UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2020

or

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

For the transition period from _____ to _____

Commission File Number: 001-35837

TETRAPHASE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-5276217**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

480 Arsenal Way
Watertown, MA
(Address of principal executive offices)

02472
(Zip Code)

Registrant's telephone number, including area code: (617) 715-3600
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	**TTPH**	**Nasdaq Global Select 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 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 Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 6, 2020, there were 7,263,236 shares of the registrant's common stock, par value $0.001 per share, outstanding.

TETRAPHASE PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2020

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Item 1. Financial Statements

TETRAPHASE PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets
(In thousands, except par value amounts)
(Unaudited)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 26,146	$ 21,239
Accounts receivable, net	1,706	1,503
Assets held for sale	—	53
Inventory	788	1,595
Prepaid expenses and other current assets	1,178	2,103
Total current assets	29,818	26,493
Property and equipment, net	78	98
Intangible assets, net	4,160	4,259
Operating lease right-of-use assets	2,598	4,836
Restricted cash	699	699
Total assets	$ 37,353	$ 36,385
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,977	$ 2,429
Accrued expenses	5,235	5,794
Operating lease liabilities	932	1,547
Total current liabilities	8,144	9,770
Long-term operating lease liabilities	1,754	3,448
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, par value $0.001 per share; 5,000 shares authorized; no shares issued and outstanding	—	—
Common stock, par value $0.001 per share; 125,000 shares authorized; 7,259 and 3,466 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	7	3
Additional paid-in capital	643,699	627,291
Accumulated deficit	(616,251)	(604,127)
Total stockholders' equity	27,455	23,167
Total liabilities and stockholders' equity	$ 37,353	$ 36,385

See accompanying notes to unaudited condensed consolidated financial statements

TETRAPHASE PHARMACEUTICALS, INC.

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

	Three Months Ended March 31,	
	2020	**2019**
Revenues:		
Product revenue, net	$ 1,755	$ 341
Government revenue	-	932
Total revenue	1,755	1,273
Expenses:		
Cost of revenue - product sales	1,360	164
Cost of revenue - intangible asset amortization	98	98
Research and development	1,893	6,737
Selling, general and administrative	10,668	13,314
Total expenses	14,019	20,313
Loss from operations	(12,264)	(19,040)
Other income and expenses		
Other income	71	—
Interest income	69	507
Interest expense	—	(955)
Net loss	$ (12,124)	$ (19,488)
Net loss per share-basic and diluted	$ (1.31)	$ (7.25)
Weighted-average number of common shares used in net loss per share-basic and diluted	9,273	2,687
Comprehensive loss	$ (12,124)	$ (19,488)

See accompanying notes to unaudited condensed consolidated financial statements

TETRAPHASE PHARMACEUTICALS, INC.

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

	Three Months Ended March 31,	
	2020	2019
Operating activities		
Net loss	$ (12,124)	$ (19,488)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	112	201
Non-cash interest expense related to notes payable	—	223
Stock-based compensation expense	480	2,723
Gain from modification of operating lease	(68)	—
Gain on asset disposal	(71)	—
Changes in operating assets and liabilities:		
Accounts receivable	(203)	457
Inventory	806	(1,600)
Prepaid expenses and other assets	927	262
Accounts payable	(452)	(518)
Accrued expenses and other liabilities	(559)	(2,387)
Deferred revenue	—	(6)
Operating lease right-of-use assets	360	342
Operating lease liabilities	(363)	(328)
Net cash used in operating activities	(11,155)	(20,119)
Investing activities		
Proceeds from sale of property and equipment	130	—
Purchases of property and equipment	—	(98)
Net cash provided by (used in) investing activities	130	(98)
Financing activities		
Proceeds from sale of common stock and prefunded warrants under a concurrent private placement and registered direct offering, net of issuance costs	15,931	—
Proceeds from issuance of stock under stock plans	1	—
Net cash provided by financing activities	15,932	—
Net increase (decrease) in cash, cash equivalents and restricted cash	4,907	(20,217)
Cash, cash equivalents and restricted cash at beginning of period	21,938	108,475
Cash, cash equivalents and restricted cash at end of period	$ 26,845	$ 88,258
Supplemental cash flow disclosures from investing activities		
Cash paid for interest	$ -	$ 539

See accompanying notes to unaudited condensed consolidated financial statements

TETRAPHASE PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Stockholders' Equity
(In thousands)
(Unaudited)

	Common Shares		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2019	3,466	$ 3	$ 627,291	$ (604,127)	$ 23,167
Issuance of common stock under stock plans	23	—	1	—	1
Issuance of common stock and prefunded warrants under a concurrent private placement and registered direct offering, less issuance costs	3,650	4	15,927	—	15,931
Issuance of common stock from warrant exercise	120	—	—	—	—
Stock-based compensation expense	—	—	480	—	480
Net loss	—	—	—	(12,124)	(12,124)
Balance at March 31, 2020	7,259	$ 7	$ 643,699	$ (616,251)	$ 27,455
Balance at December 31, 2018	2,684	$ 3	$ 613,721	$ (534,042)	$ 79,682
Issuance of common stock under stock plans	3	—	—	—	—
Stock-based compensation expense	—	—	2,723	—	2,723
Net loss	—	—	—	(19,488)	(19,488)
Balance at March 31, 2019	2,687	$ 3	$ 616,444	$ (553,530)	$ 62,917

See accompanying notes to unaudited condensed consolidated financial statements

1. Organization and Operations

Tetraphase Pharmaceuticals, Inc., or the Company, is a biopharmaceutical company using its proprietary chemistry technology to create, develop and commercialize novel tetracyclines for serious and life-threatening conditions, including bacterial infections caused by multidrug-resistant, or MDR, bacteria. There is a medical need for new antibiotics as resistance to existing antibiotics increases. In recognition of this need, the Company has developed its product, Xerava (eravacycline), a fully synthetic fluorocycline, as an intravenous, or IV, antibiotic for use as a first-line empiric monotherapy for the treatment of MDR infections, including MDR Gram-negative infections, such as those found in complicated intra-abdominal infections, or cIAI.

On March 15, 2020, the Company entered into an agreement and plan of merger, or Merger Agreement, with AcelRx Pharmaceuticals, Inc., a Delaware corporation, or AcelRx, and Consolidation Merger Sub, Inc., a Delaware corporation and an indirect wholly owned subsidiary of AcelRx, or Merger Sub. The Merger Agreement provides for, among other things, the acquisition of the Company by AcelRx, with the acquisition to be accomplished through the merger of Merger Sub with and into the Company, with the Company being the surviving corporation and becoming an indirect wholly owned subsidiary of AcelRx. The Company's Board of Directors has unanimously approved the Merger and the Merger Agreement and recommended that stockholders adopt the Merger Agreement. The Company submitted the Merger Agreement to its stockholders for their consideration at a special meeting of stockholders to be held on June 8, 2020. The Company expects the merger to be completed in the second quarter of 2020.

On March 15, 2020, concurrently with the execution of the Merger Agreement, the Company and AcelRx entered into a Co-Promotion Agreement. Under this agreement, the parties have agreed that, during the term of the agreement, their sales forces will promote and detail the other party's products in accordance with marketing plans agreed to by the parties and subject to specified minimum call requirements. The parties have established a Joint Marketing and Sales Committee to oversee the promotion and marketing of the products. There are no payments being made between the parties under the agreement, and each party will continue to receive all the revenues from the sales of its own products. The agreement is terminable by either party for any reason upon 15 months' notice or upon 90 days' notice in the case of material breach. However, in the event of a change of control of a party during the term of the agreement, the non-change of control party may terminate the agreement upon one month's notice and may be entitled to royalties in the case of a material breach by the change of control party.

On August 27, 2018, the United States Food and Drug Administration, or FDA, approved Xerava for the treatment of cIAI in adults. Approval of Xerava was based on the Company's IGNITE (**I**nvestigating **G**ram-**N**egative **I**nfections **T**reated with **E**ravacycline) phase 3 program. In October 2018, the Company commenced sales of Xerava in the United States.

On September 20, 2018, based on the results of IGNITE1, the European Commission, or EC, granted marketing authorization for Xerava for the treatment of cIAI in adults in all 28 countries of the European Union, or EU, plus Norway, Iceland and Liechtenstein. The Company has not yet commenced sales outside of the United States. In February 2018, the Company entered into a license agreement with Everest Medicines Limited, or Everest Medicines, granting Everest Medicines commercialization rights to eravacycline in China and other Asian territories.

On June 10, 2019, the Company announced a restructuring of its organization, including a 20% reduction in headcount, designed to focus its cash resources on commercializing Xerava primarily in the hospital setting. This reorganization included the elimination of the Company's internal research function. As part of its restructuring, the Company decided not to engage in further product development, including conducting clinical trials of its product candidates, and intends to seek out-licensing opportunities for all of its pipeline of early-stage antibiotics and oncology product candidates.

The Company has incurred annual net operating losses every year since its inception. As of March 31, 2020, the Company had incurred losses since inception of $616.3 million. The Company has financed its operations primarily through public offerings and private placements of equity securities, debt financings, revenue from U.S. government grants and contract awards, milestone payments from a licensing agreement and Xerava product revenue.

Liquidity and Going Concern Assessment

Accounting Standards Update ("ASU"), 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40)*, also referred to as Accounting Standards Codification ("ASC") 205-40 (“ASC 205-40”), requires the Company to evaluate whether conditions and/or events raise substantial doubt about its ability to meet its future financial obligations as they become due within one year after the financial statements are issued. This evaluation requires management to perform two steps. First, management must evaluate whether there are conditions and events that raise substantial doubt about the Company’s ability to continue as a going concern. Second, if management concludes that substantial doubt is raised, management is required to consider whether it has plans in place to alleviate that doubt. Disclosures in the notes to the financial statements are required if management concludes that substantial doubt exists or that its plans alleviate the substantial doubt that was raised.

The Company has financed its operations primarily through public offerings and private placements of equity securities, debt financings, revenue from U.S. government grants and contract awards and milestone payments from its licensing agreements. The Company will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources to fund its operations including ongoing spending to commercialize Xerava.

Based on its current operating plan, and if the Merger is not consummated when expected, the Company expects that its cash and cash equivalents of $26.1 million as of March 31, 2020, and its projected revenues from sales of Xerava, together with the $2.3 million in proceeds from its Paycheck Protection Program (“PPP”) loan via the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, received in April 2020 (“PPP Loan”) (see note 13, *Subsequent Events*), will be sufficient to fund the Company’s operations into the first quarter of 2021, but will not be sufficient to fund the Company’s operations for more than one year beyond the filing date of this Quarterly Report on Form 10-Q. This estimate is based on certain significant assumptions, which are uncertain and may turn out to be incorrect. In particular, the forecast assumes continued significant growth of Xerava revenue, for which the Company has limited historical experience to base its estimate, and a significant reduction in expenses in 2020 as a result of the restructuring implemented in June 2019. If these estimates are incorrect, the Company may use its cash resources sooner than expected. These factors raise substantial doubt about the Company’s ability to continue as a going concern.

If the Merger is not consummated, the Company will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources to fund its operations including ongoing spending to commercialize Xerava. However, there can be no assurance that the Company will be able to obtain such funding on terms acceptable to the Company, on a timely basis or at all. If the Merger is not consummated and the Company is unable to obtain funding, the Company may be required to delay, reduce or eliminate its commercialization efforts, which could adversely affect its business prospects, and the Company may be unable to continue operations.

If the Merger is not consummated and the Company is unable to raise additional capital when needed or if the Company’s operating results fall short of its current projections, or if the Company determines to explore strategic alternatives but is unable to consummate such a transaction or transactions on a timely basis or at all, the Company could be forced to significantly delay, scale back or discontinue the commercialization of Xerava or reduce other expenditures, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, its rights to Xerava and the Company’s product candidates. The Company’s failure to obtain sufficient funds on acceptable terms when needed would have a material adverse effect on its business, results of operations and financial condition. In addition, in such circumstances, the Company would consider seeking protection under the bankruptcy laws in order to continue to pursue potential transactions and conduct a wind-down of the Company. If the Company decides to seek protection under the bankruptcy laws, the Company would expect that it would file for bankruptcy at a time that is significantly earlier than when it would otherwise exhaust its cash resources. If the Company decides to dissolve and liquidate its assets or to seek protection under the bankruptcy laws, it is unclear to what extent the Company will be able to pay its obligations, and, accordingly, it is further unclear whether and to what extent any resources will be available for distributions to stockholders.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim condensed consolidated financial statements are unaudited. These unaudited financial statements have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission, or SEC, for interim financial information. Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles, or GAAP, for complete financial statements. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the accompanying notes for the year ended December 31, 2019 contained in the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2020, or the 2019 Form 10-K. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company's financial position as of March 31, 2020 and the results of its operations and comprehensive loss and cash flows for the three months ended March 31, 2020 and 2019. Interim operating results for the three months ended March 31, 2020 are not necessarily indicative of the results that may be expected for future interim periods or for the fiscal year ending December 31, 2020. The Company's significant accounting policies are described in Note 2, *Summary of Significant Accounting Policies* in the 2019 Form 10-K. The Company is disclosing certain significant policies as well as changes in its accounting policies related to guidance that became effective in this Quarterly Report on Form 10-Q.

The December 31, 2019 condensed consolidated balance sheet included herein was derived from audited consolidated financial statements, but does not include all disclosures including notes required by GAAP for complete financial statements.

Reverse Stock Split

On September 25, 2019, the Company's Board of Directors authorized a 1-for-20 reverse stock split and approved an amendment to the Company's Certificate of Incorporation (the "Amendment") to affect the 1-for-20 reverse split of the Company's common stock, which was effected at 5:00 p.m. Eastern Time on September 26, 2019. All of the share and per share amounts disclosed in these condensed consolidated interim financial statements included in this Quarterly Report on Form 10-Q have been adjusted to reflect the reverse stock split.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures. On an ongoing basis, the Company's management evaluates its estimates, including product revenue, license and collaboration revenue, inventory, impairment of intangible assets, stock-based compensation expense, contract and grant revenues, and going concern considerations. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Accounts Receivable

Accounts receivable as of March 31, 2020 and December 31, 2019 represent amounts due from two main sources: (1) trade accounts receivable of $1.0 million and $0.8 million, respectively, consisting of payments to be received from customers for sales of Xerava, net of prompt payment discounts, chargebacks, rebates and certain fees and (2) contract accounts receivable of $0.7 million and $0.7 million, respectively, related to the Company's government-related agreements.

Contract accounts receivable relate to payments from entities administering the Company's government-related agreements which include unbilled contract accounts receivable of $0.7 million as of December 31, 2019. There were no unbilled contract accounts receivable as of March 31, 2020

Inventory

Inventory is stated at the lower of cost or net realizable value on a first-in, first-out basis. Prior to the regulatory approval of Xerava, given the uncertainty of approval, the Company recognized as research and development expense costs related to the manufacture of Xerava. Upon approval of Xerava, the Company began to capitalize such costs as inventory.

During each quarter, the Company performs an assessment quantifying any potential excess or obsolete inventory and writes down any such inventory to its net realizable value in the period in which the impairment is identified. These adjustments are based upon multiple factors, including inventory levels at the Company and at its specialty distributors, projected demand and product shelf life. These impairment charges, if required, are recorded as a cost of revenue. As of March 31, 2020, there was no excess or obsolete inventory.

Long-Lived Assets

The Company evaluates the recoverability of its property, equipment and intangible assets when circumstances indicate that an event of impairment may have occurred. The Company recognizes an impairment loss only if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows. Impairment is measured based on the difference between the carrying value of the related assets or businesses and the fair value of such assets or businesses.

Restricted Cash

As of March 31, 2020, the Company had $699,000 in restricted cash deposits with a bank, of which $500,000 is serving as security for its field force corporate credit card program and $159,000 is collateral for a letter of credit issued to the landlord of the Company's leased facility. If the Company defaults on its rental obligations, $159,000 will be payable to the landlord. In addition, the Company has $40,000 in restricted cash to secure the Company's corporate purchasing credit card.

Intangible Assets

The Company maintains definite-lived intangible assets related to certain capitalized milestone payments to Harvard University (Harvard). These assets are amortized over their remaining useful lives, which are estimated based on the shorter of the remaining patent life or the estimated useful life of the underlying product. Intangible assets are amortized using the economic consumption method if future revenues can be reasonably estimated. The straight-line method is used when future revenues cannot be reasonably estimated.

The Company assesses its intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding one of the Company's drug candidates or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate, or new information regarding potential sales of the drug. If impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would determine the fair value of the intangible asset and recognize an impairment loss if the carrying value of the intangible asset exceeds its fair value.

The Company capitalized milestone payments of $4.75 million related to regulatory approval of Xerava in the United States and European Union, which will be amortized over their estimated useful lives of approximately 12 years. Amortization expense for each of the following five years is expected to be $0.4 million.

During the three months ended March 31, 2020, management identified impairment indicators related to the intangible assets for the Harvard milestones. As result, an interim test of recoverability of the intangible asset was performed based on the estimated undiscounted future cash flows related to the intangible asset, and concluded the intangible asset was recoverable. The Company's quantitative assessment considered significant assumptions related to estimates of future Xerava sales, offset by direct costs to derive the sales. The estimates of future Xerava sales include estimates of significant growth as the product was launched in the fourth quarter of 2018. Given the limited history of sales and the inherent difficulty in making a long-range forecast, such estimates contain significant uncertainty. If the assumptions regarding forecasted revenue or the costs to derive such revenues are not achieved, the Company may be required to perform future impairment analyses and record an impairment charge for the intangible asset in future periods. It is not possible at this time to determine if any such future impairment charge would result or, if it does, whether such charge would be material.

Cost of Revenue

Cost of revenue consists primarily of the manufacturing and distribution costs for Xerava, Xerava net sales-based royalties and the amortization of the intangible asset associated with certain milestones paid to Harvard related to Xerava. All manufacturing costs incurred prior to Xerava's approval in the United States on August 27, 2018 have been expensed in research and development and are not included in cost of revenue. Manufacturing costs at contract manufacturing sites not yet approved by the US FDA for commercial production have also been expensed in research and development and are not included in cost of revenue.

Recently Adopted Accounting Pronouncements

There have been no significant changes to the Company's significant accounting policies since the beginning of this fiscal year.

Recent Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments – Credit Losses (Topic 326): *Measurement of Credit Losses on Financial Instruments*, or ASU 2016-13. ASU 2016-13 will change how companies account for credit losses for most financial assets and certain other instruments. For trade receivables, loans and held-to-maturity debt securities, companies will be required to recognize an allowance for credit losses rather than reducing the carrying value of the asset. ASU 2016-13 is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the potential impact that the adoption of ASU 2016-13 will have on the Company's consolidated financial position and results of operations.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*, or ASU 2019-12, which includes amendments to simplify the accounting for income taxes by removing certain exceptions to the general principles in ASC 740, *Income Taxes*, or ASC 740. The amendments also improve consistent application of and simplify U.S. GAAP for other areas of ASC 740 by clarifying and amending existing guidance. The new guidance is effective for the Company for annual periods beginning after December 15, 2021 and interim periods within fiscal years beginning after December 15, 2022. Early adoption of the amendments is permitted. The Company is currently evaluating the potential impact that the adoption of ASU 2019-12 will have on the Company's consolidated financial statements.

3. Fair Value Measurements

The Company records its cash and cash equivalents at fair value. Fair value measurements are classified and disclosed in one of the following three categories:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Financial instruments measured at fair value as of March 31, 2020 and December 31, 2019 are classified below based on the three fair value hierarchy tiers described above (in thousands):

		Fair Value Measurements at Reporting Date Using		
	Balance	Level 1	Level 2	Level 3
March 31, 2020				
Cash and money market funds	$ 26,146	$ 26,146	$ —	$ —
December 31, 2019				
Cash and money market funds	$ 21,239	$ 21,239	$ —	$ —

The Company measures cash equivalents at fair value on a recurring basis. The fair value of cash equivalents is determined based on "Level 1" inputs, which consist of quoted prices in active markets for identical assets.

4. Net Loss per Common Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding for the period, without consideration for common stock equivalents. Shares of common stock underlying pre-funded warrants are considered outstanding as of their issuance date and are included in the basic net loss per share calculation as the exercise price was deemed non-substantive. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, warrants, stock options, and restricted stock units are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The amounts in the table below were excluded from the calculation of diluted weighted-average shares outstanding, prior to the use of the treasury stock method, due to their anti-dilutive effect:

	March 31,	
	2020	2019
Warrants	7,984,650	20,718
Unvested restricted stock units	49,773	178,225
Outstanding stock options	148,254	365,789
Totals	8,182,677	564,732

5. Inventory

Inventory consisted of the following (in thousands):

	As of March 31, 2020	As of December 31, 2019
Work in progress	$ 115	$ 115
Finished goods	673	1,480
Total inventory	$ 788	$ 1,595

There were no charges related to excess inventory for the three months ended March 31, 2020 or 2019.

6. Significant Agreements and Contracts

License Agreements

Harvard University

In August 2006, the Company entered into a license agreement for certain intellectual property with Harvard. Under the license agreement, as of March 31, 2020, the Company has paid an aggregate $17.0 million in upfront license fees, sublicense fees, development and regulatory milestone payments and royalties on net sales of such product, for the licensed Harvard technology, and has issued 1,568 shares of common stock to Harvard.

For each product covered by the license agreement, the Company is obligated to make certain payments totaling up to approximately $15.1 million upon achievement of certain development and regulatory milestones and to pay additional royalties on net sales of such product. The Company is also obligated to make certain payments to Harvard based on amounts received under its license agreement with Everest Medicines Limited. During the three months ended March 31, 2020 the Company did not make any payments to Harvard related to regulatory milestone payments. During the three months ended March 31, 2019, the Company paid Harvard $25,000 in regulatory milestone payments.

Paratek

On March 18, 2019, the Company and Paratek Pharmaceuticals, Inc., or Paratek, entered into a license agreement, or the Paratek License Agreement. Under the terms of the Paratek License Agreement, Paratek granted to Tetraphase a non-exclusive, worldwide, royalty-bearing license, with the right to grant sublicenses, under certain Paratek patents.

The terms of the Paratek License Agreement provide for the Company to pay Paratek royalties at a low single digit percent on net sales of Xerava sold in the United States. The Company’s obligation to pay royalties with respect to the licensed product is retroactive to the date of the first commercial sale of Xerava and shall continue until there is no longer any valid claims of the Paratek patents which will expire in October 2023.

Everest Medicines License Agreement

In February 2018, the Company entered into a license agreement with Everest Medicines, or the Everest License Agreement, whereby the Company granted Everest Medicines an exclusive license to develop and commercialize Xerava, for the treatment of cIAI and other indications, in mainland China, Taiwan, Hong Kong, Macau, South Korea and Singapore, or the Territory.

Under the terms of the Everest License Agreement, the Company received from Everest Medicines an upfront cash payment of $7.0 million in the first quarter of 2018 and a cash payment of $2.5 million related to Everest Medicines’ submission of an IND with the National Medical Products Administration (formerly China FDA) in June 2018. In the second quarter of 2019, the Company received a cash payment of $3.0 million related to Everest Medicine’s initiation of a Phase 3 clinical trial.

The Company is eligible to receive up to an aggregate of $11.0 million in future clinical development and regulatory milestone payments and up to an aggregate of $20.0 million in sales milestone payments. There can be no guarantee that any such milestones or sales thresholds will in fact be met. The Company is obligated to make certain payments to Harvard based on amounts received from Everest Medicines under the Everest License Agreement pursuant to the existing license agreement by and between Harvard and the Company.

The Company will also be entitled to receive low double-digit tiered royalties on sales in the Territory, if any, of products containing eravacycline. Royalties are payable with respect to each jurisdiction in the Territory until the latest to occur of: (i) the last-to-expire of specified patent rights in such jurisdiction in the Territory; (ii) expiration of marketing or regulatory exclusivity in such jurisdiction in the Territory; or (iii) ten (10) years after the first commercial sale of a product in such jurisdiction in the Territory. In addition, royalties payable under the Everest License Agreement will be subject to reduction on account of generic competition and after patent expiry in a jurisdiction if required by applicable law, with any such reductions capped at certain percentages of the amounts otherwise payable during the applicable royalty payment period.

In addition, on July 29, 2019, the Company amended its original agreement with Everest Medicines to extend Everest Medicines' exclusive license to develop and commercialize Xerava to the jurisdictions of the Malaysian Federation, the Kingdom of Thailand, the Republic of Indonesia, the Socialist Republic of Vietnam and the Republic of the Philippines. Under the terms of this amendment, the Company received from Everest Medicines an upfront, nonrefundable cash payment of $2.0 million in September 2019. As with the milestones discussed above, the Company is obligated to make certain payments to Harvard based on amounts received from Everest under this amendment pursuant to the existing license agreement by and between Harvard and the Company.

Under the terms and conditions of the Everest License Agreement, Everest Medicines will be solely responsible for the development and commercialization of licensed products in the Territory. The Company agreed to manufacture clinical material, which will be paid by Everest Medicines at the Company's cost, as well as commercial supply, which will be paid by Everest at cost plus a reasonable margin.

In evaluating the recognition of revenue under the Everest License Agreement, the Company identified the following three performance obligations under the Agreement: (i) exclusive license to develop and commercialize eravacycline for the treatment of cIAI and other potential, future indications, in the Territory, (ii) provision of information and technical assistance related to the know-how transfer for the development of eravacycline; and (iii) provision of clinical supply to Everest Medicines.

The Company evaluated the Everest License Agreement under ASC 606 at the time of execution of the arrangement. Based on that evaluation, the upfront fee of $7.0 million represented the amount of the consideration to be included in the transaction price, which will be allocated to the identified performance obligations. Subsequent to execution, the Company determined that the milestones for the Chinese IND and Phase 3 clinical trial were probable to be achieved and that a significant revenue reversal would not occur, and included the payment amounts of $2.5 and $3.0 million, respectively, in the transaction price.

No other clinical milestones, regulatory milestones, sales-based milestones or sales royalties have been included in the transaction price, as these milestones were not considered probable at upon signing or at each reporting period thereafter given Everest Medicines relatively short operating history, the uncertainty of regulatory processes in China and that commercial sales have not commenced. The Company determined that the license and related know-how were a combined performance obligation as the license is not distinct without the provision of the related know-how transfer. The Company's obligation to manufacture clinical supply for Everest Medicines is dependent on Everest Medicines' future purchases, the payment for which was determined to be at cost and therefore potentially represents a material right. However, based on the amount of clinical supply expected to be ordered by Everest Medicines, the Company estimated that the value of this right was immaterial.

Other Material Agreements

Patheon UK Limited Master Manufacturing Services Agreement

In June 2017, the Company and Patheon UK Limited and certain of its affiliates, or Patheon, entered into a master manufacturing services agreement. Under the Patheon agreement, the Company is responsible for supplying the active pharmaceutical ingredient for eravacycline to Patheon, and Patheon is responsible for manufacturing eravacycline, conducting quality control, quality assurance, analytical testing and stability testing and packaging. The Company and Patheon entered into two related product agreements pursuant to the Patheon agreement that govern the terms and conditions of Patheon's manufacture of commercial supplies of eravacycline at Patheon's Greenville, North Carolina and Ferentino, Italy manufacturing sites. Pursuant to the Patheon agreement, the Company has agreed to order from Patheon at least a certain percentage of its annual commercial requirements for eravacycline in the United States and European Union each year for the term of the Patheon agreement. The Patheon agreement has an initial term ending December 31, 2022, and will automatically renew after the initial term for successive terms of two years each, unless either party gives notice of its intention to terminate at least 18 months prior to the end of the then current term. The Company may terminate a product agreement upon 30 days' prior written notice under certain circumstances.

Finorga SAS Commercial Supply Agreement

In October 2017, the Company and Finorga SAS, or Novasep, entered into a commercial supply agreement. Under the agreement, Novasep will, pursuant to accepted purchase orders entered into under the agreement, manufacture for commercial supply the active pharmaceutical ingredient for eravacycline. This agreement has an initial term ending October 16, 2022, and will automatically renew after the initial term, unless either party gives notice of its intention to terminate at least 18 months prior to the end of the then current term. The Company may terminate the Novasep agreement upon 30 days' prior written notice under certain circumstances.

Government Grant and Contracts

BARDA Contract for Eravacycline

The Company received funding for the development of Xerava under an award from BARDA, an agency of the U.S. Department of Health and Human Services. In January 2012, BARDA awarded a five-year contract, which was subsequently extended, that provided for up to a total of $67.3 million in funding for the development, manufacturing and clinical evaluation of eravacycline for the treatment of disease caused by bacterial biothreat pathogens. The funding under the BARDA Contract was also used for the development, manufacturing and clinical evaluation of Xerava to treat certain infections caused by life-threatening MDR bacteria.

In connection with the BARDA Contract, in February 2012, the Company entered into a cost-plus-fixed-fee subcontract with CUBRC, an independent, not for profit, research corporation that specializes in U.S. government-based contracts, which was also the direct recipient of the BARDA Contract. The BARDA Contract and the Company's subcontract with CUBRC under the BARDA Contract had terms which expired on December 31, 2019. Committed funding from CUBRC under the Company's BARDA subcontract was for up to approximately $41.3 million through December 31, 2019. Total funds of $40.7 million have been received by the Company through December 31, 2019 under this contract. No revenue was recognized for the three months ended March 31, 2020 as the contract expired by its terms on December 31, 2019. The Company does not expect to receive any additional revenue under this contract. During the three months ended March 31, 2019, the Company recognized revenue of $0.6 million from the Company's subcontract under the BARDA Contract.

NIAID Grant and Contract for TP-271

The Company received funding for its phase 1 compound TP-271 from NIAID for the development, manufacturing, and clinical evaluation of TP-271 for respiratory diseases caused by biothreat and antibiotic-resistant public health pathogens, as well as bacterial pathogens associated with community-acquired bacterial pneumonia. The NIAID Contract was awarded in September 2011, provided up to a total of approximately $35.8 million and expired on March 31, 2019.

In connection with the NIAID Contract, in October 2011, the Company entered into a cost-plus-fixed-fee subcontract with CUBRC, the direct recipient of the NIAID Contract, which subcontract expired on March 31, 2019. Under the contract, the Company could originally receive funding of up to approximately $16.9 million (which was subsequently reduced to $16.3 million based on actual work performed), reflecting the portion of the NIAID Contract funding that could be paid to the Company for its activities. As of March 31, 2020, the Company had received $16.2 million. The company's obligations under the NIAID contract have been met in full as of March 31, 2020 and the Company does not expect to receive any additional revenue under this contract. No revenue was recognized for the three months ended March 31, 2020 as the contract expired by its terms on March 31, 2019. During the three months ended March 31, 2019, the Company recognized $0.1 million from the Company's subcontract under the NIAID Contract.

CARB-X Award for TP-6076

In March 2017, Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) selected the Company to receive up to $4.0 million in research funding over 18 months for TP-6076. In connection with this funding, the Company entered into a cost reimbursement Sub-Award Agreement, or the Sub-Award Agreement, with the Trustees of Boston University, the administrator of the program. The Company began recognizing revenue from the Sub-Award Agreement in April 2017. During the three months ended March 31, 2020 the Company did not recognize any revenue as the Sub-Award Agreement expired on June 30, 2019. During the three months ended March 31, 2019 the Company recognized revenue of $0.3 million under this Sub-Award Agreement. The Company does not expect to receive any additional revenue under the award.

7. Accrued Expenses

Accrued expenses at March 31, 2020 and December 31, 2019 consisted of the following (in thousands):

	March 31, 2020	December 31, 2019
Salaries and benefits	$ 2,007	$ 1,825
Drug supply and development	634	2,608
Professional fees	1,331	573
Commercial	789	516
Clinical trial related	27	111
Other	447	161
Total	$ 5,235	$ 5,794

8. Stock-Based Compensation

In January 2020, the number of shares available for issuance under the Tetraphase Pharmaceuticals, Inc. 2013 Stock Incentive Plan, as amended, or 2013 Plan, was increased by approximately 0.1 million shares as a result of the automatic increase provision of the 2013 Plan. As of March 31, 2020, the total number of shares of common stock available for issuance under the 2013 Plan was approximately 0.4 million.

Stock-Based Compensation Expense

During the three months ended March 31, 2020 and 2019, the Company recognized the following stock-based compensation expense (in thousands):

	Three Months Ended March 31,	
	2020	2019
Research and development	$ 106	$ 983
General and administrative	374	1,740
Total	$ 480	$ 2,723

	Three Months Ended March 31,	
	2020	2019
Stock options	$ 366	$ 1,977
Restricted stock units	114	726
Employee stock purchase plan	-	20
Total	$ 480	$ 2,723

Stock Options

The following table summarizes the stock option activity for the three months ended March 31, 2020:

	Shares	Weighted-Average Exercise Price
Outstanding at December 31, 2019	177,768	$ 223.53
Canceled	(29,514)	$ 265.42
Outstanding at March 31, 2020	148,254	$ 215.20
Exercisable at March 31, 2020	113,255	$ 253.33

As of March 31, 2020, there was $2.3 million of total unrecognized stock-based compensation cost related to employee unvested stock options granted under the 2013 Plan. The Company expects to recognize that cost over a remaining weighted-average period of 1.7 years.

Restricted Stock Units and Performance Stock Units

The following table summarizes the restricted stock unit, or RSU, and performance stock unit, or PSU, activity for the three months ended March 31, 2020:

	Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2019	91,981	$ 28.62
Canceled	(19,845)	$ 34.56
Vested/Released	(22,363)	$ 27.03
Unvested at March 31, 2020	49,773	$ 26.97

As of March 31, 2020, there was total unrecognized stock-based expense of $0.7 million related to RSUs and $44,000 related to PSUs. The expense is expected to be recognized over a weighted-average period of 1.5 years.

Employee stock purchase plan

On March 15, 2020, the Company's 2014 Employee Stock Purchase Plan, as amended, was terminated.

9. Stockholders' Equity

On January 17, 2017, the Company entered into a Controlled Equity Offering Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co. as sales agent, or Cantor. On July 7, 2017, the Company entered into an amendment to the Sales Agreement to increase the maximum aggregate offering price of the shares of common stock that it may issue and sell from time to time under the Sales Agreement from $40,000,000 to $80,000,000.

Under the Sales Agreement, as amended, or the Amended Sales Agreement, Cantor may sell shares of the Company's common stock by methods deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on the Nasdaq Global Select Market or on any other existing trading market for the Company's common stock.

The Company is not obligated to make any sales of shares of its common stock under the Amended Sales Agreement. The Company or Cantor may suspend or terminate the offering of shares of the Company's common stock upon notice to the other party and subject to other conditions. The Company will pay Cantor a commission rate equal to 3.0% of the gross proceeds per share sold.

As of March 31, 2020, the Company had sold an aggregate of 305,522 shares of common stock under the Sales Agreement, at an average selling price of approximately $129.80 per share for aggregate gross proceeds of $39.6 million and net proceeds of $38.2 million after deducting sales commissions and offering expenses. The Company did not sell any shares of common stock under the Sales Agreement during the three months ended March 31, 2020. As of May 6, 2020, $40.4 million of common stock remained available to be sold under the Amended Sales Agreement.

On November 1, 2019 the Company completed a registered direct offering with Armistice Capital, LLC, a healthcare-focused institutional investor priced at-the-market, of (i) 300,000 shares of common stock and accompanying warrants to purchase an aggregate of 300,000 shares of common stock, and (ii) pre-funded warrants to purchase up to an aggregate of 1,830,493 shares of common stock and accompanying warrants to purchase an aggregate of 1,830,493 shares of common stock. Each share of common stock and accompanying common stock warrant were sold together at a combined price of $3.755, and each pre-funded warrant and accompanying common stock warrant were sold together at a combined price of $3.745. Each pre-funded warrant has an exercise price of $0.01 per share, is exercisable immediately and is exercisable until exercised in full. Each common stock warrant has an exercise price of $3.62 per share, is exercisable immediately and expires five years from the date of issuance. The net proceeds to the Company from the offering, after deducting the placement agent's fees and other offering expenses payable by the Company, was approximately $7.1 million. The fair value allocated to the common stock, warrants and pre-funded warrants, less issuance costs, was $0.6 million, $2.9 million and $3.6 million, respectively. In November 2019, 400,000 of the pre-funded warrants were exercised.

On January 24, 2020, the Company completed a private placement with Armistice Capital, LLC, a healthcare-focused institutional investor priced at-the-market of (i) 1,270,000 shares of common stock and accompanying warrants to purchase an aggregate of 1,270,000 shares of common stock, and (ii) pre-funded warrants to purchase up to an aggregate of 2,063,334 shares of common stock and accompanying warrants to purchase up to an aggregate of 2,063,334 shares of common stock. Each share of common stock and accompanying common stock warrant were sold together at a combined price of $3.00, and each pre-funded warrant and accompanying common stock warrant were sold together at a combined price of $2.999, for gross proceeds of

approximately $10.0 million. Each pre-funded warrant had an exercise price of $0.001 per share, was exercisable immediately and was exercisable until all of the pre-funded warrants are exercised in full. Each common stock warrant had an exercise price of $2.87 per share, was exercisable immediately and will expire five years from the date of issuance.

Also on January 24, 2020, the Company completed a registered direct offering to certain healthcare-focused institutional investors priced at-the-market, of (i) 2,380,105 shares of common stock and accompanying warrants to purchase up to an aggregate of 2,380,105 shares of common stock, and (ii) pre-funded warrants to purchase up to an aggregate of 120,000 shares of common stock and accompanying warrants to purchase up to an aggregate of 120,000 shares of common stock. Each share of common stock and accompanying common stock warrant were sold together at a combined price of $3.00, and each pre-funded warrant and accompanying common stock warrant were sold together at a combined price of $2.999, for gross proceeds of approximately $7.5 million. Each pre-funded warrant had an exercise price of $0.001 per share, was exercisable immediately and was exercisable until all of the pre-funded warrants are exercised in full. Each common stock warrant had an exercise price of $2.87 per share, was exercisable immediately and will expire five years from the date of issuance.

The net proceeds to the Company from the registered direct offering and the concurrent private placement, after deducting the placement agent's fees and other offering expenses payable by the Company, were approximately $15.9 million.

10. Debt Facility

On November 2, 2018, the Company entered into a loan and security agreement, or the Loan Agreement, with Solar Capital, as collateral agent and lender, and the other lenders named therein (Solar Capital and the other lenders collectively, the Lenders). On August 30, 2019, the Company entered into a payoff letter with the Lenders, pursuant to which the Company agreed to pay off and thereby terminate the Loan Agreement. Pursuant to the payoff letter, the Company paid a total of $30.7 million to the Lenders, representing the principal balance, accrued interest outstanding and a portion of the final fee under the Loan Agreement in repayment of the Company’s outstanding obligations under the Loan Agreement. The Company recorded a loss from debt extinguishment of $1.6 million as the difference between the net carrying amount of the indebtedness under the Loan Agreement and the amount paid.

In connection with the Loan Agreement and the funding of the initial loan facility, the Company issued to the Lenders warrants to purchase an aggregate of 20,718 shares of the Company’s common stock, equal to 3.00% of the term loan funded divided by the exercise price of $43.44. The warrants will terminate 10 years from the date of its original issuance. The warrants were equity classified with a fair value of $0.8 million at issuance and recorded to additional paid in capital.

The Company recorded interest expense related to the loan facility of $1.0 million for the three months ended March 31, 2019.

11. Commitments and Contingencies

Operating Leases

The Company’s leases consist of office equipment and 37,438 square feet of office and laboratory space in Watertown.

On January 31, 2020, the Company amended its existing operating lease in order to surrender a portion of its leased space, reducing the leased premises by a total of 15,899 square feet from approximately 37,438 square feet to approximately 21,539 square feet. The amendment was accounted for as a modification of the original lease agreement which required the Company to reassess and remeasure the lease liability based on the incremental borrowing rate determined as of the modification date. As a result, the amendment to the original lease resulted in a $2.0 million reduction of the lease liability and corresponding right-of-use asset as of the effective date of the amendment, with an immaterial gain recorded to operating expenses.

The components of lease expense were as follows:

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019
Operating lease cost	$ 343	$ 474
Variable lease cost	226	296
Total lease cost	$ 569	$ 770
Weighted-average remaining lease term (years)	2.64	3.65
Weighted-average discount rate	9.25%	9.25%

Cash paid for amounts included in the measurement of the lease liabilities were $0.3 million for the three months ended March 31, 2020.

As of March 31, 2020, the Company's operating lease liabilities were as follows (in thousands):

	Amount
2020	907
2021	1,138
2022	1,027
Thereafter	—
Less: Imputed interest	(386)
Present value of lease payments	$ 2,686

Legal Proceedings

On February 7, 2020, DHL Supply Chain (Netherlands) B.V, or DHL, made an arbitration demand against the Company with Foundation UNUM.

As of May 6, 2020, ten lawsuits have been filed by alleged Tetraphase stockholders against us, members of our board of directors, AcelRx and/or Merger Sub, challenging the Merger.

Please refer to Part II Item 1, *Legal Proceedings*, of this Form 10-Q for further information regarding these matters.

12. Corporate Restructuring Charges

On June 10, 2019, the Company announced a restructuring of its organization, including a 20% reduction in headcount, designed to focus its cash resources on commercializing Xerava. This reorganization included the elimination of its internal research function and an exploration of out-licensing opportunities for all of its pipeline of early-stage antibiotics and oncology product candidates. The Company expects the total costs associated with the restructuring to be $2.4 million, all of which the Company incurred during the three months ended June 30, 2019. The Company expects the restructuring liability to be paid by the third quarter of 2020. The restructuring charges consist primarily of severance and benefit costs and asset impairment costs, offset in part by stock-based compensation adjustments associated with award modifications.

The restructuring charges recorded during the year ended December 31, 2019 and the related liability balance as of March 31, 2020 for each major type of cost associated with this restructuring plan are as follows:

	Restructuring Expense	Cash payments	Non-cash expense	Restructuring Liability at March 31, 2020
Employee severance, benefits and related costs	$ 2,130	$ (1,812)	$ —	$ 318
Asset impairments	335	-	(335)	-
Compensation expense	(97)	-	97	-
	$ 2,368	$ (1,812)	$ (238)	$ 318

13. Subsequent Event

On April 22, 2020, the Company entered into a promissory note evidencing the $2.3 million PPP Loan under the PPP.

The PPP Loan is evidenced by a promissory note, dated as of April 22, 2020 (the "Note"), between the Company, as borrower, and Silicon Valley Bank, N.A., as lender ("SVB"). The interest rate on the Note is 1.0% per annum, with interest accruing on the unpaid principal balance computed on the basis of the actual number of days elapsed in a year of 360 days. No payments of principal or interest are due during the six-month period beginning on the date of the Note (the "Deferral Period").

Beginning one month following expiration of the Deferral Period, and continuing monthly until 24 months from the date of the Note (the "Maturity Date"), the Company is obligated to make monthly payments of principal and interest to SVB with respect to any unforgiven portion of the Note, in such equal amounts required to fully amortize the principal amount outstanding on the Note as of the last day of the Deferral Period by the Maturity Date. The Company is permitted to prepay the Note at any time without payment of any premium.

The principal and accrued interest under the Note evidencing the PPP Loan are forgivable after eight weeks as long as the Company has used the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and maintains its payroll levels. The amount of loan forgiveness will be reduced if the Company terminates employees or reduces salaries during the eight-week period. The Company will be obligated to repay any portion of the principal amount of the Note that is not forgiven, together with interest accrued and accruing thereon at the rate set forth above, until such unforgiven portion is paid in full.

Upon a default under the Note, including the non-payment of principal or interest, the obligations of the Company under the Note may be accelerated and SVB may pursue its rights under the Uniform Commercial Code and any other applicable law or in equity.

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

The interim financial statements included in this Quarterly Report on Form 10-Q and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2019, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in our Annual Report on Form 10-K filed with the United States Securities and Exchange Commission, or the SEC, on March 12, 2020, which we refer to as our Annual Report. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company using our proprietary chemistry technology to create, develop and commercialize novel tetracyclines for serious and life-threatening conditions, including bacterial infections caused by multidrug-resistant, or MDR, bacteria. There is a medical need for new antibiotics as resistance to existing antibiotics increases. In recognition of this need, we developed our product, Xerava (eravacycline), a fully synthetic fluorocycline, as an intravenous, or IV antibiotic for use as a first-line empiric monotherapy for the treatment of MDR infections, including MDR Gram-negative infections, such as those found in complicated intra-abdominal infections, or cIAI.

On March 15, 2020, we entered into an agreement and plan of merger, or Merger Agreement, with AcelRx Pharmaceuticals, Inc., a Delaware corporation, or AcelRx, and Consolidation Merger Sub, Inc., a Delaware corporation and an indirect wholly owned subsidiary of AcelRx, or Merger Sub. The Merger Agreement provides for, among other things, our acquisition by AcelRx, with the acquisition to be accomplished through the merger of Merger Sub with and into us, with us surviving as an indirect wholly owned subsidiary of AcelRx. The Company's Board of Directors has unanimously approved the Merger and the Merger Agreement and recommended that stockholders adopt the Merger Agreement. The Company submitted the Merger Agreement to its stockholders for their consideration at a special meeting of stockholders to be held on June 8, 2020.

We have also entered into a co-promotion agreement with AcelRx, or Co-Promotion Agreement, under which the parties have agreed that, during the term of the agreement, their sales forces will promote and detail the other party's products in accordance with marketing plans agreed to by the parties and subject to specified minimum call requirements. The Co-Promotion Agreement will continue in effect even if the Merger Agreement is terminated.

On August 27, 2018, the United States Food and Drug Administration, or FDA, approved Xerava for the treatment of cIAI in adults. Approval of Xerava was based on our IGNITE (**I**nvestigating **G**ram-**N**egative **I**nfections **T**reated with **E**ravacycline) phase 3 program. In the first pivotal phase 3 trial in the IGNITE program in patients with cIAI, twice-daily IV Xerava met the primary endpoint by demonstrating statistical non-inferiority of clinical response compared to ertapenem, a carbapenem and a standard of care treatment for cIAI, and was well-tolerated. We refer to this trial as IGNITE1. In our other pivotal phase 3 clinical trial of Xerava in patients with cIAI, twice-daily IV Xerava met the primary endpoint by demonstrating statistical non-inferiority of clinical response compared to meropenem, another standard of care treatment, and was well-tolerated. We refer to this trial as IGNITE4. In both IGNITE1 and IGNITE4, Xerava achieved high cure rates in patients with poly-microbial infections (Gram-negative, Gram-positive, and anaerobic infections), including resistant isolates.

In October 2018, we commenced sales of Xerava in the United States. We are commercializing Xerava in the United States using a small, targeted commercial and medical affairs groups to build and promote access to Xerava. As of April 30, 2020, we have approximately 19 sales representatives, 2 regional business directors, 3 strategic market access executives and approximately 5 medical affairs personnel supporting Xerava in the United States. In connection with the Co-Promotion Agreement, we reduced the size of our commercial group by eight people.

On September 20, 2018, based on the results of IGNITE1, the European Commission, or EC, granted marketing authorization for Xerava for the treatment of cIAI in adults in all 28 countries of the European Union, or EU, plus Norway, Iceland and Liechtenstein. We are not selling Xerava in the EU. In February 2018 we entered into a license agreement with Everest Medicines Limited, or Everest Medicines, granting Everest Medicines commercialization rights to eravacycline in China and other Asian territories. In June 2018, Everest Medicines submitted an Investigational New Drug, or IND, application to the China National Medical Products Administration (formerly China FDA) for a phase 3 clinical trial of eravacycline in cIAI. The application was approved, and Everest Medicines began enrolling patients in this phase 3 trial in the second quarter of 2019. In April 2020, Everest Medicines notified us that its new drug application in Singapore had been approved. Everest Medicines expects to begin commercializing Xerava in Singapore later in 2020.

In addition to Xerava, we have also developed other fluorocycline antibiotic compounds, TP-6076 and TP-271, and TP-2846, a tetracycline for the treatment of acute myeloid leukemia. We developed TP-6076, a fully-synthetic fluorocycline derivative, as a lead candidate under our second-generation program to target unmet medical needs, including MDR Gram-negative bacteria such as carbapenem-resistant Enterobacteriaceae and carbapenem-resistant or pan-resistant *Acinetobacter baumanii*. To date, we have conducted phase 1 single-ascending and multiple-ascending dose studies evaluating the safety, tolerability and pharmacokinetics of IV TP-6076 in healthy volunteers. We also conducted a Phase 1 study to assess the bronchopulmonary disposition, pharmacokinetics and safety of TP-6076 in healthy volunteers. TP-271 is a fully-synthetic fluorocycline that we developed for respiratory disease caused by bacterial biothreat and antibiotic-resistant public health pathogens, as well as bacterial pathogens associated with community-acquired bacterial pneumonia. To date, we have completed single-ascending and multiple-ascending dose trials for IV and oral formulations of TP-271. We have completed pre-clinical toxicology studies for TP-2846.

In June 2019, we announced a restructuring of our organization, including a 20% reduction in headcount, designed to focus our cash resources on commercializing Xerava primarily in the hospital setting. This reorganization included the elimination of our internal research function. As part of our restructuring, we decided not to engage in further product development, including conducting clinical trials of our product candidates, and intend to seek out-licensing opportunities for all of our pipeline of early-stage antibiotics and oncology product candidates.

We commenced business operations in July 2006. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our proprietary chemistry technology, identifying potential product candidates, undertaking preclinical studies and clinical trials of our product candidates and conducting commercial sales of Xerava. Prior to October 2018, when we commenced sales of Xerava in the United States, we had not generated any product revenues. We have financed our operations primarily through the public offerings and private placements of our equity securities, debt financings, revenue from United States government grants and contract awards, milestone payments from our licensing agreement and product revenue from sales of Xerava. As of March 31, 2020, we had received an aggregate of $612.1 million in net proceeds from the issuance of equity securities and borrowings under debt facilities, an aggregate of $61.0 million from government grants and contracts and an aggregate of $14.5 million from licensing agreement milestone payments. As of March 31, 2020, our principal source of liquidity was cash and cash equivalents, which totaled $26.1 million.

On April 22, 2020, we entered into a promissory note evidencing an unsecured $2.3 million loan, or the PPP Loan, under the Paycheck Protection Program, or the PPP, which was established as part of the Coronavirus Aid, Relief, and Economic Security Act. The interest rate on the PPP Loan is 1.0% per annum, and no payments of principal or interest are due during the six-month period beginning on the date of the PPP Loan. Beginning one month following such period and continuing monthly until 24 months from the date of the PPP Loan, we are obligated to make monthly payments of principal and interest. We are permitted to prepay the PPP Loan at any time without payment of any premium. The principal and accrued interest under the Note evidencing the PPP Loan may be forgivable. See “Liquidity and Capital Resources.”

As of March 31, 2020, we had an accumulated deficit of $616.3 million. Our net losses were $12.1 million and $19.5 million for the three months ended March 31, 2020 and 2019, respectively. We expect that our expenses will decrease in 2020 compared with 2019, driven by lower costs associated with development of Xerava, our 2019 reorganization and a gradual decrease in Xerava sales and marketing expenses.

Based on our current operating plan, and assuming that the Merger is not consummated when expected, we expect that our cash and cash equivalents of $26.1 million as of March 31, 2020, and our projected revenues from sales of Xerava, together with the $2.3 million in proceeds from our PPP Loan received in April 2020, will be sufficient to fund our operations into the first quarter of 2021 but will not be sufficient to fund our operations for more than one year beyond the filing date of this Quarterly Report on Form 10-Q. This estimate is based on certain significant assumptions, which are uncertain and may turn out to be incorrect. In particular, the forecast assumes continued significant growth of Xerava revenue, for which we have limited historical experience to base our estimate. In addition, we have forecast a significant reduction in expenses in 2020 as a result of the restructuring implemented in June 2019. If these estimates are incorrect, we may use our cash resources sooner than expected.

As of March 31, 2020, management has further assessed this risk and, in accordance with the requirements of Accounting Standards Update No. 2014-15, *Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (Subtopic 205-40)*, or ASC 205-40, has determined that there is substantial doubt about our ability to continue as a going concern. There is no assurance that we will be successful in consummating the Merger and, if we do not, in obtaining additional financing on terms acceptable to us, if at all, nor is it considered probable under the accounting standards. As such, under the requirements of ASC 205-40, management may not consider the potential for future capital raises or management plans to reduce costs that are not considered probable in the assessment of our ability to meet our obligations.

If the Merger is not consummated, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources to fund our operations including ongoing spending to commercialize Xerava. However, there can be no assurance that we will be able to obtain such funding on terms acceptable to us, on a timely basis or at all. If the Merger is not consummated and we are unable to obtain funding, we may be required to delay, reduce or eliminate our commercialization efforts, which could adversely affect our business prospects, and we may be unable to continue operations.

If the Merger is not consummated and we are unable to raise additional capital when needed or if our operating results fall short of its current projections, or if we determine to explore strategic alternatives but are unable to consummate such a transaction or transactions on a timely basis or at all, we could be forced to significantly delay, scale back or discontinue the commercialization of Xerava or reduce other expenditures, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, our rights to Xerava and our product candidates. Our failure to obtain sufficient funds on acceptable terms when needed would have a material adverse effect on our business, results of operations and financial condition. In addition, in such circumstances, we would consider seeking protection under the bankruptcy laws in order to continue to pursue potential transactions and conduct a wind-down of our company. If we decide to seek protection under the bankruptcy laws, we would expect that we would file for bankruptcy at a time that is significantly earlier than when we would otherwise exhaust our cash resources. If we decide to dissolve and liquidate our assets or to seek protection under the bankruptcy laws, it is unclear to what extent we will be able to pay our obligations, and, accordingly, it is further unclear whether and to what extent any resources will be available for distributions to stockholders. See “Liquidity and Capital Resources—Operating Capital Requirements.”

Impact of COVID-19 on our Business

The spread of SARS-CoV-2 and the resulting disease COVID-19 during the first quarter of 2020 has caused a global economic downturn and resulted in significant volatility in financial markets. In March 2020 the World Health Organization declared COVID-19 a pandemic. As of May 6, 2020, we have not experienced a significant financial or supply chain impact directly related to the pandemic. In this time of uncertainty as a result of the COVID-19 pandemic, we continue to serve our customers and take precautions to provide a safe work environment for our employees. We have implemented a work from home policy for our employees. We have also continued to make internal resource allocation decisions in order to deliver on key business objectives, to increase our financial flexibility and to ensure the success of the Merger. We may have to take further actions that we determine are in the best interests of our employees or as required by federal, state, or local authorities.

The extent of the pandemic’s effect on our operational and financial performance will depend in large part on future developments, which cannot be predicted with confidence at this time. Future developments include changes in the duration, scope and severity of the pandemic, the actions taken to contain or mitigate its impact, the impact on governmental programs and budgets, the development of treatments or vaccines, and the resumption of widespread economic activity. Any prolonged material disruption of the Company’s employees, suppliers, manufacturing or customers could negatively impact its consolidated financial position, consolidated results of operations and consolidated cash flows.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, was enacted in response to the COVID-19 pandemic. The CARES Act, along with other provisions, permits carryovers and carrybacks of net operating losses generated from 2018 through 2020 to offset 100% of taxable income. In addition, the CARES Act allows net operating losses incurred in 2018, 2019 and 2020 to be carried back to each of the five preceding taxable years to generate refund of previously paid income taxes. We are currently evaluating the impact of the CARES Act, but at present we do not expect it to have a material impact on our financial statements.

Financial Overview

Product Revenue

Our lead product, Xerava, received approval on August 27, 2018 for the treatment of cIAI in adults. Following FDA approval of Xerava in the United States, we began selling Xerava in October 2018. We sell Xerava to a limited number of specialty distributors in the United States, who collectively represent our customers. These customers subsequently resell Xerava to hospitals or other treatment centers. In addition to the agreements with these distributors and the related discounts and fees, we are subject to government mandated rebates, chargebacks, and discounts with respect to the purchase of Xerava. Product revenue is recognized net of reserves for all variable consideration, including discounts, chargebacks, government rebates and product returns. For further discussion of our product revenue, see Note 2, Summary of Significant Accounting Policies to the interim condensed consolidated financial statements in this Form 10-Q.

Collaboration Revenue

In February 2018, we entered into a license agreement with Everest Medicines, whereby we granted Everest Medicines an exclusive license to develop and commercialize eravacycline, for the treatment of cIAI and other indications, in mainland China, Taiwan, Hong Kong, Macau, South Korea and Singapore. We amended this agreement in July 2019 to extend Everest Medicines' exclusive license to develop and commercialize Xerava to the jurisdictions of the Malaysian Federation, the Kingdom of Thailand, the Republic of Indonesia, the Socialist Republic of Vietnam and the Republic of the Philippines. Terms of this arrangement include various payment types, including upfront license fees, development, regulatory and commercial milestone payments, payments for clinical supply services and royalties on sales revenue. For further discussion of the Everest Medicines collaboration and the related revenue recognition, please see Note 6, Significant Agreements and Contracts to the interim condensed consolidated financial statements.

Government and Grant Revenue

Our government revenue has been derived from funding provided under four awards, all of which have terminated. These awards include a contract from the Biomedical Advanced Research and Development Authority, or BARDA, an agency of the U.S. Department of Health and Human Services, for the development of Xerava for the treatment of disease caused by bacterial biothreat pathogens, two separate awards from the National Institute of Allergy and Infectious Diseases, or NIAID, a division of the National Institutes of Health, for the development of TP-271. These three awards were made to CUBRC, Inc., or CUBRC, an independent, not-for-profit, research corporation that specializes in United States government-based contracts, with which we are collaborating. CUBRC serves as the prime contractor under these awards, primarily carrying out a program management and administrative role with additional responsibility for the management of preclinical studies. The fourth award is from Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator, or CARB-X, an international public-private partnership focused on advancing new antimicrobial products to address the threat of antibiotic resistance. For further discussion of our contract and grant revenue agreements and the related revenue recognition, please see Note 6, Significant Agreements and Contracts to the consolidated financial statements.

Cost of Revenue

Cost of revenue consists primarily of the manufacturing and distribution costs for Xerava, Xerava net sales-based royalties and the amortization of the intangible asset associated with certain milestones paid to Harvard University, or Harvard, related to Xerava. All manufacturing costs incurred prior to Xerava's approval in the United States on August 27, 2018 have been expensed in research and development and are not included in cost of revenue.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the research and development of our preclinical and clinical candidates, and include:

- personnel-related expenses, including salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with contract research organizations, contract manufacturing organizations, and consultants that provide preclinical, clinical, regulatory and manufacturing services;
- certain payments made under our license agreement with Harvard;
- the cost of acquiring, developing and manufacturing clinical trial materials and lab supplies;
- facility, depreciation and other expenses, which include direct and allocated expenses for rent, maintenance of our facilities, insurance and other supplies;
- costs associated with preclinical and regulatory activities.

We expense research and development costs to operations as incurred. We recognize costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors.

We track external development expenses and personnel expense on a program-by-program basis and allocate common expenses, such as scientific consultants and laboratory supplies, to each program based on the personnel resources allocated to such program. Expenses related to facilities, consulting, travel, conferences, stock-based compensation and depreciation are not allocated to a program and are separately classified as other research and development expenses. The following table summarizes our research and development expenses on a program-specific basis for the three months ended March 31, 2020 and 2019:

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Xerava	$ 1,455	$ 2,296
BARDA Contract	—	472
TP-6076	—	512
CARB-X Award	—	301
NIAID Contract	—	88
Other development programs	88	1,023
Other research and development	350	2,045
Total research and development expenses	$ 1,893	$ 6,737

Prior to our June 2019 reorganization, research and development activities were central to our business model. As part of our reorganization, we decided not to engage in further research and development, including conducting clinical trials of our product candidates. Instead, we intend to seek to out-license each of our pipeline candidates.

As of March 31, 2020, we had incurred an aggregate of $300.2 million in research and development expenses related to the development of Xerava, and $38.7 million in research and development expenses related to the development of Xerava that were funded under the BARDA Contract.

We have licensed our proprietary chemistry technology from Harvard on an exclusive worldwide basis under a license agreement that we entered into in August 2006. Under our license agreement, as of March 31, 2020, we have incurred expense in aggregate of $16.8 million in up front license fees, sublicense fee and development milestone payments for the licensed Harvard technology. We have also issued 1,568 shares of our common stock to Harvard under the license agreement. We have also agreed to make payments to Harvard upon the achievement of specified future development and regulatory milestones totaling up to $15.1 million for each licensed product candidate ($12.6 million of which has already been paid with respect to eravacycline), and to pay tiered royalties in the single digits based on annual worldwide net sales, if any, of licensed products, by us, our affiliates and our sublicensees. We are also obligated to pay Harvard a specified share of non-royalty sublicensing revenues that we receive from sublicensees for the grant of sublicenses under the license and to reimburse Harvard for specified patent prosecution and maintenance costs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist principally of personnel-related costs, including salaries and related costs such as benefits and stock-based compensation for personnel in executive, finance, legal, operational, corporate communications, sales, marketing, regulatory, medical affairs and human resource functions. Other significant general and administrative expenses include professional fees for legal, patent, auditing and tax services, consulting and facility costs not otherwise included in research and development expenses.

We anticipate that our selling, general and administrative expenses will plateau or decrease for a number of reasons, including a decrease of infrastructure, including reductions in personnel-related costs, consulting, legal, and accounting costs.

Other Income (Expense)

Other income (expense) consists primarily of interest income and interest expense. Interest income consists of interest earned on our cash and cash equivalents. The primary objective of our investment policy is capital preservation. We did not have any interest expense for the three months ended March 31, 2020. Interest expense for the three months ended March 31, 2019 consisted primarily of interest accrued on our outstanding indebtedness and non-cash interest related to the amortization of debt discount costs associated with our term loan facility with Solar Capital which was paid in full in August 2019.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, 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 and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, accrued clinical expenses, and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we and our management believe to be reasonable under the circumstances. The results of these estimates 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.

Our critical accounting policies are those which require the most significant judgments and estimates in the preparation of our consolidated financial statements. We have determined that our most critical accounting policies are those relating to product revenue recognition, collaboration revenue recognition, government contract and grant revenue recognition and equity compensation. There have been no significant changes to our critical accounting policies as described under Management's Discussion and Analysis of Financial Condition and Results of Operations in our annual report, filed on form 10-K with the SEC on March 12, 2020, for the year ended December 31, 2019.

Results of Operations

Comparison of the Three Months Ended March 31, 2020 and 2019

The following table summarizes the results of our operations for the three months ended March 31, 2020 and 2019, together with the changes in those items in dollars:

	Three Months Ended March 31,		Increase/ (decrease)
	2020	2019	
	(in thousands)		
Revenue:			
Product revenue, net	$ 1,755	$ 341	1,414
Government revenue	-	932	(932)
Total revenue	1,755	1,273	482
Operating expenses:			
Cost of revenue - product sales	1,360	164	1,196
Cost of revenue - intangible asset amortization	98	98	-
Research and development	1,893	6,737	(4,844)
Selling, general and administrative	10,668	13,314	(2,646)
Total operating expenses	14,019	20,313	(6,294)
Loss from operations	(12,264)	(19,040)	6,776
Other income	71	-	71
Interest income	69	507	(438)
Interest expense	-	(955)	955
Net loss	$ (12,124)	$ (19,488)	$ 7,364

Product Revenue

We initiated sales of Xerava in the United States on October 15, 2018. For the three months ended March 31, 2020 net sales of Xerava were $1.8 million. The increase in product revenue, net for the three months ended March 31, 2019 is primarily the result of increased sales volume of Xerava.

Revenue from U.S. Government Contracts and Grants

We had no government revenue for the three months ended March 31, 2020 compared to $0.9 million for the three months ended March 31, 2019. Our BARDA Contract, NIAID Contract and CARB-X Award each expired in 2019.

Cost of Revenue

Cost of product revenues for the three months ended March 31, 2020 was $1.5 million compared to $0.3 million for the three months ended March 31, 2019. Cost of product revenue consists primarily of manufacturing and distribution costs for Xerava, Xerava net sales-based royalties and the amortization of the intangible asset associated with certain milestones paid to Harvard related to Xerava. This increase was due to both increased sales of Xerava in 2020 as well as certain cost elements of inventory sold in 2019 being expensed in periods prior to the product's approval in August 2018.

Research and Development Expenses

Research and development expenses for the three months ended March 31, 2020 were $1.9 million compared to $6.7 million for the three months ended March 31, 2019, a decrease of $4.8 million. This decrease was primarily due to the completion of Xerava development and our restructuring in June 2019, which included the cessation of development of our pipeline candidates.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended March 31, 2020 were $10.7 million compared to $13.3 million for the three months ended March 31, 2019, a decrease of $2.6 million. The decrease was driven by our 2019 corporate reorganization as well as tight expense control during the three months ended March 31, 2020, partially offset by expenses related to the Merger announced in March 2020.

Other Income (Expense)

Interest expense decreased by $1.0 million for the three months ended March 31, 2020 due to early payment of our term loan facility in August 2019. Interest income decreased by $0.4 million related to the year-over-year decrease in cash and cash equivalents. For the three-month period ended March 31, 2020, we also recorded a one-time gain from our lease modification and asset sale totaling $0.1 million.

Liquidity and Capital Resources

We have incurred losses since our inception and anticipate that we will continue to incur losses for at least the next several years. We expect our total expenses to decrease but remain significant in 2020 and, as a result, if we do not consummate the Merger, we will need additional capital to fund our operations, which we may obtain from additional financings, research funding, collaborations, government contract and grant revenue or other sources.

Since our inception, we have funded our operations primarily through the public offerings and private placements of our equity securities, debt financings, revenue from U.S. government grants and contract awards, milestone payments from our licensing agreement and product revenue from sales of Xerava.

As of March 31, 2020, we had cash and cash equivalents of approximately $26.1 million. We invest cash in excess of immediate requirements in accordance with our investment policy, primarily with a view to liquidity and capital preservation. As of March 31, 2020, our funds were held in cash and money market funds.

On January 17, 2017, we entered into a Controlled Equity Offering Sales Agreement, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, as sales agent. On July 7, 2017, we entered into an amendment to the sales agreement, or the Amended Sales Agreement. In accordance with the terms of the Amended Sales Agreement, we may offer and sell through Cantor, from time to time, shares of our common stock up to an aggregate offering price of $80,000,000 through an "at-the-market" offering program. As of March 31, 2020, we had sold an aggregate of 305,522 shares under the agreement at an average price of $129.80 per share and we had received aggregate cash proceeds of $38.2 million, after deducting sales commissions and offering expenses. Under the Amended Sales Agreement, Cantor may sell shares of our common stock by methods deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on the Nasdaq Global Select Market or on any other existing trading market for our common stock. We are not obligated to make any sales of shares of our common stock under the Amended Sales Agreement. We or Cantor may suspend or terminate the offering of shares of our common stock upon notice to the other party and subject to other conditions. We will pay Cantor a commission rate equal to 3.0% of the gross proceeds per share sold. We have not sold any shares under the Amended Sales Agreement during 2019 or during the three months ended March 31, 2020

On November 2, 2018, we entered into the loan and security agreement, or the Loan Agreement, with Solar Capital, as collateral agent and lender, and the other lenders named therein (Solar Capital and the other lenders collectively, the Lenders). The Lenders agreed to make available to us term loans in an aggregate principal amount of up to $75.0 million under the Loan Agreement. The Loan Agreement provided a term loan commitment of $50.0 million in two potential tranches: (i) a $30.0 million Term A loan facility funded on November 2, 2018 and (ii) a $20.0 million Term B loan facility to be funded at the request of the Company no later than October 31, 2020, subject to (a) the Company having unrestricted net cash proceeds of not less than $50 million from the issuance and sale of common stock and/or from other business activities and (b) the Company having product revenue greater than or equal to $14.0 million on a six month trailing basis prior to September 30, 2020. Both of these term loans had a maturity date of May 2, 2023. The Loan Agreement also provided access to an additional Term C loan facility in the amount of $25.0 million, to be funded at the Lenders' sole discretion.

In connection with the Loan Agreement and the funding of the Term A facility, we issued to the Lenders warrants to purchase an aggregate of 20,718 shares of our common stock, equal to 3.00% of the term loan funded divided by the exercise price of $43.44. Each warrant will terminate 10 years from the date of its original issuance.

On August 30, 2019, we paid the Lenders a total of $30.7 million representing the principal balance, accrued interest outstanding and a portion of the final fee under the Loan Agreement in repayment of our outstanding obligations under the Loan Agreement. Upon the payment of the $30.7 million, all our outstanding indebtedness and obligations owing to the Lenders under the Loan Agreement were deemed paid in full. The Loan Agreement and the notes thereunder, as well as the security interests in the assets of the Company securing the Loan Agreement and note obligations, were terminated. The Lenders retained the warrants issued to them in connection with the origination of the Loan Agreement obligations.

On June 24, 2019, we received a deficiency letter from the Listing Qualifications Department of the Nasdaq Stock Market notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusions on the Nasdaq Global Select Market, referred to as the minimum bid price rule. On September 26, 2019 we effected a 1-for-20 reverse stock split for the purpose of regaining compliance with the minimum bid price rule.

On October 11, 2019, we received notification from the Listing Qualifications Department of the Nasdaq Stock Market that for 10 consecutive business days, the closing bid price of our common stock had been at $1.00 per share or greater, confirming that we had regained compliance with the minimum bid price rule.

On November 1, 2019, we completed a registered direct offering to Armistice Capital, LLC, a healthcare-focused institutional investor, or Armistice, priced at-the-market, of (i) 300,000 shares of common stock and accompanying warrants to purchase an aggregate of 300,000 shares of common stock, and (ii) pre-funded warrants to purchase up to an aggregate of 1,830,493 shares of common stock and accompanying warrants to purchase an aggregate of 1,830,493 shares of common stock. Each share of common stock and accompanying common stock warrant were sold together at a combined price of $3.755, and each pre-funded warrant and accompanying common stock warrant were sold together at a combined price of $3.745. Each pre-funded warrant has an exercise price of $0.01 per share, is exercisable immediately and is exercisable until exercised in full. Each common stock warrant has an exercise price of $3.62 per share, is exercisable immediately and expires five years from the date of issuance. The net proceeds from the offering, after deducting the placement agent's fees and other offering expenses payable by us, are approximately $7.1 million.

On January 24, 2020, we completed a private placement with Armistice priced at-the-market of (i) 1,270,000 shares of common stock and accompanying warrants to purchase an aggregate of 1,270,000 shares of common stock, and (ii) pre-funded warrants to purchase up to an aggregate of 2,063,334 shares of common stock and accompanying warrants to purchase up to an aggregate of 2,063,334 shares of common stock. Each share of common stock and accompanying common stock warrant were sold together at a combined price of $3.00, and each pre-funded warrant and accompanying common stock warrant were sold together at a combined price of $2.999, for gross proceeds of approximately $10 million. Each pre-funded warrant had an exercise price of $0.001 per share, was exercisable immediately and was exercisable until all of the pre-funded warrants are exercised in full. Each common stock warrant had an exercise price of $2.87 per share, was exercisable immediately and will expire five years from the date of issuance.

Also on January 24, 2020, we completed a registered direct offering to certain institutional investors priced at-the-market, of (i) 2,380,105 shares of common stock and accompanying warrants to purchase up to an aggregate of 2,380,105 shares of common stock, and (ii) pre-funded warrants to purchase up to an aggregate of 120,000 shares of common stock and accompanying warrants to purchase up to an aggregate of 120,000 shares of common stock. Each share of common stock and accompanying common stock warrant were sold together at a combined price of $3.00, and each pre-funded warrant and accompanying common stock warrant were sold together at a combined price of $2.999, for gross proceeds of approximately $7.5 million. Each pre-funded warrant had an exercise price of $0.001 per share, was exercisable immediately and was exercisable until all of the pre-funded warrants are exercised in full. Each common stock warrant had an exercise price of $2.87 per share, was exercisable immediately and will expire five years from the date of issuance.

The net proceeds from the concurrent January 2020 private placement and registered direct offering, after deducting the placement agent's fees and other estimated offering expenses payable by us, were approximately $15.9 million.

On April 22, 2020, we entered into a promissory note evidencing the PPP Loan under the PPP. The PPP Loan is evidenced by a promissory note, dated as of April 22, 2020, or the Note, between us, as borrower, and Silicon Valley Bank, N.A., as lender, or SVB. The interest rate on the Note is 1.0% per annum, with interest accruing on the unpaid principal balance computed on the basis of the actual number of days elapsed in a year of 360 days. No payments of principal or interest are due during the six-month period beginning on the date of the Note, or the Deferral Period.

Beginning one month following expiration of the Deferral Period, and continuing monthly until 24 months from the date of the Note, or the Maturity Date, we are obligated to make monthly payments of principal and interest to SVB with respect to any unforgiven portion of the Note, in such equal amounts required to fully amortize the principal amount outstanding on the Note as of the last day of the Deferral Period by the Maturity Date. We are permitted to prepay the Note at any time without payment of any premium.

The principal and accrued interest under the Note evidencing the PPP Loan are forgivable after eight weeks as long as we have used the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and maintain our payroll levels. The amount of loan forgiveness will be reduced if we terminate employees or reduce salaries during the eight-week period. We will be obligated to repay any portion of the principal amount of the Note that is not forgiven, together with interest accrued and accruing thereon at the rate set forth above, until such unforgiven portion is paid in full.

Upon a default under the Note, including the non-payment of principal or interest, our obligations under the Note may be accelerated and SVB may pursue its rights under the Uniform Commercial Code and any other applicable law or in equity.

The following table summarizes our sources and uses of cash for each of the periods set forth below (in thousands):

	Three Months Ended March 31,	
	2020	2019
Cash Flows from Operations:		
Net cash used in operating activities	$ (11,155)	$ (20,119)
Net cash provided by (used in) investing activities	130	(98)
Net cash provided by financing activities	15,932	-
Net decrease in cash and cash equivalents	$ 4,907	$ (20,217)

Cash Flows from Operating Activities. The $9.0 million decrease in cash used in operating activities for the three months ended March 31, 2020, compared to the three months ended March 31, 2019, was primarily due to our 2019 corporate restructuring and decision not to engage in further research and development, including conducting clinical trials of our product candidates.

Cash Flows from Investing Activities. The $0.2 million net increase in cash provided by investing activities for the three months ended March 31, 2020, compared to the three months ended March 31, 2019 was related to proceeds from the sales of lab equipment during the three months ended March 31, 2020 offset by asset additions during the three months ended March 31, 2019.

Cash Flows from Financing Activities. The $15.9 million increase in cash provided in financing activities for the three months ended March 31, 2020, was due to net proceeds provided by the private placement and registered direct offering completed in January 2020.

Operating Capital Requirements

We expect to incur significant operating losses for at least the next several years as we commercialize Xerava and satisfy our obligations under our license agreement with Harvard.

Based on our current operating plan, and assuming that the Merger is not consummated when expected, we expect that our cash and cash equivalents of $26.1 million as of March 31, 2020, and our projected revenues from the sales of Xerava, together with the $2.3 million in proceeds from the PPP Loan received in April 2020, will be sufficient to fund our operations into the first quarter of 2021 but will not be sufficient to fund our operations for more than one year beyond the filing date of this Quarterly Report on Form 10-Q. This estimate is based on certain significant assumptions, which are uncertain and may turn out to be incorrect. In particular, the forecast assumes continued significant growth of Xerava revenue, for which we have limited historical experience to base our estimate. In addition, we have forecast a significant reduction in expenses in 2020 as a result of the restructuring announced in June 2019. If these estimates are incorrect, we may use our cash resources sooner than expected.

If the Merger is not consummated, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources to fund our operations including ongoing spending to commercialize Xerava. However, there can be no assurance that we will be able to obtain such funding on terms acceptable to us, on a timely basis or at all. If the Merger is not consummated and we are unable to obtain funding, we may be required to delay, reduce or eliminate our commercialization efforts, which could adversely affect our business prospects, and we may be unable to continue operations.

If the Merger is not consummated and we are unable to raise additional capital when needed or if our operating results fall short of its current projections, or if we determine to explore strategic alternatives but are unable to consummate such a transaction or transactions on a timely basis or at all, we could be forced to significantly delay, scale back or discontinue the commercialization of Xerava or reduce other expenditures, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, our rights to Xerava and our product candidates. Our failure to obtain sufficient funds on acceptable terms when needed would have a material adverse effect on our business, results of operations and financial condition. In addition, in such circumstances, we would consider seeking protection under the bankruptcy laws in order to continue to pursue potential transactions and conduct a wind-down of our company. If we decide to seek protection under the bankruptcy laws, we would expect that we would file for bankruptcy at a time that is significantly earlier than when we would otherwise exhaust our cash resources. If we decide to dissolve and liquidate our assets or to seek protection under the bankruptcy laws, it is unclear to what extent we will be able to pay our obligations, and, accordingly, it is further unclear whether and to what extent any resources will be available for distributions to stockholders.

We have based our projections of operating capital requirements and revenues on assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect. However, because of the numerous risks and uncertainties associated with the commercialization of pharmaceutical products such as Xerava, our estimates of our operating capital requirements may be incorrect. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, although we intend to seek out-licensing opportunities for our pipeline of early-stage antibiotics and oncology product candidates, there can be no assurance that we will be able to out-license these on a timely basis or on terms that are favorable to us, or at all. Our failure to raise capital through financing or a license of our pipeline as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We could be forced to significantly scale back or discontinue the commercialization of Xerava and reduce other expenditures, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, our rights to Xerava and our product candidates. In addition, in such circumstance, we would consider seeking protection under the bankruptcy laws in order to continue to pursue potential transactions and conduct a wind-down of our company. If we decide to seek protection under the bankruptcy laws, we would expect that we would file for bankruptcy at a time that is significantly earlier than when we would otherwise exhaust our cash resources. If we decide to dissolve and liquidate our assets or to seek protection under the bankruptcy laws, it is unclear to what extent we will be able to pay our obligations, and, accordingly, it is further unclear whether and to what extent any resources will be available for distributions to stockholders. Our future funding requirements, both short-term and long-term, will depend on many factors, including, but not limited to:

- revenues received from commercial sales of Xerava;
- our ability to enter into collaborations, licensing, marketing, distribution or other arrangements with respect to Xerava and our product candidates, and the terms and timing of any such arrangements into which we enter;
- the timing and costs of manufacturing and other activities in connection with the commercialization of Xerava;

- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay to Harvard University, or Harvard, and other licenses under license agreements to which we may be a party;
- the costs of maintaining and protecting our intellectual property rights and defending against intellectual property related claims;
- the extent to which we in-license or acquire other products and technologies; and
- our ability to continue as a going concern.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Contractual Obligations

There were no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed in our Annual Report.

Recent Accounting Pronouncements

Refer to Note 2, *Summary of Significant Accounting Policies*, in the accompanying notes to the condensed consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and senior vice president, finance, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2020. In designing and evaluating our disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our chief executive officer and senior vice president, finance concluded that as of March 31, 2020, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our management including our principal executive officer and principal financial officer by others, particularly during the period in which this Quarterly Report on Form 10-Q was prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

The certifications of our principal executive officer and principal financial officer attached as Exhibits 31.1 and 31.2 to this report include, in paragraph 4 of such certifications, information concerning our disclosure controls and procedures and internal controls over financial reporting.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934 during the first quarter of 2020 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

On February 7, 2020, DHL Supply Chain (Netherlands) B.V, or DHL, made an arbitration demand against the Company with Foundation UNUM. The arbitration demand alleges breach of contract by the Company under a letter of intent entered into between the parties in August 2018 between the parties, and DHL seeks full indemnification for all damages and costs resulting from the alleged breach by the Company, including but not limited to loss of profit, which DHL calculates at 2,335,000 Euros. The Company does not believe it has breached any contract with DHL and plans to engage in a vigorous defense against such claims. No amounts have been accrued for this matter at March 31, 2020.

As of May 6, 2020, ten lawsuits have been filed by alleged Tetraphase stockholders against us, members of our board of directors, AcelRx and/or Merger Sub, challenging the Merger. These lawsuits, which include both putative class action and individual complaints, have been filed in the United States District Court for the District of Delaware, the Southern District of New York, the Eastern District of New York, the District of Massachusetts, and the Massachusetts State Superior Court. The complaints allege violations of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934 and Rule 14a-9 promulgated thereunder, and/or that the members of our board breached their fiduciary duties. The plaintiffs in these actions generally allege that the registration statement filed with the SEC on April 6, 2020, and/or the definitive proxy statement filed with the SEC on April 24, 2020, omit material information with respect to the proposed transaction, which renders such registration statement and/or proxy statement false and misleading. In addition, certain plaintiffs allege that the members of our board of directors breached their fiduciary duties of care, loyalty and good faith, and/or candor and disclosure by allegedly entering into the Merger through a flawed and unfair process and disseminating materially incomplete and misleading disclosures in connection with the Merger, and that we, AcelRx and/or Merger Sub aided and abetted in the alleged breach of fiduciary duties. The complaints seek preliminary and permanent injunction of the proposed transaction and, if the Merger is consummated, rescission or rescissory damages. The complaints also seek the dissemination of a registration statement and/or proxy statement that disclose certain information requested by the plaintiffs. In addition, the complaints seek attorneys' and experts' fees. We believe we have valid defenses against these claims and will engage in a vigorous defense of such litigation.

Item 1A. Risk Factors

Our business faces many risks. We caution you that the following important factors, among others, could cause our actual results to differ materially from those expressed in forward-looking statements made by us or on our behalf in this Quarterly Report on Form 10-Q and other filings with the SEC, press releases, communications with investors and oral statements. The risks described below may not be the only risks we face. Additional risks we do not yet know of or which we currently believe are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks actually occurs, our business, financial condition or results of operations could suffer, and the trading price of our common stock could decline.

Risks Related to the Merger with AcelRx

The failure to complete the announced merger with AcelRx in a timely manner, or at all, may adversely affect our business, financial results and stock price.

Our obligations to consummate our proposed merger, or the Merger, with AcelRx Pharmaceuticals, Inc., or AcelRx, are subject to the satisfaction or waiver of certain customary conditions, including, among others, (i) the Agreement and Plan of Merger, dated as of March 15, 2020, by and among us, AcelRx and Consolidation Merger Sub, Inc., or the Merger Agreement, must be adopted by the requisite vote of our stockholders; (ii) the absence of (A) any governmental restraining order or injunction having been issued with respect to the contemplated transactions and continuing in effect or (B) any legal proceeding of a governmental body challenging or seeking to prohibit the consummation of the Merger or related matters; (iii) subject to certain qualifications, the accuracy of the respective representations and warranties of us and AcelRx and compliance by the parties with their respective obligations under the Merger Agreement; (iv) the Registration Statement on Form S-4 registering the shares of AcelRx common stock issuable as merger consideration remaining in effect; and (v) the approval of the shares of AcelRx common stock issuable as merger consideration for listing on Nasdaq. We cannot provide assurance that these or the other conditions to the completion of the Merger will be satisfied in a timely manner or at all. In addition, other factors may affect when and whether the Merger will occur. If the Merger is not completed, our stock price could fall to the extent that our current stock price reflects an assumption that the Merger will be completed. Furthermore, if the Merger is not completed and the Merger Agreement is terminated, we may suffer other consequences that could adversely affect our business, results of operations and stock price, including the following:

- we have incurred and will continue to incur costs relating to the Merger (including significant legal and financial advisory fees) and many of these costs are payable by us whether or not the Merger is completed;

- we could be required, in certain circumstances, to pay an $810,000 termination fee and/or reimburse AcelRx up to $200,000 for certain of its costs incurred in connection with the Merger and the Merger Agreement;
- matters relating to the Merger (including sales integration planning and implementation) may require substantial commitments of time and resources by our management team, which could otherwise have been devoted to other opportunities that may have been beneficial to us;
- current and prospective employees could experience uncertainty about their future roles, which may adversely affect our ability to retain key employees, who may seek other employment opportunities;
- we may be subject to legal proceedings related to the Merger or the failure to complete the Merger;
- our customers, prospective customers and other business partners and investors in general may view the failure to consummate the Merger as a poor reflection on our business or prospects; and
- upon such termination, we may not have sufficient cash to continue our business and may have to consider seeking protection under the bankruptcy laws in order to continue to pursue potential transactions and conduct a wind-down of our company.

Uncertainty about the Merger may adversely affect our business and stock price, whether or not the Merger is completed.

We are subject to risks in connection with the announcement and pendency of the Merger, including the risks from possibly foregoing opportunities we might otherwise pursue absent the proposed Merger. Furthermore, uncertainties about the Merger may cause current and prospective employees to experience uncertainty about their future with us. These uncertainties may impair our ability to retain, recruit or motivate key management and other personnel.

In addition, in response to the announcement of the proposed Merger, our existing or prospective customers, suppliers or collaboration partners may:

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

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

While the Merger is pending, we are subject to contractual restrictions that could harm our business, operating results and stock price.

The Merger Agreement includes restrictions on the conduct of our business prior to the completion of the Merger, generally (i) requiring us to use commercially reasonable efforts to cause us to conduct our business and operations in the ordinary course and in accordance in all material respects with past practice, to pay our debt, payables and taxes when due, and to attempt to ensure that we preserve intact the material components of our current business organization and maintain our relations and goodwill with all material suppliers, material customers, material licensors and governmental bodies, and (ii) restricting us from taking certain specified actions absent AcelRx's prior written consent. These and other obligations in the Merger Agreement may delay or prevent us from responding or limit our ability to respond effectively to competitive pressures, industry developments and future business opportunities that may arise during such period, even if our management and our board of directors think they may be advisable. These restrictions could adversely impact our business, operating results and stock price and our perceived acquisition value, regardless of whether the Merger is completed.

The Merger Agreement limits our ability to pursue alternative transactions, which could deter a third party from proposing an alternative transaction.

The Merger Agreement contains provisions that, subject to certain exceptions, limit our ability to solicit, initiate or knowingly facilitate or knowingly encourage any inquiries or the making of any proposal or offer that constitutes, or would reasonably be expected to lead to, or engage in, continue or otherwise participate in any discussions or negotiations regarding, or furnish any non-public information in connection with, an alternative transaction. It is possible that these or other provisions in the Merger Agreement might discourage a potential competing acquirer that might have an interest in acquiring all or a significant part of the outstanding shares of our common stock from considering or proposing an acquisition or might result in a potential competing acquirer proposing to pay a lower per share price to acquire our common stock than it might otherwise have proposed to pay.

The Merger will involve substantial and potentially unexpected costs.

We have incurred and expect to continue to incur substantial costs and expenses relating directly to the Merger, including, as applicable, fees and expenses payable to financial advisors, other professional fees and expenses, insurance premium costs, fees and costs relating to regulatory filings and notices, SEC filing fees, printing and mailing costs and other transaction-related costs, fees and expenses. Actual transaction costs may substantially exceed estimates and may have an adverse effect on our financial condition and operating results. If the Merger is not completed, we will have incurred substantial expenses for which no ultimate benefit will have been received by us.

Certain of our directors and executive officers may have interests in the Merger that are or were different from, or in conflict with or in addition to, those of our stockholders generally.

Certain of our directors and executive officers have interests in the Merger that may differ from, or that are in addition, to their interests as stockholders of our company. Our board of directors was aware of these interests at the time it approved the Merger Agreement. These interests may cause our directors and officers to view the Merger differently from how our stockholders may view it.

We are and may continue to be targets of securities class action and derivative lawsuits which could result in substantial costs and may delay or prevent the Merger from being completed.

Securities class action lawsuits and derivative lawsuits are often brought against public companies that have entered into merger agreements. To date, ten putative stockholder class action lawsuits have been filed against us, our board of directors, AcelRx and others in connection with the transactions contemplated by the Merger Agreement. We and the other defendants believe the lawsuits are without merit and we intend to vigorously defend against the claims of these lawsuits; however, the outcome of all litigation is uncertain and we may not be successful in defending against these claims or any other lawsuits brought against us even if they are without merit. Regardless of the outcome of these lawsuits or any other lawsuits brought against us, such lawsuits could delay or prevent our acquisition by AcelRx, divert the attention of our management and employees from our day-to-day business, result in substantial costs and otherwise adversely affect us financially. An adverse judgment could result in monetary damages, which could have a negative impact on our liquidity and financial condition. Additionally, if a plaintiff is successful in obtaining an injunction prohibiting completion of the Merger, that injunction may delay or prevent the Merger from being completed, or from being completed within the expected timeframe, which may adversely affect our business, financial position and results of operations.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since inception, expect to incur losses for at least the next several years and may never achieve or sustain profitability.

We have incurred annual net operating losses in every year since our inception. Our net loss was $12.1 million for the three months ended March 31, 2020, $70.1 million for the year ended December 31, 2019 and $72.2 million for the year ended December 31, 2018. As noted below, we and our auditors have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. As of March 31, 2020, we had an accumulated deficit of $616.3 million. Prior to October 2018, when we commenced sales of Xerava in the United States, we had not generated any product revenues. For the year ended December 31, 2019, we generated $3.6 million in net product revenues from sales of Xerava. For the three months ended March 31, 2020, we generated $1.8 million in net product revenues from sales of Xerava. We have financed our operations primarily through the public offerings and private placements of our equity securities, debt financings, revenue from U.S. government grants and contract awards, milestone payments from our licensing agreement with Everest Medicines Limited, or Everest Medicines, and Xerava product revenue.

In the third quarter of 2018, we received marketing approval in the United States and in Europe for Xerava for the treatment of complicated intra-abdominal infections, or cIAI. Prior to the marketing approval of Xerava we had devoted substantially all of our financial resources and efforts to research and development, including preclinical and clinical development. In June 2019, we determined to devote all of our financial resources and efforts to supporting the ongoing commercialization of Xerava and announced a restructuring of our organization, including a 20% reduction in headcount, designed to focus our cash resources on commercializing Xerava primarily in the hospital setting. As a result of the restructuring, we eliminated our internal research function and intend to seek out-licensing opportunities for our pipeline of early-stage antibiotics and oncology product candidates.

Notwithstanding the initiation of sales of Xerava and our 2019 restructuring, we continue to incur significant expenses and operating losses. The net losses we incur may fluctuate significantly from quarter to quarter. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

Subject to completion of the Merger, we expect that our expenses will decrease in 2020 compared with 2019, as the cost savings associated with our June 2019 restructuring are expected to continue in 2020. Our expenses could increase if and as we:

- maintain, expand and protect our intellectual property portfolio; and
- in-license or acquire other products and technologies.

Our ability to become and remain profitable depends on our ability to generate revenue. Notwithstanding marketing approval of Xerava in the United States and Europe, we have not commenced sales of Xerava in Europe and do not expect to generate significant revenue from Xerava sales in the United States in the near future. The successful commercialization of Xerava will require us to be effective in a range of challenging activities, including:

- establishing and maintaining sales, marketing and distribution capabilities to effectively market, sell and be reimbursed for Xerava;
- contracting for the manufacture of sufficient commercial quantities of Xerava; and
- protecting and maintaining our rights to our intellectual property portfolio related to Xerava.

Because of the numerous risks and uncertainties associated with pharmaceutical product commercialization, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability.

We may be unable to successfully commercialize Xerava and, even if we do, we may never achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business or continue our operations. A decline in the value of our company could cause our stockholders to lose all or part of their investment in us.

If the Merger is not consummated, we will need additional funding to continue to commercialize Xerava. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We believe, based on our current operating plan and assuming the Merger is not consummated, that our existing cash and cash equivalents as of March 31, 2020, and our projected revenues from the sales of Xerava, together with the $2.3 million in proceeds from our PPP loan received in April 2020, will be sufficient to fund our operations into the first quarter of 2021. We have based this estimate on assumptions that may prove to be wrong, and our capital resources may be utilized faster than we currently expect. As of March 31, 2020, management has further assessed this risk and, in accordance with the requirements of Accounting Standards Update No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, or ASC 205-40, determined that there is substantial doubt about our ability to continue as a going concern. There is no assurance that we will be successful in obtaining additional financing on terms acceptable to us, if at all, nor is it considered probable under the accounting standards. As such, under the requirements of ASC 205-40, management may not consider the potential for future capital raises or management plans to reduce costs that are not considered probable in their assessment of our ability to meet our obligations. In light of our limited cash resources, we explored strategic alternatives to maximize stockholder value, including the potential sale or merger of us or our assets, which culminated with us entering into the Merger Agreement with AcelRx. If the Merger is not consummated and we are unable to obtain funding, we may be required to delay, reduce or eliminate our commercialization efforts, which could adversely affect our business prospects, and we may be unable to continue operations. We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources to fund our expenses after that time.

Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, if the Merger is not consummated and we return to exploring out-licensing opportunities for our pipeline of early-stage antibiotics and oncology product candidates, there can be no assurance that we will be able to out-license these on a timely basis or on terms that are favorable to us, or at all. Our failure to raise capital through financing or a license of our pipeline as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We could be forced to significantly scale back or discontinue the commercialization of Xerava and reduce other expenditures, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, our rights to Xerava and our other product candidates. In addition, in such circumstance, we would consider seeking protection under the bankruptcy laws in order to continue to pursue potential transactions and conduct a wind-down of our company. If we decide to seek protection under the bankruptcy laws, we would expect that we would file for bankruptcy at a time that is significantly earlier than when we would otherwise exhaust our cash resources. If we decide to dissolve and liquidate our assets or to seek protection under the bankruptcy laws, it is unclear to what extent we will be able to pay our obligations, and, accordingly, it is further unclear whether and to what extent any resources will be available for distributions to stockholders.

Our future funding requirements, both short-term and long-term, will depend on many factors, including, but not limited to:

- whether and when the Merger is consummated;
- revenue received from commercial sales of Xerava;
- the timing and costs of manufacturing and other activities in connection with the commercialization of Xerava;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay to Harvard University, or Harvard, and other licenses under license agreements to which we may be a party;
- the costs of maintaining and protecting our intellectual property rights and defending against intellectual property related claims;
- our ability to enter into collaborations, licensing, marketing, distribution or other arrangements with respect to Xerava and our product candidates, and the terms and timing of any such arrangements into which we enter;
- the extent to which we in-license or acquire other products and technologies; and
- our ability to continue as a going concern.

We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern.

We believe, based on our current operating plan and assuming the Merger is not consummated, that our existing cash and cash equivalents as of March 31, 2020 and our projected revenues from sales of Xerava, together with the $2.3 million in proceeds from our PPP loan received in April 2020, will be sufficient to fund our operations into the first quarter of 2021. We have based this estimate on assumptions that may prove to be wrong, and our capital resources may be utilized faster than we currently expect. The report from our independent registered public accounting firm for the year ended December 31, 2019 includes an explanatory paragraph stating that our recurring losses from operations, limited financial resources and the need to raise additional capital to finance our future operations raise substantial doubt about our ability to continue as a going concern. If the Merger is not consummated and we are unable to obtain sufficient funding, we may be forced to delay or reduce the scope of our commercialization efforts, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. Future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide funding to us on commercially reasonable terms, if at all.

We have no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We began operations in the third quarter of 2006. Our operations to date have been limited to financing and staffing our company, developing our technology and our product candidates, establishing a commercial infrastructure to launch Xerava in the United States and selling Xerava in the United States. We obtained marketing approval for Xerava in the United States and Europe in the third quarter of 2018 and commenced sales of Xerava in the United States in the fourth quarter of 2018. We have not yet demonstrated a long-term ability to conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies.

Unless and until we can generate a substantial amount of revenue from Xerava, if the Merger is not consummated, we expect to finance our future cash needs through public or private equity offerings, debt financings or collaborations and licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, the ownership interest of our stockholders may be materially diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect their rights. In addition, debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific corporate actions, such as incurring additional debt, merging with or acquiring another entity, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing additional financing would require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the commercialization of Xerava.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, products or product candidates or to grant licenses on terms that may not be favorable to us.

Risks Related to Product Development and Commercialization

We are dependent on the success of Xerava, and our ability to successfully commercialize Xerava. If we are unable to successfully commercialize Xerava or experience significant delays in doing so, our business could be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of Xerava for use as a first-line empiric monotherapy for the treatment of multidrug-resistant, or MDR, infections. We obtained marketing approval for Xerava for the treatment of cIAI in the United States and in Europe in the third quarter of 2018. Our prospects are substantially dependent on our ability to successfully commercialize Xerava for the treatment of cIAI. The success of Xerava will depend on several factors, including the following:

- continue growing sales of Xerava in the United States;
- acceptance of Xerava by the medical community, hospital formularies, patients and third-party payors;
- obtainment and maintenance of patent and trade secret protection and regulatory exclusivity;
- protection of our rights in our intellectual property portfolio;
- successful manufacturing of Xerava;
- favorable results of any additional clinical trials involving Xerava that we or others may conduct;
- competition with other therapies; and
- a continued acceptable safety profile of Xerava.

If we are unable to successfully commercialize Xerava for the treatment of cIAI our business could be materially harmed.

We face risks related to health epidemics and other widespread outbreaks of contagious disease, including the novel coronavirus, or COVID-19, which could significantly disrupt our operations and impact our financial results.

Significant outbreaks of contagious diseases, and other adverse public health developments, could have a material impact on our business operations and operating results. In December 2019, an outbreak of respiratory illness caused by a strain of novel coronavirus, COVID-19, began in China. As of April 2020, that outbreak has led to numerous confirmed cases worldwide, including in the Unites States. The World Health Organization declared the outbreak a global public health emergency on January 30, 2020. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the outbreak and its effects on our business and operations are uncertain.

Our supply chain for other raw materials and critical components is worldwide and accordingly could be subject to disruption, particularly since our raw materials are sourced in China. We and our third-party contract manufacturers may face disruptions in procuring items that are essential for our business, including, for example, raw materials used in the manufacturing of Xerava, for which there may be shortages because of ongoing efforts to address the outbreak. Any negative impact that the outbreak has on the ability of our suppliers to provide materials for Xerava could limit our ability to sell Xerava and have a material adverse effect on our financial results. The COVID-19 outbreak may have a materials adverse effect on our business, financial condition, results of operations and prospects. Because of social distancing guidelines and other legal orders and restrictions caused by COVID-19, many hospitals will not allow our sales representatives inside to meet with potential prescribers, hospital formulary review committee meetings have been postponed, we have been unable to meet with group purchasing organization and scientific conferences

are not being held. These measures limit our ability to have Xerava prescribed, approved in hospitals and sold. We could also experience business disruptions caused by workplace closures and reliance on employees working from home, cybersecurity and data accessibility issues, and communications or transit disruptions, any of which could adversely impact our business operations and delay necessary interactions among our employees and between our company and the third parties upon which we rely.

The pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could impact our ability to raise additional funds through public offerings and may also impact the volatility of our stock price and trading in our stock. Moreover, it is possible the pandemic will significantly impact economies worldwide, which could result in adverse effects on our business and operations. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business and it has the potential to adversely affect our business, financial condition, results of operations, and prospects.

Xerava or any additional product candidate of ours that a future collaborator develops and commercializes may fail to achieve the degree of market acceptance by physicians, patients, hospital formularies, third-party payors and others in the medical community necessary for commercial success and the market opportunity for Xerava or the additional product candidates may be smaller than we estimated.

Prior to Xerava, we had never commercialized a product candidate for any indication, and we do not plan to commercialize any additional product candidates. Efforts to educate the medical community, hospital formularies and third-party payors on the benefits of Xerava may require significant resources and may not be successful. If Xerava does not achieve an adequate level of market acceptance, we may not generate significant product revenues. Therefore, we may not become profitable. If the Merger is not consummated, we intend to seek out-licensing opportunities for our pipeline of early-stage antibiotics and oncology product candidates. If any additional product candidate of ours that a future collaborator develops does not achieve market acceptance, the amounts we could receive under the licensing or collaboration agreement could be limited. The degree of market acceptance of Xerava, or any other product candidate that is approved for commercial sale, will depend on a number of factors, including, but not limited to:

- the efficacy and safety of the product;
- the potential advantages of the product compared to alternative treatments, including convenience and ease of administration;
- the prevalence and severity of any side effects;
- the clinical indications for which the product is approved;
- limitations or warnings, including distribution or use restrictions;
- our ability to offer the product for sale at competitive prices;
- the willingness of physicians to prescribe the product;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular infections;
- the strength of marketing and distribution support;
- the approval of other new products for the same indications;
- availability and level of coverage and amount of reimbursement from government payors, managed care plans and other third-party payors;
- the effectiveness of our sales efforts;
- adverse publicity about the product or favorable publicity about competitive products; and
- the development of resistance by bacterial strains to the product.

In addition, the potential market opportunity for Xerava or any product candidate is difficult to estimate. Our estimates of the potential market opportunity for Xerava are predicated on several key assumptions such as industry knowledge, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management and are inherently uncertain, and the reasonableness of these assumptions has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, then the actual market for Xerava could be smaller than our estimates of the potential market opportunity. If the actual market for Xerava is smaller than we expect, or if the product fails to achieve an adequate level of acceptance by physicians, hospital formularies, health care payors and patients, our product revenue may be limited, and it may be more difficult for us to achieve or maintain profitability.

If we are unable to successfully establish and maintain sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing Xerava.

To achieve commercial success for Xerava, we must develop a successful sales and marketing organization. We have built a commercial organization in the United States and recruited experienced sales, marketing and distribution professionals. If we are unable to successfully operate the sales force and maintain marketing and distribution capabilities, our operating results may be adversely affected.

Factors that may inhibit our efforts to commercialize Xerava include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the ability of our sales personnel to obtain access to or persuade adequate numbers of physicians to appropriately prescribe any products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- the inability of our medical science group to educate physicians on the benefits to patients of Xerava; and
- unforeseen costs and expenses associated with maintaining an independent sales and marketing organization.

We have entered into a co-promotion agreement, or the Co-Promotion Agreement, with AcelRx, under which the parties have agreed that, during the term of the agreement, their sales forces will promote and detail the other party's products in accordance with marketing plans agreed to by the parties and subject to specified minimum call requirements. If AcelRx is unable to successfully operate its sales force and provide the co-promotion activities contemplated by the Co-Promotion Agreement, our product revenues for Xerava will be adversely affected.

We plan to seek to commercialize Xerava outside the United States with the assistance of collaborators. If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of Xerava revenues to us may be lower than if we were to directly market and sell Xerava in those markets. As an example, if Everest Medicines, our collaboration partner for Xerava in certain Asian territories, is unsuccessful in developing and commercializing Xerava in the Chinese market, we may not receive any future milestone or royalty payments. Furthermore, we may be unsuccessful in entering into the necessary arrangements with third parties or may be unable to do so on terms that are favorable to us. In addition, we likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing Xerava or any other future products.

We face substantial competition from other pharmaceutical and biotechnology companies and our operating results may suffer if we fail to compete effectively.

The development and commercialization of new drug products is highly competitive. Xerava and any product candidate of ours that we license to a third party will face competition from major pharmaceutical companies, specialty pharmaceutical companies, generic manufacturers and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products, or are pursuing the development of product candidates, for the treatment of MDR infections. Competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than Xerava or any of our product candidates that we license to a third party, which could impact the use of Xerava.

Xerava competes with a number of antibiotics that are currently marketed for the treatment of cIAI and other multidrug resistant infections, including meropenem, which is marketed by AstraZeneca as Merrem, imipenem/cilastatin, which is sold by Merck & Co., or Merck, as Primaxin, tigecycline, which is marketed by Pfizer as Tygacil, piperacillin/tazobactam, which is marketed by Pfizer as Zosyn, ceftolozane/tazobactam and imipenem/relebactam, which are marketed by Merck as Zerbaxa and Recarbrio, and ceftazidime/avibactam, which is marketed by Allergan, Inc., as Avycaz, meropenem and vaborbactam, which is marketed by Melinta Therapeutics as Vabomere. We also expect that Xerava will compete with future and current generic versions of marketed antibiotics.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials and obtaining regulatory approvals than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we are able to commercialize Xerava or a future collaborator is able to commercialize any product candidates that we license to it, the product may become subject to unfavorable pricing regulations, third-party payor coverage and reimbursement policies or healthcare reform initiatives that could harm our business.

Marketing approvals, pricing, coverage and reimbursement for new drug products vary widely by country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product 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 or a future collaborator might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate directly or indirectly from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in Xerava and any of our product candidates that are commercialized, even if our product candidates obtain marketing approval.

Our and our future collaborators' ability to successfully commercialize Xerava or any product candidate of ours that we license to a third party will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government authorities, private health insurers, health maintenance organizations and other third-party payors. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. As a result, government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect the ability to sell Xerava or any such product candidates profitably.

Increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. Moreover, obtaining coverage does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the drug and the clinical setting in which it is used. Reimbursement rates may also be based in part on existing reimbursement amounts for lower cost drugs or may be bundled into the payments for other services.

We cannot be sure that coverage will be available for Xerava or any of our product candidates that we license to a third party that is commercialized and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

We do not plan to conduct any additional clinical registration trials of Xerava or any of our product candidates other than FDA-required post-approval Phase IV trials. However, if we determine to resume clinical development of any product candidates or license any product candidates to third parties for development, we or our collaborators will be subject to the risk that such clinical trials fail to demonstrate safety and efficacy to the satisfaction of the FDA or comparable foreign regulatory authorities or do not otherwise produce favorable results, and we or our collaborators may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidate.

A company is not permitted to commercialize, market, promote, or sell any product candidate in the United States without obtaining marketing approval from the FDA or in other countries without obtaining approvals from comparable foreign regulatory authorities, such as the European Medicines Agency, or EMA, and may never receive such approvals. In addition, the company must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy of its product candidates in humans before it will be able to obtain these approvals. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome.

The clinical development of any product candidate is susceptible to the risk of failure inherent at any stage of drug development, including failure to achieve efficacy in a trial or across a broad population of patients, the occurrence of severe adverse events, failure to comply with protocols or applicable regulatory requirements, and determination by the FDA or any comparable foreign regulatory authority that a drug product is not approvable. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Success may not be achieved in any future clinical trial of any product candidate.

In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we believe that the results of clinical trials warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. In addition, in the case of clinical trials of antibiotics such as Xerava, results may differ on the basis of the type of bacteria with which patients are infected. We cannot be certain that other clinical trials will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market product candidates.

Numerous unforeseen events may occur during, or as a result of, clinical trials that could delay or prevent us or our collaborators from obtaining regulatory approval for any of our product candidates, including:

- clinical trials may produce unfavorable or inconclusive results;
- we or our collaborators may decide, or regulators may require us or our collaborators, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than anticipated, enrollment in these clinical trials may be slower than anticipated, or participants may drop out of these clinical trials at a higher rate than anticipated;
- third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all;
- regulators or institutional review boards may not authorize the commencement of a clinical trial or the conduct of a clinical trial at a prospective trial site;
- clinical trials may need to be suspended or terminated for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate;
- regulators or institutional review boards may require that clinical research be suspended or terminated for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering clinical data insufficient for approval.

If we or our collaborators are required to conduct additional clinical trials or other testing of any product candidate beyond the contemplated trials and testing or are unable to successfully complete clinical trials or other testing, if the results of these trials or tests are unfavorable or are only modestly favorable or if there are safety concerns associated with our product candidates, we or our collaborators may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other requirements; or
- remove the product from the market after obtaining marketing approval.

Serious adverse events or undesirable side effects or other unexpected properties of Xerava or any product candidate that we license to third parties may be identified during development or after approval, if obtained, that could delay, prevent or cause the withdrawal of the product candidates' regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if obtained.

Serious adverse events or undesirable side effects caused by, or other unexpected properties of, our product candidates could cause us or our collaborators, an institutional review board, or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label, the imposition of distribution or use restrictions or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. If any product candidate is associated with serious adverse events or undesirable side effects or have properties that are unexpected, we or our collaborators may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the compound. In our clinical trials of Xerava, some treatment-related adverse events were reported. The most common treatment-related adverse events observed in clinical trials of Xerava were nausea and emesis. Additional adverse events, undesirable side effects or other unexpected properties could arise or become known either during clinical development or, if approved, after the approved product has been marketed. If such an event occurs during development, trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order the cessation of further development of, or deny approval of, the product candidates. If such an event occurs with respect to Xerava or after an additional product candidate is approved, a number of potentially significant negative consequences may result, including:

- regulatory authorities may withdraw the approval of such product;
- regulatory authorities may require additional warnings on the label or impose distribution or use restrictions;
- regulatory authorities may require one or more post-marketing studies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent market acceptance of the affected product or product candidate, if approved, or could substantially increase commercialization costs and expenses, which could delay or prevent us from generating revenues from the sale of our products and harm our business and results of operations.

Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and limit commercialization of Xerava.

We face an inherent risk of product liability claims as a result of the commercialization of Xerava. For example, we may be sued if Xerava allegedly causes injury or is found to be otherwise unsuitable during manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for Xerava;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend resulting litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize Xerava.

We maintain general liability insurance of $12 million in the aggregate and clinical trial liability insurance of $10 million in the aggregate for all product candidates. This insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. In addition, insurance coverage is becoming increasingly expensive. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of Xerava, which could adversely affect our business, financial condition and results of operations and prospects.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time, and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and wastes, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts, which could adversely affect our business, financial condition, results of operations or prospects. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Risks Related to Our Dependence on Third Parties

We expect to depend on collaborations with third parties for the development and commercialization of some of our products and product candidates. Our prospects with respect to those products and product candidates will depend in part on the success of those collaborations.

Under the Co-Promotion Agreement, AcelRx's sales force promotes and markets Xerava. The Co-Promotion Agreement will continue even if the Merger Agreement is terminated. In addition, if the Merger Agreement is terminated, we intend to seek to commercialize Xerava outside the United States through collaboration arrangements. For instance, in February 2018, we entered into a license agreement with Everest Medicines under which we granted Everest Medicines an exclusive license to develop and commercialize Xerava for the treatment of cIAI and other indications, in mainland China and several other Asian territories and countries. In addition, if the Merger is not consummated, we intend to seek out-licensing opportunities for our pipeline of early-stage antibiotics and oncology product candidates. Our likely collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We are not currently party to any such arrangements other than that with AcelRx and Everest Medicines.

We may derive revenue from research and development fees, license fees, milestone payments and royalties under any collaborative arrangement into which we enter. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, our collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms. As a result, we can expect to relinquish some or all of the control over the future success of a product or product candidate that we license to a third party.

Collaborations involving our products and product candidates, such as our co-promotion and license arrangements with AcelRx and Everest Medicines, respectively, may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected or in compliance with applicable regulatory requirements;

- collaborators may not pursue development and commercialization of our products and product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of products and product candidates, might lead to additional responsibilities for us with respect to products and product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of products or product candidates in the most efficient manner or at all. If a collaborator of ours is involved in a business combination, it could decide to delay, diminish or terminate the development or commercialization of any product or product candidate licensed to it by us.

We contract with third parties for the manufacture of Xerava for commercialization. This reliance on third parties for manufacturing increases the risk that we will not have sufficient quantities of our product or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have nor do we plan to build the internal infrastructure or capability to manufacture Xerava or any product candidate for use in the conduct of clinical trials or for commercial supply. We currently rely on and expect to continue to rely on third-party contract manufacturers to manufacture commercial supplies of Xerava. Reliance on third-party manufacturers entails risks, including:

- delays in the manufacture of our clinical drug supply, registration and validation batches and commercial supply if our third-party manufacturers give greater priority to the supply of other products over Xerava or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- equipment malfunctions, power outages or other general disruptions experienced by our third-party manufacturers to their respective operations and other general problems with a multi-step manufacturing process, including the COVID-19 outbreak;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- the possible breach of the manufacturing agreement by the third party;
- the failure of the third-party manufacturer to comply with applicable regulatory requirements; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

Third-party manufacturers are required to comply with current Good Manufacturing Processes, or cGMPs, and similar regulatory requirements outside the United States. Facilities used by our third-party manufacturers must be inspected by the FDA after we submit an NDA, and before potential approval of the product candidate. Similar regulations apply to manufacturers of our product candidates for use or sale in foreign countries. We do not control the manufacturing process and are completely dependent on our third-party manufacturers for compliance with the applicable regulatory requirements for the manufacture of our product candidates. If our manufacturers cannot successfully manufacture material that conforms to the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, they will not be able to secure the applicable approval for their manufacturing facilities. If these facilities are not approved for commercial manufacture, we may need to find alternative manufacturing facilities, which could result in delays in obtaining approval for the applicable product candidate as alternative qualified manufacturing facilities may not be available on a timely basis or at all. In addition, our manufacturers are subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. Failure by any of our manufacturers to comply with applicable cGMPs or other regulatory requirements could result in sanctions being imposed on us or the contract manufacturer, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and have a material adverse impact on our business, financial condition and results of operations.

Our current and anticipated future dependence upon others for the manufacture of Xerava may adversely affect our future profit margins and our ability to commercialize Xerava on a timely and competitive basis.

We may have to alter our development and commercialization plans if we are not able to establish collaborations.

For Xerava outside the United States and for our product candidates, we intend to seek to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. For example, we collaborate with Everest Medicines for commercialization of Xerava in certain countries outside the United States. We may not be able to enter into similar arrangements for any additional product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include:

- the likelihood of approval by the FDA or comparable foreign regulatory authorities;
- the potential market for the subject product or product candidate;
- the costs and complexities of manufacturing and delivering such product or product candidate to patients;
- the potential for competing products;
- our patent position protecting the product or product candidate, including any uncertainty with respect to our ownership of our technology or our licensor's ownership of technology we license from them, which can exist if there is a challenge to such ownership without regard to the merits of the challenge;
- the need to seek licenses or sub-licenses to third-party intellectual property; and
- general industry and market conditions.

A collaborator may also consider alternative products, product candidates or technologies for similar indications that may be available for collaboration and whether such collaboration could be more attractive than the one with us for our product or product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

If we are unable to reach agreements for Xerava or any of our product candidates on a timely basis, on acceptable terms, or at all, we expect to curtail the development of Xerava or the product candidate, reduce or delay the development program for Xerava or the product candidate or one or more of our other development programs, delay its potential commercialization, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product or product candidates or bring them to market and our business may be materially and adversely affected.

If we fail to comply with our obligations in the agreements under which we in-license or acquire development or commercialization rights to products or technology from third parties, we could lose commercial rights that are important to our business.

We are a party to a license agreement with Harvard that imposes, and we may enter into additional agreements, including license agreements, with other parties in the future that impose, diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. For example, under our license agreement with Harvard, we are obligated to satisfy diligence requirements, including using commercially reasonable efforts to develop and commercialize licensed compounds and to implement a specified development plan, meeting specified development milestones and providing an update on progress on an annual basis, and to pay royalties on sales of Xerava. If we fail to comply with these obligations, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product that is covered by these agreements, which could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient patent protection for our technology, products or our product candidates, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology, products and product candidates may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary chemistry technology, products and product candidates. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel technologies, products and product candidates that are important to our business. The patent application and approval process is expensive and time consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection.

Under our license agreement with Harvard, Harvard retains the right to prosecute and maintain specified Harvard patents and patent applications in the field of tetracycline chemistry, which are exclusively licensed to us under the agreement. Moreover, if we license technology or product candidates from third parties in the future, those licensors may retain the right to prosecute, maintain and enforce the patent rights that they license to us with or without our involvement. Because control of prosecution and maintenance rests with Harvard, and prosecution, maintenance and enforcement could rest with future licensors, we cannot be certain that these in-licensed patents and applications will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If Harvard fails to prosecute or maintain, or future licensors fail to prosecute, maintain or enforce, those patents necessary for any of our products or product candidates, our ability to develop and commercialize those products or product candidates may be adversely affected and we may not be able to prevent competitors from making and selling competing products.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, recent changes in patent laws in the United States, including the America Invents Act of 2011, may affect the scope, strength and enforceability of our patent rights or the nature of proceedings which may be brought by us related to our patent rights.

Our pending and future patent applications may not result in patents being issued that protect our technology, products or product candidates, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

As a result of the America Invents Act of 2011, the United States transitioned to a first-inventor-to-file system in March 2013, under which, assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent. However, as a result of the lag in the publication of patent applications following filing in the United States, we are not notified and therefore are not able to be certain upon filing that we are the first to file for patent protection for any invention. Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, *inter partes* review or interference proceedings, in the United States or elsewhere,

challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of or invalidate our patent rights, allow third parties to commercialize our technology, products or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting Abbreviated New Drug Applications to the FDA in which they claim that patents owned or licensed by us are invalid, unenforceable and/or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid and/or unenforceable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. For example, in August 2018 we received a Notice of Opposition from the European Patent Office notifying us that one of two European patents we own having claims directed to Xerava had been opposed by a third party. We filed a Response to the Opposition in November 2018 cancelling the opposed claims and maintaining the unopposed claims. Our other European patent covering Xerava is not impacted by the filing of this Opposition and cannot itself be opposed based on its grant date of July 3, 2013. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents, trademarks, copyrights or other intellectual property, or those of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our products and product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our products and product candidates and use our proprietary chemistry technology without infringing the intellectual property and other proprietary rights of third parties. Numerous third-party U.S. and non-U.S. issued patents and pending applications exist in the area of antibacterial treatment, including compounds, formulations, treatment methods and synthetic processes that may be applied towards the synthesis of antibiotics. If any of these patents or patent applications cover our product candidates or technologies, we may not be free to manufacture or market our product candidates as planned.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology, products or product candidates and Xerava. Other possible adversarial proceedings include interference proceedings before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be ordered by a court to cease developing, manufacturing, using, selling or offering for sale the infringing product. Alternatively, we may conclude that we need to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product or product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the intellectual property and other proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed such intellectual property or other proprietary information. Litigation may be necessary to defend against these claims.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Moreover, because we have licensed intellectual property from Harvard, we must rely on Harvard's practices with regard to the assignment of intellectual property to it. To the extent we or Harvard has failed to obtain such assignments, or such assignments are breached, we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, and our business would be harmed.

In addition to seeking patents for some of our technology, products and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, in seeking to develop and maintain a competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our consultants, independent contractors, advisors, corporate collaborators, outside scientific collaborators, contract manufacturers, suppliers and other third parties. We, as well as our licensors, also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. Any party with whom we or Harvard has executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed.

We have not yet completed registration of our trademarks. Failure to secure those registrations could adversely affect our business.

We own trademark registrations for TETRAPHASE PHARMACEUTICALS, our logo, and combinations of those in the United States. TETRAPHASE PHARMACEUTICALS is either registered or pending in twelve other jurisdictions, the logo is pending or registered in the same twelve jurisdictions, and the combination of the name and logo is registered or pending in three of those jurisdictions and two TETRAPHASE PHARMACEUTICALS Chinese character marks are registered in China. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would, which could adversely affect our business.

We own a trademark registration in the United States for Xerava, the proprietary name for the Xerava product.

We own two registrations and one application to register the Xerava trademark in three jurisdictions outside the United States and the availability of the proposed names for registration and use in foreign jurisdictions is not known. In addition, in the United States Patent and Trademark Office and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to seek to cancel registered trademarks. Cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. We have also obtained registration for our product design mark in four jurisdictions, including the United States.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize any future product candidate that we develop in addition to Xerava, and our ability to generate additional revenue will be materially impaired.

The design, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, marketing, export, sale and distribution of product candidates are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities, with regulations differing from country to country. Failure to obtain marketing approval for any such future product candidate will prevent the commercialization of such product candidate.

Product candidates may not be marketed in the United States until receipt of approval of an NDA from the FDA. An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate’s safety and efficacy for each desired indication. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the product candidate. Obtaining approval of an NDA is a lengthy, expensive and uncertain process. The drug development and FDA review process typically takes years to complete. The FDA has substantial discretion in the approval process and may refuse to accept for filing any application or may decide that data are insufficient for approval and require additional preclinical, clinical or other studies or additional information regarding chemistry, manufacturing and controls for the product candidate. Foreign regulatory authorities have differing requirements for approval of drug candidates which must be complied with prior to marketing. Obtaining marketing approval for marketing of a product candidate in one country does not ensure that marketing approval will be received in other countries, but the failure to obtain marketing approval in one jurisdiction could negatively impact the ability to obtain marketing approval in other jurisdictions. Delays in approvals or rejections of marketing applications in the United States or foreign countries may be based upon many factors, including regulatory requests for additional analyses, reports, data and studies, regulatory questions regarding, or different interpretations of, data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding product candidates or related products. The FDA or equivalent foreign regulatory authorities may determine that a product candidate is not effective, or is only moderately effective, or has undesirable or unintended

side effects, toxicities, safety profile or other characteristics that preclude marketing approval or prevent or limit commercial use. The FDA may also find during its pre-approval inspection that the facilities identified in the NDA fail to comply with cGMP requirements, thereby delaying or preventing approval. In addition, any marketing approval may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Delays in obtaining approval or the failure to obtain approval of any product candidate would harm the commercial prospects for such product candidate.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad and may limit our ability to generate revenue from product sales.

In order to market and sell our products in the European Union and many other jurisdictions, we, and any future collaborators, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. We, and any future collaborators, may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA.

In many countries outside the United States, a product candidate must also be approved for reimbursement before it can be sold in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. Obtaining non-U.S. regulatory approvals and compliance with non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and any future collaborators and could delay or prevent the introduction of our product candidates in certain countries. In addition, if we or any future collaborators fail to obtain the non-U.S. approvals required to market our product candidates outside the United States or if we or any future collaborators fail to comply with applicable non-U.S. regulatory requirements, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects may be adversely affected.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. Following protracted negotiations, the United Kingdom left the European Union on January 31, 2020. Under the withdrawal agreement, there is a transitional period until December 31, 2020 (extendable up to two years). Discussions between the United Kingdom and the European Union have so far mainly focused on finalizing withdrawal issues and transition agreements but have been extremely difficult to date. To date, only an outline of a trade agreement has been reached. Much remains open but the Prime Minister has indicated that the United Kingdom will not seek to extend the transitional period beyond the end of 2020. If no trade agreement has been reached before the end of the transitional period, there may be significant market and economic disruption. The Prime Minister has also indicated that the United Kingdom will not accept high regulatory alignment with the European Union.

Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

We are subject to ongoing obligations and continuing regulatory review following the marketing approval of Xerava, which may result in significant additional expense. Xerava could be subject to restrictions or withdrawal from the market, and we may be subject to penalties, if we fail to comply with regulatory requirements or if we experience unanticipated problems with Xerava or our product candidates, when and if approved.

Xerava is subject to, and any product candidate for which a future collaborator may obtain marketing approval will also be subject to, ongoing regulatory requirements, including for labeling, manufacturing, packaging, storage, distribution, advertising, promotion, record-keeping and submission of safety and other post-market information. For example, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements or requirements of equivalent foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMPs. As such, we and our contract manufacturers will be subject to continual review and periodic inspections to assess compliance with cGMPs. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We are also required to report certain adverse reactions and production problems, if any, to the FDA or equivalent foreign authorities and to comply with requirements concerning advertising and promotion for our products.

In addition, even if marketing approval of a product candidate is granted to us or a future collaborator, the approval may be subject to limitations on the indicated uses for which the product may be marketed, may be subject to significant conditions of approval or may impose requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling and regulatory requirements. The FDA also imposes stringent restrictions on manufacturers' communications regarding uses not described in the FDA-approved label, known as off-label uses, and if we do not restrict the marketing of our products only to their approved indications, we may be subject to enforcement action for off-label promotion.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product or us. In addition, if any product fails to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning or untitled letters;
- mandate modifications to promotional materials or require provision of corrective information to healthcare practitioners and patients;
- impose restrictions or requirements on the product or its manufacturers or manufacturing processes or suspension of manufacturing processes;
- impose restrictions on the labeling or marketing of the product;
- impose restrictions on product distribution or use;
- require post-marketing clinical trials;
- require withdrawal of the product from the market;
- refuse to approve pending applications or supplements to approved applications that we submit;
- require recall of the product;
- require entry into a consent decree, which can include imposition of various fines (including restitution or disgorgement of profits or revenue), reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- suspend, vary, modify or withdraw marketing approvals;
- refuse to permit the import or export of the product;
- seize or detain supplies of the product; or
- issue injunctions, levy fines or impose other civil penalties or bring criminal prosecution.

A recall of our products, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA and equivalent foreign authorities have the authority to require the recall of commercialized drugs in the event of material deficiencies, defects in design or manufacture, or stability failures. Manufacturers may, under their own initiative, recall a product if any material deficiency in a drug is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, stability failures, drug contamination or impurities, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, financial condition and operating results, which could impair our ability to produce our products in a cost-effective and timely manner. The FDA and equivalent foreign authorities require that certain classifications of recalls be reported to them within a defined period of time (within ten working days for the FDA) after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or equivalent foreign authorities. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA or equivalent foreign authorities. If the FDA or equivalent foreign authorities disagree with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA or equivalent foreign authorities could take enforcement action for failing to report the recalls when they were conducted.

An increase in the frequency or severity of adverse events, or repeated product complaints or malfunctions, may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner and have an adverse effect on our reputation, financial condition, and operating results.

Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

Our relationships with customers and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Our arrangements with third-party payors, healthcare professionals and customers who purchase, recommend or prescribe our products are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products, and it is possible that our business activities could be subject to challenge or enforcement under one or more of these laws and regulations. These laws and regulations include the U.S. federal healthcare Anti-Kickback Statute, the federal civil False Claims Act, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, the federal Physician Payments Sunshine Act, and analogous state laws and regulations.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that we or our partners may fail to comply fully with one or more of these requirements, and we will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. If governmental authorities find that our operations violate any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and we may be required to curtail or restructure our operations, any of which could adversely affect our ability to operate our business and our financial results. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our operations and business. The extent to which future legislation or regulations, if any, relating to healthcare fraud and abuse laws or enforcement may be enacted or what effect such legislation or regulation would have on our business remains uncertain.

Similar restrictions are imposed on the promotion and marketing of medicinal products in the EU Member States and other foreign countries. These include restrictions prohibiting the promotion of a compound prior to its approval. Laws (including those governing promotion, marketing and anti-kickback provisions), industry regulations and professional codes of conduct often are strictly enforced. Even in those countries where we may decide not to directly promote or market our products, inappropriate activity by our international distribution partners could have implications for us.

We also are subject to state and federal laws governing the collection, use, and disclosure and protection of health-related and other personal information, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection laws. Failure to comply with these laws and regulations promulgated thereunder could result in government enforcement actions and create liability, private litigation, or adverse publicity. In addition, we may obtain health information from third parties, such as research institutions, that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA – other than with respect to providing certain employee benefits – we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. In addition, HIPAA does not replace federal, state, or other laws that may grant individuals even greater privacy protections.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We have substantial reporting and payment obligations under the Medicaid Drug Rebate Program and other governmental programs. Our failure to comply with these price reporting and rebate payment obligations could negatively impact our financial results.

The Centers for Medicare & Medicaid Services, or CMS, issued a final regulation, which became effective on April 1, 2016, to implement the changes to the Medicaid Drug Rebate Program under the Affordable Care Act. The issuance of the final regulation, as well as any other regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate Program, has increased and will continue to increase our costs and the complexity of compliance, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we take in our implementation of the final regulation.

We also participate in the 340B program. The U.S. Department of Health and Human Services' Health Resources and Services Administration, or HRSA, which administers the 340B program, issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. It is currently unclear how HRSA will apply its enforcement authority under the new regulation. Implementation of this regulation could affect our obligations and potential liability under the 340B program in ways we cannot anticipate.

We have obligations to report the average sales price for certain of our drugs to the Medicare program. Statutory or regulatory changes or CMS guidance could affect the average sales price calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program.

We participate in the U.S. Department of Veterans Affairs, or VA, and the Federal Supply Schedule, or FSS, pricing program. Pursuant to applicable law, knowing provision of false information in connection with price reporting under these programs can subject a manufacturer to civil monetary penalties. These program obligations also contain extensive disclosure and certification requirements. If we overcharge the government in connection with our FSS contract or Tricare Agreement, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. In addition, we may engage third party intermediaries to promote our clinical research activities abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

We have adopted a Code of Business Conduct and Ethics that mandates compliance with the FCPA and other anti-corruption laws applicable to our business throughout the world. We cannot assure you, however, that our employees and third-party intermediaries will comply with this code or such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas, investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

We are subject to governmental export and import controls that could impair our ability to compete in international markets due to licensing requirements and subject us to liability if we are not in compliance with applicable laws.

Our products and solutions are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Exports of our products and solutions outside of the United States must be made in compliance with these laws and regulations. If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges; fines, which may be imposed on us and responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers.

In addition, changes in our products or solutions or changes in applicable export or import laws and regulations may create delays in the introduction, provision, or sale of our products and solutions in international markets, prevent customers from using our products and solutions or, in some cases, prevent the export or import of our products and solutions to certain countries, governments or persons altogether. Any limitation on our ability to export, provide, or sell our products and solutions could adversely affect our business, financial condition and results of operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. We do not, however, maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Clinical development, including the conduct of clinical trials necessary to support an NDA, is a lengthy and expensive process with an uncertain outcome, and results of earlier preclinical studies and clinical trials may not be predictive of future trial results. Delays or failure can occur at any stage of clinical development and may adversely affect our business, operating results, and prospects.

Initiating and completing clinical trials necessary to support approval of products is time consuming and expensive and the outcome is uncertain. Clinical testing is expensive and can take many years to complete and its outcome is inherently uncertain. There is no guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Failure can occur at any time and for any number of reasons during the clinical trial process. The results of preclinical studies and early clinical trials and evaluations of products may not be predictive of the results of later stage clinical trials. Similarly, the final results from a clinical trial may not be as favorable as interim results reported earlier in the same clinical trial. Products in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

Clinical trial failures may occur at any stage of development and may result from a multitude of factors both within and outside our control, including flaws in formulation or manufacturing, medical device design, adverse safety or efficacy profile and flaws in trial design, among others. If the trials result in negative or inconclusive results, we or our collaborators may decide, or regulators may require us, to discontinue trials of the products or conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and we cannot guarantee that the FDA or foreign regulatory authorities will interpret data the same way that we or our collaborators do, which may delay, limit or prevent regulatory approval or clearance. The FDA or foreign regulatory authorities may also disagree with the design of clinical trials. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we or

our collaborators may be required to expend significant resources to conduct additional trials in support of potential approval of the products. Other potential reasons for clinical trial failures include, but are not limited to, inability to enroll sufficient patients, inability to engage sufficient clinical sites, inability to obtain or maintain institutional review board, or IRB, approval of the trial, or cessation of a trial for futility or safety concerns by us, or FDA, or foreign regulatory authorities, or an independent committee such as an independent data monitoring committee. As a result of any number of potential reasons, clinical trials may not be successful

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we or our collaborators may not adequately develop such protocols to support clearance and approval or the results from such studies may not sufficiently demonstrate safety and efficacy. Further, the FDA or foreign regulatory authorities may, among other things, require the submission of data on a greater number of patients than originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of the products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested, the FDA or other regulatory authority may not consider the data adequate to demonstrate safety and efficacy. In addition, many of the factors that cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval.

Risks Related to Employee Matters

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

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the regulatory, commercialization and business development expertise of our executive management team, as well as the other principal members of our management, scientific and clinical team. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time. For instance, in December 2017, our former chief medical officer terminated his employment with us, in March 2018, our former chief financial officer terminated her employment with us and in June 2019, our former chief medical officer terminated his employment with us. Also, in connection with our June 2019 restructuring, our board of directors appointed our then chief operating officer as our president and chief executive officer, effective August 1, 2019, with our then president and chief executive officer transitioning to a consulting role, which ended in December 2019.

We do not have formal employment agreements with any of our other employees. If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key 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. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to continue to commercialize Xerava will be limited.

We have reduced the size of our organization, and [if the Merger is not consummated] we may encounter difficulties in managing our business as a result of this reduction, which could disrupt our operations. In addition, we may not achieve anticipated benefits and savings from the reduction.

In June 2019, we authorized the implementation of a restructuring of our organization, including a 20% reduction in headcount, designed to focus our cash resources on commercializing Xerava primarily in the hospital setting. The restructuring, and the attrition thereafter, resulted in the loss of longer-term employees, the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. In March 2020, we terminated an additional eight salespersons in connection with our entry into the Co-Promotion Agreement. We will need to continue to implement and improve our managerial, operational and financial systems, manage our facilities and continue to recruit and retain qualified personnel. This will be made more challenging given ongoing attrition and additional measures we may take to reduce costs. As a result, our management may need to divert a disproportionate amount of its attention away from our day-to-day strategic and operational activities, and devote a substantial amount of time to managing these organizational changes. Further, possible additional cost containment measures may yield unintended consequences, such as attrition beyond our intended reduction in headcount and reduced employee morale. In addition, reductions in the size of our organization may result in employees who were not affected by the reductions in headcount seeking alternate employment, which would result in us

seeking contract support at unplanned additional expense. In addition, we may not achieve anticipated benefits from our reductions in the size of our organization. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, loss of business opportunities, loss of employees and reduced productivity among remaining employees. We may also determine to take additional measures to reduce costs, which could result in further disruptions to our operations and present additional challenges to the effective management of our company. If our management is unable to effectively manage this transition and restructuring and additional cost containment measures, our expenses may be more than expected, and we may not be able to implement our business strategy.

The business that we may conduct outside the United States may be adversely affected by international risk and uncertainties.

Although our operations are based in the United States, we plan to seek approvals to sell our products in foreign countries. Any business that we conduct outside the United States will be subject to additional risks that may materially adversely affect our ability to conduct business in international markets, including:

- the impact of COVID-19 on our business operations outside the United States;
- potentially reduced protection for intellectual property rights;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting a product candidate being developed by a future collaborator and/or finished drug product supply or manufacturing capabilities abroad;
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, hurricanes, typhoons, floods and fires; and
- failure to comply with Office of Foreign Asset Control rules and regulations and the Foreign Corrupt Practices Act.

Our internal computer systems, or those of any collaborators, contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs or overall business operations.

Our internal computer infrastructure and those of any collaborators, contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. In June 2019, we experienced unauthorized access to an employee's e-mail. We investigated this security breach and believe it was contained to this one employee. While this event did not cause an interruption in our operations any future event could result in a material disruption of our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. 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. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates by future collaborators could be delayed or halted.

Our employees may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately, or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity 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 be in compliance with such laws, standards or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those

actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Risks Related to Our Common Stock

If we fail to meet the requirements for continued listing on the Nasdaq Global Select Market, our common stock could be delisted from trading, which would decrease the liquidity of our common stock and our ability to raise additional capital.

Our common stock is currently listed for quotation on the Nasdaq Global Select Market. We are required to meet specified requirements in order to maintain our listing on the Nasdaq Global Select Market, including, among other things, a minimum bid price of $1.00 per share. On June 24, 2019, we received a deficiency letter from the Listing Qualifications Department, or the Staff, of the Nasdaq Stock Market notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the Nasdaq Global Select Market. On September 26, 2019 we effected a 1-for-20 reverse stock split for the purpose of regaining compliance with the minimum bid price rule. On October 11, 2019, we received notification from the Listing Qualifications Department of the Nasdaq Stock Market that for 10 consecutive business days, the closing bid price of our common stock had been at $1.00 per share or greater, confirming that we had regained compliance with the minimum bid price rule.

If in the future we fail to satisfy the Nasdaq Global Select Market's continued listing requirements, we may transfer to the Nasdaq Capital Market, which generally has lower financial requirements for initial listing, to avoid delisting, or, if we fail to meet its listing requirements, the OTC Bulletin Board. A transfer of our listing to the Nasdaq Capital Market or having our common stock trade on the OTC Bulletin Board could adversely affect the liquidity of our common stock. Any such event could make it more difficult to dispose of, or obtain accurate quotations for the price of, our common stock, and there also would likely be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. We may also face other material adverse consequences in such event, such as negative publicity, a decreased ability to obtain additional financing, diminished investor and/or employee confidence, and the loss of business development opportunities, some or all of which may contribute to a further decline in our stock price.

There are many factors that may adversely affect our minimum bid price, including those described throughout this section titled "Risk Factors". Many of these factors are outside our control. As a result, we may not be able to sustain compliance with the minimum bid price rule in the long term. Any potential delisting of our common stock from the Nasdaq Global Select Market would likely result in decreased liquidity and increased volatility for our common stock and would adversely affect our ability to raise additional capital or enter into strategic transactions. Any potential delisting of our common stock from the Nasdaq Global Select Market would also make it more difficult for our stockholders to sell our common stock in the public market.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price may be volatile. The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. Due to pricing pressures, slow commercial uptake for new antibiotics and general investor sentiment, antibiotic companies are presently experiencing significant volatility in their stock prices. For example, our stock traded within a range of a high price of $1,058.00 per share and a low price of $0.56 per share for the period beginning March 20, 2013, our first day of trading on the Nasdaq Global Select Market, through May 6, 2020. As a result of this volatility, you may not be able to sell your common stock at or above the public offering price. The market price for our common stock may be influenced by many factors, including:

- the outcome of the Merger;
- revenues related to Xerava;
- the impact of the COVID-19 outbreak;
- the filing and approval of marketing applications for our product candidates by future collaborators;
- the timing and results of clinical trials of any product candidates that we license to third parties;
- regulatory actions by the FDA or equivalent authorities in foreign jurisdictions with respect to Xerava and any product candidate that we license to a third party;
- failure or discontinuation of any development programs of our future collaborators;
- the success of existing or new competitive products or technologies;
- results of clinical trials of product candidates of our competitors;

- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts or licensing or other strategic transactions;
- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In addition to litigation arising from the Merger, we have been and may again be subject to class action litigation and have been and may again be subject to shareholder derivative litigation, which could distract our management and could result in substantial costs or large judgments against us.

The stock market frequently experiences extreme price and volume fluctuations. We have experienced significant declines in our stock price following our announcements that IGNITE2 and IGNITE3, our phase 3 clinical trials for Xerava for the treatment of patients with cUTI, did not meet the primary endpoints of those trials. In addition, the market prices of securities of companies in the biotechnology and pharmaceutical industry have been extremely volatile and have experienced fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. These fluctuations could adversely affect the market price of our common stock. In the past, securities class action litigation has often been brought against companies following periods of volatility in the market prices of their securities. For instance, in January 2016 and March 2016, two class action lawsuits were filed against us, our chief executive officer and certain former executives in the United States District Court for the District of Massachusetts. These cases were subsequently consolidated. The court dismissed the consolidated cases in May 2017 and in November 2017, the plaintiffs withdrew a pending appeal in the United States Court of Appeals for the First Circuit. In addition, in May 2016, a shareholder derivative action was filed against our chief executive officer, certain former executive officers, all the members of our current board of directors, a former board member, and against us as nominal defendant, in Massachusetts Superior Court (Suffolk County). This case was subsequently dismissed by the court without prejudice due to the plaintiff's failure to properly perfect service of process. Furthermore, in July 2018 a class action lawsuit was filed against us, or chief executive officer, our chief scientific officer and other third parties in the United States District Court for the Southern District of New York in connection with the failure of IGNITE3 to meet its co-primary endpoints. This case was subsequently been moved to the United States District Court for the District of Massachusetts. In August 2019, the United States District Court for the District of Massachusetts (the "Massachusetts Federal Court") granted an unopposed motion for the appointment of a lead plaintiff. In October 2019, the lead plaintiff filed a motion to voluntarily dismiss the case and on October 16, 2019 the Massachusetts Federal Court entered an order dismissing the case. Due to the volatility in our stock price and the Merger, we may be the target of similar litigation in the future.

In connection with any such future litigation, we could incur substantial costs and such costs, and any related settlements or judgments, may not be covered by insurance. We could also suffer an adverse impact on our reputation and a diversion of management's attention and resources, which could cause serious harm to our business, operating results and financial condition.

An active trading market for our common stock may not be sustained.

Although we have listed our common stock on the Nasdaq Global Select Market, an active trading market for our common stock may not be sustained. In the absence of an active trading market for our common stock, investors may not be able to sell their common stock at or above the price at which they acquired the common stock or at the times that they would like to sell. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

The number of shares of common stock underlying our outstanding warrants is significant in relation to our currently outstanding common stock, which could have a negative effect on the market price of our common stock and make it more difficult for us to raise funds through future equity offerings.

As part of our November 2019 registered direct offering, we issued (i) warrants to purchase an aggregate of 2,130,493 shares of our common stock at an exercise price of $3.62 per share, and (ii) pre-funded warrants to purchase an aggregate of 1,830,493 shares of our common stock at an exercise price of $0.01 per share. As part of our January 2020 private placement and registered direct offering, we issued (i) warrants to purchase an aggregate of 5,833,439 shares of our common stock at an exercise price of $2.87 per share, and (ii) pre-funded warrants to purchase 2,183,334 shares of our common stock at an exercise price of $0.001 per share. As of May 6, 2020, all of these warrants except for 400,000 pre-funded warrants exercised in November 2019 remained outstanding and, upon exercise in full of these, the shares issuable upon exercise would represent a significant portion of our outstanding common stock. The pre-funded warrants have no expiration, and the common warrants remain exercisable for five years from their respective dates of issuance. The 6,581,091 shares issuable upon exercise of the warrants sold in the registered direct offerings can be freely sold into the public market upon issuance, subject to volume limitations applicable to affiliates. If the Merger is not consummated, we intend to file a registration statement registering the 5,396,668 shares of common stock issuable upon exercise of the warrants sold in the private placement. Sales of these shares could cause the market price of our common stock to decline significantly. Furthermore, if our stock price rises, the holders of these warrants may be more likely to exercise their warrants and sell a large number of shares, which could negatively impact the market price of our common stock and reduce or eliminate any appreciation in our stock price that might otherwise occur.

We may also find it more difficult to raise additional equity capital while these warrants are outstanding. At any time during which these warrants are likely to be exercised, we may be unable to obtain additional equity capital on more favorable terms from other sources. In addition, the exercise of these warrants would result in a significant increase in the number of our outstanding shares of common stock, which could have the effect of significantly diluting the interest of our current stockholders, and following such exercise the former holders of such warrants could have significant influence over our company as a result of the shares of common stock they acquire upon such exercise.

We have a significant securityholder, which could exert substantial influence over our business. In addition, in connection with any merger, consolidation or sale of all or substantially all of our assets, it would be entitled to receive consideration in excess of its reported beneficial ownership of our common stock and adversely impact the consideration our other securityholders would receive.

As of May 6, 2020, Armistice Capital, LLC, or Armistice, held 1,419,502 shares of our common stock, warrants to purchase up to 2,130,493 shares of our common stock at an exercise price of $3.62 per share, warrants to purchase up to 3,333,334 shares of our common stock at an exercise price of $2.87 per share, pre-funded warrants to purchase up to 1,430,493 shares of our common stock at an exercise price of $0.01 per share and pre-funded warrants to purchase up to 2,063,334 shares of our common stock at an exercise price of $0.001 per share. In addition, two members of our board of directors are affiliates of Armistice. Under the terms of the warrants and pre-funded warrants issued to Armistice, Armistice is not permitted to exercise such warrants to the extent that such exercise would result in Armistice (and its affiliates) beneficially owning more than 19.99% of the number of shares of our common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such warrants. After giving effect to the 19.99% beneficial ownership limitation currently in effect with respect to the warrants and pre-funded warrants held by Armistice, as of May 6, 2020, Armistice beneficially owned 19.6% of our outstanding common stock. If the warrants and pre-funded warrants held by Armistice could be exercised without this limitation, then as of May 6, 2020, Armistice would have beneficially owned 49.5% of our common stock. The information in this paragraph is based on a Schedule 13D filed with the SEC on January 23, 2020.

Although there are contractual limitations on the beneficial ownership of Armistice, if Armistice were to exercise its warrants for common stock, it could be able to exert substantial influence over our business. This concentration of voting power could delay, defer or prevent a change of control, entrench our management and the board of directors or delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire. In addition, conflicts of interest could arise in the future between us, on the one hand, and Armistice on the other hand, concerning potential competitive business activities, business opportunities, the issuance of additional securities and other matters. Furthermore, in the event of a sale of our company, whether by merger, sale of all or substantially all of our assets or otherwise, Armistice would be entitled to receive, with respect to each share of common stock issuable upon exercise of the warrants then held by it and without regard to the beneficial ownership limitations imposed on the conversion or exercise of such securities, the same amount and kind of securities, cash or property as it would have been entitled to receive if such securities had been converted into or exercised for shares of our common stock immediately prior to such sale of our company. Because Armistice would receive this sale consideration with respect to warrants not included in its reported beneficial ownership of our common stock, in the event of a sale of our company, it would be entitled to receive a significantly larger portion of the total proceeds distributable to the holders of our securities than is represented by its reported beneficial ownership of our common stock.

Moreover, the warrants that are exercisable for $3.62 and $2.87 per share that are held by Armistice provide that upon a fundamental transaction, which generally includes any merger with or into another entity, sale of all or substantially all of our assets, tender offer or exchange offer, or reclassification of our common stock, Armistice will have the right to require us to repurchase its warrants at their fair value using the Black Scholes value. As a result, in the event of a sale of our company, Armistice would be entitled to receive a significantly larger portion of the total proceeds distributable to the holders of our securities than they would if they exercised the warrants immediately prior to the transaction. In addition to these warrants, there are outstanding additional warrants to purchase up to an additional 2,500,105 shares of our common stock at an exercise price of $2.87 per share that contain similar fundamental transaction repurchase provisions. As a result, if Armistice and the holders of these other warrants exercise their right in connection with a fundamental transaction and have us repurchase their warrants at the Black Scholes value, the holders of our common stock could receive significantly less than they otherwise would in such a transaction. For example, in connection with entering into the Merger Agreement, we entered into voting agreements and an exchange agreement with Armistice and the holders of these other warrants providing, among other things, that each outstanding common stock warrant issued in November 2019 will be converted into the right to receive, at the closing of the Merger, 0.8813 of a share of AcelRx common stock for each share of our common stock underlying such warrant and each outstanding common stock warrant issued in January 2020 will be converted into the right to receive, at the closing of the Merger, 0.9087 of a share of AcelRx common stock for each share of our common stock underlying such warrant, whereas each outstanding share of our common stock will be converted into the right to receive 0.6303 of a share of AcelRx common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common stock will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will cover us, or provide favorable coverage. If one or more analysts downgrade our stock or change their opinion of our stock, our share price would likely decline. In addition, if one or more analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

We have broad discretion in the use of our cash reserves and may not use them effectively.

Our management has broad discretion to use our cash reserves and could spend these reserves in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our products and product candidates. Pending their use, we may invest our cash reserves in a manner that does not produce income or that loses value.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act in the future could have a material adverse effect on our ability to produce accurate financial statements and on our stock price.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us, on an annual basis, to review and evaluate our internal controls. To maintain compliance with Section 404, we are required to document and evaluate our internal control over financial reporting, which has been both costly and challenging. We will need to continue to dedicate internal resources, continue to engage outside consultants and follow a detailed work plan to continue to assess and document the adequacy of internal control over financial reporting, continue to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. There is a risk that in the future neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future; accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the operation, development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our by-laws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, 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. Among other things, these provisions:

- establish a classified board of directors such that all members of the board are not elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or by-laws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders.

Our bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a judicial forum that they find favorable for disputes with us or our directors, officers or other employees.

Our bylaws provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty owed by any of our current or former directors, officers or other employees to our company, our agents, or our stockholders, including, without limitation, a claim alleging the aiding and abetting of such a breach of fiduciary duty, any action asserting a claim against us arising pursuant to any provisions of the DGCL, our charter or our bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine or other “internal corporate claim” as that term is defined in Section 115 of the DGCL; *provided*, that these provisions will not apply to actions or proceedings brought to enforce a duty or liability created by the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts have exclusive jurisdiction. The choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

Item 6. Exhibits

See the Exhibit Index below for a list of exhibits filed as part of this Quarterly Report on Form 10-Q, which Exhibit Index is incorporated herein by reference.

EXHIBIT INDEX

Exhibit Number	Description of Document	Incorporated by Reference from				Filed Herewith
		Registrant's Form	File No.	Date Filed with the SEC	Exhibit Number	
2.1	Agreement and Plan of Merger by and among AcelRx Pharmaceuticals, Inc., Consolidation Merger Sub, Inc. and the Company, dated March 15, 2020.	8-K	001-35837	March 16, 2020	2.1	
3.1	Amended and Restated By-laws of the Company, as amended.					X
10.1	Co-Promotion Agreement, dated March 15, 2020, by and between AcelRx Pharmaceuticals, Inc. and the Company.	8-K	001-35837	March 16, 2020	10.2	
10.2	Form of Voting Agreement, dated March 15, 2020, by and among AcelRx Pharmaceuticals, Inc., Consolidation Merger Sub, Inc. and the stockholder named therein.	8-K	001-35837	March 16, 2020	10.3	
10.3	Form of Exchange Agreement, dated March 15, 2020, by and among AcelRx Pharmaceuticals, Inc., Consolidation Merger Sub, Inc. and the stockholder named therein.	8-K	001-35837	March 16, 2020	10.4	
10.4	Promissory Note, dated April 22, 2020, by and between the Company and Silicon Valley Bank, N.A..	8-K	001-35837	April 28, 2020	10.1	
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

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: May 7, 2020

TETRAPHASE PHARMACEUTICALS, INC.

By: /s/ Christopher Watt
Christopher Watt
Senior Vice President, Finance

Exhibit 3.1

AMENDED AND RESTATED BY-LAWS

OF

TETRAPHASE PHARMACEUTICALS, INC.

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ARTICLE I

STOCKHOLDERS

1.1 Place of Meetings. All meetings of stockholders shall be held at such place as may be designated from time to time by the Board of Directors, the Chairman of the Board, the Chief Executive Officer or the President or, if not so designated, at the principal office of the corporation.

1.2 Annual Meeting. The annual meeting of stockholders for the election of directors to succeed those whose terms expire and for the transaction of such other business as may properly be brought before the meeting shall be held on a date and at a time designated by the Board of Directors, the Chairman of the Board, the Chief Executive Officer or the President (which date shall not be a legal holiday in the place where the meeting is to be held).

1.3 Special Meetings. Special meetings of stockholders for any purpose or purposes may be called at any time by only the Board of Directors, the Chairman of the Board or the Chief Executive Officer, and may not be called by any other person or persons. The Board of Directors may postpone or reschedule any previously scheduled special meeting of stockholders. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting.

1.4 Notice of Meetings. Except as otherwise provided by law, notice of each meeting of stockholders, whether annual or special, shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting. Without limiting the manner by which notice otherwise may be given to stockholders, any notice shall be effective if given by a form of electronic transmission consented to (in a manner consistent with the General Corporation Law of the State of Delaware) by the stockholder to whom the notice is given. The notices of all meetings shall state the place, date and time of the meeting and the means of remote communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such meeting. The notice of a special meeting shall state, in addition, the purpose or purposes for which the meeting is called. If notice is given by mail, such notice shall be deemed given when deposited in the United States mail, postage

prepaid, directed to the stockholder at such stockholder's address as it appears on the records of the corporation. If notice is given by electronic transmission, such notice shall be deemed given at the time specified in Section 232 of the General Corporation Law of the State of Delaware.

1.5 Voting List. The Secretary shall prepare, at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, for a period of at least 10 days prior to the meeting: (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (b) during ordinary business hours, at the principal place of business of the corporation. The list shall also be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. The list shall presumptively determine the identity of the stockholders entitled to vote at the meeting and the number of shares held by each of them.

1.6 Quorum. Except as otherwise provided by law, the Certificate of lncorporation or these By-laws, the holders of a majority in voting power of the shares of the capital stock of the corporation issued and outstanding and entitled to vote at the meeting, present in person, present by means of remote communication in a manner, if any, authorized by the Board of Directors in its sole discretion, or represented by proxy, shall constitute a quorum for the transaction of business; provided, however, that where a separate vote by a class or classes or series of capital stock is required by law or the Certificate of Incorporation, the holders of a majority in voting power of the shares of such class or classes or series of the capital stock of the corporation issued and outstanding and entitled to vote on such matter, present in person, present by means of remote communication in a manner, if any, authorized by the Board of Directors in its sole discretion, or represented by proxy, shall constitute a quorum entitled to take action with respect to the vote on such matter. A quorum, once established at a meeting, shall not be broken by the withdrawal of enough votes to leave less than a quorum.

1.7 Adjournments. Any meeting of stockholders may be adjourned from time to time to any other time and to any other place at which a meeting of stockholders may be held under these By-laws by the chairman of the meeting or by the stockholders present or represented at the meeting and entitled to vote, although less than a quorum. It shall not be necessary to notify any stockholder of any adjournment of less than 30 days if the time and place of the adjourned meeting, and the means of remote communication, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such adjourned meeting, are announced at the meeting at which adjournment is taken, unless after the adjournment a new record date is fixed for the adjourned meeting. At the adjourned meeting, the corporation may transact any business which might have been transacted at the original meeting.

1.8 Voting and Proxies. Each stockholder shall have one vote for each share of stock entitled to vote held of record by such stockholder and a proportionate vote for each fractional share so held, unless otherwise provided by law or the Certificate of Incorporation. Each stockholder of record entitled to vote at a meeting of stockholders may vote in person (including by means of remote communications, if any, by which stockholders may be deemed to be present in person and vote at such meeting) or may authorize another person or persons to vote for such stockholder by a proxy executed or transmitted in a manner permitted by the General Corporation Law of the State of Delaware by the stockholder or such stockholder's authorized agent and delivered (including by electronic transmission) to the Secretary of the corporation. No such proxy shall be voted upon after three years from the date of its execution, unless the proxy expressly provides for a longer period.

1.9 Action at Meeting. When a quorum is present at any meeting, any matter other than the election of directors to be voted upon by the stockholders at such meeting shall be decided by the vote of the holders of shares of stock having a majority in voting power of the votes cast by the holders of all of the shares of stock present or represented at the meeting and voting affirmatively or negatively on such matter (or if there are two or more classes or series of stock entitled to vote as separate classes, then in the case of each such class or series, the holders of a majority in voting power of the shares of stock of that class or series present or represented at the meeting and voting affirmatively or negatively on such matter), except when a different vote is required by law, the Certificate of lncorporation or these By-laws. When a quorum is present at any meeting, any election by stockholders of directors shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election.

1.10 Nomination of Directors.

(a) Except for (1) any directors entitled to be elected by the holders of preferred stock, (2) any directors elected in accordance with Section 2.9 hereof by the Board of Directors to fill a vacancy or newly-created directorship or (3) as otherwise required by applicable law or stock exchange regulation, at any meeting of stockholders, only persons who are nominated in accordance with the procedures in this Section 1.10 shall be eligible for election as directors. Nomination for election to the Board of Directors at a meeting of stockholders may be made (i) by or at the direction of the Board of Directors or (ii) by any stockholder of the corporation who (x) timely complies with the notice procedures in Section 1.10 (b), (y) is a stockholder of record on the date of the giving of such notice and on the record date for the determination of stockholders entitled to vote at such meeting and (z) is entitled to vote at such meeting.

(b) To be timely, a stockholder's notice must be received in writing by the Secretary at the principal executive offices of the corporation as follows: (i) in the case of an election of directors at an annual meeting of stockholders, not less than 90 days nor more than 120 days prior to the first anniversary of the preceding year's annual meeting; provided, however, that (x) in the case of the annual meeting of stockholders of the corporation to be held in 2014 or (y) in the event that the date of the annual meeting in any other year is advanced by more than 20 days, or delayed by more than 60 days, from the first anniversary of the preceding year's annual meeting, a stockholder's notice must be so received not earlier than the 120th day prior to such annual meeting and not later than the close of business on the later of (A) the 90th day prior to such annual meeting and (B) the tenth day following the day on which notice of the date of such annual meeting was mailed or public disclosure of the date of such annual meeting was made, whichever first occurs; or (ii) in the case of an election of directors at a special meeting of stockholders, provided that the Board of Directors, the Chairman of the Board or the Chief Executive Officer has determined, in accordance with Section 1.3, that directors shall be elected at such special meeting and provided further that the nomination made by the

stockholder is for one of the director positions that the Board of Directors, the Chairman of the Board or the Chief Executive Officer, as the case may be, has determined will be filled at such special meeting, not earlier than the 120th day prior to such special meeting and not later than the close of business on the later of (x) the 90th day prior to such special meeting and (y) the tenth day following the day on which notice of the date of such special meeting was mailed or public disclosure of the date of such special meeting was made, whichever first occurs. In no event shall the adjournment or postponement of a meeting (or the public disclosure thereof) commence a new time period (or extend any time period) for the giving of a stockholder's notice.

The stockholder's notice to the Secretary shall set forth: (A) as to each proposed nominee (1) such person's name, age, business address and, if known, residence address, (2) such person's principal occupation or employment, (3) the class and series and number of shares of stock of the corporation that are, directly or indirectly, owned, beneficially or of record, by such person, (4) a description of all direct and indirect compensation and other material monetary agreements, arrangements and understandings during the past three years, and any other material relationships, between or among (x) the stockholder, the beneficial owner, if any, on whose behalf the nomination is being made and the respective affiliates and associates of, or others acting in concert with, such stockholder and such beneficial owner, on the one hand, and (y) each proposed nominee, and his or her respective affiliates and associates, or others acting in concert with such nominee(s), on the other hand, including all information that would be required to be disclosed pursuant to Item 404 of Regulation S-K if the stockholder making the nomination and any beneficial owner on whose behalf the nomination is made or any affiliate or associate thereof or person acting in concert therewith were the "registrant" for purposes of such Item and the proposed nominee were a director or executive officer of such registrant, and (5) any other information concerning such person that must be disclosed as to nominees in proxy solicitations pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and (B) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination is being made (1) the name and address of such stockholder, as they appear on the corporation's books, and of such beneficial owner, (2) the class and series and number of shares of stock of the corporation that are, directly or indirectly, owned, beneficially or of record, by such stockholder and such beneficial owner, (3) a

description of any agreement, arrangement or understanding between or among such stockholder and/or such beneficial owner and each proposed nominee and any other person or persons (including their names) pursuant to which the nomination(s) are being made or who may participate in the solicitation of proxies in favor of electing such nominee(s), (4) a description of any agreement, arrangement or understanding (including any derivative or short positions, swaps, profit interests, options, warrants, convertible securities, stock appreciation or similar rights, hedging transactions, and borrowed or loaned shares) that has been entered into by, or on behalf of, such stockholder or such beneficial owner, the effect or intent of which is to mitigate loss to, manage risk or benefit of share price changes for, or increase or decrease the voting power of, such stockholder or such beneficial owner with respect to shares of stock of the corporation, (5) any other information relating to such stockholder and such beneficial owner that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for the election of directors in a contested election pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder, (6) a representation that such stockholder intends to appear in person or by proxy at the meeting to nominate the person(s) named in its notice and (7) a representation whether such stockholder and/or such beneficial owner intends or is part of a group which intends (x) to deliver a proxy statement and/or form of proxy to holders of at least the percentage of the corporation's outstanding capital stock reasonably believed by such stockholder or such beneficial owner to be sufficient to elect the nominee (and such representation shall be included in any such proxy statement and form of proxy) and/or (y) otherwise to solicit proxies from stockholders in support of such nomination (and such representation shall be included in any such solicitation materials). Not later than 10 days after the record date for the meeting, the information required by Items (A)(l)-(5) and (B)(l)-(5) of the prior sentence shall be supplemented by the stockholder giving the notice to provide updated information as of the record date. In addition, to be effective, the stockholder's notice must be accompanied by the written consent of the proposed nominee to serve as a director if elected. The corporation may require any proposed nominee to furnish such other information as the corporation may reasonably require to determine the eligibility of such proposed nominee to serve as a director of the corporation or whether such nominee would be independent under applicable Securities and Exchange Commission and stock exchange rules and the corporation's publicly disclosed

corporate governance guidelines. A stockholder shall not have complied with this Section 1.10(b) if the stockholder (or beneficial owner, if any, on whose behalf the nomination is made) solicits or does not solicit, as the case may be, proxies in support of such stockholder's nominee in contravention of the representations with respect thereto required by this Section 1.10.

(c) The chairman of any meeting shall have the power and duty to determine whether a nomination was made in accordance with the provisions of this Section 1.10 (including whether the stockholder or beneficial owner, if any, on whose behalf the nomination is made solicited (or is part of a group which solicited) or did not so solicit, as the case may be, proxies in support of such stockholder's nominee in compliance with the representations with respect thereto required by this Section 1.10), and if the chairman should determine that a nomination was not made in accordance with the provisions of this Section 1.10, the chairman shall so declare to the meeting and such nomination shall not be brought before the meeting.

(d) Except as otherwise required by law, nothing in this Section 1.10 shall obligate the corporation or the Board of Directors to include in any proxy statement or other stockholder communication distributed on behalf of the corporation or the Board of Directors information with respect to any nominee for director submitted by a stockholder.

(e) Notwithstanding the foregoing provisions of this Section 1.10, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear at the meeting to present a nomination, such nomination shall not be brought before the meeting, notwithstanding that proxies in respect of such nominee may have been received by the corporation. For purposes of this Section 1.10, to be considered a "qualified representative of the stockholder", a person must be authorized by a written instrument executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting of stockholders and such person must produce such written instrument or electronic transmission, or a reliable reproduction of the written instrument or electronic transmission, at the meeting of stockholders.

(f) For purposes of this Section 1.10, "public disclosure" shall include disclosure in a press release reported by the Dow Jones News Service, Associated Press or comparable national news service or in a document publicly filed by the corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Exchange Act.

1.11 Notice of Business at Annual Meetings.

(a) At any annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting, business must be (1) specified in the notice of meeting (or any supplement thereto) given by or at the direction of the Board of Directors, (2) otherwise properly brought before the meeting by or at the direction of the Board of Directors, or (3) properly brought before the meeting by a stockholder. For business to be properly brought before an annual meeting by a stockholder, (i) if such business relates to the nomination of a person for election as a director of the corporation, the procedures in Section 1.10 must be complied with and (ii) if such business relates to any other matter, the business must constitute a proper matter under Delaware law for stockholder action and the stockholder must (x) have given timely notice thereof in writing to the Secretary in accordance with the procedures in Section 1.11 (b), (y) be a stockholder of record on the date of the giving of such notice and on the record date for the determination of stockholders entitled to vote at such annual meeting and (z) be entitled to vote at such annual meeting

(b) To be timely, a stockholder's notice must be received in writing by the Secretary at the principal executive offices of the corporation not less than 90 days nor more than 120 days prior to the first anniversary of the preceding year's annual meeting; provided, however, that (x) in the case of the annual meeting of stockholders of the corporation to be held in 2014 or (y) in the event that the date of the annual meeting in any other year is advanced by more than 20 days, or delayed by more than 60 days, from the first anniversary of the preceding year's annual meeting, a stockholder's notice must be so received not earlier than the 120th day prior to such annual meeting and not later than the close of business on the later of(A) the 90th day prior to such annual meeting and (8) the tenth day following the day on which notice of the date of such annual meeting was mailed or public disclosure of the date of such annual meeting was made, whichever first occurs. In no event shall the adjournment or postponement of an annual meeting (or the public disclosure thereof) commence a new time period (or extend any time period) for the giving of a stockholder's notice.

The stockholder's notice to the Secretary shall set forth: (A) as to each matter the stockholder proposes to bring before the annual meeting (1) a brief description of the business desired to be brought before the annual meeting, (2) the text of the proposal (including the exact text of any resolutions proposed for consideration and, in the event that such business includes a proposal to amend the By-laws, the exact text of the proposed amendment), and (3) the reasons for conducting such business at the annual meeting, and (B) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the proposal is being made (1) the name and address of such stockholder, as they appear on the corporation's books, and of such beneficial owner, (2) the class and series and number of shares of stock of the corporation that are, directly or indirectly, owned, beneficially or of record, by such stockholder and such beneficial owner, (3) a description of any material interest of such stockholder or such beneficial owner and the respective affiliates and associates of, or others acting in concert with, such stockholder or such beneficial owner in such business, (4) a description of any agreement, arrangement or understanding between or among such stockholder and/or such beneficial owner and any other person or persons (including their names) in connection with the proposal of such business or who may participate in the solicitation of proxies in favor of such proposal, (5) a description of any agreement, arrangement or understanding (including any derivative or short positions, swaps, profit interests, options, warrants, convertible securities, stock appreciation or similar rights, hedging transactions, and borrowed or loaned shares) that has been entered into by, or on behalf of, such stockholder or such beneficial owner, the effect or intent of which is to mitigate loss to, manage risk or benefit of share price changes for, or increase or decrease the voting power of, such stockholder or such beneficial owner with respect to shares of stock of the corporation, (6) any other information relating to such stockholder and such beneficial owner that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for the business proposed pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder, (7) a representation that such stockholder intends to appear in person or by proxy at the annual meeting to bring such business before the meeting and (8) a representation whether such stockholder and/or such beneficial owner intends or is part of a group which intends (x) to deliver a proxy statement

and/or form of proxy to holders of at least the percentage of the corporation's outstanding capital stock required to approve or adopt the proposal (and such representation shall be included in any such proxy statement and form of proxy) and/or (y) otherwise to solicit proxies from stockholders in support of such proposal (and such representation shall be included in any such solicitation materials). Not later than 10 days after the record date for the meeting, the information required by Items (A)(3) and (B)(l)-(6) of the prior sentence shall be supplemented by the stockholder giving the notice to provide updated information as of the record date. Notwithstanding anything in these By-laws to the contrary, no business shall be conducted at any annual meeting of stockholders except in accordance with the procedures in this Section 1.11; provided that any stockholder proposal which complies with Rule 14a-8 of the proxy rules (or any successor provision) promulgated under the Exchange Act and is to be included in the corporation's proxy statement for an annual meeting of stockholders shall be deemed to comply with the notice requirements of this Section 1.11. A stockholder shall not have complied with this Section 1.11(b) if the stockholder (or beneficial owner, if any, on whose behalf the proposal is made) solicits or does not solicit, as the case may be, proxies in support of such stockholder's proposal in contravention of the representations with respect thereto required by this Section 1.11.

(c) The chairman of any annual meeting shall have the power and duty to determine whether business was properly brought before the annual meeting in accordance with the provisions of this Section 1.11 (including whether the stockholder or beneficial owner, if any, on whose behalf the proposal is made solicited (or is part of a group which solicited) or did not so solicit, as the case may be, proxies in support of such stockholder's proposal in compliance with the representation with respect thereto required by this Section 1.11), and if the chairman should determine that business was not properly brought before the annual meeting in accordance with the provisions of this Section 1.11, the chairman shall so declare to the meeting and such business shall not be brought before the annual meeting.

(d) Except as otherwise required by law, nothing in this Section 1.11 shall obligate the corporation or the Board of Directors to include in any proxy statement or other stockholder communication distributed on behalf of the corporation or the Board of Directors information with respect to any proposal submitted by a stockholder.

(e) Notwithstanding the foregoing provisions of this Section 1.11, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear at the annual meeting to present business, such business shall not be considered, notwithstanding that proxies in respect of such business may have been received by the corporation.

(f) For purposes of this Section 1.11, the terms "qualified representative of the stockholder" and "public disclosure" shall have the same meaning as in Section 1.10.

1.12 Conduct at Annual Meetings.

(a) Meetings of stockholders shall be presided over by the Chairman of the Board, if any, or in the Chairman's absence by the Vice Chairman of the Board, if any, or in the Vice Chairman's absence by the Chief Executive Officer, or in the Chief Executive Officer's absence, by the President, or in the President's absence by a Vice President, or in the absence of all of the foregoing persons by a chairman designated by the Board of Directors. The Secretary shall act as secretary of the meeting, but in the Secretary's absence the chairman of the meeting may appoint any person to act as secretary of the meeting.

(b) The Board of Directors may adopt by resolution such rules, regulations and procedures for the conduct of any meeting of stockholders of the corporation as it shall deem appropriate including, without limitation, such guidelines and procedures as it may deem appropriate regarding the participation by means of remote communication of stockholders and proxyholders not physically present at a meeting. Except to the extent inconsistent with such rules, regulations and procedures as adopted by the Board of Directors, the chairman of any meeting of stockholders shall have the right and authority to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such chairman, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board of Directors or prescribed by the chairman of the meeting, may include, without limitation, the following: (i) the establishment of an agenda or order of business for the meeting; (ii) rules and procedures for maintaining order at the meeting and the safety of those present; (iii) limitations on attendance at or participation in the meeting to stockholders of record of the corporation, their duly authorized and constituted proxies or such other persons as

shall be determined; (iv) restrictions on entry to the meeting after the time fixed for the commencement thereof; and (v) limitations on the time allotted to questions or comments by participants. Unless and to the extent determined by the Board of Directors or the chairman of the meeting, meetings of stockholders shall not be required to be held in accordance with the rules of parliamentary procedure.

(c) The chairman of the meeting shall announce at the meeting when the polls for each matter to be voted upon at the meeting will be opened and closed. After the polls close, no ballots, proxies or votes or any revocations or changes thereto may be accepted.

(d) In advance of any meeting of stockholders, the Board of Directors, the Chairman of the Board, the Chief Executive Officer or the President shall appoint one or more inspectors of election to act at the meeting and make a written report thereof. One or more other persons may be designated as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is present, ready and willing to act at a meeting of stockholders, the chairman of the meeting shall appoint one or more inspectors to act at the meeting. Unless otherwise required by law, inspectors may be officers, employees or agents of the corporation. Each inspector, before entering upon the discharge of such inspector's duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of such inspector's ability. The inspector shall have the duties prescribed by law and shall take charge of the polls and, when the vote is completed, shall make a certificate of the result of the vote taken and of such other facts as may be required by law. Every vote taken by ballots shall be counted by a duly appointed inspector or duly appointed inspectors.

1.13 No Action by Consent in Lieu of a Meeting. Stockholders of the corporation may not take any action by written consent in lieu of a meeting.

ARTICLE II

DIRECTORS

2.1 General Powers. The business and affairs of the corporation shall be managed by or under the direction of a Board of Directors, who may exercise all of the powers of the corporation except as otherwise provided by law or the Certificate of Incorporation.

2.2 Number, Election and Qualification. Subject to the rights of holders of any series of Preferred Stock to elect directors, the number of directors of the corporation shall be established by the Board of Directors. Election of directors need not be by written ballot. Directors need not be stockholders of the corporation.

2.3 Chairman of the Board; Vice Chairman of the Board. The Board of Directors may appoint from its members a Chairman of the Board and a Vice Chairman of the Board, neither of whom need be an employee or officer of the corporation. If the Board of Directors appoints a Chairman of the Board, such Chairman shall perform such duties and possess such powers as are assigned by the Board of Directors and, if the Chairman of the Board is also designated as the corporation's Chief Executive Officer, shall have the powers and duties of the Chief Executive Officer prescribed in Section 3.7 of these By-laws. If the Board of Directors appoints a Vice Chairman of the Board, such Vice Chairman shall perform such duties and possess such powers as are assigned by the Board of Directors. Unless otherwise provided by the Board of Directors, the Chairman of the Board or, in the Chairman's absence, the Vice Chairman of the Board, if any, shall preside at all meetings of the Board of Directors.

2.4 Classes of Directors. Subject to the rights of holders of any series of Preferred Stock to elect directors, the Board of Directors shall be and is divided into three classes: Class I, Class II and Class III. Each class shall consist, as nearly as may be possible, of one-third of the total number of directors constituting the entire Board of Directors. The allocation of directors among classes shall be determined by resolution of the Board of Directors.

2.5 Terms of Office. Subject to the rights of holders of any series of Preferred Stock to elect directors, each director shall serve for a term ending on the date of the third annual

meeting of stockholders following the annual meeting of stockholders at which such director was elected; provided that each director initially assigned to Class I shall serve for a term expiring at the corporation's first annual meeting of stockholders held after the effectiveness of these Amended and Restated By-laws; each director initially assigned to Class II shall serve for a term expiring at the corporation's second annual meeting of stockholders held after the effectiveness of these Amended and Restated By-laws; and each director initially assigned to Class III shall serve for a term expiring at the corporation's third annual meeting of stockholders held after the effectiveness of these Amended and Restated By-laws; provided further, that the term of each director shall continue until the election and qualification of his or her successor and be subject to his or her earlier death, resignation or removal.

2.6 Quorum. The greater of(a) a majority of the directors at any time in office and (b) one-third of the number of directors established by the Board of Directors pursuant to Section 2.2 of these By-laws shall constitute a quorum of the Board of Directors. If at any meeting of the Board of Directors there shall be less than such a quorum, a majority of the directors present may adjourn the meeting from time to time without further notice other than announcement at the meeting, until a quorum shall be present.

2.7 Action at Meeting. Every act or decision done or made by a majority of the directors present at a meeting duly held at which a quorum is present shall be regarded as the act of the Board of Directors, unless a greater number is required by law or by the Certificate of Incorporation.

2.8 Removal. Subject to the rights of holders of any series of Preferred Stock, directors of the corporation may be removed only for cause and only by the affirmative vote of the holders of at least 75% of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors.

2.9 Vacancies. Subject to the rights of holders of any series of Preferred Stock, any vacancy or newly-created directorship on the Board of Directors, however occurring, shall be filled only by vote of a majority of the directors then in office, although less than a quorum, or by a sole remaining director and shall not be filled by the stockholders. A director elected to fill a vacancy shall hold office until the next election of the class for which such director shall have been chosen, subject to the election and qualification of a successor or until such director's earlier death, resignation or removal.

2.10 Resignation. Any director may resign by delivering a resignation in writing or by electronic transmission to the corporation at its principal office or to the Chairman of the Board, the Chief Executive Officer, the President or the Secretary. Such resignation shall be effective upon delivery unless it is specified to be effective at some later time or upon the happening of some later event.

2.11 Regular Meetings. Regular meetings of the Board of Directors may be held without notice at such time and place as shall be determined from time to time by the Board of Directors; provided that any director who is absent when such a determination is made shall be given notice of the determination. A regular meeting of the Board of Directors may be held without notice immediately after and at the same place as the annual meeting of stockholders.

2.12 Special Meetings. Special meetings of the Board of Directors may be held at any time and place designated in a call by the Chairman of the Board, the Chief Executive Officer, the President, two or more directors, or by one director in the event that there is only a single director in office.

2.13 Notice of Special Meetings. Notice of the date, place and time of any special meeting of directors shall be given to each director by the Secretary or by the officer or one of the directors calling the meeting. Notice shall be duly given to each director (a) in person or by telephone at least 24 hours in advance of the meeting, (b) by sending written notice by reputable overnight courier, telecopy, facsimile or electronic transmission, or delivering written notice by hand, to such director's last known business, home or electronic transmission address at least 48 hours in advance of the meeting, or (c) by sending written notice by first-class mail to such director's last known business or home address at least 72 hours in advance of the meeting. A notice or waiver of notice of a meeting of the Board of Directors need not specify the purposes of the meeting.

2.14 Meetings by Conference Communications Equipment. Directors may participate in meetings of the Board of Directors or any committee thereof by means of conference

telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and participation by such means shall constitute presence in person at such meeting.

2.15 Action by Consent. Any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting, if all members of the Board of Directors or committee, as the case may be, consent to the action in writing or by electronic transmission, and the written consents or electronic transmissions are filed with the minutes of proceedings of the Board of Directors or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

2.16 Committees. The Board of Directors may designate one or more committees, each committee to consist of one or more of the directors of the corporation with such lawfully delegable powers and duties as the Board of Directors thereby confers, to serve at the pleasure of the Board of Directors. The Board of Directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members of the committee present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board of Directors and subject to the provisions of law, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the corporation and may authorize the seal of the corporation to be affixed to all papers which may require it. Each such committee shall keep minutes and make such reports as the Board of Directors may from time to time request. Except as the Board of Directors may otherwise determine, any committee may make rules for the conduct of its business, but unless otherwise provided by the directors or in such rules, its business shall be conducted as nearly as possible in the same manner as is provided in these By-laws for the Board of Directors. Except as otherwise provided in the Certificate of Incorporation, these By-laws, or the resolution of the Board of Directors designating the committee, a committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and delegate to a subcommittee any or all of the powers and authority of the committee.

2.17 Compensation of Directors. Directors may be paid such compensation for their services and such reimbursement for expenses of attendance at meetings as the Board of Directors may from time to time determine. No such payment shall preclude any director from serving the corporation or any of its parent or subsidiary entities in any other capacity and receiving compensation for such service.

ARTICLE III

OFFICERS

3.1 Titles. The officers of the corporation shall consist of a Chief Executive Officer, a President, a Secretary, a Treasurer and such other officers with such other titles as the Board of Directors shall determine, including one or more Vice Presidents, Assistant Treasurers and Assistant Secretaries. The Board of Directors may appoint such other officers as it may deem appropriate.

3.2 Election. The Chief Executive Officer, President, Treasurer and Secretary shall be elected annually by the Board of Directors at its first meeting following the annual meeting of stockholders. Other officers may be appointed by the Board of Directors at such meeting or at any other meeting.

3.3 Qualification. No officer need be a stockholder. Any two or more offices may be held by the same person.

3.4 Tenure. Except as otherwise provided by law, by the Certificate of lncorporation or by these By-laws, each officer shall hold office until such officer's successor is elected and qualified, unless a different term is specified in the resolution electing or appointing such officer, or until such officer's earlier death, resignation or removal.

3.5 Resignation and Removal. Any officer may resign by delivering a written resignation to the corporation at its principal office or to the Chief Executive Officer, the

President or the Secretary. Such resignation shall be effective upon receipt unless it is specified to be effective at some later time or upon the happening of some later event. Any officer may be removed at any time, with or without cause, by vote of a majority of the directors then in office. Except as the Board of Directors may otherwise determine, no officer who resigns or is removed shall have any right to any compensation as an officer for any period following such officer's resignation or removal, or any right to damages on account of such removal, whether such officer's compensation be by the month or by the year or otherwise, unless such compensation is expressly provided for in a duly authorized written agreement with the corporation.

3.6 Vacancies. The Board of Directors may fill any vacancy occurring in any office for any reason and may, in its discretion, leave unfilled for such period as it may determine any offices other than those of Chief Executive Officer, President, Treasurer and Secretary. Each such successor shall hold office for the unexpired term of such officer's predecessor and until a successor is elected and qualified, or until such officer's earlier death, resignation or removal.

3.7 President; Chief Executive Officer. Unless the Board of Directors has designated another person as the corporation's Chief Executive Officer, the President shall be the Chief Executive Officer of the corporation. The Chief Executive Officer shall have general charge and supervision of the business of the corporation subject to the direction of the Board of Directors, and shall perform all duties and have all powers that are commonly incident to the office of chief executive or that are delegated to such officer by the Board of Directors. The President shall perform such other duties and shall have such other powers as the Board of Directors or the Chief Executive Officer (if the President is not the Chief Executive Officer) may from time to time prescribe. In the event of the absence, inability or refusal to act of the Chief Executive Officer or the President (if the President is not the Chief Executive Officer), the Vice President (or if there shall be more than one, the Vice Presidents in the order determined by the Board of Directors) shall perform the duties of the Chief Executive Officer and when so performing such duties shall have all the powers of and be subject to all the restrictions upon the Chief Executive Officer.

3.8 Vice Presidents. Each Vice President shall perform such duties and possess such powers as the Board of Directors or the Chief Executive Officer may from time to time prescribe. The Board of Directors may assign to any Vice President the title of Executive Vice President, Senior Vice President or any other title selected by the Board of Directors.

3.9 Secretary and Assistant Secretaries. The Secretary shall perform such duties and shall have such powers as the Board of Directors or the Chief Executive Officer may from time to time prescribe. In addition, the Secretary shall perform such duties and have such powers as are incident to the office of the secretary, including without limitation the duty and power to give notices of all meetings of stockholders and special meetings of the Board of Directors, to attend all meetings of stockholders and the Board of Directors and keep a record of the proceedings, to maintain a stock ledger and prepare lists of stockholders and their addresses as required, to be custodian of corporate records and the corporate seal and to affix and attest to the same on documents.

Any Assistant Secretary shall perform such duties and possess such powers as the Board of Directors, the Chief Executive Officer or the Secretary may from time to time prescribe. In the event of the absence, inability or refusal to act of the Secretary, the Assistant Secretary (or if there shall be more than one, the Assistant Secretaries in the order determined by the Board of Directors) shall perform the duties and exercise the powers of the Secretary.

In the absence of the Secretary or any Assistant Secretary at any meeting of stockholders or directors, the chairman of the meeting shall designate a temporary secretary to keep a record of the meeting.

3.10 Treasurer and Assistant Treasurers. The Treasurer shall perform such duties and shall have such powers as may from time to time be assigned by the Board of Directors or the Chief Executive Officer. In addition, the Treasurer shall perform such duties and have such powers as are incident to the office of treasurer, including without limitation the duty and power to keep and be responsible for all funds and securities of the corporation, to deposit funds of the corporation in depositories selected in accordance with these By-laws, to disburse such funds as ordered by the Board of Directors, to make proper accounts of such funds, and to render as required by the Board of Directors statements of all such transactions and of the financial condition of the corporation.

The Assistant Treasurers shall perform such duties and possess such powers as the Board of Directors, the Chief Executive Officer or the Treasurer may from time to time prescribe. In the event of the absence, inability or refusal to act of the Treasurer, the Assistant Treasurer (or if there shall be more than one, the Assistant Treasurers in the order determined by the Board of Directors) shall perform the duties and exercise the powers of the Treasurer.

3.11 Salaries. Officers of the corporation shall be entitled to such salaries, compensation or reimbursement as shall be fixed or allowed from time to time by the Board of Directors.

3.12 Delegation of Authority. The Board of Directors may from time to time delegate the powers or duties of any officer to any other officer or agent, notwithstanding any provision hereof.

ARTICLE IV

CAPITAL STOCK

4.1 Issuance of Stock. Subject to the provisions of the Certificate of Incorporation, the whole or any part of any unissued balance of the authorized capital stock of the corporation or the whole or any part of any shares of the authorized capital stock of the corporation held in the corporation's treasury may be issued, sold, transferred or otherwise disposed of by vote of the Board of Directors in such manner, for such lawful consideration and on such terms as the Board of Directors may determine.

4.2 Stock Certificates; Uncertificated Shares. The shares of the corporation shall be represented by certificates, provided that the Board of Directors may provide by resolution or resolutions that some or all of any or all classes or series of the corporation's stock shall be uncertificated shares. Every holder of stock of the corporation represented by certificates shall be entitled to have a certificate, in such form as may be prescribed by law and by the Board of Directors, representing the number of shares held by such holder registered in certificate form. Each such certificate shall be signed in a manner that complies with Section 158 of the General Corporation Law of the State of Delaware.

Each certificate for shares of stock which are subject to any restriction on transfer pursuant to the Certificate of Incorporation, these By-laws, applicable securities laws or any agreement among any number of stockholders or among such holders and the corporation shall have conspicuously noted on the face or back of the certificate either the full text of the restriction or a statement of the existence of such restriction.

If the corporation shall be authorized to issue more than one class of stock or more than one series of any class, the powers, designations, preferences and relative participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of each certificate representing shares of such class or series of stock, provided that in lieu of the foregoing requirements there may be set forth on the face or back of each certificate representing shares of such class or series of stock a statement that the corporation will furnish without charge to each stockholder who so requests a copy of the full text of the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

Within a reasonable time after the issuance or transfer of uncertificated shares, the corporation shall send to the registered owner thereof a written notice containing the information required to be set forth or stated on certificates pursuant to Sections 151, 202(a) or 218(a) of the General Corporation Law of the State of Delaware or, with respect to Section 151 of General Corporation Law of the State of Delaware, a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

4.3 Transfers. Shares of stock of the corporation shall be transferable in the manner prescribed by law and in these By-laws. Transfers of shares of stock of the corporation shall be made only on the books of the corporation or by transfer agents designated to transfer shares of stock of the corporation. Subject to applicable law, shares of stock represented by certificates shall be transferred only on the books of the corporation by the surrender to the corporation or its

transfer agent of the certificate representing such shares properly endorsed or accompanied by a written assignment or power of attorney properly executed, and with such proof of authority or the authenticity of signature as the corporation or its transfer agent may reasonably require. Except as may be otherwise required by law, by the Certificate of Incorporation or by these By-laws, the corporation shall be entitled to treat the record holder of stock as shown on its books as the owner of such stock for all purposes, including the payment of dividends and the right to vote with respect to such stock, regardless of any transfer, pledge or other disposition of such stock until the shares have been transferred on the books of the corporation in accordance with the requirements of these By-laws.

4.4 Lost, Stolen or Destroyed Certificates. The corporation may issue a new certificate of stock in place of any previously issued certificate alleged to have been lost, stolen or destroyed, upon such terms and conditions as the Board of Directors may prescribe, including the presentation of reasonable evidence of such loss, theft or destruction and the giving of such indemnity and posting of such bond as the Board of Directors may require for the protection of the corporation or any transfer agent or registrar.

4.5 Record Date. The Board of Directors may fix in advance a date as a record date for the determination of the stockholders entitled to notice of or to vote at any meeting of stockholders, or entitled to receive payment of any dividend or other distribution or allotment of any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action. Such record date shall not precede the date on which the resolution fixing the record date is adopted, and such record date shall not be more than 60 nor less than 10 days before the date of such meeting, nor more than 60 days prior to any other action to which such record date relates.

If no record date is fixed, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day before the day on which notice is given, or, if notice is waived, at the close of business on the day before the day on which the meeting is held. If no record date is fixed, the record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating to such purpose.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for the adjourned meeting.

4.6 Regulations. The issue, transfer, conversion and registration of shares of stock of the corporation shall be governed by such other regulations as the Board of Directors may establish.

ARTICLE V

GENERAL PROVISIONS

5.1 Fiscal Year. Except as from time to time otherwise designated by the Board of Directors, the fiscal year of the corporation shall begin on the first day of January of each year and end on the last day of December in each year.

5.2 Corporate Seal. The corporate seal shall be in such form as shall be approved by the Board of Directors.

5.3 Waiver of Notice. Whenever notice is required to be given by law, by the Certificate of Incorporation or by these By-laws, a written waiver signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before, at or after the time of the event for which notice is to be given, shall be deemed equivalent to notice required to be given to such person. Neither the business nor the purpose of any meeting need be specified in any such waiver. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened.

5.4 Voting of Securities. Except as the Board of Directors may otherwise designate, the Chief Executive Officer, the President or the Treasurer may waive notice of, vote, or appoint any person or persons to vote, on behalf of the corporation at, and act as, or appoint any person or persons to act as, proxy or attorney-in-fact for this corporation (with or without power of substitution) at, any meeting of stockholders or securityholders of any other entity, the securities of which may be held by this corporation.

5.5 Evidence of Authority. A certificate by the Secretary, or an Assistant Secretary, or a temporary Secretary, as to any action taken by the stockholders, directors, a committee or any officer or representative of the corporation shall as to all persons who rely on the certificate in good faith be conclusive evidence of such action.

5.6 Certificate of lncorporation. All references in these By-laws to the Certificate of Incorporation shall be deemed to refer to the Certificate of Incorporation of the corporation, as amended and in effect from time to time.

5.7 Severability. Any determination that any provision of these By-laws is for any reason inapplicable, illegal or ineffective shall not affect or invalidate any other provision of these By-laws.

5.8 Pronouns. All pronouns used in these By-laws shall be deemed to refer to the masculine, feminine or neuter, singular or plural, as the identity of the person or persons may require.

ARTICLE VI

AMENDMENTS

These By-laws may be altered, amended or repealed, in whole or in part, or new By-laws may be adopted by the Board of Directors or by the stockholders as provided in the Certificate of Incorporation.

Amendment to
Amended and Restated By-laws
of
Tetraphase Pharmaceuticals, Inc.

The Amended and Restated By-laws of Tetraphase Pharmaceuticals, Inc. be and hereby are amended by adding by adding thereto a new Section 5.9 as follows:

> "Section 5.9. Forum Selection By-law. Unless the corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for: (a) any derivative action or proceeding brought on behalf of the corporation, (b) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, other employee, agent or stockholder of the corporation to the corporation or the corporation's stockholders, including, without limitation, a claim alleging the aiding and abetting of such a breach of fiduciary duty, (c) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, the Certificate of Incorporation or these By-laws (as each may be amended from time to time) or as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware, or (d) any action asserting a claim governed by the internal affairs doctrine or other "internal corporate claim" as that term is defined in Section 115 of the General Corporation Law of the State of Delaware. Any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of the corporation shall be deemed to have notice of and consented to the provisions of this Section 5.9."

Adopted by the Board of Directors of Tetraphase Pharmaceuticals, Inc. on March 15, 2020.

Exhibit 31.1

Certification of Chief Executive Officer
pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934,
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Larry Edwards, certify that:

(1) I have reviewed this quarterly report on Form 10-Q of Tetraphase 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 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 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: May 7, 2020

/s/ Larry Edwards
Larry Edwards
Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer
pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934,
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Christopher Watt, certify that:

(1) I have reviewed this quarterly report on Form 10-Q of Tetraphase 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 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 15d015(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 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: May 7, 2020

/s/ Christopher Watt
Christopher Watt
Senior Vice President, Finance
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

Certification of Chief Executive Officer
pursuant to 18 U.S.C. Section 1350, as adopted
pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the quarterly report on Form 10-Q of Tetraphase Pharmaceuticals, Inc. (the "Company") for the period ended March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Larry Edwards, as Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 7, 2020

/s/ Larry Edwards
Larry Edwards
Chief Executive Officer

Exhibit 32.2

Certification of Principal Financial Officer
pursuant to 18 U.S.C. Section 1350, as adopted
pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the quarterly report on Form 10-Q of Tetraphase Pharmaceuticals, Inc. (the "Company") for the period ended March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Christopher Watt, as Principal Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 7, 2020

/s/ Christopher Watt
Christopher Watt
Senior Vice President, Finance
(Principal Financial Officer and Principal Accounting Officer)