.

Section 7.3 Successors and Assigns. Parent may assign, in its sole discretion and without the consent of any other Person, any or all of its rights, interests and obligations hereunder to any Affiliate or any acquiror of the Company Products; *provided* that each such assignee agrees to assume and be bound by all of the terms and conditions of this Agreement, *provided*, *however*, that in the event that none of the chief executive officer, chief financial officer or chief marketing officer of Parent remain employees of or consultants to the successor entity upon more than one year after a Change of Control or sale of Surviving Company assets including the Company Products, then thereafter the obligation to issue equity of such Person shall be replaced with cash issued by such Person. This Agreement will be binding upon, inure to the benefit of and be enforceable by Parent's successors and each assignee. This Agreement shall not restrict Parent's or any successor's ability to merge or consolidate or enter into or consummate any Change of Control or sale of Surviving Company assets including the Company Products; *provided*, that in the event of a Change of Control or sale of Surviving Company assets including the Company Products, Parent or the Surviving Company, as applicable, shall cause the acquirer to assume Parent's obligations, duties and covenants under this Agreement, in which case the obligation to issue Parent Common Stock set forth herein shall be assumed for sale by the ultimate parent company or an Affiliate in such Change of Control and the equity issuable hereunder shall be the equity of such new Person. Except as otherwise permitted herein, Parent, the Stockholder Representative, or the Rights Agent may not assign this Agreement or any CVR or rights related thereto without the prior written consent of the other party. Any attempted assignment of this Agreement or any such rights in violation of this Section 7.3 shall be void and of no effect.

Section 7.4 No Third Party Beneficiaries. Nothing in this Agreement, express or implied, shall give to any Person (other than the Rights Agent and its permitted successors and assigns, the Stockholder Representative and its permitted successors and assigns, Parent, Parent's permitted successors and assignees, and the Holders and the Holders' successors and assigns pursuant to Permitted Transfers, each of whom is intended to be, and is, a third party beneficiary hereunder) any benefit or any legal or equitable right, remedy or claim under this Agreement or under any covenant or provision herein contained, all such covenants and provisions being for the sole benefit of the Rights Agent and its permitted successors and assigns, the Stockholder Representative and its permitted successors and assigns, Parent, Parent's permitted successors and assignees, and the Holders and the Holders' successors and assigns pursuant to Permitted Transfers. The rights hereunder of Holders and their successors and assigns pursuant to Permitted Transfers are limited to those expressly provided in this Agreement. Notwithstanding anything to the contrary contained herein, any Holder or Holder's successor or assign pursuant to a Permitted Transfer may at any time agree to renounce, in whole or in part, whether or not for consideration, its rights under this Agreement by written notice to the Rights Agent and Parent, which notice, if given, shall be irrevocable, and Parent may, in its sole discretion, at any time offer consideration to Holders in exchange for their agreement to irrevocably renounce their rights, in whole or in part, hereunder.

Section 7.5 Governing Law; Jurisdiction. This Agreement, the CVRs and all actions arising out of herewith and therewith shall be governed by and construed in accordance with the laws of the State of Delaware (regardless of the laws that might otherwise govern under applicable principles of conflicts of laws thereof).

Section 7.6 Exclusive Jurisdiction. The parties hereto agree that any action seeking to enforce any provision of, or based on any matter arising out of or in connection with this Agreement, including the CVRs, shall be brought and determined exclusively in the Delaware Court of Chancery or, if the Court of Chancery lacks jurisdiction over such dispute, then the state or federal courts of applicable jurisdiction located in Wilmington, Delaware. The parties hereto hereby (i) irrevocably submit to the exclusive personal jurisdiction of such courts for the purpose of any action arising out of or relating to this Agreement, including the CVRs, brought by any party hereto, (ii) agree that all claims in respect of such action or proceeding shall be heard and determined exclusively in such courts, and (iii) irrevocably waive, and agree not to assert by way of motion, defense, or otherwise, in any such action, any claim that it is not subject to the personal jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the action is brought in an inconvenient forum, that the venue of the Action is improper, or that this Agreement or the CVRs may not be enforced in or by any of the above-named courts.

Section 7.7 Waiver of Jury Trial. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT, OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE ACTIONS OF ANY PARTY HERETO IN NEGOTIATION, ADMINISTRATION, PERFORMANCE OR ENFORCEMENT HEREOF.

Section 7.8 Severability. In the event that any provision of this Agreement, or the application thereof, becomes or is declared by a court of competent jurisdiction to be illegal, void or unenforceable, the remainder of this Agreement shall continue in full force and effect and the application of such provision to other Persons or circumstances shall be interpreted so as reasonably to effect the intent of the parties. The parties further agree to replace such void or unenforceable provision of this Agreement with a valid and enforceable provision that will achieve, to the extent possible, the economic, business and other purposes of such void or unenforceable provision.

Section 7.9 Termination. This Agreement shall be terminated and of no force or effect, the parties hereto shall have no liability hereunder (other than with respect to monies due and payable by Parent to Rights Agent), and no payments shall be required to be made, or stock to be credited, upon the earlier to occur of (a) the payment in full of the Milestone Amounts, if any, by (i) Parent crediting (or causing its Transfer Agent to credit) the full amount of shares of Parent Common Stock reflecting each Milestone Stock Amount and/or Milestone Cash Amount to each Holder in the name of such Holder as recorded in the CVR Register or (ii) the mailing by the Rights Agent to the address of each Holder as reflected in the CVR Register the full amount of each Milestone Cash Amount and the potential cash payments in lieu of fractional shares, in each case, as required to be credited or paid, as applicable, under the terms of this Agreement, (b) December 31, 2030, if Milestone 7 has not been achieved on or prior to such date, and (c) the termination of the Merger Agreement in accordance with its terms. Notwithstanding the foregoing, no such termination shall affect any rights or obligations accrued prior to the effective date of such termination or Sections 2.4(e), 2.4(f), 3.2, 7.4, 7.5, 7.6, 7.7, 7.8, 7.10, 7.11, 7.12 or this Section 7.9, which shall survive the termination of this Agreement, or the resignation, replacement or removal of the Rights Agent.

Section 7.10 Entire Agreement. As it relates to the Rights Agent, (i) this Agreement constitutes the entire agreement of the parties hereto and supersedes all contemporaneous and prior agreements and understandings, both written and oral, among or between any of the parties hereto, with respect to the subject matter hereof, and (ii) if and to the extent that any provision of this Agreement is inconsistent or conflicts with the Merger Agreement, this Agreement shall govern and be controlling. For all other purposes, this Agreement and the Merger Agreement constitutes the entire agreement of the parties hereto and supersedes all contemporaneous and prior agreements and understandings, both written and oral, among or between any of the parties hereto, with respect to the subject matter hereof.

Section 7.11 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument. The exchange of a fully executed Agreement (in counterparts or otherwise) by PDF shall be sufficient to bind the parties hereto to the terms and conditions of this Agreement.

Section 7.12 No Fiduciary Obligations. Each of Parent, the Rights Agent and Stockholder Representative acknowledges and agrees that Parent, the Rights Agents and their respective Affiliates and officers, directors and controlling Persons do not owe any fiduciary duties to any Persons with respect to the CVRs.

[*REMAINDER OF PAGE INTENTIONALLY LEFT BLANK*]

IN WITNESS WHEREOF, each of the parties has caused this Agreement to be executed on its behalf by its duly authorized officers as of the day and year first above written.

ACELRX PHARMACEUTICALS, INC.

By: _____
Name:
Title:

[**Rights Agent**]

By: _____
Name:
Title:

Stockholder Representative

By: _____
Name: James Wilkie
Title: Stockholder Representative

FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS FIRST AMENDMENT to Loan and Security Agreement (this "**Amendment**") is entered into as of May 5, 2021, by and between **OXFORD FINANCE LLC**, a Delaware limited liability company with an office located at 115 South Union Street, Suite 300, Alexandria, Virginia 22314 ("**Oxford**"), as collateral agent (in such capacity, "**Collateral Agent**"), the Lenders listed on Schedule 1.1 of the Loan Agreement (as defined below) or otherwise party thereto from time to time (each a "**Lender**" and collectively, the "**Lenders**") including Oxford in its capacity as a Lender, **ACELRX PHARMACEUTICALS, INC.**, a Delaware corporation with offices located at 25821 Industrial Blvd., Suite 400, Hayward, California 94545 ("**Borrower**").

RECITALS

A. Collateral Agent, Lenders and Borrower have entered into that certain Loan and Security Agreement dated as of May 30, 2019 (as amended or modified from time to time, collectively, the "**Loan Agreement**").

B. Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.

C. Borrower desires to change its chief executive office effective as of May 1, 2021 from 351 Galveston Drive, Redwood City, California 94063 to 25821 Industrial Blvd., Suite 400, Hayward, California 94545 ("**Chief Executive Office Change**").

D. Borrower has requested that Collateral Agent and Lenders (i) consent to Borrower's change of its chief executive office and (ii) make certain other revisions to the Loan Agreement as more fully set forth herein.

E. Collateral Agent and Lenders have agreed to provide such consent and amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. Consent. Subject to the terms and conditions hereof, the Collateral Agent hereby consents to the Chief Executive Office Change.

3. Amendments to Loan Agreement.

3.1 Section 10 (Notices). Effective as of May 1, 2021, Section 10 of the Loan Agreement is hereby amended by replacing the notice information for Borrower with the following:

"If to Borrower: ACELRX PHARMACEUTICALS, Inc.
25821 Industrial Blvd., Suite 400
Hayward, California 94545
Attention: Raffi Asadorian, CFO
Email: rasadorian@acelrx.com

with a copy (which shall not constitute notice) to:	COOLEY LLP 299 Pennsylvania Avenue, NW, Suite 700 Washington, DC 20004-2400 Attention: Addison Pierce Email: afpierce@cooley.com".

3.2 Section 10 (Notices). Section 10 of the Loan Agreement is hereby amended by replacing the notice information for Collateral Agent with the following:

"If to Collateral Agent:	OXFORD FINANCE LLC 115 South Union Street Suite 300 Alexandria, VA 22314 Attention: Legal Department Fax: (703) 519-5225 Email: LegalDepartment@oxfordfinance.com

with a copy (which shall not constitute notice) to:

DLA Piper LLP (US)
500 8th Street, NW
Washington, DC 20004
Attention: Eric Eisenberg
Fax: (202) 799-5211
Email: eric.eisenberg@dlapiper.com".

3.3 Section 13.1 (Definitions). The following terms and their respective definitions hereby are added or amended and restated in their entirety, as applicable, to Section 13.1 of the Loan Agreement as follows:

"Basic Rate" is the per annum rate of interest (based on a year of three hundred sixty (360) days) equal to the sum of (a) the greater of (i) thirty (30) day U.S. LIBOR rate reported in The Wall Street Journal on the last Business Day of the month that immediately precedes the month in which the interest will accrue and (ii) two and one-half percent (2.50%), plus (b) six and three-quarters percent (6.75%). Notwithstanding the foregoing, the Basic Rate for the Term Loan for the period from the Effective Date through and including May 31, 2019 shall be nine and one-quarter percent (9.25%) and the Basic Rate shall not reset below nine and one-quarter percent (9.25%). Notwithstanding anything to the contrary herein or in any other Loan Document, upon the occurrence of a LIBOR Transition Event, Collateral Agent may amend this Agreement to replace the Basic Rate with a LIBOR Replacement Rate. Any such amendment with respect to a LIBOR Transition Event will become effective at 5:00 p.m. (Eastern Standard Time) on the third Business Day after Collateral Agent has notified Borrower of such amendment. Any determination, decision or election that may be made by Collateral Agent pursuant hereto will be conclusive and binding absent manifest error and may be made in Collateral Agent's sole but reasonable discretion and without consent from any other party.

"Federal Reserve Bank of New York's Website" means the website of the Federal Reserve Bank of New York at http://www.newyorkfed.org, or any successor source.

"LIBOR Replacement Rate" means the sum of: (a) the alternate benchmark rate (which may include SOFR) that has been selected by Collateral Agent in a manner that is consistent across its entire loan portfolio giving due consideration to (i) any selection or recommendation of a replacement rate or the mechanism for determining such a rate by the Relevant Governmental Body or (ii) any evolving or then-prevailing market convention for determining a rate of interest as a replacement to the LIBOR rate for U.S. dollar-denominated syndicated credit facilities and (b) the LIBOR Replacement Spread; provided that, if the LIBOR Replacement Rate as so determined would be less than zero, the LIBOR Replacement Rate will be deemed to be zero for the purposes of this Agreement.

"LIBOR Replacement Spread" means, with respect to any replacement of the Basic Rate, the spread adjustment, or method for calculating or determining such spread adjustment, (which may be a positive or negative value or zero) that has been selected by Collateral Agent in a manner that is consistent across its entire loan portfolio giving due consideration to (i) any selection or recommendation of a spread adjustment, or method for calculating or determining such spread adjustment, for the replacement of the LIBOR rate by the Relevant Governmental Body or (ii) any evolving or then-prevailing market convention for determining a spread adjustment, or method for calculating or determining such spread adjustment, for the replacement of the LIBOR rate for U.S. dollar-denominated syndicated credit facilities at such time

"LIBOR Transition Event" means the occurrence of one or more of the following events with respect to the LIBOR rate:

(1) a public statement or publication of information by or on behalf of the administrator of the LIBOR rate announcing that such administrator has ceased or will cease to provide the LIBOR Rate, permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide the LIBOR rate;

(2) a public statement or publication of information by the regulatory supervisor for the administrator of the LIBOR rate, the U.S. Federal Reserve System, an insolvency official with jurisdiction over the administrator for the LIBOR rate, a resolution authority with jurisdiction over the administrator for the LIBOR rate or a court or an entity with similar insolvency or resolution authority over the administrator for the LIBOR rate, which states that the administrator of the LIBOR rate has ceased or will cease to provide the LIBOR rate permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide the LIBOR rate; or

(3) a public statement or publication of information by the regulatory supervisor for the administrator of the LIBOR rate announcing that the LIBOR rate is no longer representative.

"Relevant Governmental Body" means the Federal Reserve Board and/or the Federal Reserve Bank of New York, or a committee officially endorsed or convened by the Federal Reserve Board and/or the Federal Reserve Bank of New York or any successor thereto.

"SOFR" with respect to any day means the secured overnight financing rate published for such day by the Federal Reserve Bank of New York, as the administrator of the benchmark, (or a successor administrator) on the Federal Reserve Bank of New York's Website.

4. Limitation of Consent and Amendment.

4.1 The consent and amendment set forth in **Sections 2** and **3** are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Collateral Agent or any Lender may now have or may have in the future under or in connection with any Loan Document.

4.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

5. Representations and Warranties. To induce Collateral Agent and Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and Lenders as follows:

5.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that are already qualified or modified by materiality in the text thereof), except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct in all material respects as of such date, and (b) no Event of Default has occurred and is continuing;

5.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

5.3 The organizational documents of Borrower delivered to Collateral Agent and Lenders prior to the date hereof remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

5.4 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;

5.5 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;

5.6 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower; and

5.7 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

6. Counterparts. This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

7. Effectiveness. This Amendment shall be deemed effective upon the due execution and delivery to Collateral Agent and Lenders of this Amendment by each party hereto.

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In Witness Whereof, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By: /s/ Colette H. Featherly
Name: Colette H. Featherly
Title: Senior Vice President

BORROWER:

ACELRX PHARMACEUTICALS, INC.

By:/s/ Raffi Asadorian
Name: Raffi Asadorian
Title: Chief Financial Officer

Exhibit 31.1

CERTIFICATION

I, Vincent J. Angotti, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AcelRx Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2021

/s/ Vincent J. Angotti
Vincent J. Angotti
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Raffi Asadorian, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AcelRx Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2021

/s/ Raffi Asadorian
Raffi Asadorian
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Vincent J. Angotti, Chief Executive Officer of AcelRx Pharmaceuticals, Inc. (the "Company"), and Raffi Asadorian, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2021, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned has set his hands hereto as of the 15th day of November 2021.

/s/ Vincent J. Angotti
Vincent J. Angotti
Chief Executive Officer

/s/ Raffi Asadorian
Raffi Asadorian
Chief Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of AcelRx Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.