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, 2019

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	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 7, 2019, there were 54,263,802 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, 2019

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

TETRAPHASE PHARMACEUTICALS, INC.

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

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 87,559	$ 107,776
Accounts receivable, net	1,818	2,274
Contract asset	3,000	3,000
Inventory	2,348	748
Prepaid expenses and other current assets	2,411	2,674
Total current assets	97,136	116,472
Noncurrent assets:		
Property and equipment, net	1,116	1,121
Operating lease right-of-use assets	5,896	—
Restricted cash	699	699
Intangible assets, net	4,553	4,652
Total assets	$ 109,400	$ 122,944
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,692	$ 3,210
Accrued expenses	9,257	11,761
Operating lease liabilities	1,398	—
Total current liabilities	13,347	14,971
Long-term operating lease liabilities	4,621	—
Loan payable	28,514	28,291
Commitments and contingencies		
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; 53,746 and 53,680 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	54	53
Additional paid-in capital	616,394	613,671
Accumulated deficit	(553,530)	(534,042)
Total stockholders' equity	62,918	79,682
Total liabilities and stockholders' equity	$ 109,400	$ 122,944

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,	
	2019	**2018**
Revenues:		
Product revenue, net	$ 341	$ —
Government revenue	932	1,891
Total revenue	1,273	1,891
Expenses:		
Cost of revenue - product	164	—
Cost of revenue - intangible asset amortization	98	—
Research and development	6,737	18,127
Selling, general and administrative	13,314	5,705
Total expenses	20,313	23,832
Loss from operations	(19,040)	(21,941)
Other income and expenses		
Interest income	507	365
Interest expense	(955)	—
Net loss	$ (19,488)	$ (21,576)
Net loss per share-basic and diluted	$ (0.36)	$ (0.42)
Weighted-average number of common shares used in net loss per share-basic and diluted	53,740	51,601
Comprehensive loss	$ (19,488)	$ (21,576)

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,	
	2019	2018
Operating activities		
Net loss	$ (19,488)	$ (21,576)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	201	116
Non-cash interest expense related to notes payable	223	—
Stock-based compensation expense	2,723	2,971
Changes in operating assets and liabilities:		
Accounts receivable	457	1,440
Inventory	(1,600)	—
Prepaid expenses and other assets	262	(548)
Accounts payable	(518)	(1,707)
Accrued expenses and other liabilities	(2,387)	(6,409)
Deferred revenue	(6)	6,819
Operating lease right-of-use assets	342	—
Operating lease liabilities	(328)	—
Net cash used in operating activities	(20,119)	(18,894)
Investing activities		
Purchases of property and equipment	(98)	(83)
Net cash used in investing activities	(98)	(83)
Financing activities		
Proceeds from issuance of stock under stock plans	—	231
Net cash provided by financing activities	—	231
Net decrease in cash, cash equivalents and restricted cash	(20,217)	(18,746)
Cash, cash equivalents and restricted cash at beginning of period	108,475	136,610
Cash, cash equivalents and restricted cash at end of period	$ 88,258	$ 117,864
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 Equity
(In thousands)
(Unaudited)

	Common Shares		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2018	53,680	$ 53	$ 613,671	$ (534,042)	$ 79,682
Issuance of common stock under stock plans	66	1	—	—	1
Stock-based compensation expense	—	—	2,723	—	2,723
Net loss	—	—	—	(19,488)	(19,488)
Balance at March 31, 2019	53,746	$ 54	$ 616,394	$ (553,530)	$ 62,918
Balance at December 31, 2017	51,458	$ 51	$ 592,243	$ (461,884)	$ 130,410
Issuance of common stock under stock plans	172	1	231	—	232
Stock-based compensation expense	—	—	2,971	—	2,971
Net loss	—	—	—	(21,576)	(21,576)
Balance at March 31, 2018	51,630	$ 52	$ 595,445	$ (483,460)	$ 112,037

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. The Company developed its lead product candidate, 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 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 the IGNITE phase 3 clinical program, 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.

In addition to Xerava, the Company has also developed TP-6076, a fully synthetic fluorocycline, targeted at unmet medical needs, including multidrug-resistant Gram-negative bacteria, and TP-271, a fully synthetic fluorocycline being developed for respiratory disease caused by bacterial biothreat pathogens, as well as bacterial pathogens associated with community-acquired pneumonia. Both of these programs are in phase 1. The Company is also pursuing development of TP-2846, a tetracycline for the treatment of acute myeloid leukemia, or AML. The Company has recently initiated pre-clinical toxicology studies in this program.

The Company has incurred annual net operating losses every year since its inception. As of March 31, 2019, the Company had incurred losses since inception of $553.5 million. The Company has financed its operations primarily through public offerings and private placements of equity securities, debt financings, revenue from United States government grants and contract awards and milestone payments from its licensing agreement. While the Company's current cash and cash equivalents as well as funds received through its revenue arrangements will be sufficient to fund its operations through at least the next 12 months, 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.

There can be no assurance that the Company will be able to obtain additional debt or equity financing or generate product revenue or revenues from collaborative partners, on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations and financial condition.

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 United States Securities and Exchange Commission, or SEC, for interim financial information. Accordingly, they do not include all of the information and footnotes required by United States 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, 2018 contained in the Company's annual report on Form 10-K filed with the SEC on March 15, 2019 (the "2018 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, 2019 and the results of operations and comprehensive loss and cash flows for the three months ended March 31, 2019 and 2018. Interim operating results for the three months ended March 31, 2019 are not necessarily indicative of the results that may be expected for future interim periods or for the fiscal year ending December 31, 2019. The Company's significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies" in the 2018 Annual Report on Form 10-K. The Company is disclosing certain significant policies as well as changes in its accounting policies related to guidance that became effective January 1, 2019 in this Quarterly Report on Form 10-Q.

The December 31, 2018 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.

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, inventory, estimates related to clinical trial accruals, 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, 2019 and December 31, 2018 represent amounts due from two main sources: (1) trade accounts receivable of $0.2 million 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 $1.6 million 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 $0.9 million and $0.7 million as of March 31, 2019 and December 31, 2018, respectively.

Contract Balances

The Company recognizes a contract asset when the Company transfers goods or services to a customer before the customer pays consideration or before payment is due, excluding any amounts presented as a receivable (i.e. accounts receivable). A contract asset represents the Company's right to consideration in exchange for goods or services that the Company has transferred to a customer.

As of March 31, 2019, such contract assets were $3.0 million in relation to milestone payments to be received under the terms of the license agreement, which we call the Everest license agreement, with Everest Medicines Limited, or 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, or the territory. See Note 6 for further details.

Inventory

Inventory is stated at the lower of cost or net realizable value on a first-in, first-out (FIFO) 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, 2019, excess inventory was deemed to be non-existent.

Leases

Effective January 1, 2019, the Company adopted Accounting Standards Codification, or ASC, Topic 842, *Leases*. The Company adopted the new guidance as of January 1, 2019 using the modified retrospective adoption method in which it did not restate prior periods. Prior periods are presented in accordance with ASC 840, *Leases.*

The Company's review and approval process for new leases, contracts, amendments and renewals includes an evaluation at the inception of each agreement to determine whether the contract within the scope of ASC Topic 842, or other areas of accounting guidance. The Company's contracts are determined to contain a lease within the scope of ASC Topic 842 when all of the following criteria based on the specific circumstances of the agreement are met: (1) there is an identified asset for which there are no substantive

substitution rights; (2) the Company has the right to obtain substantially all of the economic benefits from the identified asset; and (3) the Company has the right to direct the use of the identified asset.

Upon transition to ASC 842, an operating lease asset is valued at the amount of the lease liability adjusted for prepaid or accrued lease payments, the remaining balance of any lease incentives received, unamortized initial direct costs and impairment of the operating lease asset. Once the Company assesses a contract for a lease, it will only reassess whether a contract is or contains a lease if the terms and conditions of the contract are amended. Leases with a greater than one year duration are categorized on the balance sheet as operating lease assets, lease liabilities, and if applicable, long-term lease liabilities. Leases with a duration of less than one year are not presented on the balance sheet.

The Company records the operating lease asset and related lease liability based upon the present value of the lease payments not yet paid using the discount rate for the lease established at the commencement date. The discount rate associated with each lease agreement is based upon either (i) the rate implicit in the lease or (ii) the Company's incremental borrowing rate if the rate implicit in the lease is indeterminable.

Although separation of lease and non-lease components is required, certain practical expedients are available to entities. The Company's facilities operating leases have lease and non-lease components which the Company has elected to account for as one single lease component. The lease component results in an operating lease asset being recorded on the balance sheet and amortized as lease expense on a straight-line basis to the statements of operations.

Revenue Recognition

Product Revenue

Revenue recognition under ASC Topic 606 is applied through a five-step model as follows: (1) identify the contract(s) with the customer; (2) identify performance obligations in the contract; (3) determine the transaction price; (4) allocate transaction price to the performance obligation; and (5) recognize revenue when (or as) each performance obligation is satisfied.

The Company's arrangements with its distributors are determined to be contracts within the scope of ASC Topic 606 when all five criteria in ASC Topic 606 are met. These five criteria were assessed at the inception of each arrangement. Since the criteria were met during this initial assessment, the Company will not reassess the criteria unless there is an indication of a significant change in facts and circumstances. In order to meet the definition of a contract, it must also be probable that the Company will collect the consideration to which it is entitled for goods or services to be transferred. Once the contract is determined to be within the scope of ASC Topic 606, the Company assesses the goods or services to be delivered with each contract, determines whether those are performance obligations and the related transaction price. The Company then recognizes revenue based on the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied.

The Company's product revenue consists of the sales of Xerava, which the Company began selling to customers in October 2018. The Company sells Xerava to specialty distributors. These customers resell Xerava to hospitals or other treatment centers. In addition to these distributor agreements and the related discounts and allowances, the Company is subject to government mandated rebates, chargebacks, and discounts with respect to the purchase of the Company's product. Product revenue is recognized net of reserves for all variable consideration, including discounts, chargebacks, government rebates and product returns. The Company is expensing the costs of obtaining and fulfilling these contracts when incurred. The Company has opted to immediately expense the incremental cost of obtaining a contract when the underlying related asset would have been amortized over one year or less.

Reserves for Variable Consideration

The Company evaluates its contracts with customers for forms of variable consideration which may require an adjustment to the transaction price based on their estimated impact. Revenues from product sales are recorded at the gross sales price, net of variable consideration, as described above.

The Company estimates variable consideration using the expected value method, which is the sum of probability-weighted amounts in a range of possible outcomes. These outcomes include market events and trends, forecasted product demand patterns, customer buying patterns and statutory requirements. The resulting reserves represent the Company's best estimates of variable consideration it expects to occur.

Before it can include an amount of variable consideration in the transaction price, the Company must consider whether the amount of variable consideration is constrained. The Company includes estimates of variable consideration in revenue only when it has a "high degree of confidence" that revenue will not be reversed in a subsequent reporting period. To include variable consideration

in the estimated transaction price, the entity has to conclude that it is "probable" that a significant revenue reversal will not occur in future periods, considering both the likelihood and magnitude of a revenue reversal to apply the constraint. Based on the above, the Company applies the constraint to variable consideration included in its contracts if it cannot conclude that it is probable that a significant revenue reversal will not occur in future periods.

Trade Discounts and Allowances: The Company offers its customers prompt pay discounts and service fees as stated in its customer contracts. The Company pays these service fees to its customers in exchange for their performance of various product distribution, marketing and promotional services targeted at advancing end-user sales of the Company's product. The related reserves are set in the same period the corresponding revenue is recognized, resulting in a reduction of product revenue.

Government Chargebacks and Rebates: Under the terms of the Company's master agreements, customers may charge back the Company for reimbursement when they are contractually obligated to sell products to government entities or other end-users at a lower price than the wholesale acquisition cost at which those products were acquired from the Company. These rebates consist of Medicare and Medicaid rebates as well as those related to other government drug pricing and reimbursement programs.

Product Returns: Products are eligible for return by the Customers in various scenarios under the Company's returns policies included as part of its master distribution agreements. Return options are provided for expired merchandise, short-dated merchandise, products damaged in transit, or any discontinued, withdrawn, or recalled products. The Company estimates the amount of product that may be returned and records this as a reduction in revenue in the relevant period. The Company currently estimates product return liabilities using available industry data, sales information and visibility into the inventory remaining in the distribution channel. The Company has not received any returns to date since launch.

The Company will continue to assess its estimates of the various components of variable consideration as it accumulates additional historical data and make adjustments to these estimates and allowances accordingly.

Collaboration Revenue

The Company has entered into an out-licensing agreement that is evaluated under Accounting Standards Codification, Topic 606, or Topic 606, *Revenue from Contracts with Customers*, through which the Company licenses certain of its product candidates' rights to a third party. Any future out-licensing agreements entered into by the Company and additional third parties shall also be evaluated under Topic 606. Terms of these arrangements include various payment types, typically including one or more of the following: upfront license fees; development, regulatory and commercial milestone payments; payments for manufacturing supply services; and/or royalties on net sales of licensed products.

To determine the amount and timing of revenue to be recognized under each agreement, the Company evaluates the following criteria: (i) confirming the goods or services in the contract; (ii) defining the performance obligations under the agreement; (iii) determining the transaction price, including any constraint on variable consideration; (iv) allocating the transaction price to the performance obligations; and (v) defining how the revenue will be recognized for each performance obligation. In determining the accounting treatment for these arrangements, the Company develops assumptions to determine the stand-alone selling price for each performance obligation in the contract. These assumptions may include forecasted revenues, development timelines, discount rates and probabilities of technical and regulatory success.

Licenses of Intellectual Property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from upfront fees allocated to the license when the license, including any associated know-how, is transferred to the licensee and the licensee can use and benefit from the license. For licenses that are bundled with other obligations, the Company uses judgment to evaluate the combined performance obligation to determine whether it is satisfied over time or at a point in time and the appropriate method of measuring completion for purposes of recognizing revenue.

Milestone Payments: For arrangements that include development milestone payments, the Company evaluates whether the milestones are considered probable and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received.

Manufacturing Supply: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. If the

Company is entitled to additional payments when the licensee exercises these options, the Company recognizes revenue when the licensee obtains control of the goods, which is upon delivery.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Government Contract Revenue

The Company's government contract revenue has been derived from its subcontracts with CUBRC, Inc., or CUBRC, an independent, not-for-profit, research corporation that specializes in U.S. government-based contracts, with which we are collaborating. These subcontracts with CUBRC relate to the following funding awards: (1) an award 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, which the Company refers to as the BARDA Contract; (2) two awards from the National Institute of Allergy and Infectious Diseases, or NIAID, for the development, manufacturing and clinical evaluation of TP-271, which the Company refers to as the NIAID Contract and the NIAID Grant, respectively. The Company is also the recipient of its cost reimbursement Sub-Award Agreement with the Trustees of Boston University, the administrator of the CARB-X program, for the development of TP-6076 (see Note 3). The Company recognizes revenue under these best-efforts, cost-reimbursable and cost-plus-fixed-fee subcontracts and subaward as the Company performs services under the subcontracts and subaward so long as a subcontract and subaward has been executed and the fees for these services are fixed or determinable, legally billable and reasonably assured of collection. Recognized amounts reflect the Company's partial performance under the subcontracts and subaward and equal direct and indirect costs incurred plus fixed fees, where applicable. The Company does not recognize revenue under these arrangements for amounts related to contract periods where funding is not yet committed as amounts above committed funding thresholds would not be considered fixed or determinable or reasonably assured of collection. Revenues and expenses under these arrangements are presented gross on the consolidated statements of operations and comprehensive loss as the Company has determined it is the primary obligor under these arrangements relative to the research and development services it performs as lead technical expert.

Revenue under the Company's subcontracts under both the NIAID Contract and the BARDA Contract and under the CARB-X Award are earned under a cost-plus-fixed-fee arrangement in which the Company is reimbursed for direct costs incurred plus allowable indirect costs and a fixed-fee earned. Billings under these arrangements are based on approved provisional indirect billing rates, which permit recovery of allowable fringe benefits, allowable overhead and general and administrative expenses and a fixed fee.

Revenue under the Company's subaward under the NIAID Grant was earned under a cost-reimbursable arrangement in which the Company was reimbursed for direct costs incurred plus allowable indirect costs. Billings under the NIAID Grant are based on approved provisional indirect billing rates, which permit recovery of fringe benefits and allowable general and administrative expenses.

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.

Liquidity and Going Concern Assessment

Accounting Standards Update, or ASU, No. 2014-15, *Presentation of Financial Statements - Going Concern,* requires management to evaluate the Company's ability to continue as a going concern one year beyond the filing date of the given financial statements. This evaluation requires management to perform two steps. First, management must evaluate whether there are conditions and events that raise substantial doubt about the entity'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.

Based on its analysis, the Company expects its cash to last more than one year beyond the filing date of the financial statements.

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842), which among other things, results in the recognition of lease assets and lease liabilities by lessees on the Company's balance sheets for virtually all leases. ASU 2016-02 supersedes most previous lease accounting guidance and is effective for interim and annual periods beginning after December 15, 2018. The Company adopted the new guidance as of January 1, 2019 using the modified retrospective adoption method in which it did not restate prior periods. The Company has elected the transition relief package of practical expedients permitted within Topic 842. Accordingly, the Company has not reassessed the classification of its existing leases as the transition date, whether existing contracts at the transition date contain a lease, or whether unamortized initial direct costs before the transition adjustments would have met the definition of initial direct costs at lease commencement. The Company does not allocate consideration in its leases to lease and non-lease components and does not record leases on its balance sheet with terms of 12 months or less.

The Company uses its estimated incremental borrowing rate, which is derived from information available at the lease commencement date, in determining the present value of lease payments. The Company's incremental borrowing rate represents the rate of interest that the Company would have to pay to borrow over a similar term an amount equal to the lease payments in a similar economic environment. The Company considers its recent debt issuances and publicly available data for instruments with similar terms and characteristics when calculating its incremental borrowing rates.

The adoption had a material impact on the consolidated balance sheet related to the recognition of operating lease assets of $6.2 million and lease liabilities of $6.3 million, along with derecognition of deferred rent originally accounted for under the legacy guidance. The adoption did not have a material impact on the consolidated statement of operations. The Company has implemented changes to related processes, controls and disclosures.

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

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, 2019 and December 31, 2018 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, 2019				
Cash and money market funds	$ 87,559	$ 87,559	$ —	$ —
December 31, 2018				
Cash and money market funds	$ 107,776	$ 107,776	$ —	$ —

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. The Company's potentially dilutive shares, which

include outstanding stock options, unvested restricted stock units, or RSU's, and warrants, 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 net loss per share, due to their anti-dilutive effect:

	March 31,	
	2019	2018
Warrants	414,365	—
Unvested restricted stock units	3,564,505	456,348
Outstanding stock options	7,315,779	7,083,688
Totals	11,294,649	7,540,036

5. Inventories

Inventory consisted of the following:

(in thousands)	As of March 31, 2019	As of December 31, 2018
Work in progress	$ 915	$ 655
Finished goods	1,433	93
Total inventory	$ 2,348	$ 748

There were no charges related to excess inventory for the three months ended March 31, 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, 2019, the Company has paid Harvard an aggregate of $15.8 million in upfront license fees, sublicense fees and development milestone payments for the licensed Harvard technology, and has issued 31,379 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. During the three months ended March 31, 2019 and 2018, the Company paid Harvard $25 thousand and $3.0 million, respectively, 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 the Everest License Agreement with Everest Medicines, 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 (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 Investigational New Drug Application, or IND, with the National Medical Products Administration (formerly CHINA FDA) in June 2018. In 2019, the Company expects to receive an additional cash payment of $3.0 million related to Everest Medicine's initiation of a Phase 3 clinical trial. The Company has determined that it is probable that this milestone will be achieved and that a significant revenue reversal will not occur, based on the National Medical Products Administration having furnished to Everest Medicines an IND approval letter to initiate a Phase 3 clinical trial in October 2018.

The Company is also 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.

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 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 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 Topic 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 are not considered probable 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 requirement 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 has estimated that the value of this right would be immaterial.

The Company satisfied no performance obligations during the three months ended March 31, 2019, and therefore recognized no revenue.

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 ("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 has received funding for its lead product 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 has since been extended, that provides 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 (or BARDA Contract). The funding under the BARDA Contract is also being used for the development, manufacturing and clinical evaluation of eravacycline 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 is also the direct recipient of the BARDA Contract. This subcontract, which currently expires on August 1, 2019, granted the Company initial funding of up to approximately $41.8 million, reflecting the portion of the BARDA Contract funding that could be paid to the Company for its activities.

The BARDA Contract and the Company's subcontract with CUBRC under the BARDA Contract have terms which currently expire on August 1, 2019, BARDA is entitled to terminate the project for convenience at any time and is not obligated to provide continued funding beyond current-year amounts from congressionally approved annual appropriations. To the extent that BARDA ceases to provide funding of the program to CUBRC, CUBRC has the right to cease providing funding to the Company. Committed funding from CUBRC under the Company's BARDA subcontract is for up to approximately $41.8 million through August 1, 2019, the current contract end date, as a result of the exercise of several options by BARDA under the BARDA Contract. Total funds of $39.9 million had been received by the Company through March 31, 2019 under this contract. During the three months ended March 31, 2019 and 2018, the Company recognized revenue of $0.6 million and $0.4 million, respectively, from the Company's subcontract under the BARDA Contract.

NIAID Grant and Contract for TP-271

The Company has 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 pneumonia:

- the NIAID Contract awarded in September 2011 that provides up to a total of approximately $35.8 million over five years.

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 which the Company could have originally received 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.

The NIAID Contract and the Company's subcontract with CUBRC under the NIAID Contract expired on March 31, 2019. As of March 31, 2019, committed funding from CUBRC under the Company's subcontract with respect to NIAID Contract was $16.3 million, of which $16.1 million has been received through March 31, 2019.

During the three months ended March 31, 2019 and 2018, the Company recognized revenue of $0.1 million and $0.7 million, respectively, 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 eighteen 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, 2019 and 2018, the Company recognized revenue of $0.3 million and $0.7 million, respectively, under this Sub-Award Agreement. This Sub-Award Agreement will fund certain activities through June 30, 2019. This Sub-Award Agreement can be terminated for convenience at any time, subject to 30 days prior written notice.

7. Accrued Expenses

Accrued expenses at March 31, 2019 and December 31, 2018 consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Drug supply and development	$ 3,297	$ 3,901
Salaries and benefits	2,028	3,801
Professional fees	1,136	1,178
Commercial	1,147	910
Royalties and license payments	629	617
Other	1,020	1,354
Total	$ 9,257	$ 11,761

8. Stock-Based Compensation

In January 2019, 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 2.1 million shares as a result of the automatic increase provision of the 2013 Plan. As of March 31, 2019, the total number of shares of common stock available for issuance under the 2013 Plan was approximately 0.3 million.

Stock-Based Compensation Expense

During the three months ended March 31, 2019 and 2018, the Company recognized the following stock-based compensation expense (in thousands):

	Three Months Ended March 31,	
	2019	2018
Research and development	$ 983	$ 1,360
General and administrative	1,740	1,611
Total	$ 2,723	$ 2,971

	Three Months Ended March 31,	
	2019	2018
Stock options	$ 1,977	$ 2,787
Restricted stock units	726	168
Employee stock purchase plan	20	16
Total	$ 2,723	$ 2,971

Stock Options

The following table summarizes the stock option activity for the three months ended March 31, 2019:

	Shares	Weighted-Average Exercise Price
Outstanding at December 31, 2018	7,322,436	$ 11.16
Granted	57,000	$ 1.20
Forfeited	(63,657)	$ 6.93
Outstanding at March 31, 2019	7,315,779	$ 11.11
Exercisable at March 31, 2019	4,214,128	$ 15.13

As of March 31, 2019, there was $11.4 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 2.3 years.

Restricted Stock Units and Performance Stock Units

In January 2019 the Company awarded 2,297,950 restricted stock units, or RSU's, to employees. These RSU's vest in annual increments over two to three years, subject to continued employment with the Company and had a grant date fair value of $1.39 per share which was the closing price of the Company's common stock on the date of grant.

In January 2019 the Company issued to certain employees 265,000, performance stock units, or PSU's, which vest based on service and performance conditions. The number of units represents the target number of shares of common stock that may be earned; however, the actual number of shares that may be earned ranges from 0%-150% of the target number. None of these awards vested as of March 31, 2019. Vesting of these awards is contingent on the occurrence of certain milestone events and fulfillment of any remaining service condition. As a result, the related compensation cost is recognized as an expense when achievement of the milestone is considered probable over the remaining requisite service period.

The following table summarizes the RSU and PSU activity for the three months ended March 31, 2019:

	Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2018	1,080,440	$ 4.21
Awarded	2,562,950	$ 1.39
Forfeited	(13,205)	$ 1.70
Vested/Released	(65,680)	$ 8.47
Unvested at March 31, 2019	3,564,505	$ 2.11

As of March 31, 2019, there was total unrecognized stock-based expense of $3.3 million related to RSU's and $0.3 million related to PSU's. The expense is expected to be recognized over a weighted-average period of 1.9 years.

Employee stock purchase plan

Under the Company's 2014 Employee Stock Purchase Plan, or 2014 ESPP, an aggregate of 300,000 shares of common stock have been reserved for issuance pursuant to purchase rights granted to the Company's employees. As of March 31, 2019, 52,733 shares remained available for issuance. During the three months ended March 31, 2019 and 2018 the Company did not issue any shares under the 2014 ESPP and recognized approximately $20,000 and $16,000 in related stock-based compensation expense, respectively.

9. 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, 2019, the Company had sold an aggregate of 6,110,446 shares of common stock under the Sales Agreement, at an average selling price of approximately $6.49 per share for aggregate gross proceeds of $39.6 million and net proceeds of $38.2 million after deducting sales commissions and offering expenses. As of May 6, 2019, $40.4 million of common stock remained available to be sold under the Amended Sales Agreement.

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). The Lenders have agreed to make available to the Company term loans in an aggregate principal amount of up to $75.0 million under the Loan Agreement. The Company plans to use the proceeds of the term loans to support commercial launch of Xerava as well as for working capital and general corporate purposes. The Loan Agreement provides 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 have a maturity date of May 2, 2023. The Loan Agreement also provides access to an additional Term C loan facility in the amount of $25.0 million, to be funded at the Lenders' sole discretion.

Borrowings under all three loan facilities bear interest at a floating per annum rate equal to the 1 Month LIBOR Rate plus 7.25%. The Company is permitted to make interest-only payments on the initial $30.0 million Term A loan for the fifteen (15) months following the funding date. The interest-only period can be extended by an additional nine (9) months subject to certain conditions being met, including a 12-month trailing revenue milestone of $8.5 million by December 31, 2019; and by an additional six (6) months if the Company has met certain other conditions, including a 6-month trailing revenue milestone of $14.0 million by September 30, 2020 and raising $50.0 million in new capital. The term of the combined facility will be 54 months, with repayment paid in equal monthly installments commencing at the end of the resulting interest-only period as outlined above through the end of the 54-month term.

The Company is obligated to pay a final fee equal to 4.00% of the aggregate amount of the term loans funded, to occur upon the earliest of (i) the maturity date, (ii) the acceleration of the term loans, and (iii) the prepayment of the term loans. The Company has the option to prepay all, but not less than all of the outstanding principal balance of the term loans under the Loan Agreement. If the Company prepays all or a portion of the term loans prior to the maturity date, it will pay the Lenders a prepayment penalty fee based on a percentage of the outstanding principal balance, equal to 3% if the payment occurs on or before 12 months after the initial funding date, 2% if the prepayment occurs more than 12 months after, but on or before 24 months after, the initial funding date, or 1% if the prepayment occurs more than 24 months after the initial funding date.

In connection with the Loan Agreement and the funding of the Term A loan facility, the Company issued to the Lenders warrants to purchase an aggregate of 414,365 shares of the Company's common stock, equal to 3.00% of the term loan funded divided by the exercise price of $2.172. The Company is obligated to issue additional warrants to the Lenders in the event the Term B loan facility and/or the Term C loan facility is funded. Those warrants shall also be equal to 3.00% of the term loan funded. The warrants are exercisable at the option of the holder and the exercise price will be the lesser of (a) the 10-day trailing average of the Company's common stock price, as determined as of the close of business day immediately prior to the funding date of the respective term loan, and (b) the Company's common stock price, as determined as of the close of business day immediately prior to the funding date of the respective term loan. Each warrant will terminate 10 years from the date of its original issuance. The warrants issued in connection with the Term A loan were equity classified with a fair value of $0.8 million at issuance and recorded to additional paid in capital.

The Loan Agreement was amended in March 2019 for the primary purpose of adding a newly-opened operating bank account to the agreement as collateral.

The Company's obligations under the Loan Agreement are secured by a first priority security interest in substantially all of its assets. The Loan Agreement contains customary representations, warranties and covenants and also includes customary events of default, including payment defaults, breaches of covenants, change of control and a material adverse change default. The Company has agreed to maintain cash on hand at all times equal to $10.0 million plus an amount equal to 90 days aged accounts payable subject to certain exceptions, or it is in breach of the Loan Agreement.

Upon the occurrence of an event of default, a default interest rate of an additional 4.00% per annum may be applied to the outstanding loan balances, and the Lenders may declare all outstanding obligations immediately due and payable and exercise all of its rights and remedies as set forth in the Loan Agreement and under applicable law.

The Company recorded interest expense related to the loan facility of $955,000 for the three months ended March 31, 2019. The fair value of the loan at March 31, 2019 approximates its face amount given the close proximity of execution to March 31, 2019.

The Company evaluated the accounting for the Loan Agreement and identified an embedded derivative related to repayment upon default, which it evaluated and deemed immaterial. The Company will reassess this conclusion at each reporting period.

Future principal debt payments on the loan payable are as follows (in thousands):

	March 31, 2019
2019	$ —
2020	8,462
2021	9,231
2022	9,231
2023	3,076
Total principal payments	30,000
Final fee due at maturity in 2023	1,200
Total principal and final fee payments	31,200
Unamortized debt issuance costs and final fee	(2,686)
Loan payable, long term	$ 28,514

11. Commitments and Contingencies

Operating Leases

The Company's leases consist of office equipment and office and laboratory space in Watertown, MA. On March 24, 2015, the Company amended its existing operating lease to expand its existing premises by an additional 13,711 square, and on June 18, 2015, the Company amended its existing operating lease to expand its existing premises by an additional 7,828 square feet, resulting in a total of 37,438 square feet of office and laboratory space.

In the third quarter of 2016, the Company entered into a sublease with respect to a portion of its principal facilities with an unrelated third party. The term of the sublease expires in November 2019, with the sublessee obligated to pay rent to the Company that approximates the rent the Company is currently paying to its landlord with respect to such portion of its facility.

On November 29, 2018, the Company amended its existing operating lease to extend the lease term through November 30, 2022 for all of its existing operating leases. There are no extension or early termination options available to the Company which it is reasonably certain to exercise.

The Company identified and assessed significant assumptions in recognizing the right-of-use asset and lease liability as follows:

- *Incremental borrowing rate* - The Company's lease agreements do not provide implicit rates. The Company has one outstanding loan facility which was utilized to derive the Company's incremental borrowing rate for its existing

leases at the transition date. The Company estimated its incremental borrowing rate based on its credit quality indicators from its outstanding loan facility. The Company compared its incremental borrowing rate to rates available in the market for similar borrowings, and adjusted these rates based on the impact of collateral over the term of the lease to substantiate the incremental borrowing rate applied to its leases at the transition date.

- *Lease and non-lease components* – The Company is required to pay fixed fees for operating expenses in addition to monthly base rent for certain operating leases. The amounts of additional rent associated with these fees are considered non-lease components. The Company has elected the practical expedient which allows non-lease components to be combined with lease components and will therefore include these additional rent amounts in its lease payments. Any variable components of these operating costs are excluded from lease payments and are recognized in the period incurred.

The components of lease expense were as follows:

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

Cash paid for amounts included in the measurement of the lease liabilities were $0.5 million for the quarter ended March 31, 2019.

As of March 31, 2019, the maturities of the Company's operating lease liabilities were as follows (in thousands):

Years Ending December 31,	
2019	$ 1,387
2020	1,916
2021	1,950
2022	1,785
Thereafter	—
Less: Imputed interest	(1,019)
Present value of lease payments	$ 6,019

Disclosures related to periods prior to adoption of the New Lease Standard

The Company recorded $1.4 million and $1.4 million in rent expense for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, the aggregate minimum future rent payments under the lease agreement, net of the sublease agreement, are as follows (in thousands):

Year ending December 31,	
2019	$ 1,806
2020	1,875
2021	1,913
2022	1,785
Total minimum lease payments	$ 7,379

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, 2018, 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 15, 2019, 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. These forward-looking statements are subject to risks and uncertainties, including those set forth in Part II — Other Information, Item 1A. Risk Factors below and elsewhere in this report that could cause actual results to differ materially from historical results or anticipated results.

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 many 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 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 intravenous (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 a result, as of March 31, 2019, we have approximately 35 sales representatives, 5 regional business directors, three strategic market access executives and approximately 10 medical affairs personnel in the field supporting Xerava in the United States.

On September 20, 2018, based on the results of the IGNITE phase 3 clinical program, 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. 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 National Medical Products Administration (formerly CHINA FDA) for a phase 3 clinical trial of eravacycline in cIAI. We expect Everest Medicines to begin enrolling patients in this phase 3 clinical trial in the second quarter of 2019.

Subject to obtaining additional financing, we intend to pursue development of Xerava for the treatment of additional indications, including other serious and life-threatening infections. We may pursue these development activities either by ourselves or with collaborators.

We believe that the ability of Xerava to cover MDR Gram-negative bacteria, as well as MDR Gram-positive, anaerobic and atypical bacteria, may enable Xerava to become the drug of choice for first-line empiric treatment of patients with cIAI. Based on *in vitro* data, Xerava has demonstrated the ability to cover a wide variety of MDR Gram-negative bacteria, including MDR *Klebsiella pneumoniae* and MDR *Acinetobacter*. Multidrug-resistant *Klebsiella pneumoniae* is one of the carbapenem-resistant *Enterobacteriaceae* (or CREs) listed as an urgent threat and MDR *Acinetobacter* is listed as a serious threat by the Centers for Disease Control and Prevention in a September 2013 report. They are also listed as "Priority 1; Critical Pathogens" in the World Health Organization's priority pathogens list for R&D, published in February 2017. CREs were a confirmed area of great concern by the World Health Organization in an April 2014 global surveillance report. Gram-negative bacteria that are resistant to multiple available antibiotics are increasingly common and a growing threat to public health.

In addition to Xerava we are also developing other fluorocycline antibiotic compounds, TP-6076 and TP-271, and a tetracycline for the treatment of acute myeloid leukemia, or AML, TP-2846. We are developing 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 *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 are currently conducting 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 are developing for respiratory disease caused by bacterial biothreat and antibiotic-resistant public health pathogens, as well as bacterial pathogens associated with community-acquired pneumonia. To date, we have completed a single- and multiple-ascending dose trials for the IV and oral formulations of TP-271. In February 2017, we received Qualified Infectious Disease Product and Fast Track designations from the FDA for TP-271. We are also developing TP-2846, a fully-synthetic tetracycline discovered by us, for the treatment of AML. We have recently initiated pre-clinical toxicology studies for this program.

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 initiating 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. For the three months ended March 31, 2019, we generated $0.3 million in net product revenues from sales of Xerava. We have financed our operations primarily through public offerings and private placements of our equity securities, debt financings, revenue from United States government grants and contract awards and milestone payments from our licensing agreement. As of March 31, 2019, we had received an aggregate of $589.0 million in net proceeds from the issuance of equity securities and borrowings under debt facilities, an aggregate of $59.3 million from government grants and contracts and an aggregate of $9.5 million from licensing agreement milestone payments. As of March 31, 2019, our principal source of liquidity was cash and cash equivalents, which totaled $87.6 million.

As of March 31, 2019, we had an accumulated deficit of $553.5 million. Our net losses were $19.5 million and $21.6 million for the three months ended March 31, 2019 and 2018, respectively. We expect that our expenses will decrease in 2019 compared with 2018, as the lower costs we expect to incur on our IGNITE clinical program, given its completion in 2018, will offset increased sales, marketing, distribution and outsourced manufacturing expenses related to the launch of Xerava.

We believe that our existing cash and cash equivalents and proceeds from the sales of Xerava will enable us to fund our operating expenses and capital expenditures into the third quarter of 2020. 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. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. Moreover, we will need to generate significant revenue to achieve profitability, and we may never do so. Our failure to generate sufficient cash from operations or to raise additional capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

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 U.S., 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 consolidated financial statements.

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. Terms of this arrangement include various payment types, including upfront license fees, development, regulatory and commercial milestone payments and payments for clinical supply services. For further discussion of the Everest Medicines collaboration and the related revenue recognition, please see Note 6, *Significant Agreements and Contracts* to the consolidated financial statements.

Government Revenue

Our government revenue is derived from funding provided under three awards. 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 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;
- 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, regulatory and medical affairs activities; and
- fees and costs related to regulatory filings and operations.

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, 2019 and 2018:

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Xerava	$ 2,296	$ 12,150
TP-6076	512	553
BARDA Contract	472	437
CARB-X Award	301	742
NIAID Contract	88	546
Other development programs	1,023	539
Other research and development	2,045	3,160
Total research and development expenses	$ 6,737	$ 18,127

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

As of March 31, 2019, we had incurred an aggregate of $290.2 million in research and development expenses related to the development of Xerava, and $38.2 million in research and development expenses related to the development of Xerava that were funded under the BARDA Contract.

Because of the numerous risks and uncertainties associated with product development, however, we cannot determine with certainty the duration and completion costs of current or future clinical trials of our pipeline product candidates. We may never succeed in achieving regulatory approval for any of these product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rate and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability.

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, 2019, we have paid Harvard an aggregate of $15.8 million in up front license fees, sublicense fee and development milestone payments. We have also issued 31,379 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, 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 remain stable for the immediate future.

Interest Income

Interest income consists of interest earned on our cash and cash equivalents. The primary objective of our investment policy is capital preservation.

Interest Expense

Interest expense consists 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. We expect that our interest expense will increase in future periods due to the term loan being outstanding for a longer period, rising interest rates and in the event of additional tranches becoming available to us over the term of the loan.

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, accrued research and development expenses 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 13, 2019, for the year ended December 31, 2018.

Results of Operations

Comparison of the Three Months Ended March 31, 2019 and 2018

The following table summarizes the results of our operations for the three months ended March 31, 2019 and 2018, together with the changes in those items in dollars:

	Three Months Ended March 31,		Increase/ (decrease)
	2019	2018	
	(in thousands)		
Revenue:			
Product revenue, net	$ 341	$ —	341
Government revenue	932	1,891	(959)
Total revenue	1,273	1,891	(618)
Operating expenses:			
Cost of revenue - product	164	—	164
Cost of revenue - intangible asset amortization	98	—	98
Research and development	6,737	18,127	(11,390)
Selling, general and administrative	13,314	5,705	7,609
Total operating expenses	20,313	23,832	(3,519)
Loss from operations	(19,040)	(21,941)	2,901
Interest income	507	365	142
Interest expense	(955)	—	(955)
Net loss	$ (19,488)	$ (21,576)	$ 2,088

Product Revenue

We initiated sales of, and therefore realized revenue with respect to our first commercial product, Xerava, in the United States on October 15, 2018. For the three months ended March 31, 2019, net sales of Xerava were $0.3 million.

Revenue from U.S Government Contracts and Grants

The following table sets forth our government contract and grant revenue for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,		Increase/ (decrease)
	2019	2018	
	(in thousands)		
Revenues			
BARDA Contract	$ 559	$ 420	$ 139
CARB-X Award	278	738	(460)
NIAID Contract	95	733	(638)
	$ 932	$ 1,891	$ (959)

Government revenue was $0.9 million for the three months ended March 31, 2019 compared to $1.9 million for the three months ended March 31, 2018, a decrease of $1.0 million. This decrease was due to the scope and timing of activities conducted under our subcontract with respect to the CARB-X Award and the BARDA and NIAID Contracts. Based on current expected duration of these agreements, we expect government revenue to continue to decline.

Research and Development Expenses

Research and development expenses for the three months ended March 31, 2019 were $6.7 million compared to $18.1 million for the three months ended March 31, 2018, a decrease of $11.4 million. This decrease was primarily due to lower clinical trial costs associated with the IGNITE Phase 3 clinicals trials, which concluded in the first quarter of 2018 and lower license and milestone payments to Harvard University that occurred in the first quarter of 2018.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended March 31, 2019 were $13.3 million compared to $5.7 million for the three months ended March 31, 2018, an increase of $7.6 million. This increase was primarily due to an increase in commercial related expenses for XERAVA.

Interest income

The increase of $0.1 million in interest income for the three months ended March 31, 2019 as compared to three months ended March 31, 2018 was driven by improved overall yields on our money market fund investments.

Interest expense

The increase of $1.0 million in interest expense for the three months ended March 31, 2019 is related to the loan and security agreement, or the Loan Agreement, with Solar Capital Ltd., or Solar Capital, as collateral agent and lender, and the other lenders named therein, collectively, the Lenders.

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 2019 and, as a result, we will need additional capital to fund our operations, which we may obtain from additional financings, research funding, collaborations, contract, grant revenue, licenses of our product candidates or other sources.

Since our inception, we have funded our operations principally through the receipt of funds from public offerings and private placements of equity securities, debt financings and contract research funding and research grants from the United States government.

As of March 31, 2019, we had cash and cash equivalents of approximately $87.6 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, 2019, 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, 2019, we had sold an aggregate of 6,110,446 shares under the agreement at an average price of $6.49 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.

On November 2, 2018, we entered into the Loan Agreement the Lenders. The Lenders have agreed to make available to us term loans in an aggregate principal amount of up to $75.0 million under the Loan Agreement. We plan to use the proceeds of the term loans to support commercial launch of Xerava as well as for working capital and general corporate purposes. The Loan Agreement provides 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 have a maturity date of May 2, 2023. The Loan Agreement also provides access to an additional Term C loan facility in the amount of $25.0 million, to be funded at the Lenders' sole discretion.

Borrowings under all three loan facilities bear interest at a floating per annum rate equal to the one Month LIBOR Rate plus 7.25%. We are permitted to make interest-only payments on the initial $30.0 million Term A loan for the fifteen (15) months following the funding date. The interest-only period can be extended by an additional nine (9) months subject to certain conditions being met, including a 12-month trailing revenue milestone of $8.5 million by December 31, 2019; and by an additional six (6) months if we have met certain other conditions, including a 6-month trailing revenue milestone of $14.0 million by September 30, 2020 and raising $50.0 million in new capital. The term of the combined facility will be 54 months, with repayment paid in equal monthly installments commencing at the end of the resulting interest-only period as outlined above through the end of the 54-month term.

We are obligated to pay a final fee equal to 4.00% of the aggregate amount of the term loans funded, to occur upon the earliest of (i) the maturity date, (ii) the acceleration of the term loans, and (iii) the prepayment of the term loans. We have the option to prepay all, but not less than all, of the outstanding principal balance of the term loans under the Loan Agreement. If we prepay all or a portion of the term loans prior to the maturity date, we will pay the Lenders a prepayment penalty fee based on a percentage of the outstanding principal balance, equal to 3% if the payment occurs on or before 12 months after the initial funding date, 2% if the prepayment occurs more than 12 months after, but on or before 24 months after, the initial funding date, or 1% if the prepayment occurs more than 24 months after the initial funding date.

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 414,365 shares of our common stock, equal to 3.00% of the term loan funded divided by the exercise price of $2.172. We are obligated to issue additional warrants to the Lenders in the event the Term B loan facility and/or the Term C loan facility is funded. Those warrants shall also be equal to 3.00% of the term loan funded. The warrants are exercisable at the option of the holder and the exercise price will be the lesser of (a) the 10-day trailing average of our common stock price, as determined as of the close of business day immediately prior to the funding date of the respective term loan, and (b) our common stock price, as determined as of the close of business day immediately prior to the funding date of the respective term loan. Each warrant will terminate 10 years from the date of its original issuance.

Upon the occurrence of an event of default, a default interest rate of an additional 4.00% per annum may be applied to the outstanding loan balances, and the Lenders may declare all outstanding obligations immediately due and payable and exercise all of its rights and remedies as set forth in the Loan Agreement and under applicable law.

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,	
	2019	2018
Cash Flows from Operations:		
Net cash used in operating activities	$ (20,119)	$ (18,894)
Net cash used in investing activities	(98)	(83)
Net cash provided by financing activities	—	231
Net (decrease) increase in cash and cash equivalents	$ (20,217)	$ (18,746)

Cash Flows from Operating Activities. The $1.2 million increase in cash used in operating activities for the three months ended March 31, 2019, compared to the three months ended March 31, 2018, was primarily due to increased operating expenses that related to commercialization of Xerava offset by decreased spending on IGNITE clinical trials and Harvard license payments.

Cash Flows from Investing Activities. The $15,000 increase in cash used in investing activities for the three months ended March 31, 2019, compared to the three months ended March 31, 2018 was due to an increase in purchases of equipment related to our research and development activities

Cash Flows from Financing Activities. The $0.2 million decrease in cash provided by financing activities was due to no ATM activity for the three months ended March 31, 2019 as compared to the three months ended March 31, 2018.

Operating Capital Requirements

We expect to incur significant operating losses for at least the next several years as we commercialize Xerava and continue development of our pipeline programs, satisfy our obligations under our license agreement with Harvard and meet our obligations under our debt facility with Solar Capital. We may not be able to complete the development of our other product candidates if, among other things, our preclinical research and clinical trials with respect to our other product candidates are not successful and our manufacturing efforts are not successful,

We believe that our available funds will be sufficient to support our operations into the third quarter of 2020, which we believe will allow us to fund the initial launch of IV Xerava for the treatment of cIAI. 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.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products and the variable nature of the interest-only period and funds accessibility under our debt facility with Solar Capital, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- costs related to the sales and marking of Xerava;
- revenue received from commercial sales of Xerava;
- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our other product candidates and potential product candidates;
- the outcome, timing and costs of seeking regulatory approvals;
- the number and characteristics of product candidates that we pursue;
- the costs of commercialization activities for our product candidates if we receive marketing approval, including the timing and costs of establishing product sales, marketing, distribution and manufacturing capabilities;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish, as we did with Everest Medicines;
- 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, pursuant to our license agreement as well as the royalty payments that we are obligated to pay Paratek pursuant to our license agreement;

- the costs of preparing, filing and prosecuting patent applications, 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
- the funding, interest and repayment obligations of our debt facility with Solar Capital.

We expect that we will need to obtain substantial additional funding in order to successfully commercialize Xerava. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, the ownership interests of our existing stockholders may be materially diluted and the terms of these securities could include liquidation or other preferences that could adversely affect the rights of our existing stockholders. In addition, additional 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 actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. If we are unable to raise capital when needed or on attractive terms, we could be forced to significantly delay, scale back or discontinue the development or commercialization of Xerava and our product candidates, 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 that we otherwise would seek to develop or commercialize ourselves.

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, filed on form 10-K with the SEC on March 15, 2019 for the year ended December 31, 2018.

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

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, 2019. 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, 2019, 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

We implemented the new lease standard as of January 1, 2019. As a result, we made the following significant modifications to our internal control over financial reporting, including changes to accounting policies and procedures, operational processes, and documentation practices:

- updated our policies and procedures related to lease accounting and added documentation processes related to accounting for the new standard;
- modified our contract review controls to take into account the new criteria for lease accounting; and
- added controls to address related required disclosures for lease accounting.

Other than the items described above, 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 covered by this quarterly report on Form 10-Q 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

In July 2018, a purported securities class action lawsuit was filed against us, our chief executive officer, our chief scientific officer and the underwriters of our July 2017 public offering, in the United States District Court for the Southern District of New York. The complaint is brought on behalf of an alleged class of those who purchased our securities pursuant and/or traceable to our July and August 2017 public offering and those who purchased our securities between March 8, 2017 and February 13, 2018. The complaint purports to allege claims arising under Sections 10 and 20 of the Exchange Act of 1934, as amended, and Sections 11 and 15 of the Securities Act of 1933, as amended. The complaint generally alleges that the defendants violated the federal securities laws by, among other things, making material misstatements or omissions concerning IGNITE3. The complaint seeks, among other relief, unspecified compensatory damages, attorneys' fees, and costs. The defendants have moved to transfer the lawsuit to the United States District Court for the District of Massachusetts. 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 Relating 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 $19.5 million for the three months ended March 31, 2019, $72.2 million for the year ended December 31, 2018 and $114.8 million for the year ended December 31, 2017. As of March 31, 2019, we had an accumulated deficit of $553.5 million. Prior to October 2018, when we commenced sales of Xerava in the United States, we had not generated any product revenues. For the three months ended March 31, 2019, we generated $0.3 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 United States government grants and contract awards and milestone payments from our licensing agreement.

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. Since approval of Xerava for cIAI, we have denoted and expect that we will continue to devote a substantial portion of our financial resources and efforts to supporting the ongoing commercialization of Xerava.

Notwithstanding the initiation of sales of Xerava, we expect to continue to incur significant expenses and operating losses for at least the next several years. 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.

We expect that our expenses will decrease in 2019 compared with 2018, as the lower costs we expect to incur on our IGNITE (**I**nvestigating **G**ram-**N**egative **I**nfections with **E**ravacycline) clinical program, given its completion in 2018, will offset increased sales, marketing, distribution and outsourced manufacturing expenses related to the launch of Xerava. 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 do not expect to generate significant revenue from Xerava sales 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, pricing, 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 development and 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. Our expenses could increase if there are any delays in the development of any of our products or product candidates or delays in the manufacture of any of our products or product candidates, particularly Xerava.

We may be unable to successfully commercialize Xerava or develop and commercialize any additional product candidates 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.

We expect that we will need additional funding. 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 that our existing cash and cash equivalents and proceeds from the sales of Xerava will enable us to fund our operating expenses and capital expenditures into the third quarter of 2020. However, 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.

This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control.

Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- revenue received from commercial sales of Xerava;
- the costs of commercialization activities for Xerava and our product candidates if such additional product candidates receive marketing approval, including the timing and costs of establishing product sales, marketing, distribution and manufacturing capabilities;
- our ability to access the remaining $45.0 million potentially available to us under our Loan and Security Agreement, or the Loan Agreement, with Solar Capital Ltd., or Solar Capital, as collateral agent and lender and the other lenders named therein, collectively the Lenders, dated November 2, 2018, as amended on March 14, 2019.
- the timing and costs of manufacturing activities in connection with the commercialization of Xerava;
- the timing and costs of clinical trials of our product candidates and other development activities;
- the number and characteristics of product candidates that we pursue;
- the terms and timing of any future collaborations, licensing, marketing, distribution or other arrangements that we may establish;

- 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; and
- the extent to which we in-license or acquire other products and technologies.

We have a limited operating history and 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 and establishing a commercial infrastructure to launch Xerava. 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.

Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations.

On November 2, 2018, we entered into the Loan Agreement with the Lenders. The Lenders have 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 provides a term loan commitment of $50.0 million in two potential tranches: (i) a $30.0 million Term A loan facility that was funded on November 2, 2018 and (ii) a $20.0 million Term B loan facility to be funded at the request of the Company, subject to certain conditions being met, no later than October 31, 2020. Both of these term loans have a maturity date of May 2, 2023. The Loan Agreement also provides access to an additional Term C loan facility in the amount of $25.0 million, to be funded at the Lenders' sole discretion.

All obligations under the Loan Agreement are secured by substantially all of our existing property and assets. This indebtedness may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. This indebtedness could also have important negative consequences, including:

- the need to repay our indebtedness by making payment of interest only initially and then interest and principal, which will reduce the amount of funds available to finance our operations, our research and development efforts and our general corporate activities; and
- our failure to comply with the restrictive covenants in the Loan Agreement could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and the lenders could seek to enforce its security interest in the assets securing such indebtedness.

To the extent additional debt is added to our current debt levels, the risks described above could increase.

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

Currently, our only external committed source of funds is funding under subcontracts awarded to us by CUBRC pursuant to government contracts from BARDA, and an award from CARB-X. Although the BARDA Contract and the Company's subcontract with CUBRC under the BARDA Contract have expired by their terms on March 31, 2019, and we expect to reach an agreement with both parties to extend the performance date to September 30, 2019, BARDA is also entitled to terminate the project for convenience at any time and is not obligated to provide continued funding beyond current-year amounts from congressionally approved annual appropriations. To the extent that BARDA ceases to provide funding of the program to CUBRC, CUBRC has the right to cease providing funding to us. Committed funding from CUBRC under our BARDA subcontract is for up to approximately $41.8 million from the initial contract date through March 30, 2019, of which $39.9 million had been received through March 31, 2019.

Although the CARB-X Award expired by its terms on December 31, 2018, we reached an agreement with CARB-X to extend the performance date out to June 30, 2019. CARB-X is entitled to terminate the project for convenience at any time.

Committed funding from the CARB-X Award is for up to $4.0 million, of which $2.3 million had been received through March 31, 2019.

Furthermore, we may not be able to access the additional $45.0 million of funding available under the Loan Agreement. Under the terms of the Loan Agreement we may only access $20.0 million of such funds if we meet specific revenue and other milestones and the remaining $25.0 million is only available to us at the discretion of the Lenders.

As a result, unless and until we can generate a substantial amount of revenue from Xerava or any other additional product candidates, 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 development and commercialization of our products and product candidates.

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.

We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due.

We cannot assure you that our business will generate sufficient cash flow from operations or that future borrowings will be available to us under our Loan Agreement or otherwise in an amount sufficient to enable us to repay our indebtedness or fund our other liquidity needs. We may need to refinance all or a portion of our indebtedness, on or before its maturity. We cannot assure you that we will be able to refinance any of our indebtedness on commercially reasonable terms, on a timely basis or at all. Any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. Failure to satisfy our current and future debt obligations could result in an event of default and, as a result, the Lenders could accelerate all of the amounts due. In the event of an acceleration of amounts due under the Loan Agreement as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness. In addition, the Lenders could seek to enforce their security interests in the assets securing such indebtedness.

Our ability to make scheduled payments on or to refinance our debt obligations depends on our financial condition and operating performance and the condition of the debt and capital markets, which are subject to prevailing economic, industry and competitive conditions, as well as certain financial, business, legislative, political, regulatory and other factors beyond our control. If our cash flow and capital resources are insufficient to fund our debt service obligations, we could face substantial liquidity problems, be forced to reduce or delay capital expenditures, strategic acquisitions, investments and partnerships, dispose of material assets or operations, seek additional debt or equity capital or restructure or refinance our indebtedness. We cannot assure you that any such actions, if necessary, could be effected on commercially reasonable terms or at all, or on terms that would be advantageous to our stockholders or on terms that would not require us to breach the terms and conditions of our existing or future debt agreements, and our financial position and results of operations could be materially adversely affected.

We are subject to certain restrictive covenants that may restrict our ability to pursue our business strategies, and the failure to comply with such restrictions could materially adversely affect our business.

The Loan Agreement imposes operating and other restrictions on us. Such restrictions will affect, and in many respects limit or prohibit, our ability and the ability of any future subsidiary to, among other things:

- invest in our subsidiaries and make other investments;
- dispose of certain assets;
- change our lines of business;

- engage in mergers or consolidations;
- incur additional indebtedness;
- create liens on assets;
- pay dividends and make distributions or repurchase our capital stock
- amend our material agreements;
- permit our qualified cash subject to a control account in favor of the Lenders to be below $10 million plus the amount (if any) of accounts payable aged over 90 days; and
- engage in certain transactions with affiliates.

The restrictions contained in the Loan Agreement could limit our ability to plan for or react to market conditions, meet capital needs or make acquisitions or could otherwise restrict our business and growth strategies, which could materially adversely affect our business, financial condition and operating results. We may not be able to comply with the minimum liquidity covenant.

If we fail to comply with the covenants under the Loan Agreement, we will be in default and, as a result, the Lenders could accelerate all of the amounts due.

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:

- successful commercial launch of Xerava;
- acceptance of Xerava by the medical community, 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.

Xerava or any additional product candidate that we develop and commercialize may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for Xerava or any additional product candidates may be smaller than we estimate.

Prior to Xerava, we had never commercialized a product candidate for any indication. Efforts to educate the medical community and third-party payors on the benefits of Xerava or any additional product candidate may require significant resources and may not be successful. If Xerava or any additional product candidate that we develop does not achieve an adequate level of market acceptance, we may not generate significant product revenues and, therefore, we may not become profitable. 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, contained in the product's approved labeling or an approved risk evaluation and mitigation strategy;
- our ability to offer the product for sale at competitive prices;
- the willingness of the target patient population to try, and 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;
- the timing of market introduction of our approved products as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- 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 and marketing 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 is difficult to estimate. Our estimates of the potential market opportunity 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, 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, 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 or any product candidate that we develop.

To achieve commercial success for any approved product, including Xerava, we must develop a successful sales and marketing organization or outsource these functions to third parties. 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 or any additional product candidates that we develop and commercialize on our own 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 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 Limited, or 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. We face competition from major pharmaceutical companies, specialty pharmaceutical companies, generic manufacturers and biotechnology companies worldwide with respect to Xerava and to any product candidates that we may seek to develop or commercialize in the future. 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. Potential competitors also include academic institutions, government agencies and other public and private research organizations. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than Xerava or any product candidates that we are currently developing or that we may develop, which could render our products and product candidates obsolete or noncompetitive.

There are a variety of available therapies that are generic or marketed for the treatment of cIAI that we would expect would compete with Xerava. The generic agents include piperacillin/tazobactam, imipenem/cilastatin, ertapenem, meropenem, doripenem, ampicillin/sulbactam and tigecycline. The marketed products include Zerbaxa and Invanz which are marketed by Merck & Co., Inc., Avycaz which is marketed by Allergan, Inc, and Tygacil which is marketed by Pfizer, Inc. Many of the available therapies are well established and widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products.

There are also a number of products currently in phase 3 development by third parties to treat MDR infections, including imipenem/relebactam, which is being developed by Merck & Co., Inc.; sulopenem, which is being developed by Iterum Therapeutics; azetronam/avibactam being developed by Pfizer, Inc.; and cefiderocol, which is being developed by Shionogi. If these products are approved, they may also compete with Xerava.

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.

In July 2012, the Food and Drug Administration Safety and Innovation Act was passed, which included the GAIN Act. The GAIN Act is intended to provide incentives for the development of new, qualified infectious disease products. These incentives may result in more competition in the market for new antibiotics and may cause pharmaceutical and biotechnology companies with more resources than we have to shift their efforts towards the development of products that could be competitive with Xerava and our product candidates.

Even if we are able to commercialize Xerava or any product candidate that we develop, 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 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 from the sale of the product in that country. Adverse

pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize Xerava or any other product candidate 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 our ability to sell our product candidates profitably.

There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the U.S. Food and Drug Administration, or FDA, or comparable foreign regulatory authorities. 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 other product candidate that we commercialize 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. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

If clinical trials of any product candidate that we advance to 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, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidate.

We are 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 we may never receive such approvals. We must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we 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 our product candidates 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. For example, in the first quarter of 2018 we reported top-line data for our IGNITE3 phase 3 clinical trial evaluating the safety and efficacy of Xerava with intravenous, or IV, administration for the treatment of complicated urinary tract infections. IGNITE3 failed to meet the co-primary efficacy endpoints of responder rate (a combination of clinical cure and microbiological success) in the microbiological intent-to-treat population at the end-of-IV treatment visit and at the test-of-cure visit, which were evaluated using a 10% non-inferiority margin. We may fail to achieve success 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 our clinical trials warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

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 our clinical trials, results may differ on the basis of the type of bacteria with which patients are infected. We cannot be certain that other clinical trials that we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

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

- clinical trials of our product candidates may produce unfavorable or inconclusive results;
- we may decide, or regulators may require us, 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 we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our 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 to us in a timely manner, or at all;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have to suspend or terminate clinical trials of our product candidates 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 we or our investigators suspend or terminate clinical research 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 of our product candidates 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 our clinical data insufficient for approval.

If we are required to conduct additional clinical trials or other testing of any product candidate that we develop beyond the trials and testing that we contemplate, if we are unable to successfully complete clinical trials of our product candidates 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 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.

Our product development costs will also increase if we experience delays in testing or marketing approvals and we may be required to obtain additional funds to complete clinical trials. We cannot be certain that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, clinical trial delays may ultimately lead to the denial of regulatory approval of any product candidate.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for any product candidate that we develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in clinical trials for such other product candidate as required by the FDA or comparable foreign regulatory authorities, such as the EMA. Patient enrollment is a significant factor in the timing of clinical trials, and is affected by many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the proximity of patients to clinical sites;
- the eligibility criteria for the trial;
- the design of the clinical trial; and
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

Serious adverse events or undesirable side effects or other unexpected properties of Xerava or any product candidate 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, an institutional review board, or regulatory authorities to interrupt, delay or halt our 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 of our product candidates are associated with serious adverse events or undesirable side effects or have properties that are unexpected, we 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 have been reported. The most common treatment-related adverse events observed in clinical trials of Xerava have been nausea and emesis. Additional adverse events, undesirable side effects or other unexpected properties of any of our product candidates 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, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of, or deny approval of, our 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 us from achieving or maintaining 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 or of any other products that we may develop.

We face an inherent risk of product liability claims as a result of the clinical testing of our product candidates despite obtaining appropriate informed consents from our clinical trial participants. We face an even greater risk with respect to Xerava or any other product that we sell. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, 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 our product candidates or products that we may develop;
- 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 any products that we may develop.

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 and our product candidates, 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.

Our research and development efforts may not result in additional product candidates being discovered on anticipated timelines, which could limit our ability to generate revenues.

Some of our research and development programs are at preclinical stages. Additional product candidates that we may develop or acquire will require significant commitment of resources. We cannot predict whether our research will lead to the discovery and development of any additional product candidates that could generate revenues for us.

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.

Although we are commercializing Xerava ourselves in the United States, we also 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, we may seek third-party collaborators for development and commercialization of our 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 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 license arrangement with Everest Medicines, 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 and for the manufacture for clinical trials and commercialization of any additional product candidates that we develop and commercialize. This reliance on third parties for manufacturing increases the risk that we will not have sufficient quantities of our product or product candidates 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 our product candidates for use in the conduct of our 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 and clinical supplies of our product candidates. Further, we have relied on and expect to continue to rely on third-party contract manufacturers to manufacture registration batches and commercial quantities of any product candidate that we commercialize following approval for marketing by applicable regulatory authorities. 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 our products and product candidates 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;
- 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.

We currently rely on a small number of third-party contract manufacturers for all of our required raw materials, drug substance and finished product for our preclinical research and clinical trials. We do not have long-term agreements with any of these third parties. We also do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates. If any of our existing manufacturers should become unavailable to us for any reason, we may incur some delay in identifying or qualifying replacements.

We have entered into agreements with third-party contract manufacturers for the commercial production of Xerava and intend to do the same for any additional product candidate that is approved by any regulatory agency. We intend to enter into agreements with third-party contract manufacturers for the commercial production of those products. This process is difficult and time consuming and we may face competition for access to manufacturing facilities, as there are a limited number of contract manufacturers operating under current Good Manufacturing Practices, or cGMPs, that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with third-party manufacturers on satisfactory terms, which could delay our commercialization.

Third-party manufacturers are required to comply with 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 a New Drug Application, or 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 and any other product candidate that we develop may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

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

We will require additional funds to complete the development and potential commercialization of any product candidates and/or for the development and potential commercialization of Xerava for other indications. For some of our product candidates, we may decide 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 with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product or product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, 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.

We rely on third parties to conduct our clinical trials. If they do not perform satisfactorily, our business may be materially harmed.

We do not independently conduct clinical trials of our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials.

Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for clinical development activities limits our control over these activities but we remain responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards. For example, notwithstanding the obligations of a contract research organization for a trial of one of our product candidates, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as current Good Clinical Practices, or cGCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites and institutional review boards. If we or our third-party contractors fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our product candidates, which would delay the regulatory approval process. We cannot be certain that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. We are also required to register clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time and resources to our ongoing development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any additional product candidate that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue.

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 United States 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 their 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, including patent infringement litigation with respect to the third-party United States patent referred to above, 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, such as the third-party United States patent referred to above, 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.

Trademark applications for TETRAPHASE PHARMACEUTICALS, our logo, and combinations of those are allowed in the United States, meaning we can perfect registration once use in commerce has commenced 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 pending in three jurisdictions. 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 pending trademark application in the United States for Xerava, the proprietary name for the Xerava product.

We own applications 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 design mark in two jurisdictions, and applications remain pending for those design marks in the United States and one other jurisdiction.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

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 our current and future products will be 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. We cannot 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 our 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.

Our products are in various stages of development. Clinical trial failures may occur at any stage 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 our data the same way that we do, which may delay, limit or prevent regulatory approval or clearance. The FDA or foreign regulatory authorities may also disagree with the design of our 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 may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our 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, 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, our current and future clinical trials may not be successful

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we 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 us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our 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 our products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, the FDA or other regulatory authority may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects. 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 of our products.

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.

Our future product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, marketing, export, sale and distribution, 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 us from commercializing such product candidate.

We are not permitted to market our product candidates in the United States until we receive 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 our 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 with which we must comply prior to marketing. Obtaining marketing approval for marketing of a product candidate in one country does not ensure that we

will be able to obtain marketing approval in other countries, but the failure to obtain marketing approval in one jurisdiction could negatively impact our 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 Xerava or any other product candidate that we develop 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 our NDA fail to comply with cGMP requirements, thereby delaying or preventing approval. In addition, any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of any product candidate that we develop, the commercial prospects for such product candidate may be harmed and our ability to generate revenues will be materially impaired.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad. Any approval we are granted for our product candidates in the United States would not assure approval of our product candidates in foreign jurisdictions.

In order to market and sell our products in the European Union and other foreign 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. In addition, in many countries outside the United States, a product must be approved for reimbursement before the product can be approved for sale in that country. 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. We may file for marketing approvals but not receive necessary approvals to commercialize our products in any market.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. On March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the referendum could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union and could prevent or delay our marketing approval in the European Union or United Kingdom in addition to delaying the pricing arrangements or reimbursements for any approved product candidates. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced 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 we 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, 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 and product candidates 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 United States 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.

Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of our product candidates and affect the prices we, or they, may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved products.

We expect that existing healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

The costs of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the United States, and members of Congress and the Trump Administration have stated that they will address such costs through new legislative and administrative measures. The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

At the same time, the Trump Administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump Administration released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump Administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

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, Federal Supply Schedule, or FSS, pricing program and the Tricare Retail Pharmacy 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 United States 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 United States 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, United States Customs regulations, and various economic and trade sanctions regulations administered by the United States 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.

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 research and development, 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 and in March 2018, our former chief financial officer terminated her employment with us.

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 develop and commercialize product candidates will be limited.

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

Although our operations are based in the United States, we conduct business outside the United States and expect to continue to do so in the future. For instance, many of the sites at which our clinical trials are or may be conducted are outside the United States. In addition, 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:

- 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 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. While we have precautions in place and have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and 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 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

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. For example, our stock traded within a range of a high price of $52.90 per share and a low price of $0.95 per share for the period beginning March 20, 2013, our first day of trading on the Nasdaq Global Select Market, through May 6, 2019. As a result of this volatility, investors may not be able to sell their common stock at or above the prices they paid for it. The market price for our common stock may be influenced by many factors, including:

- revenues related to Xerava;
- the filing and approval of marketing applications for our product candidates;
- the timing of clinical trials of our product candidates;
- results of clinical trials of our product candidates;
- regulatory actions by the FDA or equivalent authorities in foreign jurisdictions with respect to Xerava and any other product candidate;
- failure or discontinuation of any of our development programs;
- 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;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to develop, in-license or acquire additional product candidates or products;
- 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.

We have been, currently are 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. Due to the volatility in our stock price, we may be the target of similar litigation in the future.

In connection with our current litigation and 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.

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. The terms of the Loan Agreement precluded us from paying dividends, and any future debt agreements may also preclude us from paying dividends. 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, 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.

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	
10.1	Amendment No. 1 to Tetraphase Pharmaceuticals, Inc. 2014 Employee Stock Purchase Plan, dated March 13, 2019.					X
10.2	First Amendment to Loan and Security Agreement, dated as of March 14, 2019, by and between the registrant and Solar Capital Ltd., in its capacity as collateral agent.					X
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 8, 2019

TETRAPHASE PHARMACEUTICALS, INC.

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

Exhibit 10.1

AMENDMENT NO. 1

TO

TETRAPHASE PHARMACEUTICALS, INC.

2014 EMPLOYEE STOCK PURCHASE PLAN

The 2014 Employee Stock Purchase Plan (the "Plan") of Tetraphase Pharmaceuticals, Inc. is hereby amended as follows:

1. Section 2(b) shall be amended to delete "six months" and insert "thirty (30) days" in its place.

2. Section 9(a) shall be amended and restated in its entirety as follows:

"(a) Number of Shares. On the first day of each Plan Period, the Company will grant to each eligible employee who is then a participant in the Plan an option (an "Option") to purchase on the last business day of such Plan Period (the "Exercise Date") at the applicable purchase price (the "Option Price") up to a whole number of shares of Common Stock not to exceed 10,000 shares; provided, however, that no employee may be granted an Option which permits his or her rights to purchase Common Stock under this Plan or any other employee stock purchase plan (as defined in Section 423(b) of the Code) of the Company and its subsidiaries, to accrue at a rate which exceeds $25,000 of the fair market value of such Common Stock (determined at the date such Option is granted) for each calendar year in which the Option is outstanding at any time."

Except as set forth above, the remainder of the Plan remains in full force and effect.

Adopted by the Board of Directors on

March 13, 2019

Exhibit 10.2

FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "**Amendment**"), dated as of March 14, 2019 (the "**Amendment Effective Date**"), is made among Tetraphase Pharmaceuticals, Inc., a Delaware corporation (the "**Borrower**"), Solar Capital Ltd., a Maryland corporation ("**Solar**"), in its capacity as collateral agent (in such capacity, together with its successors and assigns in such capacity, "**Collateral Agent**") and the Lenders listed on Schedule 1.1 of the Loan and Security Agreement (as defined below) or otherwise a party hereto from time to time including Solar in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**").

The Borrower, the Lenders and Collateral Agent are parties to a Loan and Security Agreement dated as of November 2, 2018 (as amended, restated or modified from time to time, the "**Loan and Security Agreement**"). The Borrower has requested that the Lenders agree to certain amendments to the Loan and Security Agreement. The Lenders constituting all of the Lenders under the Loan and Security Agreement, have agreed to such request, subject to the terms and conditions hereof.

Accordingly, the parties hereto agree as follows:

SECTION 1 Definitions; Interpretation.

(a) **Terms Defined in Loan and Security Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement.

(b) **Interpretation**. The rules of interpretation set forth in Section 1.1 of the Loan and Security Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2 Amendments to the Loan and Security Agreement; Consent.

(a) The Loan and Security Agreement shall be amended as follows effective as of the Amendment Effective Date:

(i) Section 6.6(a). Section 6.6(a) is hereby amended and restated as follows:

"(a) Maintain Borrower's and Guarantors Collateral Accounts depositary institutions that have agreed to execute Control Agreements in favor of Collateral Agent with respect to such Collateral Accounts. The provisions of the previous sentence shall not apply to (i) Deposit Accounts exclusively used for payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of Borrower's, or any Guarantor's, employees (provided that the amounts deposited therein shall not exceed the amount reasonably expected to be due and payable on the next two succeeding pay dates) and as identified to Collateral Agent by Borrower as such in the Perfection Certificate, (ii) that certain account at Bank of America ending with 7281 solely in connection with the credit card Indebtedness permitted under clause (d) of the definition of "Permitted Indebtedness," solely as in effect on the Effective Date and not exceeding the amounts in such account as of the Effective Date, (iii) that certain account at Wells Fargo ending with 3718 solely to the extent that the amounts in such account do not exceed Fifty Thousand Dollars ($50,000) at any time, and (iv) to other accounts in an aggregate amount not to exceed One Hundred Thousand Dollars ($100,000) and as identified to Collateral Agent by Borrower as such in the Perfection Certificate."

(b) The Lenders hereby consent to a license agreement between the Borrower and a specified third party, in substantially the form sent to the Collateral Agent by email dated March 1, 2019; provided that the terms of such license are not modified in any manner adverse to the Lenders.

(c) **References Within Loan and Security Agreement**. Each reference in the Loan and Security Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 3 Conditions of Effectiveness. The effectiveness of Section 2 of this Amendment shall be subject to the satisfaction of each of the following conditions precedent:

(a) **Fees and Expenses**. The Borrower shall have paid (i) all invoiced costs and expenses then due in accordance with Section 5(f), and (ii) all other fees, costs and expenses, if any, due and payable as of the Amendment Effective Date under the Loan and Security Agreement and invoiced at least one Business Day prior to the Amendment Effective Date.

(b) **This Amendment**. Collateral Agent shall have received this Amendment, executed by Collateral Agent, the Lenders and the Borrower.

(c) **Representations and Warranties; No Default**. On the Amendment Effective Date, after giving effect to the amendment of the Loan and Security Agreement contemplated hereby:

(i) The representations and warranties contained in Section 4 shall be true and correct on and as of the Amendment Effective Date as though made on and as of such date; and

(ii) There exist no Events of Default or events that solely with the passage of time would result in an Event of Default.

SECTION 4 Representations and Warranties. To induce the Lenders to enter into this Amendment, the Borrower hereby confirms, as of the date hereof, (a) that the representations and warranties made by it in Section 5 of the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects; *provided*, *however*, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; (b) that, since December 31, 2017, there has not been a Material Adverse Change; and (c) that the information included in the Perfection Certificate delivered to Collateral Agent on the Effective Date remains true and correct in all material respects. For the purposes of this Section 4, (i) each reference in Section 5 of the Loan and Security Agreement to "this Agreement," and the words "hereof," "herein," "hereunder," or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment, and (ii) any representations and warranties which relate solely to an earlier date shall not be deemed confirmed and restated as of the date hereof (provided that such representations and warranties shall be true and correct in all material respects as of such earlier date).

SECTION 5 Miscellaneous.

(a) **Loan Documents Otherwise Not Affected; Reaffirmation**. Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. The Lenders' and Collateral Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future. The Borrower hereby reaffirms the grant of security under Section 4.1 of the Loan and Security Agreement and hereby reaffirms that such grant of security in the Collateral secures all Obligations under the Loan and Security Agreement, including without limitation any Term Loans funded on or after the Amendment Effective Date, as of the date hereof.

(b) **No Novation**. Each of the parties hereto irrevocably and unconditionally agrees that this Amendment shall not be deemed to evidence or result in a novation or repayment and reborrowing of the Obligations under the Loan and Security as in effect prior to the effectiveness of this Amendment. Nothing herein contained shall be construed as a substitution or novation of the Obligations of Borrower outstanding under the Loan and Security Agreement as in effect prior to the effectiveness of this Amendment or instruments securing the same, which Obligations shall remain in full force and effect, except to the extent that the terms thereof are modified hereby or by

instruments executed concurrently herewith. Nothing expressed or implied in this Amendment shall be construed as a release or other discharge of Borrower from any of the Obligations or any liabilities under the Loan and Security Agreement as in effect prior to the effectiveness of this Amendment or any of the other Loan Documents executed in connection therewith

(c) **Conditions**. For purposes of determining compliance with the conditions specified in Section 3, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Collateral Agent shall have received notice from such Lender prior to the Amendment Effective Date specifying its objection thereto.

(d) **Release.** In consideration of the agreements of Collateral Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Borrower, on behalf of itself and its successors, assigns, and other legal representatives, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Collateral Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Collateral Agent, Lenders and all such other persons being hereinafter referred to collectively as the "**Releasees**" and individually as a "**Releasee**"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment, including, without limitation, for or on account of, or in relation to, or in any way in connection with the Loan Agreement, or any of the other Loan Documents or transactions thereunder or related thereto. Borrower understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above.

(e) **No Reliance**. The Borrower hereby acknowledges and confirms to Collateral Agent and the Lenders that the Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(f) **Costs and Expenses**. The Borrower agrees to pay to Collateral Agent within ten (10) days of its receipt of an invoice (or on the Amendment Effective Date to the extent invoiced at least one Business Day prior to the Amendment Effective Date), the out-of-pocket costs and expenses of Collateral Agent and the Lenders party hereto, and the fees and disbursements of counsel to Collateral Agent and the Lenders party hereto (including allocated costs of internal counsel), in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the Amendment Effective Date or after such date.

(g) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(h) **Governing Law**. **THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAWS OTHER THAN THE LAWS OF THE STATE OF NEW YORK), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL.**

(i) **Complete Agreement; Amendments**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(j) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(k) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(l) **Loan Documents**. This Amendment and the documents related thereto shall constitute Loan Documents.

[Balance of Page Intentionally Left Blank; Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

TETRAPHASE PHARMACEUTICALS, INC.,
as Borrower

By: /s/ Guy Macdonald
Title: CEO/

COLLATERAL AGENT AND LENDERS:

SOLAR CAPITAL LTD.
as Collateral Agent and a Lender

By: /s/Anthony J. Storino
Name: Anthony J. Storino
Title: Authorized Signatory

SCP PRIVATE CREDIT INCOME FUND L.P.
as a Lender

By: /s/Anthony J. Storino
Name: Anthony J. Storino
Title: Authorized Signatory

SCP Private Credit Income BDC SPV LLC
as a Lender

By: /s/Anthony J. Storino
Name: Anthony J. Storino
Title: Authorized Signatory

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, Guy Macdonald, 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 8, 2019

/s/ Guy Macdonald
Guy Macdonald
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 8, 2019

/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, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Guy Macdonald, 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 8, 2019

/s/ Guy Macdonald
Guy Macdonald
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, 2019, 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 8, 2019

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