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 June 30, 2020

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.)**

351 Galveston Drive
Redwood City, CA 94063
(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 August 3, 2020, the number of outstanding shares of the registrant's common stock was 90,324,147.

ACELRX PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED June 30, 2020

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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, such as Zimmer Biomet Dental;
- the expected benefits of the co-promotion agreement with Tetraphase Pharmaceuticals, Inc.;
- the size and growth potential of the markets for DSUVIA, and Zalviso® (sufentanil sublingual tablet system), if approved 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;
- the integration and performance of any businesses we acquire;
- 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 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 maintain regulatory approval of DZUVEO™ in the European Union, or EU, and enter into a collaboration agreement with a strategic partner for the commercialization of DZUVEO in Europe;
- our ability to manufacture and supply DZUVEO in Europe to any future strategic partner;
- the impact of the termination of the Collaboration and License Agreement and the Manufacture and Supply Agreement with Grünenthal GmbH, or Grünenthal, both of which will terminate on or about November 14, 2020;
- our ability to manufacture and supply Zalviso to Grünenthal in accordance with their forecast and the Manufacture and Supply Agreement through the remaining term of the agreement;
- the impact of the termination of the Grünenthal agreements on our obligations under the Purchase and Sale Agreement with PDL BioPharma, Inc., or PDL, including our obligation to use commercially reasonable efforts to negotiate a replacement license agreement 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)

	June 30, 2020 (Unaudited)	December 31, 2019(1)
Assets		
Current Assets:		
Cash and cash equivalents	$ 21,789	$ 14,684
Short-term investments	21,897	51,453
Accounts receivable, net	195	432
Inventories, net	2,639	3,295
Prepaid expenses and other current assets	2,099	1,824
Total current assets	48,619	71,688
Operating lease right-of-use assets	3,509	3,928
Property and equipment, net	14,488	14,552
Other assets	784	1,188
Total Assets	$ 67,400	$ 91,356
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	$ 2,395	$ 1,720
Accrued liabilities	3,749	5,528
Long-term debt, current portion	8,707	4,630
Deferred revenue, current portion	343	411
Operating lease liabilities, current portion	1,076	970
Liability related to the sale of future royalties, current portion	160	352
Total current liabilities	16,430	13,611
Long-term debt, net of current portion	17,324	20,517
Deferred revenue, net of current portion	—	2,833
Operating lease liabilities, net of current portion	3,092	3,640
Liability related to the sale of future royalties, net of current portion	90,042	91,683
Other long-term liabilities	644	490
Total liabilities	127,532	132,774
Commitments and Contingencies		
Stockholders' Deficit:		
Common stock, $0.001 par value—200,000,000 shares authorized as of June 30, 2020 and December 31, 2019; 80,890,185 and 79,573,101 shares issued and outstanding as of June 30, 2020 and December 31, 2019	80	79
Additional paid-in capital	360,425	356,609
Accumulated deficit	(420,637)	(398,106)
Total stockholders' deficit	(60,132)	(41,418)
Total Liabilities and Stockholders' Deficit	$ 67,400	$ 91,356

(1) The condensed consolidated balance sheet as of December 31, 2019 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, 2019.

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue:				
Product sales	$ 303	$ 768	$ 577	$ 894
Contract and other collaboration	2,621	173	2,733	312
Total revenue	2,924	941	3,310	1,206
Operating costs and expenses:				
Cost of goods sold	1,370	1,810	2,881	3,040
Research and development	813	1,163	2,225	2,540
Selling, general and administrative	7,575	11,329	20,886	21,305
Total operating costs and expenses	9,758	14,302	25,992	26,885
Loss from operations	(6,834)	(13,361)	(22,682)	(25,679)
Other income (expense):				

Interest expense	(872)	(500)	(1,727)	(876)
Interest income and other (expense) income, net	270	456	205	1,083
Non-cash interest income (expense) on liability related to future sale of royalties	834	996	1,677	(611)
Total other income (expense)	232	952	155	(404)
Net loss before income taxes	(6,602)	(12,409)	(22,527)	(26,083)
Provision for income taxes	(4)	(3)	(4)	(3)
Net loss	$ (6,606)	$ (12,412)	$ (22,531)	$ (26,086)
Comprehensive loss	$ (6,606)	$ (12,412)	$ (22,531)	$ (26,086)
Net loss per share of common stock, basic and diluted	$ (0.08)	$ (0.16)	$ (0.28)	$ (0.33)
Shares used in computing net loss per share of common stock, basic and diluted – See Note 12	80,661,853	78,902,470	80,359,679	78,845,944

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (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	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	80,890,185	$ 80	$ 360,425	$ (420,637)	$ (60,132)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance as of December 31, 2018	78,757,930	$ 78	$ 349,194	$ (345,019)	$ 4,253
Cumulative effect adjustment for adoption of ASU No. 2016-02	—	—	—	153	153
Stock-based compensation	—	—	1,107	—	1,107
Issuance of common stock upon exercise of stock options	13,583	—	31	—	31
Issuance of common stock upon ESPP purchase	85,135	1	238	—	239
Net loss	—	—	—	(13,674)	(13,674)
Balance as of March 31, 2019	78,856,648	$ 79	$ 350,570	$ (358,540)	$ (7,891)
Stock-based compensation	—	—	1,346	—	1,346
Issuance of common stock upon exercise of stock options	57,522	—	155	—	155
Issuance of warrants related to debt financing	—	—	383	—	383
Net loss	—	—	—	(12,412)	(12,412)
Balance as of June 30, 2019	78,914,170	$ 79	$ 352,454	$ (370,952)	$ (18,419)

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

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

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (22,531)	$ (26,086)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash royalty revenue related to royalty monetization	(121)	(118)
Non-cash interest (income) expense on liability related to royalty monetization	(1,677)	611
Depreciation and amortization	979	734
Non-cash interest expense related to debt financing	558	234
Stock-based compensation	2,236	2,453
Other	341	(212)
Changes in operating assets and liabilities:		
Accounts receivable	237	(172)
Inventories	277	(1,990)
Prepaid expenses and other assets	94	(946)
Accounts payable	675	559
Accrued liabilities	(1,779)	(164)
Operating lease liabilities	(442)	(313)
Deferred revenue	(2,901)	(149)
Net cash used in operating activities	(24,054)	(25,559)
Cash flows from investing activities:		
Purchase of property and equipment	(170)	(1,790)
Purchase of investments	(28,807)	(28,156)
Proceeds from maturities of investments	58,555	19,700
Net cash provided by (used in) investing activities	29,578	(10,246)
Cash flows from financing activities:		
Proceeds from issuance of long-term debt	—	25,000
Payment of costs in connection with refinancing of long-term debt	—	(190)
Payment of long-term debt	—	(3,470)
Extinguishment of debt	—	(8,864)
Net proceeds from issuance of common stock in connection with equity financings	1,449	—
Net proceeds from issuance of common stock through equity plans	218	425
Payment of employee tax obligations related to vesting of restricted stock units	(86)	—
Net cash provided by financing activities	1,581	12,901
Net increase (decrease) in cash and cash equivalents	7,105	(22,904)
Cash and cash equivalents—Beginning of period	14,684	87,975
Cash and cash equivalents—End of period	$ 21,789	$ 65,071

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements
(Unaudited)
(In thousands, except where otherwise noted)

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 Redwood City, 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 treatment of patients with moderate-to-severe acute pain 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, although it has not yet entered into any such arrangement. 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 is currently being commercialized by Grünenthal GmbH, or Grünenthal.

The Company has incurred recurring operating losses and negative cash flows from operating activities since inception. 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 is entitled to receive under the Amended License Agreement with Grünenthal to PDL BioPharma, Inc., or PDL, in a transaction referred to as the Royalty Monetization. In consideration of the expected termination of the Amended License Agreement, under the Royalty Monetization, the Company must use commercially reasonable efforts to negotiate a replacement license agreement with a third party. The FDA approved DSUVIA in November 2018 and the Company began its commercial launch of DSUVIA in the first quarter of 2019. 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 approved 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, 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 in 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 Amended 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 grants 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 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 approved 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 will exclusively manufacture and supply the Product to Grünenthal for the Field in the 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 Amended Agreements.

On May 18, 2020, the Company received a notice from Grünenthal that it is exercising its right to terminate the Amended Agreements between the Company and Grünenthal, effective on or about November 14, 2020. Upon termination, the rights to market and sell Zalviso in the European Union, Switzerland, Liechtenstein, Iceland, Norway and Australia, or the Territory, will revert immediately back to the Company, although Grünenthal has the right to sell down its existing Zalviso inventory.

On May 20, 2020, the Company agreed to provide a right of first negotiation for a license agreement to replace the Grünenthal Amended License Agreement to a third party with which the Company is currently negotiating a license agreement for DZUVEO for the European market.

Termination of Proposed Acquisition of Tetraphase Pharmaceuticals, Inc.

On March 15, 2020, the Company entered into the Agreement and Plan of Merger (as amended on May 27, 2020 and May 29, 2020, the Merger Agreement) with Tetraphase Pharmaceuticals, Inc., or Tetraphase, and Consolidation Merger Sub, Inc., a Delaware corporation and indirect wholly-owned subsidiary of the Company, or Merger Sub, which provided for the merger of Merger Sub with and into Tetraphase, with Tetraphase continuing as the surviving corporation and an indirect wholly-owned subsidiary of AcelRx.

On June 4, 2020, Tetraphase terminated the Merger Agreement pursuant to its terms and paid AcelRx a termination fee of approximately $1.8 million.

Co-Promotion Agreement

On March 15, 2020, the Company entered into the Co-Promotion Agreement with Tetraphase, or the Co-Promotion Agreement, to co-promote DSUVIA and Tetraphases's XERAVA™ (eravacycline). Under the terms of the Co-Promotion Agreement, each company is responsible for maintaining compliance under the agreed marketing and promotion plan and achieving a minimum number of sales calls for each product. Either party can terminate the agreement with 15 months written notice. In the event of a change of control, or CoC, of either party, the CoC party will be subject to meeting certain performance standards, and if these performance standards are not met, then a royalty of 10% of net sales on the CoC party's product will be payable to the non-CoC party until the end of the agreement. The non-CoC party will also be able to solicit the employees of the CoC party in the event of a change of control and have the right to terminate the agreement with one month's written notice. On July 28, 2020, Tetraphase was acquired by La Jolla Pharmaceutical Company, and as a result, Tetraphase became a CoC party under the Co-Promotion Agreement. There were no material revenues or expenses related to the Co-Promotion Agreement in the three and six months ended June 30, 2020.

Principles of Consolidation

The Condensed Consolidated Financial Statements include the accounts of the Company and its wholly-owned subsidiaries, ARPI LLC, which was formed in September 2015 for the sole purpose of facilitating the Royalty Monetization, and Merger Sub and AcelRx Intermediate Sub, Inc., both of which were formed in connection with the Merger Agreement. 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 year amounts in the Condensed Consolidated Financial Statements have been reclassified to conform to the current year'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 for interim financial information and the rules and regulations of the United States. Securities and Exchange Commission, or SEC. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States 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 six months ended June 30, 2020, are not necessarily indicative of the results that may be expected for the year ending December 31, 2020. The Condensed Consolidated Balance Sheet as of December 31, 2019, was derived from the Company's audited financial statements as of December 31, 2019, included in the Company's Annual Report on Form 10-K filed with the SEC. These financial statements should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2019, 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 accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the 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.

Restructuring Costs

The Company's restructuring costs consist of employee termination benefit costs. Liabilities for costs associated with the cost reduction plan are recognized when the liability is incurred and are measured at fair value. One-time termination benefits are expensed at the date the Company notifies the employee, unless the employee must provide future service, in which case the benefits are expensed ratably over the future service period.

On March 16, 2020, in connection with entering into the Co-Promotion Agreement, the Company initiated a reduction in headcount, designed to eliminate the overlap with the Tetraphase commercial team in order to more efficiently commercialize DSUVIA alongside the Tetraphase commercial team and reduce operating expenses. The Company eliminated 30 positions, primarily within the commercial organization. For the six months ended June 30, 2020, the Company incurred and paid $0.5 million in employee termination benefits related to this restructuring.

The headcount reduction was completed in the first quarter of 2020. No additional expenses are anticipated in connection with this cost reduction plan.

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, 2019. There have been no significant changes to the Company's significant accounting policies during the six months ended June 30, 2020, from those previously disclosed in its 2019 Annual Report on Form 10-K.

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 and 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.

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 June 30, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 4,660	$ —	$ —	$ 4,660
Money market funds	1,334	—	—	1,334
U.S. government agency securities	5,999	—	—	5,999
Commercial paper	9,796	—	—	9,796
Total cash and cash equivalents	21,789	—	—	21,789
Short-term investments:				
U.S. government agency securities	13,052	—	—	13,052
Commercial paper	8,845	—	—	8,845
Total short-term investments	21,897	—	—	21,897
Total cash, cash equivalents and short-term investments	$ 43,686	$ —	$ —	$ 43,686

	As of December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 1,957	$ —	$ —	$ 1,957
Money market funds	598	—	—	598
Commercial paper	12,129	—	—	12,129
Total cash and cash equivalents	14,684	—	—	14,684
Short-term investments:				
U.S. government agency securities	14,268	—	—	14,268
Commercial paper	27,131	—	—	27,131
Corporate debt securities	10,054	—	—	10,054
Total short-term investments	51,453	—	—	51,453
Total cash, cash equivalents and short-term investments	$ 66,137	$ —	$ —	$ 66,137

There were no other-than-temporary impairments for these securities at June 30, 2020 or December 31, 2019. 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 six months ended June 30, 2020 and June 30, 2019.

As of June 30, 2020 and December 31, 2019, 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 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. treasury, U.S. government agency securities and commercial paper. As of June 30, 2020, and December 31, 2019, the Company held, in addition to Level II assets, a contingent put option liability 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 by 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 June 30, 2020			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 1,334	$ 1,334	$ —	$ —
U.S. government agency securities	19,051	—	19,051	—
Commercial paper	18,641	—	18,641	—
Total assets measured at fair value	$ 39,026	$ 1,334	$ 37,692	$ —
Liabilities				
Contingent put option liability	$ 591	$ —	$ —	$ 591
Total liabilities measured at fair value	$ 591	$ —	$ —	$ 591

	As of December 31, 2019			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 598	$ 598	$ —	$ —
U.S. government agency securities	14,268	—	14,268	—
Commercial paper	39,260	—	39,260	—
Corporate debt securities	10,054	—	10,054	—
Total assets measured at fair value	$ 64,180	$ 598	$ 63,582	$ —
Liabilities				
Contingent put option liability	$ 437	$ —	$ —	$ 437
Total liabilities measured at fair value	$ 437	$ —	$ —	$ 437

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 six months ended June 30, 2020 and June 30, 2019 (in thousands):

	Three Months Ended June 30, 2020	Six Months Ended June 30, 2020
Fair value—beginning of period	$ 746	$ 437
Fair value of contingent put option associated with the Loan Agreement	(155)	154
Fair value—end of period	$ 591	$ 591

	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Fair value—beginning of period	$ 98	$ 121
Fair value of contingent put option associated with the Loan Agreement	657	657
Change in fair value of contingent put option associated with the Prior Agreement	(98)	(121)
Fair value—end of period	$ 657	$ 657

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	
	June 30, 2020	December 31, 2019
Raw materials	$ 693	$ 1,153
Work-in-process	—	593
Finished goods	1,946	1,549
Total	$ 2,639	$ 3,295

During the three and six months ended June 30, 2020, the Company recorded inventory impairment charges of $0.3 million and $0.4 million, respectively. In the six months ended June 30, 2020, $0.3 million of these charges related to the termination of the Amended Agreements, while $0.1 million related to DSUVIA 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 six months ended June 30, 2020 and 2019 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 June 30, 2020	Six Months Ended June 30, 2020
Product sales:		
DSUVIA	$ 2	$ 157
Zalviso	301	420
Total product sales	303	577
Contract and other collaboration:		
Non-cash royalty revenue related to Royalty Monetization (See Note 7)	37	121
Royalty revenue	12	40
Other revenue	2,572	2,572
Total revenues from contract and other collaboration	2,621	2,733
Total revenue	$ 2,924	$ 3,310

	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Product sales:		
DSUVIA	$ 55	$ 102
Zalviso	713	792
Total product sales	768	894
Contract and other collaboration:		
Non-cash royalty revenue related to Royalty Monetization (See Note 7)	118	203
Royalty revenue	40	67
Other revenue	15	42
Total revenues from contract and other collaboration	173	312
Total revenue	$ 941	$ 1,206

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, 2019.

Product Sales

The Company's commercial launch of DSUVIA in the United States occurred in the first quarter of 2019. Zalviso has been sold in Europe by the Company's collaboration partner, Grünenthal. Grünenthal has exercised its right to terminate the Amended Agreements, effective on or about November 14, 2020.

Contract and Other Collaboration

Amended License Agreement

Under the Amended License Agreement with Grünenthal, the Company is eligible to receive approximately $194.5 million in additional milestone payments, based upon successful regulatory and product development efforts ($28.5 million) and net sales target achievements ($166.0 million). Grünenthal will also make tiered royalty and supply and trademark fee payments in the mid-teens up to the mid-twenties percent range, depending on the level of sales achieved, on net sales of Zalviso. A portion of the tiered royalty payment, exclusive of the supply and trademark fee payments, will be paid to PDL BioPharma, Inc. or PDL, in connection with the Royalty Monetization. For additional information on the Royalty Monetization, see Note 7 "Liability Related to Sale of Future Royalties".

Amended MSA

Under the terms of the Amended MSA with Grünenthal, the Company will manufacture and supply the Product for use in the Field for the Territory exclusively for Grünenthal. The Product will be supplied at prices approximating the Company's manufacturing cost, subject to certain caps, as defined in the MSA Amendment. The MSA Amendment requires the Company to use commercially reasonable efforts to enter stand-by contracts with third parties providing significant supply and manufacturing services and, under certain specified conditions, permits Grünenthal to use a third-party back-up manufacturer to manufacture the Product for Grünenthal's commercial sale in the Territory.

As mentioned above, Grünenthal has exercised its right to terminate the Amended Agreements, effective on or about November 14, 2020. In May 2020, upon notification of early termination by Grünenthal, the Company recognized approximately $2.6 million of deferred revenue for the future significant and incremental discount on Zalviso manufacturing services which are no longer a performance obligation.

Contract Liability

At June 30, 2020, approximately $0.3 million of deferred revenue, all of which represented the current portion, was attributable to the significant and incremental discount on Zalviso manufacturing services for Grünenthal under the Amended Agreements. This deferred revenue is being recognized on a straight-line basis over the period such discount is made available to Grünenthal, which will continue until the contract termination date on or about November 14, 2020.

The following table presents changes in the Company's contract liability for the six months ended June 30, 2020 (in thousands):

	Balance at Beginning of the Period	Additions	Deductions	Balance at the end of the Period
Contract liability:				
Deferred revenue – Amended Agreements	$ 3,148	$ —	$ (2,805)	$ 343
Deferred revenue – Other	96	—	(96)	—
Deferred revenue	$ 3,244	$ —	$ (2,901)	$ 343

For the three and six months ended June 30, 2020 and 2019, the Company recognized the following revenue from performance obligations satisfied or eliminated under the Amended Agreements (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Amounts included in contract liabilities at the beginning of the period:				
Performance obligations satisfied	$ 154	$ 79	$ 233	$ 158
Performance obligations eliminated upon termination	2,572	—	2,572	—
New activities in the period from performance obligations satisfied:				
Performance obligations satisfied	147	649	187	676
Total revenue from performance obligations satisfied or eliminated	$ 2,873	$ 728	$ 2,992	$ 834

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. The Company used approximately $8.9 million of the proceeds from the Loan to repay its outstanding obligations under the Prior Agreement, as described above. After deducting all loan initiation costs and outstanding interest on the Prior Agreement, the Company received $15.9 million in net proceeds.

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. For further discussion, see Note 9 "Warrants".

As of June 30, 2020, the accrued balance due under the Loan Agreement with Oxford was $24.7 million. Interest expense related to the Loan Agreement was $0.9 million, $0.3 million of which represented amortization of the debt discount, for the three months ended June 30, 2020, and $1.7 million, $0.5 million of which represented amortization of the debt discount, for the six months ended June 30, 2020.

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. The leasehold improvements are recorded as property and equipment, net, in our Condensed Consolidated Balance Sheets. As of June 30, 2020, $1.7 million of these leasehold improvements have been capitalized. The total obligation under the SRA is $2.0 million all of which was incurred as of March 31, 2020. The effective interest rate related to the payments at June 30, 2020 was 14.35%.

6. Leases

The Company leases office and laboratory space for its corporate headquarters, located at 301 – 351 Galveston Drive, Redwood City, California, and has entered into an agreement to sublease approximately 47% of this office and laboratory space. 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating lease costs	$ 269	$ 340	$ 609	$ 680
Sublease income	(149)	(150)	(299)	(296)
Net lease costs	$ 120	$ 190	$ 310	$ 384

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

	June 30, 2020
Weighted-average remaining term – operating lease (years)	3.58
Weighted-average discount rate – operating lease	11.72%

Future minimum lease payments as of June 30, 2020 are presented in the following table (in thousands):

Year:	
2020 (remaining six months)	$ 634
2021	1,364
2022	1,345
2023	1,386
2024	116
Total future minimum lease payments	4,845
Less imputed interest	(677)
Total	$ 4,168

Reported as:

Operating lease liabilities	$ 1,076
Operating lease liabilities, net of current portion	3,092
Total lease liability	$ 4,168

Future minimum sublease payments as of June 30, 2020 are presented in the following table (in thousands):

Year:	
2020 (remaining six months)	$ 297
2021	610
2022	629
2023	648
2024	54
Total future minimum sublease payments	$ 2,238

The rent receivable balance is reported in the balance sheet as follows (in thousands):

Reported as:	
Prepaid expenses and other current assets	$ 87
Other assets	307
Total rent receivable	$ 394

7. Liability Related to Sale of Future Royalties

In September 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 will 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, 2019, the Company made a material revision to its estimates which resulted in an interest income rate on the Royalty Monetization liability balance at a prospective average rate of approximately 4.2%, which will be applied over the remaining term of the agreement. The change in estimate of future payments to PDL was a result of lower projected European royalties and milestones from sales of Zalviso over the life of the liability. The change in estimate results in interest income being recognized prospectively, over the remaining term of the agreement, as the estimated expected payments are less than the $65.0 million in gross proceeds received. During the three months ended June 30, 2020, Grünenthal notified the Company that it was terminating the Amended License Agreement, effective on or about November 14, 2020. There is a continuing obligation on the Company's part, through the term of the Royalty Monetization, to use commercially reasonable efforts to negotiate a replacement license agreement, or New Arrangement. However, without a New Arrangement to commercialize Zalviso in the Territory, the Company is currently unable to estimate the future payments to PDL over the remaining life of the Royalty Monetization. If the Company is unable to find a New Arrangement, a contingent gain of up to approximately $65 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 change in estimate reduced the effective interest rate over the life of the liability to 0% by recording 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 rates for both the three and six months ended June 30, 2020 was approximately 4.0%. The change in estimate during the three months ended June 30, 2019, resulted in a decrease of $2.7 million to the net loss and a decrease of $0.03 to the net loss per share of common stock, basic and diluted, for both the three and six months ended June 30, 2019. The effective interest income rate for the three months ended June 30, 2019 was approximately 4.2%. The effective interest expense rate for the six months ended June 30, 2019 was 1.4%.

The following table shows the activity within the liability account for the six months ended and the period from inception to June 30, 2020 (in thousands):

	Six months ended June 30, 2020	Period from inception to June 30, 2020
Liability related to sale of future royalties — beginning balance	$ 92,035	$ —
Proceeds from sale of future royalties	—	61,184
Non-cash royalty revenue	(156)	(840)
Non-cash interest (income) expense recognized	(1,677)	29,858
Liability related to sale of future royalties as of June 30, 2020	90,202	90,202
Less: current portion	(160)	(160)
Liability related to sale of future royalties — net of current portion	$ 90,042	$ 90,042

As royalties are remitted to PDL 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, 2019, 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 expense within its Condensed Consolidated Statements of Comprehensive Loss over the term of the Royalty Monetization.

8. Legal Proceedings

As previously disclosed, several lawsuits were filed in connection with the Company's proposed acquisition of Tetraphase. Following termination of the Merger Agreement, each of the merger-related complaints naming the Company as a defendant were voluntarily dismissed on or about June 9, 2020.

9. Warrants

Loan Agreement Warrants

In connection with the Loan Agreement, on May 30, 2019, the Company issued warrants to the Lender and its affiliates, 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, or the Warrants. As of June 30, 2020, warrants to purchase 176,679 shares of common stock issued to the Lender and its affiliates had not been exercised and were still outstanding. These warrants expire in May 2029.

10. Stockholders' Equity

Common Stock

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 $40.0 million. On May 9, 2019, the Company increased the aggregate offering amount of shares of the Company's common stock which may be offered and sold under the ATM Agreement by $40.0 million, for a total of $80.0 million.

During the three and six months ended June 30, 2020, the Company issued and sold 445,000 and 876,800 shares of common stock pursuant to the ATM Agreement, respectively, for which the Company received net proceeds of approximately $0.7 million and $1.5 million, respectively. As of June 30, 2020, the Company has the ability to sell $43.8 million of the Company's common stock under the ATM Agreement.

New and Amended Stock Plans

2020 Equity Incentive Plan

On June 16, 2020, at the 2020 Annual Meeting of Stockholders of the Company, the Company's stockholders, upon the recommendation of the Company's Board of Directors, approved the Company's 2020 Equity Incentive Plan, or the 2020 EIP.

As of June 16, 2020, no more awards may be granted under the 2011 Equity Incentive Plan, or the 2011 EIP, although all outstanding stock options and other stock awards previously granted under the 2011 EIP will continue to remain subject to the terms of the 2011 EIP.

The initial aggregate number of shares of the Company's common stock issuable pursuant to stock awards under the 2020 EIP was 5,500,000 shares. In addition, the share reserve will be increased by the number of returning shares, if any, as such shares become available from time to time under the 2006 Plan and the 2011 EIP, for an additional number of shares not to exceed 14,892,170 shares. The term of any option granted under the 2020 EIP is determined on the date of grant but shall not be longer than 10 years. The Company issues new shares for settlement of vested restricted stock units and exercises of stock options. The Company does not have a policy of purchasing its shares relating to its stock-based programs.

Amended and Restated 2011 Employee Stock Purchase Plan

Additionally, on June 16, 2020, the Company's stockholders, upon the recommendation of the Company's Board of Directors, approved the Amended and Restated 2011 Employee Stock Purchase Plan, or the Amended 2011 ESPP, which increased the aggregate number of shares of the Company's common stock reserved for issuance under the 2011 Employee Stock Purchase Plan, or ESPP, to 4,900,000 shares, subject to adjustment for certain changes in the Company's capitalization, and removed the "evergreen" provision from the ESPP.

11. Stock-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Cost of goods sold	$ 27	$ 68	$ 73	$ 129
Research and development	184	233	384	457
Selling, general and administrative	879	1,045	1,779	1,867
Total	$ 1,090	$ 1,346	$ 2,236	$ 2,453

As of June 30, 2020, there were 5,775,140 shares available for grant, 13,026,080 options outstanding and 1,444,095 restricted stock units outstanding under the Company's equity incentive plans, and 4,900,000 shares available for grant under the Amended 2011 ESPP.

12. 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 if 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:

	June 30,	
	2020	**2019**
ESPP, RSUs and stock options to purchase common stock	14,816,721	14,090,688
Common stock warrants	176,679	176,679

13. Subsequent Event

Registered Direct Offering

On July 23, 2020, the Company completed a registered direct offering in which it issued and sold 9,433,962 shares of its common stock at a price of $1.06 per share. The total net proceeds from this offering were approximately $10.0 million, after deducting estimated expenses payable by the Company of $25,000. No underwriter or placement agent participated in the offering.

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 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, 2019, 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.

Product	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 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 supervised setting, administered by a healthcare professional	Received European Commission, or EC, approval in June 2018.
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 NDA, which is in part dependent on the finalization of the FDA's new opioid approval guidelines and process. Approved in the European Union and currently marketed commercially by Grünenthal.

Distribution Agreement

On July 17, 2020, we entered into a distribution agreement, or the Distribution Agreement, with Zimmer Biomet Dental, or ZB Dental, pursuant to which ZB Dental obtained the exclusive right to promote, market, sell, and arrange to distribute DSUVIA in the United States to clinicians, dentists, surgeons and other licensed health care practitioners that perform dental (including specialty dental), oral-maxillofacial, cranio-maxillofacial or oral surgery procedures, or Professionals, and their respective institutions and facilities that are permitted to use DSUVIA.

ZB Dental's distribution rights are non-exclusive for crossover ambulatory surgery centers and certain government customers, and do not extend to ambulatory care centers outside the class of trade or into hospitals. ZB Dental will conduct any distribution activities in a manner consistent with DSUVIA's FDA-approved indication and REMS program, and within the parameters established in the Distribution Agreement. ZB Dental has the right to sublicense its distribution rights to its qualified marketing partners but may not otherwise sublicense its distribution rights to any third party without our prior written consent.

Termination of Grünenthal Amended Agreements

On May 18, 2020, we received a notice from Grünenthal GmbH, or Grünenthal, that it is exercising its right to terminate the amended Collaboration and License Agreement, or the Amended License Agreement, and the amended Manufacture and Supply Agreement, or the Amended MSA, together referred to as the Amended Agreements, between AcelRx and Grünenthal, effective on or about November 14, 2020. Upon termination, the rights to market and sell Zalviso in the European Union, Switzerland, Liechtenstein, Iceland, Norway and Australia, or the Territory, will revert immediately back to us, although Grünenthal has the right to sell down its existing Zalviso inventory. We have a continuing obligation to use commercially reasonable efforts to negotiate a replacement license agreement, or New Arrangement; however, we have not yet entered into such an arrangement.

On May 20, 2020, we agreed to provide a right of first negotiation for a license agreement to replace the Grünenthal Amended License Agreement to a third party with which the Company is currently negotiating a license agreement for DZUVEO for the European market.

Termination of Proposed Acquisition of Tetraphase Pharmaceuticals, Inc.

On March 15, 2020, we entered into the Agreement and Plan of Merger (as amended on May 27, 2020 and May 29, 2020, the Merger Agreement) with Tetraphase Pharmaceuticals, Inc., or Tetraphase, and Consolidated Merger Sub, Inc., a Delaware corporation and indirect wholly-owned subsidiary of the Company, or Merger Sub, which provided for the merger of Merger Sub with and into Tetraphase, with Tetraphase continuing as the surviving corporation and an indirect wholly-owned subsidiary of AcelRx.

On June 4, 2020, Tetraphase terminated the Merger Agreement pursuant to its terms and paid AcelRx a termination fee of approximately $1.8 million.

Co-Promotion Agreement

On March 15, 2020, we entered into the Co-Promotion Agreement with Tetraphase to co-promote DSUVIA and Tetraphases's XERAVA™ (eravacycline), which was subsequently amended on May 26, 2020. Under the terms of this agreement, each company is responsible for maintaining compliance under the agreed marketing and promotion plan and achieving a minimum number of sales calls for each product. On March 16, 2020, in connection with entering into the Co-Promotion Agreement, we initiated a reduction in headcount, designed to eliminate the overlap with the Tetraphase commercial team in order to more efficiently commercialize DSUVIA alongside the Tetraphase commercial team and reduce operating expenses. We eliminated 30 positions, mainly within the commercial organization.

Either party can terminate the Co-Promotion Agreement with 15 months written notice. In the event of a change of control, or CoC, of either party, the CoC party will be subject to meeting certain performance standards, and if these performance standards are not met, then a royalty of 10% of net sales on the CoC party's product will be payable to the non-CoC party until the end of the agreement. The non-CoC party will also be able to solicit the employees of the CoC party in the event of a change of control and have the right to terminate the agreement with one month's written notice. On July 28, 2020, Tetraphase was acquired by La Jolla Pharmaceutical Company, and as a result, Tetraphase became a CoC party under the Co-Promotion Agreement.

General Trends and Outlook

COVID-19-related

Government-mandated shelter-in-place 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 March and April of 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, 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, and we have no visibility as to when these restrictions will be lifted. As a result, the educational and promotional efforts of our commercial and medical affairs personnel have been substantially reduced, and in some cases, stopped. We expect our near-term sales volumes to be adversely impacted as long as access to healthcare facilities by our commercial and medical affairs personnel continues to be limited. As a result, we also anticipate our operating expenses during this period to be lower than expected, primarily due to reduced travel, educational and promotional activities by our commercial and medical affairs teams. 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.

We have heard from a number of hospital customers and government representatives, and also read numerous media reports about a severe shortage of intravenous sedatives and analgesics, namely fentanyl, which we understand is directly and indirectly attributable to the COVID-19 situation. We remain in discussions with these potential customers as to how AcelRx, and specifically DSUVIA, can support this crisis and the patients requiring appropriate care. In addition, in response to a shortage of intravenous fentanyl and other IV opioids during the COVID-19 pandemic, AcelRx began outreach efforts to health care settings to inform them of how DSUVIA may help with these shortages.

One Zalviso supplier was unable to perform certain services as planned, given government orders impacting their business, and as a result, this supplier provided us with a force majeure notice. We, in turn, provided a force majeure notice to Grünenthal under our Amended MSA. At this time, we believe this halt in production will not have a significant impact on our financial results, but we continue to work with our suppliers and Grünenthal to manage Zalviso production activities until on or about November 14, 2020 when the agreement with Grünenthal will terminate.

As a result of international travel restrictions, the timing for testing and acceptance of our DSUVIA high-volume packaging line has been delayed. Based on our best estimate, we project that the line will be installed and qualification completed in 2021.

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.

Department of Defense

In April 2020, DSUVIA achieved Milestone C approval by the Department of Defense, a decision that clears the path for the Department of Defense to begin placing orders for DSUVIA.

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 Zalviso by Grünenthal or any replacement partner, and any

future research and development activities needed to support the U.S. approval of Zalviso, once, and if, the NDA is resubmitted. 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 the installation of our high-volume automated packaging line for DSUVIA, from which we expect to have qualified product being packaged beginning in 2021. We anticipate that the high-volume 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 six months ended June 30, 2020 was $6.6 million and $22.5 million, respectively, compared to net losses of $12.4 million and $26.1 million for the three and six months ended June 30, 2019, respectively. As of June 30, 2020, we had an accumulated deficit of $420.6 million. As of June 30, 2020, we had cash, cash equivalents and short-term investments totaling $43.7 million compared to $66.1 million as of December 31, 2019.

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 six months ended June 30, 2020, from those previously disclosed in our Annual Report.

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 and development efforts 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 restricted from accessing hospitals and ambulatory surgical centers due to COVID-19, and to the extent government authorities and healthcare providers are continuing to limit elective surgeries, we expect our sales volume to be adversely affected.

Three and Six Months Ended June 30, 2020 and 2019

Revenue

Product Sales Revenue

The Company’s product sales revenue consists of sales of DSUVIA in the U.S. and Zalviso in Europe.

Product sales revenue by product for the three and six months ended June 30, 2020 and 2019 was as follows:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2020	2019	$ Change 2020 vs. 2019	% Change 2020 vs. 2019	2020	2019	$ Change 2020 vs. 2019	% Change 2020 vs. 2019
	(In thousands, except percentages)							
DSUVIA	$ 2	$ 55	$ (53)	(96)%	$ 157	$ 102	$ 55	54%
Zalviso	301	713	(412)	(58)%	420	792	(372)	(47)%
Total product sales revenue	$ 303	$ 768	$ (465)	(61)%	$ 577	$ 894	$ (317)	(35)%

The decrease in DSUVIA product sales revenue for the three months ended June 30, 2020, as compared to the prior year period, is primarily due to the adverse effects of the COVID-19 pandemic on our sales efforts. The increase in DSUVIA product sales revenue for the six months ended June 30, 2020, as compared to the prior year period, is due to the ramp of the commercial launch of DSUVIA in the United States, which began in the first quarter of 2019.

The decrease in Zalviso product sales revenue for the three and six months ended June 30, 2020, as compared to the prior year period, was primarily the result of decreased orders from Grünenthal. During the three months ended June 30, 2020, Grünenthal terminated the Amended Agreements, effective on or about November 14, 2020. As of June 30, 2020, we had current deferred revenue under the Amended Agreements with Grünenthal of $0.3 million.

Contract and Other Collaboration Revenue

Contract and other collaboration revenue includes revenue under the Amended 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.

Contract and other collaboration revenue for the three and six months ended June 30, 2020 and 2019 was as follows (in thousands):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2020	2019	$ Change 2020 vs. 2019	% Change 2020 vs. 2019	2020	2019	$ Change 2020 vs. 2019	% Change 2020 vs. 2019
	(In thousands, except percentages)							
Non-cash royalty revenue related to Royalty Monetization (See Note 7)	$ 37	$ 118	$ (81)	(69)%	$ 121	$ 203	$ (82)	(40)%
Royalty revenue	12	40	(28)	(70)%	40	67	(27)	(40)%
Other revenue	2,572	15	2,557	17,047%	2,572	42	2,530	6,024%
Total contract and other collaboration revenue	$ 2,621	$ 173	$ 2,448	1,415%	$ 2,733	$ 312	$ 2,421	776%

As of June 30, 2020, the deferred revenue balance under the Amended Agreements with Grünenthal was $0.3 million, all of which is current due to the contract termination on or about November 14, 2020. The estimated margin we expect to receive on transfer prices under the Amended Agreements was deemed to be a significant and incremental discount on manufacturing services, as compared to market rates for contract manufacturing margin. The deferred revenue balance will decline on a straight-line basis through the contract termination, on or about November 14, 2020, as we recognize product sales revenue under the Amended Agreements.

We estimate and recognize royalty revenue and non-cash royalty revenue on a quarterly basis. Adjustments to estimated revenue are recognized in the subsequent quarter based on actual revenue earned per the royalty reports received from Grünenthal. In addition, under the Royalty Monetization, we sold a portion of the expected royalty stream and commercial milestones from the European sales of Zalviso by Grünenthal to PDL.

Cost of Goods Sold

As mentioned above, we commenced commercial sales of DSUVIA in the first quarter of 2019.

Total cost of goods sold for the three and six months ended June 30, 2020 and 2019 was as follows (in thousands):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2020	2019	$ Change 2020 vs. 2019	% Change 2020 vs. 2019	2020	2019	$ Change 2020 vs. 2019	% Change 2020 vs. 2019
	(In thousands, except percentages)							
Direct costs	$ 379	$ 563	$ (184)	(33)%	$ 625	$ 687	$ (62)	(9)%
Indirect costs	991	1,247	(256)	(21)%	2,256	2,353	(97)	(4)%
Total costs of goods sold	$ 1,370	$ 1,810	$ (440)	(24)%	$ 2,881	$ 3,040	$ (159)	(5)%

Direct costs from contract manufacturers for DSUVIA and Zalviso in the three and six months ended June 30, 2020 totaled $0.4 million and $0.6 million, respectively, including inventory impairment charges of $0.3 million, and $0.4 million, respectively. In the six months ended June 30, 2020, $0.3 million of these charges related to the termination of the Amended Agreements, while $0.1 million related to DSUVIA inventory that may expire before being sold. Direct costs from contract manufacturers for DSUVIA and Zalviso in the three and six months ended June 30, 2019 totaled $0.6 million and $0.7 million, respectively. 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 $1.0 million and $2.3 million in the three and six months ended June 30, 2020, respectively, while the indirect costs to manufacture DSUVIA and Zalviso in the three and six months ended June 30, 2019 totaled $1.3 million and $2.4 million, 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 the Zalviso NDA, once, and if, it is resubmitted. 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 during the three and six months ended June 30, 2020 and 2019 (in thousands, except percentages):

	Three Months Ended June 30,				Six Months Ended June 30,			
Drug Indication/Description	2020	2019	$ Change 2020 vs. 2019	% Change 2020 vs. 2019	2020	2019	$ Change 2020 vs. 2019	% Change 2020 vs. 2019
	(In thousands, except percentages)							
DSUVIA	$ 187	$ 130	$ 57	44%	$ 479	$ 276	$ 203	74%
Zalviso	3	158	(155)	(98)%	32	339	(307)	(91)%
Overhead	623	875	(252)	(29)%	1,714	1,925	(211)	(11)%
Total research and development expenses	$ 813	$ 1,163	$ (350)	(30)%	$ 2,225	$ 2,540	$ (315)	(12)%

Research and development expenses during the three and six months ended June 30, 2020 decreased as compared to the three and six months ended June 30, 2019 and included decreases in Zalviso-related spending and overhead expenses, partially offset by increases in DSUVIA-related spending.

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 six months ended June 30, 2020 and 2019, were as follows (in thousands, except percentages):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2020	2019	$ Change 2020 vs. 2019	% Change 2020 vs. 2019	2020	2019	$ Change 2020 vs. 2019	% Change 2020 vs. 2019
	(In thousands, except percentages)							
Selling, general and administrative expenses	$ 7,575	$ 11,329	$ (3,754)	(33)%	$ 20,886	$ 21,305	$ (419)	(2)%

Selling, general and administrative expenses decreased by $3.8 million during the three months ended June 30, 2020, as compared to the three months ended June 30, 2019 and decreased by $0.4 million during the six months ended June 30, 2019. The decrease in the three months ended June 30, 2020 as compared to the three months ended June 30, 2019, is primarily due to net decreases in selling, general and administrative expenses of $1.9 million in DSUVIA commercialization-related expenses, such as travel, a $1.3 million reduction in personnel costs and a decrease in business development expenses of $0.6 million, including a decrease of $0.5 million related to the Merger Agreement with Tetraphase (net of the associated $1.8 million termination fee). The decrease in the six months ended June 30, 2020 as compared to the six months ended June 30, 2019, is primarily due to net decreases in selling, general and administrative expenses of $1.7 million in DSUVIA commercialization-related expenses, partially offset by an increase in business development-related expenses of $1.3 million, including $1.2 million related to the Merger Agreement with Tetraphase (net of the associated $1.8 million termination fee).

On March 16, 2020, in connection with entering into the Co-Promotion Agreement with Tetraphase, we eliminated 30 positions, mainly within the commercial organization. For additional information regarding the Co-Promotion Agreement and related Restructuring Costs see Note 1 “Organization and Summary of Significant Accounting Policies” in the accompanying notes to the Condensed Consolidated Financial Statements.

Other Income (Expense)

Total other expense for the three and six months ended June 30, 2020 and 2019, was as follows (in thousands, except percentages):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2020	2019	$ Change 2020 vs. 2019	% Change 2020 vs. 2019	2020	2019	$ Change 2020 vs. 2019	% Change 2020 vs. 2019
	(In thousands, except percentages)							
Interest expense	$ (872)	$ (500)	$ (372)	74%	$ (1,727)	$ (876)	$ (851)	97%
Interest income and other income (expense), net	270	456	(186)	(41)%	205	1,083	(878)	(81)%
Non-cash interest income (expense) on liability related to sale of future royalties	834	996	(162)	(16)%	1,677	(611)	2,288	(374)%

Total other income (expense)	$ 232	$ 952	$ (720)	(76)%	$ 155	$ (404)	$ 559	(138)%

Interest expense consisted primarily of interest accrued or paid on our debt obligation agreements and amortization of debt discounts. Interest expense increased in the three and six months ended June 30, 2020, as compared to the three months ended June 30, 2019, primarily as a result of a higher outstanding loan balance. As of June 30, 2020, the accrued balance due under the Loan Agreement with Oxford was $24.7 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 six months ended June 30, 2020 and 2019 primarily consisted of interest earned on our investments. Interest income decreased in the three and six months ended June 30, 2020 as compared to the three and six months ended June 30, 2019, primarily due to a lower average investment balance, combined with lower yields on those investments.

The non-cash interest income (expense) 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. During the three months ended June 30, 2019, we made a material revision to our estimates as the expected payments under the Royalty Monetization are less than the $65.0 million in gross proceeds received. The change in estimate reduced the effective interest rate over the life of the liability to 0% by recording interest income over the remaining term of the arrangement, prospectively, as an offset to the interest expense that was recognized in prior periods. During the three months ended June 30, 2020, Grünenthal terminated the Amended License Agreement, effective on or about November 14, 2020. There is a continuing obligation on our part, through the term of the Royalty Monetization, to use commercially reasonable efforts to negotiate a replacement license agreement, or New Arrangement. However, without a New Arrangement to commercialize Zalviso in the Territory, we are currently unable to estimate the future payments to PDL over the remaining life of the Royalty Monetization. If the Company is unable to find a New Arrangement, a contingent gain of up to approximately $65 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 income rate for both the three and six months ended June 30, 2020 was approximately 4.0%. The effective interest income rate for the three months ended June 30, 2019 was approximately 4.2%, and the effective interest expense rate for the six months ended June 30, 2019 was approximately 1.4%. 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, 2020.

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 2020 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 our commercial partner, Grünenthal, monetization of certain future royalties and commercial sales milestones from the European sales of Zalviso by Grünenthal, funding from the DoD, and more recently with revenues from sales of DSUVIA since the commercial launch in the first quarter of 2019.

As of June 30, 2020, we had cash, cash equivalents and investments totaling $43.7 million compared to $66.1 million as of December 31, 2019. The decrease was primarily due to cash required to fund our continuing operations, as we continued our commercialization activities for DSUVIA and support for Grünenthal’s European sales of Zalviso, as well as business development activities. We anticipate that our existing capital resources will permit us to meet our capital and operational requirements through the third quarter of 2021; 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 July 23, 2020, we completed a registered direct offering in which we issued and sold 9,433,962 shares of our common stock at a price of $1.06 per share. The total net proceeds from this offering were approximately $10.0 million, after deducting estimated expenses payable by us of $25,000.

We have 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 June 30, 2020, we had issued and sold an aggregate of approximately 11.2 million shares of common stock pursuant to the ATM Agreement, for which we had received net proceeds of approximately $35.3 million, after deducting commissions, fees and expenses of approximately $1.0 million. As of June 30, 2020, we have the ability to sell approximately $43.8 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 and used approximately $8.9 million of the proceeds from the Loan to repay our outstanding obligations under the Prior Agreement with Hercules. After deducting all loan initiation costs and outstanding interest on the Prior Agreement, we received $15.9 million in net proceeds. As of June 30, 2020, the accrued balance under the Loan Agreement was $24.7 million. For more information, see Note 5 “Long-Term Debt” in the accompanying notes to the Condensed Consolidated Financial Statements.

During the three months ended June 30, 2020, Grünenthal terminated the Amended License Agreement, effective on or about November 14, 2020. There is a continuing obligation on our part, through the term of the Royalty Monetization, to use commercially reasonable efforts to negotiate a New Arrangement. The Royalty Monetization will be repaid to PDL over the life of the agreement through a portion of the European royalties and milestones received under the Amended License Agreement with Grünenthal and any New Arrangement, if executed. For more information, see Note 7 “Liability Related to the Sale of Future Royalties” 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):

	Six Months Ended June 30,	
	2020	**2019**
Net cash used in operating activities	$ (24,054)	$ (25,559)
Net cash provided by (used in) investing activities	29,578	(10,246)
Net cash provided by financing activities	1,581	12,901

Cash Flows from Operating Activities

The primary use of cash for our operating activities during these periods was to fund commercial readiness activities for our approved product, DSUVIA, and our product candidate, Zalviso, in addition to the support of Grünenthal's European sales of Zalviso. 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 $24.1 million during the six months ended June 30, 2020, reflected a net loss of $22.5 million, partially offset by aggregate non-cash charges of $2.3 million and included an approximate $3.8 million net change in our operating assets and liabilities. Non-cash charges included $2.2 million for stock-based compensation expense, $1.7 million in non-cash interest income on the liability related to the royalty monetization and $1.0 million in depreciation expense. The net change in our operating assets and liabilities included a $1.8 million decrease in accrued liabilities, a $2.9 million decrease in deferred revenue and a $0.7 million increase in accounts payable.

Cash used in operating activities of $25.6 million during the six months ended June 30, 2019, reflected a net loss of $26.1 million, partially offset by aggregate non-cash charges of $3.7 million. Non-cash charges included $2.5 million in stock-based compensation expense, $0.7 million in depreciation expense and $0.6 million in non-cash interest expense on the liability related to the Royalty Monetization. The net change in our operating assets and liabilities of $3.2 million included a $2.0 million increase in inventories.

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 six months ended June 30, 2020, cash provided by investing activities of $29.6 million was the net result of $58.6 million in proceeds from maturity of investments, offset by $28.8 million for purchases of investments and purchases of property and equipment of $0.2 million. During the six months ended June 30, 2019, cash used in investing activities of $10.2 million was the net result of $28.2 million for purchases of investments and $1.8 million for purchases of property and equipment, offset by $19.7 million in proceeds from maturity of investments.

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 six months ended June 30, 2020, cash provided by financing activities was primarily due to $1.4 million in net proceeds received under the ATM Agreement and $0.2 million in proceeds as a result of stock purchases made under our Amended 2011 ESPP, partially offset by $0.1 million used for payment of employee tax obligations relating to the vesting of restricted stock units. During the six months ended June 30, 2019, cash provided by financing activities was primarily due to $24.8 million in net proceeds received in connection with the Loan Agreement with Oxford, offset by $8.9 million for the repayment of the Prior Agreement, $3.5 million in payments of long-term debt under the Prior Agreement and $0.4 million in proceeds as a result of stock purchases made under our ESPP and stock option exercises.

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 on access to potential customers and elective surgeries will continue to be lifted, as well as anticipated activities required to resubmit the Zalviso NDA. 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 Zalviso 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 the third quarter of 2021 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 accuracy of our estimates regarding the sufficiency of our cash resources and expenses;
- 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 Zalviso;
- future manufacturing, selling and marketing costs related to DSUVIA and Zalviso, including our contractual obligations to Grünenthal or another third party for Zalviso;
- costs associated with business development activities and licensing transactions;
- the outcome, timing and cost of the regulatory resubmission of Zalviso and any approval for Zalviso;
- the initiation, progress, timing and completion of any post-approval clinical trials for DSUVIA, or Zalviso, 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;
- 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 Zalviso;
- the extent to which we acquire or invest in businesses, products or technologies; and
- the expenses associated with any possible 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 June 30, 2020, 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

During the three and six months ended June 30, 2020, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A, “Quantitative and Qualitative Disclosures About Market Risk” in our Annual Report on Form 10-K for the year ended December 31, 2019.

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.

As previously disclosed, several lawsuits were filed in connection with our proposed acquisition of Tetraphase. Following Tetraphase’s termination of our merger agreement, the below merger-related complaints naming AcelRx and Consolidation Merger Sub, Inc. as defendants were voluntarily dismissed on or about June 9, 2020:

- the putative class action complaint, captioned *Plumley v. Tetraphase Pharmaceuticals, Inc., et al.*, Case No. 1:20-cv-00496, filed by Patrick Plumley in the United States District Court for the District of Delaware;

- the putative class action complaint, captioned *Garity v. Tetraphase Pharmaceuticals, Inc., et al.*, Case No. 1:20-cv-00542, filed by Edward Garity in the United States District Court for the District of Delaware;

- the putative class action complaint, captioned *Kashavena v. Tetraphase Pharmaceuticals, Inc., et al.*, Case No. 2081-cv-01005, filed by Vanamala Kashavena in the Middlesex County Superior Court.

The *Plumley and Garity* complaints alleged violations of Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder. The plaintiffs in these actions generally alleged that the registration statement on Form S-4 omitted material information with respect to the proposed transaction, which rendered such registration statement false and misleading. The *Kashavena* complaint alleged that the members of the Tetraphase Board breached their fiduciary duties of care, loyalty/good faith and candor/disclosure by allegedly entering into the merger through a flawed and unfair process and disseminating a materially incomplete and misleading registration statement in connection with the merger. The *Kashavena* complaint alleged that Tetraphase, AcelRx and Merger Sub aided and abetted in the alleged breach of fiduciary duties. The complaints sought preliminary and permanent injunction of the proposed transaction and, if the merger was consummated, rescission or rescissory damages. The complaints also sought the dissemination of a registration statement that disclosed certain information requested by the plaintiffs. In addition, the complaints sought attorneys' and experts' fees.

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.

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, 2019.

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 recent COVID-19 outbreak. Federal, state, local and foreign government orders on account of the COVID-19 pandemic are preventing us from conducting certain activities and obtaining supplies required to manufacture and deliver certain components for Zalviso. As such, one of our suppliers has provided us a notice of force majeure, and we, in turn, have provided a similar notice to Grünenthal. Furthermore, following local and state government orders in California and the counties in which 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. Moreover, hospitals and other healthcare facilities have implemented policies that limit access of our sales representatives to such facilities, which is causing a delay to, and thwarting, our educational and promotional efforts. Governments, hospitals and doctors, as a measure to combat the further spread of COVID-19, have reduced the number of procedures in which DSUVIA is administered as part of the pain treatment program, and temporarily halted performing elective surgeries, which will adversely impact the levels of our sales relating to such procedures. The ultimate impact of the COVID-19 outbreak is 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 of DSUVIA® and Zalviso®

Our success is highly dependent on our ability to successfully commercialize DSUVIA. To the extent DSUVIA is not commercially successful, our business, financial condition and results of operations will be materially harmed.*

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 of DSUVIA by physicians, patients and the healthcare community;
- acceptance of pricing and placement of DSUVIA 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.

In response to the COVID-19 pandemic, 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 this restriction 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 substantially reduced, and in some cases, stopped. As a result, 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 continues to be limited.

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 Zalviso, if approved, 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 Zalviso, if approved, in the United States, or DZUVEO and Zalviso in Europe, 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 DSUVIA for the management of moderate-to-severe acute pain by a healthcare professional for patient types that were not specifically studied in our Phase 3 trials;
- the use of Zalviso for the management of moderate-to-severe acute pain in the hospital setting for patient types that were not specifically studied in our Phase 3 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, or the European Medicines Agency, or EMA,-approved label for DZUVEO or Zalviso;
- restrictions or limitations placed on DSUVIA due to the REMS program;
- availability of alternative treatments;
- existing capital investment by hospitals in IV PCA technology;
- pricing and cost-effectiveness;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- our ability to obtain formulary approval; 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 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 outside of the United States, we may be unable to generate sufficient product revenue.*

In order to commercialize DSUVIA and Zalviso, if approved, 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 plan to enter into such agreements for Zalviso, if approved, in the United States; however, if these third parties do not perform as expected or there are delays in establishing such relationships for Zalviso, if approved, our ability to effectively distribute products would suffer.

We have entered into a collaboration with Grünenthal for the commercialization of Zalviso in Europe and Australia and Grünenthal has exercised its right to terminate the collaboration, effective on or about November 14, 2020. 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 royalty monetization arrangement with PDL, we are obligated to use commercially reasonable efforts to negotiate a replacement license agreement. Accordingly, even if we are able to enter into a replacement license agreement, 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 PDL is reached. DZUVEO was approved by the EC in June 2018. We have not yet entered into a collaboration agreement with a strategic partner for the commercialization of DZUVEO in Europe, and there can be no assurance that we will successfully enter into such an agreement. We may also consider the option to enter into strategic partnerships for DSUVIA, or Zalviso, if approved, in the United States. 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 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 Zalviso or DSUVIA/DZUVEO, 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.

In March 2020, in connection with the Co-Promotion Agreement with Tetraphase Pharmaceuticals, Inc., we reduced the size of our commercial team to eliminate the overlap with the Tetraphase commercial team and, given our reduced workforce, we may experience difficulties in retaining our existing employees and managing our operations, including our continued commercialization of DSUVIA.*

As of June 30, 2020, we had 54 full-time employees. On March 15, 2020, we entered into the Agreement and Plan of Merger, or Merger Agreement, and the Co-Promotion Agreement with Tetraphase Pharmaceuticals, Inc., or Tetraphase. In connection with the Co-Promotion Agreement, we reduced the size of our commercial team to eliminate the overlap with the Tetraphase commercial team and reduce operating expenses. The restructuring resulted in the

elimination of 30 positions, or approximately 33% of our workforce. On June 4, 2020 Tetraphase terminated the Merger Agreement pursuant to its terms and paid AcelRx a termination fee of approximately $1.8 million. On July 28, 2020, Tetraphase was acquired by La Jolla Pharmaceutical Company. It is unclear what impact the acquisition may have on the Co-Promotion Agreement.

We will 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 our workforce reduction may be disruptive to our operations, may negatively affect our productivity, and constrain our commercialization activities. For example, our workforce reduction could yield unanticipated consequences, such as attrition beyond planned staff reductions, negative impact on employee morale and our corporate culture, or increase 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 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 Act or state False Claims Act, 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.

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, during the three months ended June 30, 2020, Grünenthal terminated the Amended License Agreement, effective on or about November 14, 2020. We have a continuing obligation, through the term of the Royalty Monetization with PDL, to use commercially reasonable efforts to negotiate a replacement license agreement, or New Arrangement. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully and timely transition terminated collaborative agreements, including entering into a New Arrangement for Zalviso in Europe, we may have to undertake development and commercialization activities at our own expense or find alternative sources of capital.

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 existing collaboration with Grünenthal for Zalviso requires us to supply product to support the European commercialization of Zalviso and it is possible that any New Arrangement would also include such a requirement. In addition, with the June 2018 approval of DZUVEO in Europe, we intend to enter into agreements with third parties to market DZUVEO in Europe, which may also require us to supply product to those third parties. We may be subject to additional risks related to entering into international business relationships, 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;
- 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 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 Zalviso, 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.

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 Zalviso, 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 restrictions on our commercial and medical affairs teams' access to hospitals and other health care facilities could adversely impact the number of formulary approvals we anticipated achieving in 2020, 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 approval will limit our commercial success. If we are successful in obtaining formulary approvals, we may need to complete evaluation programs whereby DSUVIA, or Zalviso, if approved, is 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 Zalviso, if approved. Further, even successful formulary approvals may be subject to certain restrictions based on patient type or hospital protocol. Failure to obtain timely formulary approvals for DSUVIA, or Zalviso, 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 Zalviso, 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 Zalviso, if approved, in the United States, and any future 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 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, European sales of Zalviso, and future product sales of DZUVEO, 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 Zalviso, 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, we anticipate we may need comparator studies of DZUVEO in Europe 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 Zalviso, 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 Zalviso, 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 Zalviso, 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 Zalviso, 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 Zalviso, 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 Zalviso, if approved, in the United States.

We intend to rely primarily upon distributors and pharmaceutical wholesalers in connection with the distribution of DSUVIA and Zalviso, 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 Clinical Development and Regulatory Approval

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 July 2019, the FDA informed two New Drug Application, or NDA, applicants with August 2019 Prescription Drug User Fee Act, or PDUFA, dates for their opioid candidate products that the FDA was postponing product-specific advisory committee meetings for opioid analgesics while it continues to consider a number of scientific and policy issues relating to this class of drug. 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 the European Union, or EU, the pricing of prescription drugs is subject to government control. In addition, the EU 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 the United States, the Affordable Care Act (as defined below) 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 has the potential to substantially change health care financing and delivery by both governmental and private insurers and may also increase our regulatory burdens and operating costs.

There remain judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part 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". Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act's mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax, and effective January 1, 2021, also eliminates the health insurer tax. In December 2018, the Centers for Medicare & Medicaid Services, or CMS, published a new final rule, starting in 2020, permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. It is unclear how this decision, such litigation and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act. We expect that the Affordable Care Act, as currently enacted or as it may be amended or repealed in the future, 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 will stay in effect through 2030 unless Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. 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, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump Administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has begun soliciting feedback on some of these measures and has implemented others under its existing authority. For example, in September 2018, Centers for Medicare & Medicaid Services, or CMS, announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019. Additionally, on July 24, 2020, President Trump announced four executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals, including a policy that would tie Medicare Part B drug prices to international drug prices; one that directs HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for plans, pharmacies, and pharmaceutical benefit managers; and one that reduces costs of insulin and EpiPens to patients of federally qualified health centers. Although these, and other measures will require additional authorization to become effective, Congress and the Trump Administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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 example, it is possible that additional governmental action is taken to address 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. A draft protocol for this trial was submitted in May 2020 and the final protocol is planned for August 2020. 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 serious adverse events, or 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 draft protocol for this trial was submitted in May 2020 and the final protocol is planned for August 2020. 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 and are subject to FDA review, in addition to other potentially applicable federal and state laws. 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 approved 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. The Amended Agreements with Grünenthal are terminating on or about November 14, 2020. 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. We have not yet entered into a collaboration agreement with a strategic partner for the commercialization of DZUVEO in Europe and there can be no assurance that we will successfully enter into such an agreement.

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, even if we are successful in entering into a collaboration agreement with a commercial partner, we will be substantially dependent on that commercial partner 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 2020 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 June 30, 2020, we had an accumulated deficit of $420.6 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 our commercial partner, Grünenthal, monetization of certain future royalties and commercial sales milestones from the European sales of Zalviso by Grünenthal, funding from the DoD, and more recently with revenues from sales of DSUVIA since the commercial launch in the first quarter of 2019. 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, conduct research and development activities, including the FDA regulatory review of the Zalviso NDA, once resubmitted, and support the manufacturing and supply of Zalviso in Europe for Grünenthal until our obligations under the Amended Agreements terminate. Grünenthal's sales of Zalviso in Europe have historically been small. If DSUVIA is not successfully commercialized in the U.S., or if Zalviso is 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 or 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 Zalviso, if approved, in the United States to become profitable. Although DZUVEO was approved by the EC in June 2018, we have not yet entered into a collaboration agreement with a strategic partner to commercialize DZUVEO in Europe and there can be no assurance that we will successfully enter into such an agreement. While we have a collaboration agreement with Grünenthal for commercialization of Zalviso in Europe and Australia that terminates on or about November 14, 2020, Grünenthal was unable to achieve a level of commercial sales of Zalviso for which we were able to receive sales milestone payments.

In September 2015, we consummated a monetization transaction with PDL BioPharma, Inc., or 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, referred to as the Royalty Monetization. As mentioned above, during the three months ended June 30, 2020, Grünenthal terminated the Amended License Agreement, effective on or about November 14, 2020. Per the terms of the Royalty Monetization, we are obligated to use commercially reasonable efforts to negotiate a replacement license agreement. Accordingly, even if we are able to enter into a replacement license agreement, 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 PDL is reached. We do not anticipate generating significant near-term revenues from DSUVIA or Zalviso, 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 Zalviso in the United States; and
- launching and commercializing DSUVIA and Zalviso, 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 by entering into 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 Zalviso 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 Zalviso, if approved, in the United States, we may not become profitable and may need to obtain additional funding to continue operations.

We have been substantially dependent on our commercial partner, 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 the Territory for human use in pain treatment within, or dispensed by, hospitals, hospices, nursing homes and other medically supervised settings. In September 2015, the EC approved 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. On May 18, 2020, we received a notice from Grünenthal that it is exercising its right to terminate the Amended Agreements, effective on or about November 14, 2020.

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 have assisted Grünenthal with implementing additional training for HCPs and we have revised the controller software. Controllers with the revised software, which were delivered in December 2016, have undergone extensive bench testing and we believe we have successfully addressed the issues as 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 the current and future sales of Zalviso in Europe. Further, if new issues occur, there may be a material adverse impact on the future sales of Zalviso in Europe which may have a negative impact on future revenues received and recognized by us.

We have not realized 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 Grünenthal and any future collaboration partner in Europe;
- Grünenthal has changed the focus of its commercialization efforts to pursue higher-priority programs and any future collaboration partner may do the same;
- Grünenthal has reduced and will stop its commercialization efforts in countries where it currently has the sole right to commercialize Zalviso requiring us to find another collaboration partner for Zalviso in Europe; and
- Grünenthal has 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 Amended Agreements under our agreements with PDL, and, if we breach those representations or covenants, we may become subject to indemnification claims by PDL and liable to PDL 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 have not yet entered into a collaboration agreement with a strategic partner for the commercialization of DZUVEO in Europe.

DZUVEO was approved by the EC in June 2018, but we have not yet entered into a collaboration agreement with a strategic partner to commercialize DZUVEO in Europe. If we are unable to enter into such an agreement, we may never generate revenues from sales of DZUVEO. If we are successful in identifying a commercial partner and entering into a collaboration agreement, we will be substantially dependent on this partner 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.

Any future collaboration agreement for DZUVEO will likely require us to support the manufacturing and supply of the product in Europe for our commercial partner. 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 any future commercial partner, 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 our ongoing activities including the commercial launch of DSUVIA in the United States and support for FDA regulatory review of the Zalviso NDA, once resubmitted. While we believe we have sufficient capital resources to continue planned operations through the third quarter of 2021, we will need additional capital to pursue full commercialization of DSUVIA and Zalviso, if approved.

Clinical trials, regulatory reviews, and the launch of commercial product are expensive activities. In addition, commercialization costs for DSUVIA and Zalviso, 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 Zalviso 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 Zalviso. 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 Zalviso;
- 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, the Company 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 June 30, 2020, we had approximately $24.7 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. 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, we have not yet entered into a collaboration agreement for the sale of DZUVEO in Europe, but we anticipate that any future collaboration agreement will likely require us to manufacture and supply DZUVEO to our commercial partner. As mentioned above, we are obligated to manufacture and supply Zalviso under the Amended Agreements with Grünenthal for use in Europe and their other licensed territories and may be required to do so under any New Arrangement. 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 in a timely manner or at all, and we may, as a result, be in breach of any New Arrangement. If any such breach, or other breach, were to be material and remain uncured, it could result in termination of the New Arrangement, which in turn could result in us being responsible for indemnification of losses suffered by 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 will need to be addressed before the submission can be approved. 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 need to use dedicated equipment throughout development and commercial manufacturing to avoid the possibility of cross-contamination. If our 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 existing facility or equipment, including ongoing expansion, may impair our ability to successfully commercialize DSUVIA or Zalviso, if approved, 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 Zalviso 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 have produced a number of commercial lots to support Grünenthal's launch in Europe, our experience is limited, which has 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 finished goods of DZUVEO in the same manner. The capacity and cost to package the finished goods under this manual process is not optimal to support successful future sales of DSUVIA and DZUVEO. We have initiated the process to purchase an automated filling and packaging line to support increased capacity packaging for DSUVIA and DZUVEO. Despite the delays due to the impact of COVID-19, we are projecting to complete the acquisition and installation of this line in 2021. There is no assurance that we will be able to successfully purchase, install or validate the automated filling and packaging line for DSUVIA and DZUVEO. If we are successful in the purchase, installation and validation of this equipment and process, there can be no assurance that we will be able to 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 penalties.

Healthcare providers, 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, as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, 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 by such law, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- 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 Grünenthal, or any future collaborator, for commercial sales, 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 Grünenthal, or 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. 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, we may 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 includes the sale of Zalviso to our 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 June 30, 2020, we are the owner of record of 80 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 $3.93 and $1.66 during 2019, and between $0.76 and $2.07 during the first six months of 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 Zalviso in the United States;
- inability to obtain additional funding needed to conduct our planned business operations;
- the integration and performance of any businesses we may acquire;
- 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 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 or stockholder 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.

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 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.

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 future complete response letters, 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.

If AcelRx experiences a decline in its stock price, we could face additional securities class action lawsuits. Securities class actions are often expensive and can divert management's attention and our financial resources, which could adversely affect our business.

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

As of December 31, 2019, we had federal net operating loss carryforwards of $212.4 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 $97.5 million generated in 2019 and 2018 will carryforward indefinitely but are subject to the 80% taxable income limitation. As of December 31, 2019, we had state net operating loss carryforwards of $113.5 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 new 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, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to 80% of current year taxable income.

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.

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.

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

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant, currently in effect.	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, currently in effect.	S-1	333-170594	3.4	01/07/2011
10.1+§	Transition Services Agreement and General Release between the Registrant and Lawrence Hamel, dated April 3, 2020.	8-K	333-170594	10.1	04/08/2020
10.2+§	Consulting Agreement, between the Registrant and Lawrence Hamel, dated April 3, 2020.	8-K	333-170594	10.2	04/08/2020
10.3+	2020 Cash Bonus Plan Summary.	10-Q	001-35068	10.7	5/11/2020
10.4	Amendment No. 1 to Co-Promotion Agreement, between the Registrant and Tetraphase, dated as of May 26, 2020.	8-K	001-35068	10.3	05/29/2020
10.5	Amendment No. 1 to the Controlled Equity Offering™ Sales Agreement between the Registrant and Cantor Fitzgerald & Co., dated as of April 29, 2020.	S-3	333-239156	1.3	06/12/2020
10.6+	2020 Equity Incentive Plan.	S-8	333-239213	99.1	06/16/2020
10.7+	Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the 2020 Equity Incentive Plan.	S-8	333-239213	99.2	06/16/2020
10.8+	Forms of RSU Award Grant Notice and Award Agreement (RSU Award) under the 2020 Equity Incentive Plan.	S-8	333-239213	99.3	06/16/2020
10.9+	Amended and Restated 2011 Employee Stock Purchase Plan.	S-8	333-239213	99.4	06/16/2020
10.10+	Non-Employee Director Compensation Policy.				
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	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	XBRL Taxonomy Schema Document.				
101.CAL	XBRL Taxonomy Calculation Linkbase Document.				

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
101.DEF	XBRL Taxonomy Definition Linkbase Document.				
101.LAB	XBRL Taxonomy Label Linkbase Document.				
101.PRE	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).				

+ Indicates management contract or compensatory plan.
§ 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.
* 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: August 10, 2020

AcelRx Pharmaceuticals, Inc.
(Registrant)

/s/ Raffi Asadorian

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

Exhibit 10.10

Non-Employee Director Compensation Policy

Compensation for our non-employee directors consists of cash, restricted stock units and stock options. The Compensation Committee periodically reviews the compensation paid to non-employee directors for their service on the Board and its committees and recommends any changes considered appropriate to the full Board for its approval. In February 2020, the Board approved the recommendations of the Compensation Committee to align our non-employee director cash compensation with the 50th percentile of our peer group and equity compensation with the 25th percentile of our peer group. Accordingly, effective January 1, 2020, each member of our Board who is not our employee will receive an annual retainer of $40,000. In addition, our non-employee directors will receive the following cash compensation for Board services, as applicable:

- the Board Chair receives an additional annual retainer of $30,000;
- the Audit Committee Chair receives an additional annual retainer of $20,000;
- the Compensation Committee Chair receives an additional annual retainer of $15,000;
- the Nominating and Corporate Governance Committee Chair receives an additional annual retainer of $10,000;
- an Audit Committee member receives an additional annual retainer of $10,000;
- a Compensation Committee member receives an additional annual retainer of $7,500; and
- a Nominating and Corporate Governance Committee member receives an additional retainer of $5,000.

Beginning in June 2020, upon election or appointment to our Board, a new non-employee director will be granted an initial stock option to purchase 22,500 shares of our common stock, which will vest as to 1/3rd of the shares subject to the option on the one-year anniversary of the date of grant and as to the remaining shares subject to the option on an equal monthly basis over the following two-year period, and 11,250 RSUs, which will vest as to 1/3rd of the RSUs on each anniversary of the date of grant over a three-year period. Each non-employee director who is then serving as a director or who is elected to our Board on the date of an annual meeting will be granted a stock option to purchase 15,000 shares of our common stock, which will vest in full on the one-year anniversary of the date of grant, and 7,500 RSUs, which will vest in full on the one-year anniversary of the date of grant.

All Board and committee retainers accrue and are payable on a quarterly basis at the end of each calendar quarter of service. We reimburse our non-employee directors for travel, lodging and other reasonable expenses incurred in connection with their attendance at Board or committee meetings.

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: August 10, 2020

/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: August 10, 2020

/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 June 30, 2020, 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 10th day of August 2020.

/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.