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 September 30, 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 November 8, 2019, there were 3,015,824 shares of the registrant's common stock, par value $0.001 per share, outstanding.

TETRAPHASE PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2019

TABLE OF CONTENTS

		Page No.
PART I. FINANCIAL INFORMATION		4
Item 1.	**Financial Statements (Unaudited)**	4
	Condensed Consolidated Balance Sheets as of September 30, 2019 and December 31, 2018	4
	Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2019 and 2018	5
	Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2019 and 2018	6
	Condensed Consolidated Statements of Shareholders' Equity for the Nine Months Ended September 30, 2019 and 2018	7
	Notes to Condensed Consolidated Financial Statements	8
Item 2.	**Management's Discussion and Analysis of Financial Condition and Results of Operations**	24
Item 3.	**Quantitative and Qualitative Disclosures About Market Risk**	35
Item 4.	**Controls and Procedures**	35
PART II. OTHER INFORMATION		36
Item 1.	**Legal Proceedings**	36
Item 1A.	**Risk Factors**	36
Item 6.	**Exhibits**	62
	SIGNATURES	63

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

TETRAPHASE PHARMACEUTICALS, INC.

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

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 24,508	$ 107,776
Accounts receivable, net	1,710	2,274
Contract asset	—	3,000
Assets held for sale	544	—
Inventory	2,434	748
Prepaid expenses and other current assets	2,718	2,674
Total current assets	31,914	116,472
Property and equipment, net	113	1,121
Intangible assets, net	4,357	4,652
Operating lease right-of-use assets	5,197	—
Restricted cash	699	699
Total assets	$ 42,280	$ 122,944
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,752	$ 3,210
Accrued expenses	8,568	11,761
Operating lease liabilities	1,497	—
Total current liabilities	11,817	14,971
Long-term operating lease liabilities	3,850	—
Loan payable, long-term	—	28,291
Total liabilities	15,667	43,262
Commitments and contingencies (Note 13)		
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; 2,716 and 2,684 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	3	3
Additional paid-in capital	619,364	613,721
Accumulated deficit	(592,754)	(534,042)
Total stockholders' equity	26,613	79,682
Total liabilities and stockholders' equity	$ 42,280	$ 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Product revenue, net	$ 978	$ —	$ 2,115	$ —
License and collaboration revenue	2,000	—	2,000	9,500
Government revenue	362	1,151	1,571	5,120
Total revenue	3,340	1,151	5,686	14,620
Expenses:				
Cost of revenue - product sales	882	—	1,353	—
Cost of revenue - intangible asset amortization	98	—	295	—
Research and development	5,348	11,665	20,252	44,162
Selling, general and administrative	11,350	9,481	39,776	22,350
Total expenses	17,678	21,146	61,676	66,512
Loss from operations	(14,338)	(19,995)	(55,990)	(51,892)
Other income and expenses				
Loss on extinguishment of debt	(1,568)	—	(1,568)	—
Other income	—	—	250	—
Interest income	252	437	1,175	1,215
Interest expense	(650)	—	(2,580)	—
Net loss	$ (16,304)	$ (19,558)	$ (58,713)	$ (50,677)
Net loss per share-basic and diluted	$ (6.00)	$ (7.39)	$ (21.70)	$ (19.44)
Weighted-average number of common shares used in net loss per share-basic and diluted	2,716	2,647	2,706	2,607
Comprehensive loss	$ (16,304)	$ (19,558)	$ (58,713)	$ (50,677)

See accompanying notes to unaudited condensed consolidated financial statements

TETRAPHASE PHARMACEUTICALS, INC.

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

	Nine Months Ended September 30,	
	2019	**2018**
Operating activities		
Net loss	$ (58,713)	$ (50,677)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	520	357
Non-cash interest expense related to notes payable	621	—
Stock-based compensation expense	5,603	9,880
Loss on extinguishment of debt	1,568	—
Impairment of equipment related to restructuring	335	—
Changes in operating assets and liabilities:		
Accounts receivable	565	2,056
Contract asset	3,000	—
Inventory	(1,686)	—
Prepaid expenses and other assets	(44)	1,081
Accounts payable	(1,458)	(1,852)
Accrued expenses and other liabilities	(3,078)	(3,397)
Deferred revenue	(6)	(651)
Operating lease right-of-use assets	1,042	—
Operating lease liabilities	(1,000)	—
Net cash used in operating activities	(52,731)	(43,203)
Investing activities		
Acquisition of intangible assets	—	(3,000)
Proceeds from sale of property and equipment	12	—
Purchases of property and equipment	(108)	(105)
Net cash used in investing activities	(96)	(3,105)
Financing activities		
Repayment of debt, including final payment	(30,480)	—
Proceeds from sale of common stock, net of issuance costs	—	6,985
Proceeds from issuance of stock under stock plans	39	371
Net cash provided by (used in) financing activities	(30,441)	7,356
Net decrease in cash, cash equivalents and restricted cash	(83,268)	(38,952)
Cash, cash equivalents and restricted cash at beginning of period	108,475	136,610
Cash, cash equivalents and restricted cash at end of period	$ 25,207	$ 97,658
Supplemental cash flow information:		
Cash paid for interest on long-term debt	$ 1,955	$ —
Acquisition of intangible asset included in accounts payable	—	1,750

See accompanying notes to unaudited condensed consolidated financial statements

TETRAPHASE PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Stockholders' Equity

(In thousands)

(Unaudited)

	Common Shares		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2018	2,684	$ 3	$ 613,721	$ (534,042)	$ 79,682
Issuance of common stock under stock plans	3	—	—	—	—
Stock-based compensation expense	—	—	2,723	—	2,723
Net loss	—	—	—	(19,488)	(19,488)
Balance at March 31, 2019	2,687	$ 3	$ 616,444	$ (553,530)	$ 62,917
Issuance of common stock under stock plans	26	—	—	—	—
Issuance of common stock under employee stock purchase plan	3	—	40	—	40
Stock-based compensation expense	—	—	1,709	—	1,709
Net loss	—	—	—	(22,920)	(22,920)
Balance at June 30, 2019	2,716	$ 3	$ 618,193	$ (576,450)	$ 41,746
Stock-based compensation expense	—	—	1,171	—	1,171
Net loss	—	—	—	(16,304)	(16,304)
Balance at September 30, 2019	2,716	$ 3	$ 619,364	$ (592,754)	$ 26,613
Balance at December 31, 2017	2,577	$ 3	$ 592,291	$ (461,884)	$ 130,410
Issuance of common stock under stock plans	9	—	231	—	231
Stock-based compensation expense	—	—	2,972	—	2,972
Net loss	—	—	—	(21,576)	(21,576)
Balance at March 31, 2018	2,586	$ 3	$ 595,494	$ (483,460)	$ 112,037
Issuance of common stock under stock plans	—	—	30	—	30
Issuance of common stock under "at-the-market" equity offering sales agreement, less issuance costs	59	—	4,713	—	4,713
Issuance of common stock under employee stock purchase plan	2	—	101	—	101
Stock-based compensation expense	—	—	3,392	—	3,392
Net loss	—	—	—	(9,543)	(9,543)
Balance at June 30, 2018	2,647	$ 3	$ 603,730	$ (493,003)	$ 110,730
Issuance of common stock under stock plans	—	—	9	—	9
Issuance of common stock under "at-the-market" equity offering sales agreement, less issuance costs	37	—	2,273	—	2,273
Stock-based compensation expense	—	—	3,516	—	3,516
Net loss	—	—	—	(19,558)	(19,558)
Balance at September 30, 2018	2,684	$ 3	$ 609,528	$ (512,561)	$ 96,970

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 develop and commercialize novel tetracyclines for serious and life-threatening conditions, including bacterial infections caused by multidrug-resistant, or MDR, bacteria. The Company's commercial product, Xerava™ (eravacycline), a fully synthetic fluorocycline, is an intravenous, or IV, antibiotic that is approved for use as a first-line empiric monotherapy for the treatment of MDR infections, including 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 addressing unmet medical needs, including MDR Gram-negative bacteria, and TP-271, a fully synthetic fluorocycline developed for respiratory disease caused by bacterial biothreat pathogens, as well as bacterial pathogens associated with community-acquired pneumonia. Both of these programs have completed phase 1. The Company also developed TP-2846, a tetracycline for the treatment of acute myeloid leukemia, or AML. The Company has completed pre-clinical toxicology studies in this program and intends to file an investigational new drug application, or IND, with the FDA for TP-2846. The Company is seeking to out-license each of these product candidates.

On June 10, 2019, the Company announced a restructuring of its organization, including a 20% reduction in headcount, designed to focus its cash resources on commercializing Xerava primarily in the hospital setting. This reorganization included the elimination of the Company's internal research function and an exploration of out-licensing opportunities for all of the Company's pipeline of early-stage antibiotics and oncology product candidates. The reduction in headcount did not impact the commercial organization. Following the restructuring, over 50% of the Company's full-time employees are commercial and medical affairs personnel.

The Company has incurred annual net operating losses every year since its inception. As of September 30, 2019, the Company had incurred losses since inception of $592.8 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, milestone payments from a licensing agreement and Xerava product 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 current operating plan, the Company expects that its cash and cash equivalents as of September 30, 2019, its projected revenues from sales of Xerava and the net proceeds from the Company's registered direct offering of equity securities completed on November 1, 2019 (note 13) will not be sufficient to fund the Company's operations for more than one year beyond the filing date of this quarterly report, but only into the third quarter of 2020. This estimate is based on certain significant assumptions, which are uncertain and may turn out to be incorrect. In particular, the forecast assumes continued significant growth of Xerava revenue, for which the Company has limited historical experience to base its estimate. In addition, the Company has forecast a significant reduction in expenses as a result of the restructuring announced in June 2019. If these estimates are incorrect, the Company may use its cash resources sooner than expected.

In addition, 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. In light of its limited cash resources, the Company may also determine to explore strategic alternatives to maximize shareholder value, including the potential sale or merger of the Company or its assets. These factors raise substantial doubt about the Company's ability to continue as a going concern.

If the Company is unable to raise capital when needed or if its operating results fall short of its current projections, or if the Company determines to explore strategic alternatives but is unable to consummate such a transaction or transactions on a timely basis or at all, the Company could be forced to significantly delay, scale back or discontinue the commercialization of Xerava or reduce other expenditures, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, the Company's rights to Xerava and its product candidates. The failure of the Company to obtain sufficient funds on acceptable terms would have a material adverse effect on the Company's business, results of operations and financial condition.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim condensed consolidated financial statements are unaudited. These unaudited financial statements have been prepared in accordance with the rules and regulations of the 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, or 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 September 30, 2019 and the results of its operations and comprehensive loss and cash flows for the three and nine months ended September 30, 2019 and 2018. Interim operating results for the three and nine months ended September 30, 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 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 and April 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.

Reverse Stock Split

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

Use of Estimates

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

Accounts Receivable

Accounts receivable as of September 30, 2019 and December 31, 2018 represent amounts due from two main sources: (1) trade accounts receivable of $0.5 million and $0.1 million, respectively, consisting of payments to be received from customers for sales of Xerava, net of prompt payment discounts, chargebacks, rebates and certain fees and (2) contract accounts receivable of $1.2 million and $2.2 million, respectively, related to the Company's government-related agreements.

Contract accounts receivable relate to payments from entities administering the Company's government-related agreements which include unbilled contract accounts receivable of $0.5 million and $0.7 million as of September 30, 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.

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 September 30, 2019, there was no excess or obsolete inventory.

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 is 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.

Property and Equipment

Property and equipment are stated at cost. Costs of major additions and betterments are capitalized; maintenance and repairs which do not improve or extend the life of the respective assets are charged to expense. Upon disposal, the related cost and accumulated depreciation or amortization is removed from the accounts and any resulting gain or loss is included in the consolidated statements of operations and comprehensive loss. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which range from three to five years. Leasehold improvements are amortized over the estimated useful lives of the assets or related lease terms, whichever is shorter.

Assets Held-for-Sale

The Company classifies assets as held-for-sale when the following conditions are met: (1) management has committed to a plan to sell, (2) the assets are available for immediate sale in their present condition, (3) the Company has initiated an active program to identify a buyer, (4) it is probable that a sale will occur within one year, (5) the assets are actively marketed for sale at a reasonable price in relation to their current fair value, and (6) there is a low likelihood of significant changes to the plan or that the plan will be withdrawn. If all of the criteria are met as of the balance sheet date, the assets are presented separately in the balance sheet as held-for-sale at the lower of the carrying amount or fair value less costs to sell. The assets are then no longer depreciated or amortized while classified as held-for-sale.

Long-Lived Assets

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

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 and 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. 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 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 will make adjustments to these estimates and allowances accordingly.

Collaboration Revenue

The Company has entered into an out-licensing agreement that is evaluated underAccounting 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 withCUBRC, Inc., or CUBRC, an independent, not-for-profit, research corporation that specializes in U.S. government-based contracts, with which the Company is 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 Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator, or CARB-X, program, for the development of TP-6076 (see Note 6). 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 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 Contract and NIAID Grant were earned under a cost-reimbursable arrangement in which the Company was reimbursed for direct costs incurred plus allowable indirect costs. Billings under the NIAID Contract and NIAID Grant were 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 University, or Harvard, related to Xerava. All manufacturing costs incurred prior to Xerava's approval in the United States on August 27, 2018 have been expensed in research and development and are not included in cost of revenue.

Recently Adopted Accounting Pronouncements

In June 2018, the FASB issued ASU 2018-07, Compensation – "Stock Compensation (Topic 718), Improvements to Nonemployee Share-based Payment Accounting, which addresses aspects of the accounting for nonemployee share-based payment transactions. This pronouncement is effective for annual reporting periods and interim periods within those annual periods beginning after December 15, 2019. The Company early adopted ASU 2018-07 on April 1, 2019 and there was no impact on adoption.

In February 2016, the Financial Accounting Standards Board, or FASB, issued 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 as of January 1, 2019, 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 upon adoption of the standard.

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

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Measurement of Credit Losses on Financial Instruments*, or ASU 2016-13. ASU 2016-13 will change how companies account for credit losses for most financial assets and certain other instruments. For trade receivables, loans and held-to-maturity debt securities, companies will be required to recognize an allowance for credit losses rather than reducing the carrying value of the asset. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the potential impact that the adoption of ASU 2016-13 will have on the Company's financial position and results of operations.

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 September 30, 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
September 30, 2019				
Cash and money market funds	$ 24,508	$ 24,508	$ —	$ —
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:

	September 30,	
	2019	2018
Warrants	20,718	—
Unvested restricted stock units	141,716	54,426
Outstanding stock options	269,689	358,574
Totals	432,123	413,000

5. Property and Equipment and Assets Held-for-Sale

As of September 30, 2019, and December 31, 2018, property and equipment, net and assets held-for-sale consists of the following (in thousands):

	As of September 30, 2019	As of December 31, 2018	Depreciable lives
Leasehold improvements	$ 923	$ 923	shorter of assets life or lease term
Furniture and fixtures	234	509	5 years
Office and computer equipment	135	217	3 years
Laboratory Equipment	-	3,278	5 years
Less accumulated depreciation	(1,179)	(3,806)	
Property and equipment, net	$ 113	$ 1,121	
Assets held-for-sale	$ 544	-	

During the third quarter of 2019, the Company disposed of property and equipment with a gross carrying amount of $0.1 million and accumulated depreciation of $0.1 million. The Company did not dispose of any property and equipment during 2018. Depreciation and amortization expense amounted to $0.2 million, and $0.5 million in the periods ended September 30, 2019 and December 31, 2018, respectively.

The Company initially recorded certain laboratory equipment asset impairments in the second quarter of 2019 in accordance with ASC 360 *Property, Plant and Equipment* for assets held-and-used, as the criteria to classify the laboratory equipment as held-for-sale had not been met. The Company identified an indicator of impairment related to this held-and-used laboratory equipment as it was more likely than not that some of its laboratory equipment would be sold or otherwise disposed of significantly before the end of its previously estimated useful life primarily as a result of the restructuring described in Note 14. For the laboratory equipment where its fair value did not exceed its carrying amount, an impairment was recognized. Fair value was an estimate of the sales price less cost to sell. In the third quarter of 2019, the Company committed to a plan to actively sell certain of its laboratory equipment. Having met all other criteria, the laboratory equipment met the criteria to classify that equipment as held-for-sale. At September 30, 2019, $0.5 million of laboratory equipment was classified as held-for-sale as reflected in the consolidated balance sheet. The sale is expected to be complete by the end of the fourth quarter of 2019. Laboratory equipment held-for-sale is reflected at the lower of its carrying amount or fair value less the cost to sell, with any excess recorded as an impairment. In aggregate, impairment losses recognized in

connection with laboratory equipment was $0.3 million and included in research and development costs in the consolidated statement of operations for the period ended September 30, 2019.

6. Intangible Assets

Intangible assets consist solely of the payments made to Harvard related to the regulatory approvals of Xerava. The intangible assets are being amortized using the straight-line method over the estimated useful life of approximately 12 years. As of September 30, 2019, and December 31, 2018, intangible assets, net of accumulated amortization, are as follows (in thousands):

	As of September 30, 2019		As of December 31, 2018	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Total intangible asset for Harvard milestones	$ 4,750	$ 393	$ 4,750	$ 98

Amortization expense was approximately $0.3 million, and $0.1 million in the periods ended September 30, 2019 and December 31, 2018, respectively.

The Company expects to incur amortization expense of approximately $0.4 million per period from 2019 to 2029 and $0.3 million in the final year (2030).

During the three months ended September 30, 2019, management identified impairment indicators related to the intangible assets for the Harvard milestones. As result, an interim test of recoverability of the intangible asset was performed based on the estimated undiscounted future cash flows related to the intangible asset, and concluded the intangible asset was recoverable. The Company's quantitative assessment considered significant assumptions related to estimates of future Xerava sales, offset by direct costs to derive the sales. The estimates of future Xerava sales include estimates of significant growth as the product was recently launched in the fourth quarter of 2018. Given the limited history of sales and the inherent difficulty in making a long-range forecast, such estimates contain significant uncertainty. If the assumptions regarding forecasted revenue or the costs to derive such revenues are not achieved, we may be required to perform future impairment analyses and record an impairment charge for the intangible asset in future periods. It is not possible at this time to determine if any such future impairment charge would result or, if it does, whether such charge would be material.

7. Inventory

Inventory consisted of the following (in thousands):

	As of September 30, 2019	As of December 31, 2018
Work in progress	$ 115	$ 655
Finished goods	2,319	93
Total inventory	$ 2,434	$ 748

There were no charges related to excess inventory for the three and nine months ended September 30, 2019 or 2018.

8. 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 September 30, 2019, the Company has incurred expense in aggregate of $16.8 million in upfront license fees, sublicense fees and development milestone payments for the licensed Harvard technology, and has issued 1,569 shares of common stock to Harvard.

For each product covered by the license agreement, the Company is obligated to make certain payments totaling up to approximately $15.1 million upon achievement of certain development and regulatory milestones and to pay additional royalties on net sales of such product. The Company is also obligated to make certain payments to Harvard based on amounts received under its license agreement with Everest Medicines Limited. During the nine months ended September 30, 2019 and September 30, 2018, the

Company incurred expense of $1.0 million and $1.9 million, respectively, related to the Everest Medicines license agreement. During the three months ended September 30, 2019 the Company incurred expense of $0.4 million related to the Everest Medicines license agreement. During the three months ended September 30, 2018, the Company incurred expense of $3.0 million 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, or the Territory.

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

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

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

In addition, on July 29, 2019, the Company amended its original agreement with Everest Medicines to extend Everest Medicines' exclusive license to develop and commercialize Xerava to the jurisdictions of the Malaysian Federation, the Kingdom of Thailand, the Republic of Indonesia, the Socialist Republic of Vietnam and the Republic of the Philippines. Under the terms of this amendment, the Company received from Everest Medicines an upfront, nonrefundable cash payment of $2.0 million in September 2019. As with the milestones discussed above, the Company is obligated to make certain payments to Harvard based on amounts received from Everest under this amendment pursuant to the existing license agreement by and between Harvard and the Company. During the three months ended September 30, 2019, the Company incurred expense of $0.4 million related to this milestone.

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

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

The Company evaluated the Everest License Agreement under 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 Chinaand 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 recognized the $2.0 million territory expansion upfront payment associated with the July 2019 amendment as collaboration revenue during the three months ended September 30, 2019 as the Company has no further performance obligations pursuant to the arrangement.

Other Material Agreements

Patheon UK Limited Master Manufacturing Services Agreement

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

Finorga SAS Commercial Supply Agreement

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

Government Grant and Contracts

BARDA Contract for Eravacycline

The Company received funding for the development of Xerava under an award from BARDA, an agency of the U.S. Department of Health and Human Services. In January 2012, BARDA awarded a five-year contract, which 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 Xerava to treat certain infections caused by life-threatening MDR bacteria.

In connection with the BARDA Contract, in February 2012, the Company entered into a cost-plus-fixed-fee subcontract with CUBRC, an independent, not for profit, research corporation that specializes in U.S. government-based contracts, which is also the direct recipient of the BARDA Contract. This subcontract, which currently expires on December 31, 2019, granted the Company initial funding of up to approximately $41.3 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 Contracthave terms which currently expire on December 31, 2019, BARDA is entitled to terminate the project for convenience at anytime 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 $41.3 million through December 31, 2019, the current contract end date, as a result of the exercise of several options by BARDA under the BARDA Contract.Total funds of $40.0 million had been received by the Company through September 30, 2019 under this contract. During the three months ended September 30, 2019 and 2018, the Company recognized revenue of $0.4 million and $0.2 million, respectively, from the Company's subcontract under the BARDA Contract. During the nine months ended September 30, 2019 and 2018, the Company recognized revenue of $1.0 million and $1.2 million, respectively, from the Company's subcontract under the BARDA Contract.

NIAID Grant and Contract for TP-271

The Company received funding for its phase 1 compound TP-271 from NIAID for the development, manufacturing and clinical evaluation of TP-271 for respiratory diseases caused by biothreat and antibiotic-resistant public health pathogens, as well as bacterial pathogens associated with community-acquired pneumonia:

- The NIAID Contract awarded in September 2011 provided up to a total of approximately $35.8 million and expired on March 31, 2019.

In connection with the NIAID Contract, in October 2011, the Company entered into a cost-plus-fixed-fee subcontract with CUBRC, the direct recipient of the NIAID Contract, which subcontract expired on March 31, 2019 under 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 September 30, 2019, the Company had received $16.2 million. The Company has not received any additional funds under this agreement since that date.

During the three months ended September 30, 2019 the Company recognized no revenue under the NIAID Contract compared to $0.7 million for the three months ended September 30, 2018, as the contract expired on March 31, 2019. During the nine months ended September 30, 2019 and 2018, the Company recognized revenue of $0.1 million and $2.3 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 September 30, 2019 the Company did not recognize any revenue as the Sub-Award Agreement expired on June 30, 2019. During the three months ended September 30, 2018 the Company recognized revenue of $0.2 million under this Sub-Award Agreement. During the nine months ended September 30, 2019 and 2018, the Company recognized revenue of $0.5 million and $1.6 million, respectively, under this Sub-Award Agreement and does not expect to receive any additional revenue under the award.

9. Accrued Expenses

Accrued expenses at September 30, 2019 and December 31, 2018 consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Salaries and benefits	$ 3,303	$ 3,801
Drug supply and development	2,893	3,901
Professional fees	811	1,178
Commercial	1,057	910
Royalties and license payments	71	617
Other	433	1,354
Total	$ 8,568	$ 11,761

10. 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 0.1 million shares as a result of the automatic increase provision of the 2013 Plan. As of September 30, 2019, the total number of shares of common stock available for issuance under the 2013 Plan was approximately 0.1 million.

Stock-Based Compensation Expense

During the three and nine months ended September 30, 2019 and 2018, the Company recognized the following stock-based compensation expense (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 218	$ 1,639	$ 1,691	$ 4,585
General and administrative	953	1,877	3,912	5,295
Total	$ 1,171	$ 3,516	$ 5,603	$ 9,880

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Stock options	$ 736	$ 2,820	$ 4,301	$ 8,406
Restricted stock units	424	661	1,254	1,387
Employee stock purchase plan	11	35	48	87
Total	$ 1,171	$ 3,516	$ 5,603	$ 9,880

Stock Options

The following table summarizes the stock option activity for the nine months ended September 30, 2019:

	Shares	Weighted-Average Exercise Price
Outstanding at December 31, 2018	366,020	$ 223.11
Granted	9,200	$ 17.72
Forfeited	(105,531)	$ 151.71
Outstanding at September 30, 2019	269,689	$ 244.04
Exercisable at September 30, 2019	199,178	$ 298.11

As of September 30, 2019, there was $4.4 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 2.0 years.

Restricted Stock Units and Performance Stock Units

In 2019 the Company awarded 127,742 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. In connection with the restructuring in June 2019 (see Note 14), the Company modified certain RSUs.

In January 2019 and August 2019 the Company issued to certain employees 16,650 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 September 30, 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 nine months ended September 30, 2019:

	Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2018	54,035	$ 60.10
Awarded	144,392	$ 22.99
Forfeited	(27,498)	$ 36.20
Vested/Released	(29,213)	$ 69.57
Unvested at September 30, 2019	141,716	$ 24.97

As of September 30, 2019, there was total unrecognized stock-based expense of $1.5 million related to RSU's and $0.1 million related to PSU's. The expense is expected to be recognized over a weighted-average period of 1.3 years.

Employee stock purchase plan

Under the Company's 2014 Employee Stock Purchase Plan, as amended, or 2014 ESPP, an aggregate of 30,000 shares of common stock have been reserved for issuance pursuant to purchase rights granted to the Company's employees. As of September 30, 2019, 15,000 shares remained available for issuance.

11. 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 September 30, 2019, the Company had sold an aggregate of 305,522 shares of common stock under the Sales Agreement, at an average selling price of approximately $129.70 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 November 11, 2019, $40.4 million of common stock remained available to be sold under the Amended Sales Agreement.

12. 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 agreed to make available to the Company term loans in an aggregate principal amount of up to $75.0 million under the Loan Agreement. A $30.0 million term loan was funded on November 2, 2018, with a maturity date of May 2, 2023. Borrowings under the term loan bore interest at a floating per annum rate equal to the 1 Month LIBOR Rate plus 7.25%. The loan facility also included 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 was also subject a prepayment penalty fee based on a percentage of the outstanding principal balance, equal to 3% if the payment occurred on or before 12 months after the initial funding date, 2% if the prepayment occurred more than 12 months after, but on or before 24 months after, the initial funding date, or 1% if the prepayment occurred more than 24 months after the initial funding date.

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.

On August 30, 2019, the Company entered into a payoff letter with the Lenders, pursuant to which the Company agreed to pay off and thereby terminate the Loan Agreement. Pursuant to the payoff letter, the Company paid a total of $30.7 million to the Lenders, representing the principal balance, accrued interest outstanding and a portion of the final fee under the Loan Agreement in repayment of the Company's outstanding obligations under the Loan Agreement. The Company recorded a loss from debt extinguishment of $1.6 million as the difference between the net carrying amount of the indebtedness under the Loan Agreement and the amount paid.

The Company recorded interest expense related to the loan facility of $0.7 and $2.6 million and for the three and nine months ended September 30, 2019, respectively.

13. 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 feet, 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 September 30, 2019	Nine Months Ended September 30, 2019
Operating lease cost	$ 474	$ 1,423
Variable lease cost	314	893
Total lease cost	$ 788	$ 2,316
Weighted-average remaining lease term (years)	3.15	3.15
Weighted-average discount rate	9.25%	9.25%

Cash paid for amounts included in the measurement of the lease liabilities were $0.5 million and $1.4 million for the three and nine months ended September 30, 2019, respectively.

As of September 30, 2019, the Company's operating lease liabilities were as follows (in thousands):

	Amount
2019 (excluding the nine months ended September 30, 2019)	$ 466
2020	1,916
2021	1,950
2022	1,785
Thereafter	—
Less: Imputed interest	(770)
Present value of lease payments	$ 5,347

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

The Company recorded $0.4 million and $1.1 million in rent expense for the three and nine months ended September 30, 2018, respectively.

14. Corporate Restructuring Charges

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

The restructuring charges recorded during the nine months ended September 30, 2019 and the related liability balance as of September 30, 2019 for each major type of cost associated with this restructuring plan are as follows:

	Restructuring Expense	Cash payments	Non-cash expense	Restructuring Liability at September 30, 2019
Employee severance, benefits and related costs	$ 2,130	$ (1,324)	$ —	$ 806
Asset impairments	335	-	(335)	-
Compensation expense	(97)	-	97	-
	$ 2,368	$ (1,324)	$ (238)	$ 806

The company did not incur any restructuring charges during the three months ended September 30, 2019.

15. Subsequent Events

On November 1, 2019 the Company completed a registered direct offering to a healthcare-focused institutional investor priced at-the-market, of (i) 300,000 shares of common stock and accompanying warrants to purchase an aggregate of 300,000 shares of common stock, and (ii) pre-funded warrants to purchase up to an aggregate of 1,830,493 shares of common stock and accompanying warrants to purchase an aggregate of 1,830,493 shares of common stock. Each share of common stock and accompanying common stock warrant were sold together at a combined price of $3.755, and each pre-funded warrant and accompanying common stock warrant were sold together at a combined price of $3.745. Each pre-funded warrant has an exercise price of $0.01 per share, is exercisable immediately and is exercisable until exercised in full. Each common stock warrant has an exercise price of $3.62 per share, is exercisable immediately and expires five years from the date of issuance.

The net proceeds to the Company from the offering, after deducting the placement agent's fees and other estimated offering expenses payable by the Company, are approximately $7.0 million.

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 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. Our commercial product, Xerava™ (eravacycline), a fully synthetic fluorocycline, is an intravenous, or IV, antibiotic that is approved for use as a first-line empiric monotherapy for the treatment of MDR infections, including 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 IV Xerava met the primary endpoint by demonstrating statistical non-inferiority of clinical response compared to ertapenem, 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 clinical 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 small, targeted commercial and medical affairs groups to build and promote access to Xerava. As of September 30, 2019, we have approximately 31 sales representatives, five regional business directors, two strategic market access executives and approximately nine 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, which was amended in July 2019, granting Everest Medicines commercialization rights to eravacycline in China and other Asian territories. In June 2018, Everest Medicines submitted an IND to the National Medical Products Administration (formerly CHINA FDA) for a phase 3 clinical trial of eravacycline in cIAI. Everest Medicines began enrolling patients in this phase 3 clinical trial in the second quarter of 2019.

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. Xerava has demonstrated the ability to cover a wide variety of MDR Gram-negative bacteria, including MDR *Klebsiella pneumoniae* and MDR *Acinetobacter* in *in vitro* studies. 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 have also developed other fluorocycline antibiotic compounds, TP-6076 and TP-271, and a tetracycline for the treatment of acute myeloid leukemia, or AML, TP-2846. We developed TP-6076, a fully-synthetic fluorocycline derivative, as a lead candidate under our second-generation program to target unmet medical needs, including MDR Gram-negative bacteria such as carbapenem-resistant Enterobacteriaceae and carbapenem-resistant *Acinetobacter baumanii*. To date, we have conducted phase 1 single-ascending and multiple-ascending dose studies evaluating the safety, tolerability and pharmacokinetics of IV TP-6076 in healthy volunteers. We also conducted a Phase 1 study to assess the bronchopulmonary disposition, pharmacokinetics, and safety of TP-6076 in healthy volunteers. TP-271 is a fully-synthetic fluorocycline that we developed for respiratory disease caused by bacterial biothreat and antibiotic-resistant public health pathogens, as well as bacterial pathogens associated with community-acquired pneumonia. To date, we have completed single- and multiple-ascending dose trials for the IV and oral formulations of TP-271. We have recently initiated pre-clinical toxicology studies in TP-2846 and intend to file an investigational new drug application, or IND, with the FDA for TP-2846. We are seeking to out-license each of these product candidates.

On June 10, 2019, we announced a restructuring of our organization, including a 20% reduction in headcount, designed to focus our cash resources on commercializing Xerava primarily in the hospital setting. This reorganization included the elimination of our internal research function and an exploration of out-licensing opportunities for all of our pipeline of early-stage antibiotics and oncology product candidates. The reduction in headcount did not impact the commercial organization. Following the restructuring, over 50% of our full-time employees are commercial and medical affairs personnel. The total costs associated with the restructuring were $2.4 million.

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 nine months ended September 30, 2019, we generated $2.1 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 September 30, 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 $60.3 million from government grants and contracts and an aggregate of $14.5 million from licensing agreement milestone payments. As of September 30, 2019, our principal source of liquidity was cash and cash equivalents, which totaled $24.5 million.

As of September 30, 2019, we had an accumulated deficit of $592.8 million. Our net losses were $16.3 million and $19.6 million for the three months ended September 30, 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, and our restructuring, 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, our projected revenues from sales of Xerava and the net proceeds from our registered direct offering of equity securities completed on November 1, 2019 (Note 15) will not be sufficient to fund our operations for more than one year beyond the filing date of this quarterly report, but only into the third quarter of 2020. As a result, we have concluded that there is substantial doubt regarding our ability to continue as a going concern. 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. In light of our limited cash resources, we may also determine to explore strategic alternatives to maximize shareholder value, including the potential sale or merger of us or our assets. 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 interim condensed consolidated financial statements in this Form 10-Q.

Collaboration Revenue

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

Government Revenue

Our government revenue has been derived from funding provided under four 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 and nine months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Xerava	$ 3,695	$ 5,463	$ 8,770	$ 26,218
BARDA Contract	317	213	862	1,229
TP-6076	18	562	1,255	1,471
CARB-X Award	-	253	460	1,613
NIAID Contract	-	693	88	2,097
Other development programs	601	837	2,980	1,849
Other research and development	717	3,644	5,837	9,685
Total research and development expenses	$ 5,348	$ 11,665	$ 20,252	$ 44,162

Prior to our June 2019 reorganization, research and development activities were 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 September 30, 2019, we had incurred an aggregate of $296.6 million in research and development expenses related to the development of Xerava, and $38.6 million in research and development expenses related to the development of Xerava that were funded under the BARDA Contract.

As part of our restructuring, we decided not to engage in further product development, including conducting clinical trials of our product candidates. While we intend to seek to out-license all of our pipeline candidates, there are numerous risks and uncertainties associated with product development by a third-party collaborator.

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 September 30, 2019, we have incurred expense in aggregate of $16.8 million in up front license fees, sublicense fee and development milestone payments for the licensed Harvard technology. We have also issued 1,569 shares of our common stock to Harvard under the license agreement. We have also agreed to make payments to Harvard upon the achievement of specified future development and regulatory milestones totaling up to $15.1 million for each licensed product candidate ($12.6 million of which has already been paid with respect to eravacycline), and to pay tiered royalties in the single digits based on annual worldwide net sales, if any, of licensed products, by us, our affiliates and our sublicensees. We are also obligated to pay Harvard a specified share of non-royalty sublicensing revenues that we receive from sublicensees for the grant of sublicenses under the license and to reimburse Harvard for specified patent prosecution and maintenance costs.

Selling, General and Administrative Expenses

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

We anticipate that our selling, general and administrative expenses will remain stable for the immediate future.

Other Income (Expense)

Other income (expense) consists primarily of interest income, interest expenses and expenses related to the early payment of indebtedness under our term loan facility, which we paid off in August 2019. Interest income consists of interest earned on our cash and cash equivalents. The primary objective of our investment policy is capital preservation. 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 decrease in future periods due to the early payment of the term loan in August 2019. For the three-month period ended September 30, 2019, we recorded a one-time loss from debt extinguishment of $1.6 million as the difference between the net carrying amount of the indebtedness under the term loan facility and the amount paid.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, accrued clinical expenses, and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we and our management believe to be reasonable under the circumstances. The results of these estimates form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies are those which require the most significant judgments and estimates in the preparation of our consolidated financial statements. We have determined that our most critical accounting policies are those relating to product revenue recognition, collaboration revenue recognition, government contract and grant revenue recognition and equity compensation. There have been no significant changes to our critical accounting policies as described under *Management's Discussion and Analysis of Financial Condition and Results of Operations* in our annual report, filed on form 10-K with the SEC on March 13, 2019, for the year ended December 31, 2018.

Results of Operations

Comparison of the Three Months Ended September 30, 2019 and 2018

The following table summarizes the results of our operations for the three months ended September 30, 2019 and 2018, together with the changes in those items in dollars:

Product Revenue

	Three Months Ended September 30,		Increase/ (decrease)
	2019	2018	
	(in thousands)		
Revenue:			
Product revenue, net	$ 978	$ -	978
License and collaboration revenue	2,000	-	2,000
Government revenue	362	1,151	(789)
Total revenue	3,340	1,151	2,189
Operating expenses:			
Cost of revenue - product sales	882	-	882
Cost of revenue - intangible asset amortization	98	-	98
Research and development	5,348	11,665	(6,317)
Selling, general and administrative	11,350	9,481	1,869
Total operating expenses	17,678	21,146	(3,468)
Loss from operations	(14,338)	(19,995)	5,657
Loss on extinguishment of debt	(1,568)	-	(1,568)
Other income	-	-	-
Interest income	252	437	(185)
Interest expense	(650)	-	(650)
Net loss	$ (16,304)	$ (19,558)	$ 3,254

We initiated sales of Xerava in the United States on October 15, 2018. For the three months ended September 30, 2019, net sales of Xerava were $1.0 million.

Cost of Revenue

Cost of product revenues was $1.0 million for the three months ended September 30, 2019, consisting primarily ofmanufacturing 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, with no corresponding amounts in the previous year. All of our manufacturing costs incurred prior to Xerava's approval have been expensed in research and development expenses and are not included in cost of revenue. We expect cost of revenue to increase as we deplete these inventories manufactured prior to approval.

License and Collaboration Revenue

We recognized $2.0 million in license and collaboration revenue during the three months ended September 30, 2019 from the July 2019 amendment entered into with Everest Medicines.

Revenue from U.S. Government Contracts and Grants

The following table sets forth our government contract and grant revenue for the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Increase/ (decrease)
	2019	2018	
	(in thousands)		
Revenues			
BARDA Contract	$ 363	$ 216	$ 147
CARB-X Award	-	246	(246)
NIAID Contract	-	689	(689)
	$ 363	$ 1,151	$ (788)

Government revenue was $0.4 million for the three months ended September 30, 2019 compared to $1.2 million for the three months ended September 30, 2018, a decrease of $0.8 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 Contract as well as the completion of the NIAID Contract in the first quarter of 2019 and CARB-X Award in second quarter of 2019. 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 September 30, 2019 were $5.3 million compared to $11.7 million for the three months ended September 30, 2018, a decrease of $6.4 million. This decrease was primarily due to a decrease in activity across all of our pipeline programs as compared to the prior year reflecting our determination not to further engage in product development.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended September 30, 2019 were $11.4 million compared to $9.5 million for the three months ended September 30, 2018, an increase of $1.9 million. This increase was primarily due to an increase in commercial related expenses for Xerava.

Other Income (Expense)

Interest expense increased by $0.7 million for the three months ended September 30, 2019 reflecting interest expense under our term loan facility. Interest income decreased by $0.2 million related to the year-over-year decrease in cash and cash equivalents. For the three-month period ended September 30, 2019, we also recorded a one-time loss from debt extinguishment of $1.6 million as the difference between the net carrying amount of the indebtedness under the term loan facility and the amount paid.

Comparison of the Nine Months Ended September 30, 2019 and 2018

The following table summarizes the results of our operations for the nine months ended September 30, 2019 and 2018, together with the changes in those items in dollars and as a percentage:

	Nine Months Ended September 30,		Increase/ (decrease)
	2019	2018	
		(in thousands)	
Revenues			
Product revenue, net	$ 2,115	$ -	2,115
License and collaboration revenue	2,000	9,500	(7,500)
Government revenue	1,571	5,120	(3,549)
Total revenues	5,686	14,620	(8,934)
Operating expenses:			
Cost of revenue - product sales	1,353	-	1,353
Cost of revenue - intangible asset amortization	295	-	295
Research and development	20,252	44,162	(23,910)
Selling, general and administrative	39,776	22,350	17,426
Total operating expenses	61,676	66,512	(4,836)
Loss from operations	(55,990)	(51,892)	(4,098)
Loss from extinguishment of debt	(1,568)	-	(1,568)
Other income	250	-	250
Interest income	1,175	1,215	(40)
Interest expense	(2,580)	-	(2,580)
Net loss	$ (58,713)	$ (50,677)	$ (8,036)

Product Revenue

We initiated sales of Xerava, in the United States on October 15, 2018. For the nine months ended September 30, 2019, net sales of Xerava were $2.1 million.

Cost of Revenue

Cost of product revenues was $1.6 million for the nine months ended September 30, 2019, consisting primarily ofmanufacturing 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, with no corresponding amounts in the previous year. All of our manufacturing costs incurred prior to Xerava's approval have been expensed in research and development expenses and are not included in cost of revenue. We expect cost of revenue to increase as we deplete these inventories manufactured prior to approval.

License and Collaboration Revenue

We recognized $2.0 million in license and collaboration revenue during the nine months ended September 30, 2019 from the territory expansion payment received from Everest Medicines. License and collaboration revenue for the same period in 2018 was $9.5 million, related to the initiation of our agreement with Everest Medicines.

Revenue from U.S Government Contracts and Grants

The following table sets forth our government contract and grant revenue for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,		Increase/
	2019	2018	(decrease)
	(in thousands)		
Revenues			
BARDA Contract	$ 1,024	$ 1,243	$ (219)
CARB-X Award	452	1,597	(1,145)
NIAID Contract	95	2,280	(2,185)
	$ 1,571	$ 5,120	$ (3,549)

Government revenue was $1.6 million for the nine months ended September 30, 2019 compared to $5.1 million for the nine months ended September 30, 2018, a decrease of $3.5 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 nine months ended September 30, 2019 were $20.3 million compared to $44.2 million for the nine months ended September 30, 2018, a decrease of $23.9 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 license and milestone payments to Harvard University that occurred in the first and second quarter of 2018. As a result of our determination in connection with the restructuring we announced in June 2019 to discontinue further product development, we expect future research and development costs to decrease significantly.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the nine months ended September 30, 2019 were $39.8 million compared to $22.4 million for the nine months ended September 30, 2018, an increase of $17.4 million. This increase was primarily due to an increase in commercial related expenses for Xerava.

Other Income (Expense)

Interest expense increased by $2.6 million for the nine months ended September 30, 2019 related to the Solar debt facility put in place in November 2018. Interest income was largely unchanged, as the year-over-year decrease in cash and equivalents was off-set by the temporary increase in cash from the debt facility, which was paid off in August 2019. For the nine-month period ended September 30, 2019, we also recorded a one-time loss from debt extinguishment of $1.6 million as the difference between the net carrying amount of the indebtedness under the term loan facility and the amount paid.

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 September 30, 2019, we had cash and cash equivalents of approximately $24.5 million after paying off the Loan Agreement. 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 September 30, 2019, our funds were all 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 September 30, 2019, we had sold an aggregate of 305,522 shares under the agreement at an average price of $129.70 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 with the Lenders. The Lenders agreed to make available to us term loans in an aggregate principal amount of up to $75.0 million under the Loan Agreement. The Loan Agreement provided a term loan commitment of $50.0 million in two potential tranches: (i) a $30.0 million Term A loan facility funded on November 2, 2018 and (ii) a $20.0 million Term B loan facility to be funded at the request of the Company no later than October 31, 2020, subject to (a) the Company having unrestricted net cash proceeds of not less than $50 million from the issuance and sale of common stock and/or from other business activities and (b) the Company having product revenue greater than or equal to $14.0 million on a six month trailing basis prior to September 30, 2020. Both of these term loans had a maturity date of May 2, 2023. The Loan Agreement also provided access to an additional Term C loan facility in the amount of $25.0 million, to be funded at the Lenders' sole discretion.

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

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

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

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

On November 1, 2019 we completed a registered direct offering to a healthcare-focused institutional investor priced at-the-market, of (i) 300,000 shares of common stock and accompanying warrants to purchase an aggregate of 300,000 shares of common stock, and (ii) pre-funded warrants to purchase up to an aggregate of 1,830,493 shares of common stock and accompanying warrants to purchase an aggregate of 1,830,493 shares of common stock. Each share of common stock and accompanying common stock warrant were sold together at a combined price of $3.755, and each pre-funded warrant and accompanying common stock warrant were sold together at a combined price of $3.745. Each pre-funded warrant has an exercise price of $0.01 per share, is exercisable immediately and is exercisable until exercised in full. Each common stock warrant has an exercise price of $3.62 per share, is exercisable immediately and expires five years from the date of issuance. The net proceeds from the offering, after deducting the placement agent's fees and other estimated offering expenses payable by us, are approximately $7.0 million.

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

	Nine Months Ended September 30,	
	2019	2018
Cash Flows from Operations:		
Net cash used in operating activities	$ (52,731)	$ (43,203)
Net cash used in investing activities	(96)	(3,105)
Net cash (used in) provided by financing activities	(30,441)	7,356
Net decrease in cash and cash equivalents	$ (83,268)	$ (38,952)

Cash Flows from Operating Activities. The $9.5 million increase in cash used in operating activities for the nine months ended September 30, 2019, compared to the nine months ended September 30, 2018, was primarily due to our increased operating loss compared to the same period in 2018.

Cash Flows from Investing Activities. The $3.0 million decrease in cash used in investing activities for the nine months ended September 30, 2019, compared to the nine months ended September 30, 2018 was due to a $3.0 million payment to Harvard upon FDA approval of Xerava during the third quarter 2018.

Cash Flows from Financing Activities. The $37.8 million increase in cash used in financing activities was due principally to the repayment of debt and related fees in August 2019.

Operating Capital Requirements

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

We believe, based on our current operating plan, that our existing cash and cash equivalents and projected revenues from sales of Xerava, together with the net proceeds from the November 2019 registered direct offering, will be sufficient to fund our operations 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 beyond such time. In light of our limited cash resources, we may also determine to explore strategic alternatives to maximize stockholder value, including the potential sale or merger of us or our assets.

We have based our projections of operating capital requirements and revenues on assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect. However, because of the numerous risks and uncertainties associated with the commercialization of pharmaceutical products such as Xerava, our estimates of our operating capital requirements may be incorrect. If we are unable to raise capital when needed or if our product revenue does not meet our current projections, or if we determine to explore strategic alternatives but are unable to consummate such a transaction or transactions on a timely basis or at all, we could be forced to significantly scale back or discontinue the commercialization of Xerava and reduce other expenditures, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, our rights to Xerava and our other product candidates. In addition, in such circumstance, we would consider seeking protection under the bankruptcy laws in order to continue to pursue potential transactions and conduct a winddown. If we decide to seek protection under the bankruptcy laws, we would expect we would file for bankruptcy at a time that is significantly earlier than when we would otherwise exhaust our cash resources.

Our future funding requirements and our projected revenues will depend on many factors, including, but not limited to:

- revenue received from commercial sales of Xerava;
- our ability to enter into collaborations, licensing, marketing, distribution or other arrangements with respect to Xerava and our product candidates, and the terms and timing of any such arrangements into which we enter;
- the timing and costs of manufacturing and other activities in connection with the commercialization of Xerava;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay to Harvard 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 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 or if our product revenue does not meet our current projections, or if we determine to explore strategic alternatives but we are unable to consummate such a transaction or transactions on a timely basis or at all, we could be forced to significantly delay, scale back or discontinue the commercialization of Xerava or reduce other expenditures, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, our rights to Xerava and our other product candidates.

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

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and senior vice president, finance, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 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 September 30, 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

There have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934 during the third quarter of 2019 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. In May 2019, the United States District Court for the Southern District of New York granted the defendants motion to transfer the matter to the United States District Court for the District of Massachusetts. In August 2019, the United States District Court for the District of Massachusetts (the "Massachusetts Federal Court") granted an unopposed motion for the appointment of a lead plaintiff. In October 2019, the lead plaintiff filed a motion to voluntarily dismiss the case and on October 16, 2019 the Massachusetts Federal Court entered an order dismissing the case.

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.

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 $58.7 million for the nine months ended September 30, 2019, $72.2 million for the year ended December 31, 2018 and $114.8 million for the year ended December 31, 2017. As of September 30, 2019, we had an accumulated deficit of $592.8 million. Prior to October 2018, when we commenced sales of Xerava in the United States, we had not generated any product revenues. For the nine months ended September 30, 2019, we generated $2.1 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. In June 2019, we determined to devote all of our financial resources and efforts to supporting the ongoing commercialization of Xerava and announced a restructuring of our organization, including a 20% reduction in headcount, designed to focus our cash resources on commercializing Xerava primarily in the hospital setting. As a result of the restructuring, we have eliminated our internal research function and are exploring out-licensing opportunities for our pipeline of early-stage antibiotics and oncology product candidates.

Notwithstanding the initiation of sales of Xerava and our 2019 restructuring, we 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 that we have incurred on our IGNITE (**I**nvestigating **G**ram-**N**egative **I**nfections with **E**ravacycline) clinical program in 2019, given its completion in 2018, will offset increased sales, marketing, distribution and outsourced manufacturing expenses related to the launch of Xerava and charges associated with our June 2019 restructuring. Our expenses could increase if and as we:

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

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

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

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

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

We will need additional funding to commercialize Xerava. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We believe that our existing cash and cash equivalents, our projected revenues from sales of Xerava, will not be sufficient to fund our operations for at least 12 months; only into the third second of 2020. On November 1, 2019, we completed a registered direct offering of equity securities for net proceeds of approximately $7.0 million. As a result of this offering, our cash and cash equivalents are sufficient to fund the Company's operations 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 expenses after that time. In light of our limited cash resources, we may also determine to explore strategic alternatives to maximize shareholder value, including the potential sale or merger of us or our assets.

Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, although we are exploring out-licensing opportunities for our pipeline of early-stage antibiotics and oncology product candidates, there can be no assurance that we will be able to out-license these on a timely basis or on terms that are favorable to us, or at all. Our failure to raise capital through financing or a license of our pipeline as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

In addition, if we are unable to raise capital, we may instead determine to dissolve and liquidate our assets or seek protection under the bankruptcy laws. If we decide to dissolve and liquidate our assets or to seek protection under the bankruptcy laws, it is unclear to what extent we will be able to pay our obligations, and, accordingly, it is further unclear whether and to what extent any resources will be available for distributions to stockholders.

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

- revenue received from commercial sales of Xerava;
- our ability to enter into collaborations, licensing, marketing, distribution or other arrangements with respect to Xerava and our product candidates, and the terms and timing of any such arrangements into which we enter;
- the timing and costs of manufacturing and other activities in connection with the commercialization of Xerava;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay to Harvard University, or Harvard, and other licenses under license agreements to which we may be a party;
- the costs of maintaining and protecting our intellectual property rights and defending against intellectual property related claims; 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, establishing a commercial infrastructure to launch Xerava in the United States and selling Xerava in the United States. We obtained marketing approval for Xerava in the United States and Europe in the third quarter of 2018 and commenced sales of Xerava in the United States in the fourth quarter of 2018. We have not yet demonstrated a long-term ability to conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

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

Unless and until we can generate a substantial amount of revenue from Xerava, we expect to finance our future cash needs through public or private equity offerings, debt financings or collaborations and licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

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

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

Risks Related to Product Development and Commercialization

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

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

- successful commercial launch of Xerava in the United States;
- 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 of ours that a future collaborator develops and commercializes 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 the additional product candidates may be smaller than we estimated.

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

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

In addition, the potential market opportunity for Xerava or any product candidate is difficult to estimate. Our estimates of the potential market opportunity for Xerava are predicated on several key assumptions such as industry knowledge, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, 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.

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

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

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, Recarbrio and Invanz which are marketed by Merck & Co., Inc., Avycaz which is marketed by Allergan, Inc, and Vabomere which is marketed by Melinta Therapeutics, 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 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.

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

Marketing approvals, pricing, coverage and reimbursement for new drug products vary widely by country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after

marketing or product approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we or a future collaborator might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate directly or indirectly from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in Xerava and any of our product candidates that are commercialized, even if our product candidates obtain marketing approval.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

Although we are commercializing Xerava ourselves in the United States, we intend to seek to commercialize Xerava outside the United States through collaboration arrangements. For instance, in February 2018, we entered into a license agreement with Everest Medicines under which we granted Everest Medicines an exclusive license to develop and commercialize Xerava for the treatment of cIAI and other indications, in mainland China and several other Asian territories and countries. In addition, we are exploring out-licensing opportunities for our pipeline of early-stage antibiotics and oncology product candidates. Our likely collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We are not currently party to any such arrangements other than that with 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. This reliance on third parties for manufacturing increases the risk that we will not have sufficient quantities of our product or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

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

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

Third-party manufacturers are required to comply with current Good Manufacturing Processes, or cGMPs, and similar regulatory requirements outside the United States. Facilities used by our third-party manufacturers must be inspected by the FDA after we submit an NDA, and before potential approval of the product candidate. Similar regulations apply to manufacturers of our product candidates for use or sale in foreign countries. We do not control the manufacturing process and are completely dependent on our third-party manufacturers for compliance with the applicable regulatory requirements for the manufacture of our product candidates. If our manufacturers cannot successfully manufacture material that conforms to the strict regulatory requirements of the FDA and any

applicable foreign regulatory authority, they will not be able to secure the applicable approval for their manufacturing facilities. If these facilities are not approved for commercial manufacture, we may need to find alternative manufacturing facilities, which could result in delays in obtaining approval for the applicable product candidate as alternative qualified manufacturing facilities may not be available on a timely basis or at all. In addition, our manufacturers are subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. Failure by any of our manufacturers to comply with applicable cGMPs or other regulatory requirements could result in sanctions being imposed on us or the contract manufacturer, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and have a material adverse impact on our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

We are a party to a license agreement with Harvard that imposes, and we may enter into additional agreements, including license agreements, with other parties in the future that impose, diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. For example, under our license agreement with Harvard, we are obligated to satisfy diligence requirements, including using commercially reasonable efforts to develop and commercialize licensed compounds

and to implement a specified development plan, meeting specified development milestones and providing an update on progress on an annual basis, and to pay royalties on sales of Xerava. If we fail to comply with these obligations, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product that is covered by these agreements, which could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

Risks Related to Our Intellectual Property

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

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

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

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

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

As a result of the America Invents Act of 2011, the United States transitioned to a first-inventor-to-file system in March 2013, under which, assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent. However, as a result of the lag in the publication of patent applications following filing in the United States, we are not notified and therefore are not able to be certain upon filing that we are the first to file for patent protection for any invention. Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination*, inter partes* review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of or invalidate our patent rights, allow third parties to commercialize our technology, products or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-

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

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

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

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

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

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

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our products and product candidates and use our proprietary chemistry technology without infringing the intellectual property and other proprietary rights of third parties. Numerous third-party 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 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 ableto do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

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

We may be subject to claims that we or our employeeshave 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, and are expected to proceed to registration shortly as allegations of use have been filed and accepted. 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. The application has been allowed and is expected to proceed to registration in due course upon the filing and acceptance of an allegation of use.

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

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

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

Product candidates may not be marketed in the United States until receipt of approval of an NDA from the FDA. An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and efficacy for each desired indication. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the product candidate. Obtaining approval of an NDA is a lengthy, expensive and uncertain process. The drug development and FDA review process typically takes years to complete. The FDA has substantial discretion in the approval process and may refuse to accept for filing any application or may decide that data are insufficient for approval and require additional preclinical, clinical or other studies or additional information regarding chemistry, manufacturing and controls for the product candidate. Foreign regulatory authorities have differing requirements for approval of drug candidates which must be complied withprior to marketing. Obtaining marketing approval for marketing of a product candidate in one country does not ensure that marketing approval will be received in other countries, but the failure to obtain marketing approval in one jurisdiction could negatively impact the ability to obtain marketing approval in other jurisdictions. Delays in approvals or rejections of marketing applications in the United States or foreign countries may be based upon many factors, including regulatory requests for additional analyses, reports, data and studies, regulatory questions regarding, or different interpretations of, data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding product candidates or related products. The FDA or equivalent foreign regulatory authorities may determine that a product candidate is not effective, or is only moderately effective, or has undesirable or unintended side effects, toxicities, safety profile or other characteristics that preclude marketing approval or prevent or limit commercial use. The FDA may also find during its pre-approval inspection that the facilities identified in the NDA fail to comply with cGMP requirements, thereby delaying or preventing approval. In addition, any marketing approval may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Delays in obtaining approval or the failure to obtain approval of any product candidate would harm the commercial prospects for such product candidate.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad. 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. On October 28, 2019, that deadline was extended from October 31, 2019 to January 31, 2020 to allow the parties to continue to negotiate a withdrawal agreement. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, Brexit 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.

The United Kingdom had a period of a maximum of two years from the date of its formal notification to negotiate the terms of its withdrawal from, and future relationship with, the European Union. If no formal withdrawal agreement can be reached between the United Kingdom and the European Union, then it is expected that the United Kingdom's membership in the European Union would automatically terminate on the deadline, which has been extended to October 31, 2019 to allow the parties to negotiate a withdrawal agreement. Such negotiations have proven to be extremely difficult to date. On July 24, 2019, Boris Johnson, who has previously suggested the country should leave the European Union without an agreement, was elected prime minister of the United Kingdom. Discussions between the United Kingdom and the European Union will continue to focus on finalizing withdrawal issues and transition agreements. However, limited progress to date in these negotiations and ongoing uncertainty within the UK Government and Parliament sustains the possibility of the United Kingdom leaving the European Union without a withdrawal agreement and associated transition period in place, which is likely to cause significant market and economic disruption.

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

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

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

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

- issue warning or untitled letters;
- mandate modifications to promotional materials or require provision of corrective information to healthcare practitioners and patients;

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

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

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

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

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

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

Our arrangements with third-party payors, healthcare professionals and customers who purchase, recommend or prescribe our products are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products, and it is possible that our business activities could be subject to challenge or enforcement under one or more of these laws and regulations. These laws and regulations include the 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.

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

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

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

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

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

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

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

We are subject to 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.

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

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

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

to engage sufficient clinical sites, inability to obtain or maintain institutional review board, or IRB, approval of the trial, or cessation of a trial for futility or safety concerns by us, or FDA, or foreign regulatory authorities, or an independent committee such as an independent data monitoring committee. As a result of any number of potential reasons, clinical trials may not be successful

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

Risks Related to Employee Matters

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

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

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

We have recently reduced the size of our organization, and we may encounter difficulties in managing our business as a result of this reduction, or the attrition that may occur following this reduction, which could disrupt our operations. In addition, we may not achieve anticipated benefits and savings from the reduction.

In June 2019, we authorized the implementation of a restructuring of our organization, including a 20% reduction in headcount, designed to focus our cash resources on commercializing Xerava primarily in the hospital setting. The restructuring, and the attrition thereafter, resulted in the loss of longer-term employees, the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. Given the complexity and nature of our business, we must continue to implement and improve our managerial, operational and financial systems, manage our facilities and continue to recruit and retain qualified personnel. This will be made more challenging given the restructuring described above and additional measures we may take to reduce costs. As a result, our management may need to divert a disproportionate amount of its attention away from our day-to-day strategic and operational activities, and devote a substantial amount of time to managing these organizational changes. Further, the restructuring and possible additional cost containment measures may yield unintended consequences, such as attrition beyond our intended reduction in headcount and reduced employee morale. In addition, the restructuring may result in employees who were not affected by the reduction in headcount seeking alternate employment, which would result in us seeking contract support at unplanned additional expense. In addition, we may not achieve anticipated benefits from the restructuring. Due to our limited resources, we may not be able to effectively manage our

operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, loss of business opportunities, loss of employees and reduced productivity among remaining employees. We may also determine to take additional measures to reduce costs, which could result in further disruptions to our operations and present additional challenges to the effective management of our company. If our management is unable to effectively manage this transition and restructuring and additional cost containment measures, our expenses may be more than expected, and we may not be able to implement our business strategy.

The business that we 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 being developed by a future collaborator and/or finished drug product supply or manufacturing capabilities abroad;
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, hurricanes, typhoons, floods and fires; and
- failure to comply with Office of Foreign Asset Control rules and regulations and the Foreign Corrupt Practices Act.

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

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

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

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

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

Risks Related to Our Common Stock

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

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

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

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

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

Our stock price may be volatile. The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. For example, our stock traded within a range of a high price of $1,058.00 per share and a low price of $3.05 per share for the period beginning March 20, 2013, our first day of trading on the Nasdaq Global Select Market, through November 11, 2019. As a result of this volatility, you may not be able to sell your common stock at or above the public offering price. The market price for our common stock may be influenced by many factors, including:

- revenues related to Xerava;
- the filing and approval of marketing applications for our product candidates by future collaborators;
- the timing and results of clinical trials of any product candidates that we license to third parties;
- regulatory actions by the FDA or equivalent authorities in foreign jurisdictions with respect to Xerava and any product candidate that we license to a third party;
- failure or discontinuation of any development programs of our future collaborators;
- the success of existing or new competitive products or technologies;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the results of our efforts to out-license our product candidates;
- 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 and may again be subject to class action litigation and have been and may again be subject to shareholder derivative litigation, which could distract our management and could result in substantial costs or large judgments against us.

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

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

As part of our November 2019 registered direct offering, we issued warrants to purchase an aggregate of 2,130,493 shares of common stock at an exercise price of $3.62 per share. As of November 11, 2019, all of these warrants remained outstanding and, upon exercise in full of these warrants, the shares issuable upon exercise would represent a significant portion of our outstanding common stock. The warrants were fully exercisable upon issuance and remain exercisable for five years from their respective dates of issuance. We have registered the issuance of shares upon exercise of these warrants under a registration statements under the Securities Act of 1933, as amended, and, accordingly, such shares can be freely sold into the public market upon issuance, subject to volume limitations applicable to affiliates. Sales of these shares could cause the market price of our common stock to decline significantly. Furthermore, if our stock price rises, the holders of these warrants may be more likely to exercise their warrants and sell

a large number of shares, which could negatively impact the market price of our common stock and reduce or eliminate any appreciation in our stock price that might otherwise occur.

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

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

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

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

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

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

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

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

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

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

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

- establish a classified board of directors such that all members of the board are not elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;

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

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, 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

		Incorporated by Reference from				
Exhibit Number	**Description of Document**	**Registrant's Form**	**File No.**	**Date Filed with the SEC**	**Exhibit Number**	**Filed Herewith**
3.1	Restated Certificate of Incorporation, as amended, of Tetraphase Pharmaceuticals, Inc.					X
10.1	Payoff Letter, entered into as of August 30, 2019, by and among Tetraphase Pharmaceuticals, Inc. and Solar Capital Ltd. as collateral agent and lender, and the other lenders named therein	8-K	001-35837	August 30, 2019	10.1	
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

SIGNATURES

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

Date: November 12, 2019

TETRAPHASE PHARMACEUTICALS, INC.

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

RESTATED CERTIFICATE OF INCORPORATION OF
TETRAPHASE PHARMACEUTICALS, INC.

(originally incorporated on July 7, 2006)

Exhibit 3.1

Tetraphase Pharmaceuticals, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the provisions of the Delaware General Corporation Law (the "DGCL"), does hereby certify as follows:

A. The current name of the Corporation is Tetraphase Pharmaceuticals, Inc. The original Certificate of Incorporation of the Corporation was filed with the Secretary of State ofthe State of Delaware on July 7, 2006 and was amended and restated on August 8, 2006, further amended on September 28, 2007, February 27, 2008, June 24, 2008 and September 10,
2009, further amended and restated on May 14, 2010 and further amended on May 10, 2011, December 14, 2012 and
March 5, 2013.

B. A resolution was duly adopted by the Board of Directors of the Corporation pursuant to Sections 242 and 245 of the DGCL proposing this Restated Certificate of Incorporation and declaring the advisability of this Restated Certificate of Incorporation. The stockholders of the Corporation duly approved and adopted this Restated Certificate of Incorporation by written consent in accordance with Sections 228, 242 and 245 of the DGCL.

Accordingly, the Certificate oflncorporation of the Corporation, as previously amended and restated, is hereby further amended and restated in its entirety to read as follows:

FIRST: The name of the Corporation is Tetraphase Pharmaceuticals, Inc.

SECOND: The address of the Corporation's registered office in the State of Delaware is Corporation Trust Center,
1209 Orange Street, in the City of Wilmington, County of New Castle, 19801. The name of its registered agent at that address is The Corporation Trust Company.

THIRD: The nature of the business or purposes to be conducted or promoted by the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware.

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is
130,000,000 shares, consisting of (i) 125,000,000 shares of Common Stock, par value $0.001 per share ("Common Stock"), and (ii) 5,000,000 shares of Preferred Stock, par value $0.001 per share ("Preferred Stock").

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

A COMMON STOCK.

1. General. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights of the holders of the Preferred Stock of any series as may be designated by the Board of Directors of the Corporation (the "Board of Directors") upon any issuance of the Preferred Stock of any series.

2. Voting. The holders of the Common Stock shall have voting rights at all meetings of stockholders, each such holder being entitled to one vote for each share thereof held by such holder; provided, however, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (which, as used herein, shall mean the certificate of incorporation of the Corporation, as amended from time to time, including the terms of any certificate of designations of any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation. There shall be no cumulative voting.

The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

3. Dividends. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Board of Directors and subject to any preferential dividend or other rights of any then outstanding Preferred Stock.

4. Liquidation. Upon the dissolution or liquidation of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation available for distribution to its stockholders, subject to any preferential or other rights of any then outstanding Preferred Stock.

B PREFERRED STOCK.

Preferred Stock may be issued from time to time in one or more series, each of such series to have such terms as stated or expressed herein and in the resolution or resolutions providing for the issue of such series adopted by the Board of Directors as hereinafter provided. Any shares of Preferred Stock which may be redeemed, purchased or acquired by the Corporation may be reissued except as otherwise provided by law.

Authority is hereby expressly granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by adopting a resolution or resolutions providing for the issuance of the shares thereof and by filing a certificate of designations relating thereto in accordance with the General Corporation Law of the State of Delaware, to determine and fix the number of shares of such series and such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or

restrictions thereof, including without limitation thereof, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be stated and expressed in such resolutions, all to the full extent now or hereafter permitted by the General Corporation Law of the State of Delaware. Without limiting the generality of the foregoing, the resolutions providing for issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or be junior to any other series of Preferred Stock to the extent permitted by law.

The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares then outstanding) by the affirmative vote of the holders of a majority of the voting power of the capital stock of the Corporation entitled to vote thereon, voting as a single class, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

FIFTH: Except as otherwise provided herein, the Corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute and this Certificate of Incorporation, and all rights conferred upon stockholders herein are granted subject to this reservation.

SIXTH: In furtherance and not in limitation of the powers conferred upon it by the General Corporation Law of the State of Delaware, and subject to the terms of any series of Preferred Stock, the Board of Directors shall have the power to adopt, amend, alter or repeal the By-laws of the Corporation by the affirmative vote of a majority of the directors present
at any regular or special meeting of the Board of Directors at which a quorum is present. The stockholders may not adopt, amend, alter or repeal the By-laws of the Corporation, or adopt any provision inconsistent therewith, unless such action is approved, in addition to any other vote required by this Certificate of Incorporation, by the affirmative vote of the holders of at least seventy-five percent (75%) of the votes that all the stockholders would be entitled to cast in any annual election of directors or class of directors. Notwithstanding any other provisions of law, this Certificate of Incorporation or the By• laws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative
vote of the holders of at least seventy-five percent (75%) of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article SIXTH.

SEVENTH: Except to the extent that the General Corporation Law of the State of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty, no director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability. No amendment to or repeal of this provision shall apply to or have any effect on the liability or alleged liability of any director of the Corporation for or with respect to any acts or omissions of such director occurring prior to such amendment or repeal. If the General Corporation Law of the State of Delaware is amended to permit further elimination or limitation of the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware as so amended.

EIGHTH: The Corporation shall provide indemnification as follows:

1. Actions, Suits and Proceedings Other than by or in the Right of the Corporation. The Corporation shall indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Corporation) by reason of the fact that he or she is or was, or has agreed to become, a director or officer of the Corporation, or is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan) (all such persons being referred to hereafter as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974), and amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that Indemnitee did not act in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his or her conduct was unlawful.

2. Actions or Suits by or in the Right of the Corporation. The Corporation shall indemnify any Indemnitee who was or is a party to or threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Corporation to procure a judgment in its favor by reason of the fact that Indemnitee is or was, or has agreed to become, a director or officer of the Corporation, or is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred by or on behalf oflndemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, except that no indemnification shall be made under this Section 2 in respect of any claim, issue or matter as to which Indemnitee shall have been adjudged to be liable to the Corporation, unless, and only to the extent, that the Court of Chancery of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of such liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnity for such expenses (including attorneys' fees) which the Court of Chancery of Delaware or such other court shall deem proper.

3. Indemnification for Expenses of Successful Party. Notwithstanding any other provisions of this Article EIGHTH, to the extent that an Indemnitee has been successful, on the

merits or otherwise, in defense of any action, suit or proceeding referred to in Sections 1 and 2 of this Article EIGHTH, or in defense of any claim, issue or matter therein, or on appeal from any such action, suit or proceeding, Indemnitee shall be indemnified against all expenses (including attorneys' fees) actually and reasonably incurred by or on behalf of
Indemnitee in connection therewith. Without limiting the foregoing, if any action, suit or proceeding is disposed of, on the
merits or otherwise (including a disposition without prejudice), without (i) the disposition being adverse to lndemnitee, (ii) an adjudication that Indemnitee was liable to the Corporation, (iii) a plea of guilty or nolo contendere by lndemnitee, (iv) an adjudication that Indemnitee did not act in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the Corporation, and (v) with respect to any criminal proceeding, an adjudication that Indemnitee had reasonable cause to believe his or her conduct was unlawful, Indemnitee shall be considered for the purposes hereof to have been wholly successful with respect thereto.

4. Notification and Defense of Claim. As a condition precedent to an lndemnitee's right to be indemnified, such Indemnitee must notify the Corporation in writing as soon as practicable of any action, suit, proceeding or investigation involving such Indemnitee for which indemnity will or could be sought. With respect to any action, suit, proceeding or investigation of which the Corporation is so notified, the Corporation will be entitled to participate therein at its own expense and/or to assume the defense thereof at its own expense, with legal counsel reasonably acceptable to Indemnitee. After notice from the Corporation to Indemnitee of its election so to assume such defense, the Corporation shall not be liable to Indemnitee for any legal or other expenses subsequently incurred by Indemnitee in connection with such action, suit, proceeding or investigation, other than as provided below in this Section 4. Indemnitee shall have the right to employ his or her own counsel in connection with such action, suit, proceeding or investigation, but the fees and expenses of such counsel incurred after notice from the Corporation of its assumption of the defense thereof shall be at the expense of Indemnitee unless (i) the employment of counsel by Indemnitee has been authorized by the Corporation, (ii) counsel to Indemnitee shall have reasonably concluded that there may be a conflict of interest or position on any significant issue between the Corporation and Indemnitee in the conduct of the defense of such action, suit, proceeding or investigation or (iii) the Corporation shall not in fact have employed counsel to assume the defense of such action, suit, proceeding or investigation, in each of which cases the fees and expenses of counsel for Indemnitee shall be at the expense of the Corporation, except as otherwise expressly provided by this Article EIGHTH. The Corporation shall not be entitled, without the consent of Indemnitee, to assume the defense of any claim brought by or in the right of the Corporation or as to which counsel for Indemnitee shall have reasonably made the conclusion provided for in clause (ii) above. The Corporation shall not be required to indemnify Indemnitee under this Article EIGHTH for any amounts paid in settlement of any action, suit, proceeding or investigation effected without its written consent. The Corporation shall not settle any action, suit, proceeding or investigation in any manner which would impose any penalty or limitation on Indemnitee without Indemnitee's written consent. Neither the Corporation nor Indemnitee will unreasonably withhold or delay its consent to any proposed settlement.

5. Advance of Expenses. Subject to the provisions of Section 6 of this Article EIGHTH, in the event of any threatened or pending action, suit, proceeding or investigation of which the Corporation receives notice under this Article EIGHTH, any expenses (including attorneys' fees) incurred by or on behalf of an Indemnitee in defending an action, suit,

proceeding or investigation or any appeal therefrom shall be paid by the Corporation in advance of the final disposition of such matter; provided, however, that the payment of such expenses incurred by or on behalf of Indemnitee in advance of the final disposition of such matter shall be made only upon receipt of an undertaking by or on behalf of Indemnitee to repay all amounts so advanced in the event that it shall ultimately be determined that Indemnitee is not entitled to be indemnified by the Corporation as authorized in this Article EIGHTH; and provided further that no such advancement of expenses shall be made under this Article EIGHTH if it is determined (in the manner described in Section 6 of this Article EIGHTH) that (i) Indemnitee did not act in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the Corporation, or (ii) with respect to any criminal action or proceeding, Indemnitee had reasonable cause to believe his or her conduct.was unlawful. Such undertaking shall be accepted without reference to the financial ability of Indemnitee to make such repayment.

6. Procedure for Indemnification and Advancement of Expenses. In order to obtain indemnification or advancement of expenses pursuant to Section 1, 2, 3 or 5 of this Article EIGHTH, an Indemnitee shall submit to the Corporation a written request. Any such advancement of expenses shall be made promptly, and in any event within 60 days after receipt by the Corporation of the written request oflndemnitee, unless (i) the Corporation has assumed the defense pursuant to Section 4 of this Article EIGHTH (and none of the circumstances described in Section 4 of this Article EIGHTH that would nonetheless entitle the Indemnitee to indemnification for the fees and expenses of separate counsel have occurred) or (ii) the Corporation determines within such 60-day period that Indemnitee did not meet the applicable standard of conduct set forth in Section 1, 2 or 5 of this Article EIGHTH, as the case may be. Any such indemnification, unless ordered by a court, shall be made with respect to requests under Section 1 or 2 of this Article EIGHTH only as authorized in the specific case upon a determination by the Corporation that the indemnification of Indemnitee is proper because Indemnitee has met the applicable standard of conduct set forth in Section 1 or 2 of this Article EIGHTH, as the case may be. Such determination shall be made in each instance (a) by a majority vote of the directors of the Corporation consisting of persons who are not at that time parties to the action, suit or proceeding in question ("disinterested directors"), whether or not a quorum, (b) by a committee of disinterested directors designated by majority vote of disinterested directors, whether or not a quorum, (c) if there are no disinterested directors, or if the disinterested directors so direct, by independent legal counsel (who may, to the extent permitted by law, be regular legal counsel to the Corporation) in a written opinion, or (d) by the stockholders of the Corporation.

7. Remedies. The right to indemnification or advancement of expenses as granted by this Article EIGHTH shall be enforceable by Indemnitee in any court of competent jurisdiction. Neither the failure of the Corporation to have made a determination prior to the commencement of such action that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Corporation pursuant to Section 6 of this Article EIGHTH that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct. In any suit brought by Indemnitee to enforce a right to indemnification, or brought by the Corporation to recover an advancement of expenses
pursuant to the terms of an undertaking, the Corporation shall have the burden of proving that Indemnitee is not entitled to be indemnified, or to such advancement of expenses,

under this Article EIGHTH. lndemnitee's expenses (including attorneys' fees) reasonably incurred in connection with successfully establishing Indemnitee's right to indemnification, in whole or in part, in any such proceeding shall also be indemnified by the Corporation. Notwithstanding the foregoing, in any suit brought by Indemnitee to enforce a right to indemnification hereunder it shall be a defense that the Indemnitee has not met any applicable standard for indemnification set forth in the General Corporation Law of the State of Delaware.

8. Limitations. Notwithstanding anything to the contrary in this Article EIGHTH, except as set forth in Section 7 of this Article EIGHTH, the Corporation shall not indemnify an Indemnitee pursuant to this Article EIGHTH in connection with a proceeding (or part thereof) initiated by such Indemnitee unless the initiation thereof was approved by the Board of Directors of the Corporation. Notwithstanding anything to the contrary in this Article EIGHTH, the Corporation shall not indemnify an Indemnitee to the extent such Indemnitee is reimbursed from the proceeds of insurance, and in the event the Corporation makes any indemnification payments to an Indemnitee and such Indemnitee is subsequently reimbursed from the proceeds of insurance, such Indemnitee shall promptly refund indemnification payments to the Corporation to the extent of such insurance reimbursement.

9. Subsequent Amendment. No amendment, termination or repeal of this Article EIGHTH or of the relevant provisions of the General Corporation Law of the State of Delaware or any other applicable laws shall adversely affect or diminish in any way the rights of any Indemnitee to indemnification under the provisions hereof with respect to any
action, suit, proceeding or investigation arising out of or relating to any actions, transactions or facts occurring prior to the final adoption of such amendment, termination or repeal.

I 0. Other Rights. The indemnification and advancement of expenses provided by this Article EIGHTH shall not be deemed exclusive of any other rights to which an Indemnitee seeking indemnification or advancement of expenses may be entitled under any law (common or statutory), agreement or vote of stockholders or disinterested directors or otherwise, both as to action in Indemnitee's official capacity and as to action in any other capacity while holding office for the Corporation, and shall continue as to an Indemnitee who has ceased to be a director or officer, and shall inure to the benefit of the estate, heirs, executors and administrators oflndemnitee. Nothing contained in this Article EIGHTH shall be deemed to prohibit, and the Corporation is specifically authorized to enter into, agreements with officers and directors providing indemnification rights and procedures different from those set forth in this Article EIGHTH. In addition, the Corporation may, to the extent authorized from time to time by its Board of Directors, grant indemnification rights to other employees or agents of the Corporation or other persons serving the Corporation and such rights may be equivalent to, or greater or less than, those set forth in this Article EIGHTH.

11. Partial Indemnification. Ifan Indemnitee is entitled under any provision of this Article EIGHTH to indemnification by the Corporation for some or a portion of the expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of
1974) or amounts paid in settlement actually and reasonably incurred by or on behalfoflndemnitee in connection with any action, suit, proceeding or investigation and any appeal therefrom but not, however, for the total amount thereof, the Corporation shall nevertheless indemnify Indemnitee for the portion of

such expenses (including attorneys' fees), liabilities, losses,judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) or amounts paid in settlement to which Indemnitee is entitled.

12. Insurance. The Corporation may purchase and maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan) against any expense, liability or loss incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the General Corporation Law of the State of Delaware.

13. Savings Clause. If this Article EIGHTH or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the Corporation shall nevertheless indemnify each Indemnitee as to any expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) and amounts paid in settlement in connection with any action, suit, proceeding or investigation, whether civil, criminal or administrative, including an action by or in the right of the Corporation, to the fullest extent permitted by any applicable portion of this Article EIGHTH that shall not have been invalidated and to the fullest extent permitted by applicable law.

14. Definitions. Terms used herein and defined in Section 145(h) and Section 145(i) of the General Corporation Law of the State of Delaware shall have the respective meanings assigned to such terms in such Section 145(h) and Section 145 (i).

NINTH: This Article NINTH is inserted for the management of the business and for the conduct of the affairs of the Corporation.

l. General Powers. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors.

2. Number of Directors; Election of Directors. Subject to the rights of holders of any series of Preferred Stock to elect directors, the number of directors of the Corporation shall be established by the Board of Directors. Election of directors need not be by written ballot, except as and to the extent provided in the By-laws of the Corporation.

3. Classes of Directors. Subject to the rights of holders of any series of Preferred Stock to elect directors, the Board of Directors shall be and is divided into three classes, designated Class I, Class II and Class III. Each class shall consist, as nearly as may be possible, of one-third of the total number of directors constituting the entire Board of Directors. The Board of Directors is authorized to assign members of the Board of Directors already in office to Class I, Class II or Class III at the time such classification becomes effective.

4. Terms of Office. Subject to the rights of holders of any series of Preferred Stock to elect directors, each director shall serve for a term ending on the date of the third annual meeting of stockholders following the annual meeting of stockholders at which such director was

elected; provided that each director initially assigned to Class I shall serve for a term expiring at the Corporation's first annual meeting of stockholders held after the effectiveness of this Restated Certificate of Incorporation; each director initially assigned to Class II shall serve for a term expiring at the Corporation's second annual meeting of stockholders held after the effectiveness of this Restated Certificate of Incorporation; and each director initially assigned to Class III
shall serve for a term expiring at the Corporation's third annual meeting of stockholders held after the effectiveness of this Restated Certificate of Incorporation; provided further, that the term of each director shall continue until the election and qualification of his or her successor and be subject to his or her earlier death, resignation or removal.

5. Quorum. The greater of(a) a majority of the directors at any time in office and (b) one-third of the number of directors fixed pursuant to Section 2 of this Article NINTH shall constitute a quorum of the Board of Directors. If at any meeting of the Board of Directors there shall be less than such a quorum, a majority of the directors present may adjourn the meeting from time to time without further notice other than announcement at the meeting, until a quorum shall be present.

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

7. Removal. Subject to the rights of holders of any series of Preferred Stock, directors of the Corporation may be removed only for cause and only by the affrrmative vote of the holders ofat least seventy-five percent (75%) ofthe votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors.

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

9. Stockholder Nominations and Introduction of Business, Etc. Advance notice of stockholder nominations for election of directors and other business to be brought by stockholders before a meeting of stockholders shall be given in the manner provided by the By-laws of the Corporation.

I 0. Amendments to Article. Notwithstanding any other provisions oflaw, this Certificate oflncorporation or the By• laws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affrrmative vote of the holders ofat least seventy-five percent (75%) of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article NINTH.

TENTH: Stockholders of the Corporation may not take any action by written consent in lieu of a meeting. Notwithstanding any other provisions of law, this Certificate of Incorporation or the By-laws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least seventy-five percent (75%) of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article TENTH.

ELEVENTH: Special meetings of stockholders for any purpose or purposes may be called at any time by only the Board of Directors, the Chairman of the Board of Directors or the Chief Executive Officer of the Corporation, and may not be called by any other person or persons. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting. Notwithstanding any other provisions of law, this Certificate oflncorporation or the By-Jaws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders ofat least seventy-five percent (75%) of the votes which all the stockholders would be entitled to cast in any annual election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article ELEVENTH.

IN WITNESS WHEREOF, this Restated Certificate oflncorporation, which restates, integrates and amends the certificate of incorporation of the Corporation, and which has been duly adopted in accordance with Sections 228, 242 and 245 of the General Corporation Law of the State of Delaware, has been executed by its duly authorized officer this 25th day of March, 2013.

TETRAPHASE PHARMACEUTICALS, INC. By: *Isl* Guy Macdonald

Name: Guy Macdonald
Title: President

CERTIFICATE OF AMENDMENT TO
RESTATED CERTIFICATE OF INCORPORATION OF
TETRAPHASE PHARMACEUTICALS, INC.

Pursuant to Section 242 of the
General Corporation Law of the State of Delaware

Tetraphase Pharmaceuticals, Inc. (hereinafter called the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware, does hereby certify as follows:

FIRST: A resolution was duly adopted by the Board of Directors of the Corporation pursuant to Section 242 of the General Corporation Law of the State of Delaware setting forth an amendment to the Restated Certificate of Incorporation of the Corporation and declaring said
amendment to be advisable. The stockholders of the Corporation duly approved and adopted said proposed amendment at a special meeting of stockholders in accordance with Section 242 of the General Corporation Law of the State of Delaware. The resolution setting forth the amendment is as follows:

RESOLVED: That the first sentence of Article FOURTH of the Restated Certificate of Incorporation of the Corporation be and hereby is deleted in its entirety and the following three paragraphs are inserted in lieu thereof:

"FOURTH: That, effective upon the effective time of this Certificate of Amendment to Restated Certificate of Incorporation (this "Certificate of Amendment") with the Secretary of State of the State of Delaware (the "Effective Time"), a one-for-20 reverse stock split of the Corporation's common stock,
$0.001 par value per share (the "Common Stock"), shall become effective, pursuant to which each 20 shares of Common Stock outstanding and held of record by each stockholder of the Corporation (including treasury shares) immediately prior to the Effective Time shall be reclassified and combined into one validly issued, fully paid and nonassessable share of Common Stock automatically and without any action by the holder thereof upon the Effective Time and shall represent one share of Common Stock from and after the Effective Time (such reclassification and combination of shares, the "Reverse Stock Split"). The par value of the Common Stock following the Reverse Stock Split shall remain at $0.001 per share. No fractional shares of Common Stock shall be issued as a result of the Reverse Stock Split and, in lieu thereof, upon surrender after the Effective Time of a certificate or book entry position which formerly represented shares of Common Stock that were issued and outstanding immediately prior to
the Effective Time, any person who would otherwise be entitled to a fractional

share of Common Stock as a result of the Reverse Stock Split, following the Effective Time, shall be entitled to receive a cash payment equal to the fraction of a share of Common Stock to which such holder would otherwise be entitled multiplied by the closing price per share of the Common Stock on the Nasdaq Global Select Market at the close of business on the date of the Effective Time.

Each stock certificate or book entry position that, immediately prior to the Effective Time, represented shares of Common Stock that were issued and outstanding immediately prior to the Effective Time shall, from and after the Effective Time, automatically and without the necessity of presenting the same for exchange, represent that number of whole shares of Common Stock after the Effective Time into which the shares formerly represented by such certificate or book entry position have been reclassified (as well as the right to receive cash in lieu of fractional shares of Common Stock after the Effective Time); provided, however, that each person of record holding a certificate or book entry position
that represented shares of Common Stock that were issued and outstanding
immediately prior to the Effective Time shall receive, upon surrender of such certificate or book entry position, a new certificate or book entry position evidencing and representing the number of whole shares of Common Stock after the Effective Time into which the shares of Common Stock formerly represented by such certificate or book entry position shall have been reclassified.

The total number of shares of all classes of stock which the Corporation shall have authority to issue is 130,000,000 shares, consisting of (i) 125,000,000 shares of Common Stock, $0.001 par value per share ("Common Stock"), and (ii) 5,000,000 shares of Preferred Stock, $0.001 par value per share ("Preferred Stock")."

SECOND: This Certificate of Amendment shall be effective at 5:00 p.m., Eastern Time, on September 26, 2019.

IN WITNESS WHEREOF, the Corporation has caused its corporate seal to be affixed hereto and this Certificate of Amendment to be signed by its President this 26th day of September, 2019.

TETRAPHASE PHARMACEUTICALS, INC.

By: /s/Larry Edwards
Larry Edwards, President and Chief Executive Officer

Exhibit 31.1

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

I, Larry Edwards, certify that:

(1) I have reviewed this quarterly report on Form 10-Q of Tetraphase Pharmaceuticals, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

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

Exhibit 31.2

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

I, Christopher Watt, certify that:

(1) I have reviewed this quarterly report on Form 10-Q of Tetraphase Pharmaceuticals, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d015(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 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 September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Larry Edwards, as Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

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

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

Dated: November 12, 2019

/s/ Larry Edwards
Larry Edwards
Chief Executive Officer

Exhibit 32.2

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

In connection with the quarterly report on Form 10-Q of Tetraphase Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 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: November 12, 2019

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