TETRAPHASE PHARMACEUTICALS INC
Form 10-Q
November 09, 2018

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, 2018

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

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, 2018, there were 53,625,717 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, 2018

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

TETRAPHASE PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(In thousands, except par value amounts)

(Unaudited)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 96,959	$ 136,411
Accounts receivable	2,597	4,653
Prepaid expenses and other current assets	5,302	6,382
Total current assets	104,858	147,446
Property and equipment, net	1,142	1,395
Restricted cash	699	199
Intangible assets, net	4,750	—
Total assets	$ 111,449	$ 149,040
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,203	$ 5,306
Accrued expenses	9,188	12,559
Deferred revenue	9	660
Total current liabilities	14,400	18,525
Other long term liabilities	79	105
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value $0.001 per share; 5,000 shares authorized; no shares issued and outstanding	—	—
Common stock, par value $0.001 per share; 125,000 shares authorized; 53,545 and 51,458 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	54	51
Additional paid-in capital	609,477	592,243
Accumulated deficit	(512,561)	(461,884)
Total stockholders' equity	96,970	130,410
Total liabilities and stockholders' equity	$ 111,449	$ 149,040

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,	
	2018	2017	2018	2017
Revenues				
License revenue	$—	$—	$9,500	$—
Government revenue	1,151	4,067	5,120	7,138
Total revenues	1,151	4,067	14,620	7,138
Operating expenses				
Research and development	11,665	28,777	44,162	83,237
Selling, general and administrative	9,481	5,600	22,350	15,797
Total operating expenses	21,146	34,377	66,512	99,034
Loss from operations	(19,995)	(30,310)	(51,892)	(91,896)
Other income	437	302	1,215	620
Net loss	$(19,558)	$(30,008)	$(50,677)	$(91,276)
Net loss per share-basic and diluted	$(0.37)	$(0.63)	$(0.97)	$(2.23)
Weighted-average number of common shares used in net loss per share-basic and diluted	52,937	47,347	52,131	40,942
Comprehensive loss	$(19,558)	$(30,008)	$(50,677)	$(91,276)

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,	
	2018	2017 (as revised) *
Operating activities		
Net loss	$(50,677)	$(91,276)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	357	315
Stock-based compensation expense	9,880	9,358
Changes in operating assets and liabilities:		
Accounts receivable	2,056	(1,776)
Prepaid expenses and other assets	1,081	1,089
Accounts payable	(1,852)	6,338
Accrued expenses and other liabilities	(3,397)	5,160
Deferred revenue	(651)	(473)
Net cash used in operating activities	(43,203)	(71,265)
Investing activities		
Acquisition of intangible asset	(3,000)	—
Purchases of property and equipment	(105)	(685)
Net cash used in investing activities	(3,105)	(685)
Financing activities		
Proceeds from sale of common stock, net of issuance costs	6,985	90,863
Proceeds from issuance of stock under stock plans	371	366
Net cash provided by financing activities	7,356	91,229
Net decrease in cash, cash equivalents and restricted cash	(38,952)	19,279
Cash, cash equivalents and restricted cash at beginning of period	136,610	142,285
Cash, cash equivalents and restricted cash at end of period	$97,658	$161,564
Supplemental cash flow disclosures from investing activities:		
Acquisition of intangible asset included in accounts payable	$1,750	$—

See accompanying notes to unaudited condensed consolidated financial statements

*Cash flow presentation has been revised due to adoption of ASU 2016-18.

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Tetraphase Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Organization and Operations

Tetraphase Pharmaceuticals, Inc. (the "Company") is a biopharmaceutical company using its proprietary chemistry technology to create, develop and commercialize novel antibiotics for serious and life-threatening multidrug-resistant infections. On August 27, 2018, the United States Food and Drug Administration ("FDA") approved the Company's lead product candidate, Xerava™ (eravacycline), for the treatment of complicated intra-abdominal infections ("cIAI") in adults. In October 2018, the Company announced the commercial launch of Xerava in the United States. As a result, the Company now has approximately 40 sales representatives in the field and approximately 10 medical science affairs personnel supporting Xerava. The Company also has internal sales and marketing support teams located at its headquarters in Watertown, Massachusetts.

On September 20, 2018, the European Commission ("EC") granted marketing authorization for Xerava for injection for the treatment of cIAI in adults in all 28 countries of the European Union, Norway, Iceland and Liechtenstein.

In addition to eravacycline, the Company is pursuing development of TP-271, a fully synthetic fluorocycline being developed for respiratory disease caused by bacterial biothreat pathogens, as well as bacterial pathogens associated with community-acquired bacterial pneumonia, and TP-6076, a fully synthetic fluorocycline, targeted at unmet medical needs, including multidrug-resistant, or MDR, Gram-negative bacteria such as carbapenem-resistant Enterobacteriaceae and carbapenem-resistant Acinetobacter baumanii. Both of these product candidates are in phase 1 clinical trials.

The Company has incurred annual net operating losses each year since its inception. As of September 30, 2018, the Company had an accumulated deficit of $512.6 million. Through September 30, 2018, the Company had not generated any product revenues. The Company has financed its operations primarily through public offerings and private placements of its equity securities, debt financings, funding from the United States government and licenses of its product candidates.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim condensed consolidated financial statements are unaudited. These unaudited financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, they do not include all of the information and footnotes required by United States generally accepted accounting principles ("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, 2017 contained in the Company's annual report on Form 10-K filed with the SEC on March 6, 2018 (the "2017 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, 2018 and the results of operations and comprehensive loss and cash flows for the three and nine months ended September 30, 2018 and 2017. Interim operating results for the three and nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for future interim periods or for the fiscal year ending December 31, 2018.

The December 31, 2017 condensed consolidated balance sheet included herein was derived from audited consolidated financial statements, but does not include all disclosures including notes required by GAAP for complete financial statements.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures. On an ongoing basis, the Company's management evaluates its estimates, including estimates related to its going concern evaluation, clinical trial accruals,

stock-based compensation expense, contract, grant and license revenues, and expenses. 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.

Out-Licensing Revenue Recognition

The Company has entered into an out-licensing agreement that is evaluated under Accounting Standards Codification, Topic 606 ("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).

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Intangible Assets

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

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

The Company capitalized milestone payments of $4.75 million related to regulatory approval of Xerava in the US and EU, which will be amortized over their estimated useful lives of approximately 12 years. Amortization expense for each of the following 5 years is expected to be $0.4 million.

Going Concern Assessment

Accounting Standards Update ("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 this analysis, the Company expects its cash to last more than one year beyond the filing date of the financial statements. In November 2018, the Company entered into a term loan with Solar Capital Ltd., with an initial draw of $30 million (see Note 10).

Recently Adopted Accounting Pronouncements

In November 2016, the Financial Accounting Standard Board (FASB) issued Accounting Standards Update No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (ASU 2016-18), which requires companies to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statements of cash flows. The Company adopted the new standard effective January 1, 2018, using the retrospective transition approach. The reclassified restricted cash balances from operating activities to changes in cash, cash equivalents and restricted cash on the condensed consolidated statements of cash flows were not material for all periods presented.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. The FASB has subsequently issued ASU 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net); ASU 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing; ASU 2016-12, Revenue from Contracts with Customers (Topic

606): Narrow-Scope Improvements and Practical Expedients; and ASU 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers.

The Company has concluded that its government grants are not within the scope of Topic 606, as they do not meet the definition of a contract with a “customer”. The Company has concluded that the grants meet the definition of a contribution and are non-reciprocal transactions. The Company has further concluded that Subtopic 958-605, Not-for-Profit-Entities-Revenue Recognition also does not apply, as the Company is a business entity and the grants are with governmental agencies or units. The government grant is technically to a non-profit entity that specializes in government grant administration, project management and oversight (i.e. CUBRC). However, the Company has concluded that, in effect, it is a grant from the government; as the contracting counterparty CUBRC is merely administering the agreement between the government (who is funding the work) and the Company (who is performing the work).

In the absence of applicable guidance under GAAP as of January 1, 2018 for the grants, the Company has developed a policy for the recognition of revenue for the grants as follows:

- Revenue is recognized when the right to payment is realized or is realizable
- Revenues are realized when services are exchanged for cash or claims to cash. Revenues are not recognized until earned.
- The Company's revenue-earning activities involve rendering services that constitute its ongoing major or central operations, and revenues are considered to have been earned when the Company has substantially accomplished what it must do to be entitled to the benefits represented by the revenues.

The Company believes this policy is consistent with the overarching premise in Topic 606, to ensure that it recognizes revenues to reflect the transfer of promised goods or services to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services, even though there is no "exchange" as defined in the ASC. The Company believes the recognition of revenue as costs are incurred and amounts become earned/realizable is analogous to the concept of transfer of control of a service over time under ASC 606.

Prior to January 1, 2018, the Company recognized revenue as it performed services under the grants so long as an agreement had been executed and the fees for these services were fixed or determinable, legally billable and reasonably assured of collection. Recognized amounts reflected the Company's partial performance under the grants and equal direct and indirect costs incurred plus fixed fees, where applicable. Revenues and expenses under these arrangements were presented gross. Revenue recognition under this new policy is not materially different than would have been calculated under the old guidance. As a result of the adoption of this policy, there was no change to the amounts the Company has historically recorded to its financial statements.

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 February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The new standard will be effective for the Company on January 1, 2019. The FASB subsequently issued the following amendments to ASU 2016-02, which have the same effective date and transition date of January 1, 2019: ASU No. 2018-10, Codification Improvements to Topic 842, Leases, which amends certain narrow aspects of the guidance issued in ASU 2016-02 and ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, which allows for a transition approach to initially apply ASU 2016-02 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption as well as an additional practical expedient for lessors to not separate non-lease components from the associated lease component. Currently, the Company is gathering information, reviewing its portfolio of existing leases, and continuing to evaluate the potential changes to the Company's future financial reporting and disclosures that may result from adopting this ASU. The Company plans to elect the practical expedient which will allow it to not apply the amended lease accounting guidance to comparative periods that will be presented. The Company expects that all of its lease commitments will be subject to the new standard with the cumulative effect of adoption recognized to retained earnings on January 1, 2019.

3. Fair Value of Financial Instruments

The Company's financial instruments consist principally of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities. 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, 2018 and December 31, 2017 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, 2018				
Cash and money market funds	$96,959	$96,959	$ —	$ —
December 31, 2017				
Cash and money market funds	$136,411	$136,411	$ —	$ —

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 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,	
	2018	2017
Warrants	—	1,103
Unvested restricted stock units	1,088,273	338,700
Outstanding stock options	7,173,359	6,116,217
Totals	8,261,632	6,456,020

5. Inventories

The Company began capitalizing inventory costs associated with Xerava following Food and Drug Administration, or FDA, approval at the end of August 2018, when future commercialization was considered probable and the future economic benefit was expected to be realized. During the three months ended September 30, 2018, no inventory amounts were capitalized, as no raw materials were purchased and no components of inventory were completed. In the future, inventories will be stated at the lower of cost and net realizable value with cost determined on a first-in, first-out basis. Prior to FDA approval, costs to manufacture the Company’s product candidates were expensed to

research and development. Costs related to the validation of additional manufacturing locations will continue to be expensed when it is determined the commercial salability of the resulting finished goods or other inventory components is not probable.

6. Significant Agreements and Contracts

Harvard License Agreement

In August 2006, the Company entered into a license agreement for certain intellectual property with Harvard University ("Harvard"). Under the license agreement, as of September 30, 2018, the Company has paid Harvard an aggregate of $12.1 million and accrued $1.8 million in upfront license fees and regulatory development milestone payments. 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, 2018 the Company paid Harvard $1.9 million related to amounts received under the Everest Medicines license agreement.

Harvard milestones paid in advance of regulatory approval have been recorded as research and development expense. Milestone payments due to Harvard based upon regulatory approval will be capitalized and amortized over the remaining product patent life (see Note 2, Summary of Significant Accounting Policies – Intangible Assets).

Other Material Agreements

Everest Medicines License Agreement

In February 2018, the Company entered into a license agreement (the "Everest License Agreement") with Everest Medicines Limited ("Everest Medicines"), whereby the Company granted Everest Medicines an exclusive license to develop and commercialize eravacycline, for the treatment of complicated intra-abdominal infections and other indications, in mainland China, Taiwan, Hong Kong, Macau, South Korea and Singapore (the "Territory").

Under the terms of the Everest License Agreement, the Company received from Everest Medicines an upfront cash payment of $7.0 million in the first quarter of 2018 and a cash payment of $2.5 million related to Everest Medicines' submission of an Investigational New Drug Application, or IND, with the Chinese Food and Drug Administration in June 2018. The Company is also eligible to receive up to an aggregate of $14.0 million in future clinical development milestone payments and up to an aggregate of $20.0 million in sales milestone payments. There can be no guarantee that any such milestones or sales thresholds will in fact be met. The Company is obligated to make certain payments to Harvard based on amounts received from Everest Medicines under the Everest License Agreement pursuant to the existing license agreement by and between Harvard and the Company.

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

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

In evaluating the recognition of revenue under the Agreement, the Company identified the following three performance obligations under the Agreement: (i) exclusive license to develop and commercialize eravacycline for the treatment of complicated intra-abdominal infections 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 deemed a $2.5 million milestone payment to the Chinese IND as probable and included the amount in the transaction price.

No other clinical milestones, regulatory milestones, sales-based milestones or sales royalties have been included in the transaction price, as these milestones are not considered probable given Everest Medicines relatively short operating history, the uncertainty of regulatory processes in China and that commercial sales have not commenced. The Company determined that the license and related know-how were a combined performance obligation as the license is not distinct without the provision of the related know-how transfer. The Company's requirement to manufacture

clinical supply for Everest Medicines is dependent on Everest Medicines' future purchases, the payment for which was determined to be at cost and therefore potentially represents a material right. However, based on the amount of clinical supply expected to be ordered by Everest Medicines, the Company has estimated that the value of this right would be immaterial.

The Company satisfied the combined performance obligation and recognized the $7.0 million upfront payment as revenue during the nine months ended September 30, 2018. The Company also recognized the $2.5 million Chinese IND milestone payment as revenue during the nine months ended September 30, 2018.

Patheon UK Limited Master Manufacturing Services Agreement

In June 2017, the Company and Patheon UK Limited and certain of its affiliates ("Patheon") entered into a master manufacturing services agreement. Under the Patheon agreement, the Company is responsible for supplying the active pharmaceutical ingredient for eravacycline to Patheon, and Patheon is responsible for manufacturing eravacycline, conducting quality control, quality

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

Finorga SAS Commercial Supply Agreement

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

Government Grant and Contracts

BARDA Contract for Eravacycline

The Company has received funding for its lead product Xerava, under an award from the Biomedical Advanced Research and Development Authority, or 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 ("BARDA Contract"). The funding under the BARDA Contract is also being used for the development, manufacturing and clinical evaluation of eravacycline to treat certain infections caused by life-threatening MDR bacteria.

In connection with the BARDA Contract, in February 2012, the Company entered into a cost-plus-fixed-fee subcontract with CUBRC Inc. ("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, 2018, granted the Company initial funding of up to approximately $41.8 million, reflecting the portion of the BARDA Contract funding that may be paid to the Company for its activities.

Although the BARDA Contract and the Company's subcontract with CUBRC under the BARDA Contract have terms which currently expire on December 31, 2018, BARDA is entitled to terminate the project for convenience at any time and is not obligated to provide continued funding beyond current-year amounts from congressionally approved annual appropriations. To the extent that BARDA ceases to provide funding of the program to CUBRC, CUBRC has the right to cease providing funding to the Company. Committed funding from CUBRC under the Company's BARDA subcontract is for up to approximately $41.8 million through December 31, 2018, the current contract end date, as a result of the exercise of several options by BARDA under the BARDA Contract. Total funds of $39.5 million had been received by the Company through September 30, 2018 under this contract. During the three months ended September 30, 2018 and 2017, the Company recognized revenue of $0.2 million and $2.1 million, respectively, from the Company's subcontract under the BARDA Contract. During the nine months ended September 30, 2018 and 2017, the Company recognized revenue of $1.2 million and $3.6 million, respectively, from the Company's subcontract under the BARDA Contract.

NIAID Grant and Contract for TP-271

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

- the NIAID Grant awarded in July 2011 that provides up to a total of approximately $2.9 million over five years; and
- the NIAID Contract awarded in September 2011 that provides up to a total of approximately $35.8 million over five years.

In connection with the NIAID Grant, in November 2011, CUBRC, the direct recipient of the NIAID Grant, awarded the Company a no-fee subaward of approximately $0.9 million, reflecting the portion of the NIAID Grant funding that may be paid to the Company for its activities. Through September 30, 2018, the Company had received all committed funding of $0.9 million from CUBRC under the Company's subaward with respect to the NIAID Grant.

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 currently expires on March 31, 2019 under which the Company may receive funding of up to approximately $16.9 million, reflecting the portion of the NIAID Contract funding that may be paid to the Company for its activities.

Although the NIAID Contract and the Company's subcontract with CUBRC under the NIAID Contract have terms which currently expire on March 31, 2019, NIAID is entitled to terminate the project for convenience at any time and is not obligated to provide continued funding beyond the respective expiration dates. To the extent that NIAID ceases to provide funding of the programs to CUBRC, CUBRC has the right to cease providing funding to the Company. As of September 30, 2018, committed funding from CUBRC under the Company's subcontract with respect to the NIAID Contract is $16.9 million, of which $15.1 million had been received through September 30, 2018.

During the three months ended September 30, 2018 and 2017, the Company recognized revenue of $0.7 million and $1.5 million, respectively, from the Company's subcontract under the NIAID Contract. During the three months ended September 30, 2018 and 2017 the Company recognized no revenue from its subaward under the NIAID Grant, as the grant expired in May 2017. During the nine months ended September 30, 2018 and 2017, the Company recognized revenue of $2.3 million and $2.7 million, respectively, from the Company's subcontract under the NIAID Contract. During the nine months ended September 30, 2018, the Company recognized no revenue from its subaward under the NIAID Grant compared to revenue of $9,000 for the nine months ended September 30, 2017, as the grant expired in May 2017.

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 (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, 2018 and 2017, the Company recognized revenue of $0.2 million and $0.4 million, respectively, under this Sub-Award Agreement. During the nine months ended September 30, 2018 and 2017, the Company recognized revenue of $1.6 million and $0.9 million, respectively and has received $0.8 million from its inception through September 30, 2018. This Sub-Award Agreement will fund certain activities through the end of 2018. This Sub-Award Agreement can be terminated for convenience at any time, subject to 30 days prior written notice.

7. Accrued Expenses

Accrued expenses at September 30, 2018 and December 31, 2017 consisted of the following (in thousands):

	September 30, 2018	December 31, 2017

Salaries and benefits	$ 2,389	$ 4,137
Drug supply and development	3,067	2,298
Clinical trial and related	591	3,401
Preclinical	605	188
Professional fees	1,213	1,911
Commercial	941	213
Other	382	411
Total	$ 9,188	$ 12,559

8. Stock-Based Compensation

In January 2018, the number of shares available for issuance under the Tetraphase Pharmaceuticals, Inc. 2013 Stock Incentive Plan, as amended ("2013 Plan") was increased by approximately 2.1 million shares as a result of the automatic increase provision of the 2013 Plan. As of September 30, 2018, the total number of shares of common stock available for issuance under the 2013 Plan was approximately 1.3 million.

Stock-Based Compensation Expense

During the three and nine months ended September 30, 2018 and 2017, the Company recognized the following stock-based compensation expense (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	$1,639	$1,545	$4,585	$4,719
General and administrative	1,877	1,577	5,295	4,639
Total	$3,516	$3,122	$9,880	$9,358

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Stock options	$2,820	$2,880	$8,406	$8,695
Restricted stock units	661	211	1,387	579
Employee stock purchase plan	35	31	87	84
Total	$3,516	$3,122	$9,880	$9,358

Stock Options

The following table summarizes the stock option activity for the nine months ended September 30, 2018:

	Shares	Weighted-Average Exercise Price
Outstanding at December 31, 2017	5,997,794	$ 13.33
Granted	2,343,475	$ 5.80
Exercised	(115,064)	$ 2.35
Forfeited	(1,052,846)	$ 10.69
Outstanding at September 30, 2018	7,173,359	$ 11.44
Exercisable at September 30, 2018	3,524,635	$ 15.93

As of September 30, 2018, there was $15.8 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 2.5 years.

Restricted Stock Units

In April 2018, the Company granted restricted stock units to employees. These restricted stock units vest in quarterly increments over one to two years, subject to continued employment with the Company and had a grant date fair value of $3.04 per share, which was the closing price of the Company's common stock on the date of grant.

In January 2018 and 2017, the Company issued 284,000 and 175,000 restricted stock units, respectively, with service and performance conditions to certain employees, none of which vested during the nine months ended September 30, 2018. 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 restricted stock unit activity for the nine months ended September 30, 2018:

	Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2017	282,034	$ 6.09
Granted	937,460	$ 4.02
Forfeited	(62,693)	$ 5.30
Vested/Released	(68,528)	$ 8.47
Unvested at September 30, 2018	1,088,273	$ 4.20

As of September 30, 2018, there was $1.8 million of total unrecognized stock-based compensation expense related to restricted stock units granted under the 2013 Plan. The expense is expected to be recognized over a weighted-average period of 1.2 years.

Employee stock purchase plan

Under the Company's 2014 Employee Stock Purchase Plan ("2014 ESPP"), an aggregate of 300,000 shares of common stock have been reserved for issuance pursuant to purchase rights granted to the Company's employees. As of September 30, 2018, 106,833 shares remained available for issuance. During the nine months ended September 30, 2018 and 2017 the Company issued 32,045 shares and 44,785 shares of common stock under the 2014 ESPP and recognized approximately $87,000 and $84,000 in related stock-based compensation expense, respectively.

9. Equity

On January 17, 2017, the Company entered into a Controlled Equity Offering Sales Agreement (the "Sales Agreement"), with Cantor Fitzgerald & Co. as sales agent ("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 (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, 2018, the Company had sold an aggregate of 6,090,044 shares of common stock under the Sales Agreement, at an average selling price of approximately $6.50 per share for aggregate gross proceeds of $39.6

million and net proceeds of $38.1 million after deducting sales commissions and offering expenses. An additional 20,402 shares were sold under the Amended Sales Agreement between October 1, 2018 and November 8, 2018, for net proceeds of $54,000 after deducting sales commissions. As of November 8, 2018, $40.4 million of common stock remained available to be sold under the Amended Sales Agreement.

On August 2, 2017, the Company sold 10,000,000 shares of common stock in an underwritten public offering at an offering price to the public of $6.50 per share, resulting in net proceeds to the Company of $60.7 million after deducting underwriting discounts and commissions of $3.9 million and offering costs of $0.4 million. In connection with the offering, the Company granted the underwriters an option to purchase up to an additional 1,500,000 shares on the same terms and conditions as the offering, pursuant to which the underwriters exercised an option to purchase 107,000 additional shares on August 25, 2017, resulting in additional net proceeds to the Company of approximately $0.7 million after deducting underwriting discounts and commissions.

10. Subsequent Events

On November 2, 2018, the Company entered into a loan and security agreement (the “Loan Agreement”) with Solar Capital Ltd., as collateral agent and lender, and the other lenders named therein (Solar Capital Ltd. and the other lenders collectively, the

"Lenders"). The Lenders have agreed to make available to the Company term loans in an aggregate principal amount of up to $75.0 million under the Loan Agreement. The Company plans to use the proceeds of the term loans to support commercial launch of Xerava as well as for working capital and general corporate purposes. The Loan Agreement provides a term loan commitment of $50.0 million in two potential tranches: (i) a $30.0 million Term A loan facility funded on November 2, 2018 and (ii) a $20.0 million Term B loan facility to be funded at the request of the Company no later than October 31, 2020, subject to (A) the Company having unrestricted net cash proceeds of not less than $50 million from the issuance and sale of common stock and/or from other business activities and (B) the Company having product revenue greater than or equal to $14.0 million on a six month trailing basis prior to September 30, 2020. Both of these term loans have a maturity date of May 2, 2023. The Loan Agreement also provides access to an additional Term C loan facility in the amount of $25.0 million, to be funded at the Lenders' sole discretion.

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

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

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

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

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

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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, 2017, 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 6, 2018, which we refer to as our annual report. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements are subject to risks and uncertainties, including those set forth in Part II — Other Information, Item 1A. Risk Factors below and elsewhere in this report that could cause actual results to differ materially from historical results or anticipated results.

Overview

We are a biopharmaceutical company using our proprietary chemistry technology to create, develop and commercialize novel antibiotics for serious and life-threatening multidrug-resistant, or MDR, infections. On August 27, 2018, the United States Food and Drug Administration, or FDA, approved our lead product candidate, Xerava (eravacycline), for the treatment of complicated intra-abdominal infections, or cIAI, in adults. In October 2018, we announced the commercial launch of Xerava in the United States. As a result, we now have approximately 40 sales representatives in the field and approximately 10 medical science affairs personnel supporting Xerava. We also have internal sales and marketing support teams located at our headquarters in Watertown, Massachusetts.

Approval of Xerava was based on our IGNITE (Investigating Gram-Negative Infections Treated with Eravacycline) phase 3 program. In the first pivotal phase 3 trial in the IGNITE program in patients with cIAI, twice-daily intravenous (IV) eravacycline met the primary endpoint by demonstrating statistical non-inferiority of clinical response compared to ertapenem and was well-tolerated. We refer to this trial as IGNITE1. In the second pivotal phase 3 clinical trial in patients with cIAI, twice-daily IV eravacycline met the primary endpoint by demonstrating statistical non-inferiority of clinical response compared to meropenem and was well-tolerated. We refer to this trial as IGNITE4. In both IGNITE1 and IGNITE4, Xerava achieved high cure rates in patients with Gram-negative pathogens, including resistant isolates.

On September 20, 2018, the European Commission ("EC") granted marketing authorization for Xerava for injection for the treatment of cIAI in adults in all 28 countries of the European Union, Norway, Iceland and Liechtenstein. This approval was primarily based on the results of IGNITE1.

Eravacycline is designed to treat a broad range of infections, including infections due to MDR bacteria. We believe that the ability of eravacycline to cover MDR Gram-negative bacteria, as well as MDR Gram-positive, anaerobic and atypical bacteria, may enable eravacycline to become the drug of choice for first-line empiric treatment of patients with cIAI. In in vitro experiments, eravacycline has demonstrated the ability to cover a wide variety of multidrug-resistant Gram-negative, Gram-positive, anaerobic and atypical bacteria, including multidrug-resistant Klebsiella pneumoniae and multi-drug resistant Acinetobacter. Multidrug-resistant Klebsiella pneumoniae is one of the carbapenem-resistant Enterobacteriaceae (or CREs) listed as an urgent threat and multi-drug resistant 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 June 2017, we announced positive results from a phase 1 single-ascending dose clinical trial of the IV formulation of TP-271 in healthy volunteers. TP-271 is a fully-synthetic fluorocycline being developed for respiratory disease caused by bacterial biothreat and antibiotic-resistant public health pathogens, as well as bacterial pathogens associated with community-acquired bacterial pneumonia. In the study, TP-271 was well-tolerated at single doses that resulted in high plasma exposures. There were no clinically significant changes in lab values, ECG parameters, or physical exam findings. There were no serious or severe adverse events, or discontinuations due to an adverse event during the study. We are also completing a single-ascending dose trial for the oral formulation of TP-271, and multiple-ascending dose trials for the IV and oral formulations of TP-271; we expect to report results of these studies at a future scientific meeting. In February 2017, we received Qualified Infectious Disease Product and Fast Track designations from the FDA for TP-271.

In addition, we are developing TP-6076, a fully-synthetic fluorocycline derivative, as a lead candidate under our second-generation program to target unmet medical needs, including MDR Gram-negative bacteria such as carbapenem-resistant Enterobacteriaceae and carbapenem-resistant Acinetobacter baumanii. In June 2017, we announced positive results from a phase 1 randomized, placebo-controlled, double-blind, single-ascending dose study evaluating the safety, tolerability and pharmacokinetics of IV TP-6076. In the study, TP-6076 was well-tolerated, and there were no serious or severe adverse events, or discontinuations due to

an adverse event. In October 2018, we announced results of a phase 1 study of the safety, tolerability, and pharmacokinetics of multiple doses of IV TP-6076 in healthy volunteers. In this study, multiple does of TP-6076 were generally well tolerated with no serious or severe adverse events and no clinically significant findings in any laboratory assessments, vital signs, ECGs, or physical examinations.

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 and undertaking preclinical studies and clinical trials of our product candidates. Through September 30, 2018, we have not generated any product revenue and have primarily financed our operations through public offerings and private placements of our equity securities, debt financings and funding from the United States government. As of September 30, 2018, we had received an aggregate of $560.0 million in net proceeds from the issuance of equity securities and borrowings under debt facilities and an aggregate of $56.4 million from government grants and contracts. As of September 30, 2018, our principal source of liquidity was cash and cash equivalents, which totaled $97.0 million.

As of September 30, 2018, we had an accumulated deficit of $512.6 million. Our net losses were $19.6 million and $30.0 million for the three months ended September 30, 2018 and 2017, respectively, and $50.7 million and $91.3 million for the nine months ended September 30, 2018 and 2017, respectively. We expect that our expenses will decrease in 2018 compared with 2017, as the completion of the IGNITE clinical program will offset cost increases associated with conducting pre-commercialization and launch activities for eravacycline. We also expect to incur significant sales, marketing, distribution and outsourced manufacturing expenses to support the commercial launch of Xerava.

We believe that our available funds, including the $30 million first tranche received via our debt financing in November 2018 with Solar Capital, will be sufficient to support our operations into the second quarter of 2020, which we believe will allow us to fund the initial launch of IV Xerava for the treatment of cIAI. We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources to fund our operations including ongoing spending to commercialize eravacycline. 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

Revenue

We have derived all of our revenue through September 30, 2018 from our license agreement with Everest Medicines and from funding provided under three U.S. government awards for the development of our compounds.

Other than Xerava product revenue and the license agreement and government awards described above, we do not expect to receive any revenue from any product candidates that we develop until we obtain regulatory approval and commercialize such products or enter into additional ex-US outlicensing agreements. We continue to pursue government funding for other preclinical and clinical programs.

We expect that our revenue will be less than our expenses for the foreseeable future and that we will experience increasing losses as we begin to commercialize Xerava and continue our development of, and seek regulatory approvals for, our other product candidates. Even if we are able to generate revenue from the sale of one or more products, we may not become profitable.

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, 2018 and 2017:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(in thousands)		(in thousands)	
Eravacycline	$5,463	$21,179	$26,218	$63,971
NIAID Contract and NIAID Grant	693	1,394	2,097	2,353
CARB-X Award	253	434	1,613	832
BARDA Contract	213	2,076	1,229	3,420
TP-6076	562	266	1,471	1,915
Other development programs	837	291	1,849	1,272
Other research and development	3,644	3,137	9,685	9,474
Total research and development expenses	$11,665	$28,777	$44,162	$83,237

Research and development expense allocations by program for the first and second quarter of 2018 in the table above have been updated to conform to reporting methodology employed during the third quarter of 2018. This update resulted in $0.9 million and $1.6 million in the first and second quarter of 2018, respectively, being reclassified from other research and development to eravacycline.

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

As of September 30, 2018, we had incurred an aggregate of $282.5 million in research and development expenses related to the development of eravacycline, and $37.5 million in research and development expenses related to the development of eravacycline that were funded under the BARDA Contract. We expect that our research and development expenses will decrease as we complete the IGNITE program for eravacycline.

Because of the numerous risks and uncertainties associated with product development, however, we cannot determine with certainty the duration and completion costs of current or future clinical trials of our pipeline product candidates. We may never succeed in achieving regulatory approval for any of these product candidates. The duration, costs and

timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rate and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability.

We have licensed our proprietary chemistry technology from Harvard on an exclusive worldwide basis under a license agreement that we entered into in August 2006. Under our license agreement, as of September 30, 2018, we have paid Harvard an aggregate of $12.1 million and accrued $1.8 million in upfront license fees, and development and regulatory milestone payments. We have also issued 31,379 shares of our common stock to Harvard under the license agreement. In addition, we have 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 ($10.8 million of which has already been paid with respect to eravacycline), and to pay tiered royalties in the single digits based on annual worldwide net sales, if any, of licensed products, our affiliates and our sublicensees. We are also obligated to pay Harvard a specified share of non-royalty sublicensing revenues that we receive from sublicensees for the grant of sublicenses under the license and to reimburse Harvard for specified patent prosecution and maintenance costs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist principally of personnel-related costs, including salaries and related costs such as benefits and stock-based compensation for personnel in executive, finance, legal, operational, corporate communications, marketing 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 increase for a number of reasons, including:

- support of our anticipated research and development activities as we continue the development of our product candidates;
- expansion of infrastructure, including increases in personnel-related costs, consulting, legal, accounting and investor relations costs, and directors and officers insurance premiums; and
- anticipated increases in our personnel-related and consulting costs as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of Xerava.

Other Income

Other income consists primarily of interest income earned on our cash and cash equivalents.

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.

In May 2014, the Financial Accounting Standard Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. The FASB has subsequently issued ASU 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net); ASU 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing; ASU 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients; and ASU 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers.

We have concluded that our grants are not within the scope of Topic 606, as they do not meet the definition of a contract with a "customer". We have concluded that the Grants meet the definition of a contribution and are

non-reciprocal transactions. We have further concluded that Subtopic 958-605, Not-for-Profit-Entities-Revenue Recognition also does not apply, as we are a business entity and the grants are with governmental agencies or units. The government grants are technically to a non-profit entity that specializes in government grant administration, project management and oversight (i.e. CUBRC). However, we have concluded that, in effect, it is a grant from the government; as the contracting counterparty CUBRC is merely administering the agreement between the government (who is funding the work) and us (who are performing the work).

In the absence of applicable guidance under GAAP as of January 1, 2018 for the grants, we have developed a policy for the recognition of revenue for the grants as follows:

- Revenue is recognized when the right to payment is realized or is realizable,
- Revenues are realized when services are exchanged for cash or claims to cash. Revenues are not recognized until earned, and

- Our revenue-earning activities involve rendering services that constitute our ongoing major or central operations, and revenues are considered to have been earned when we have substantially accomplished what we must do to be entitled to the benefits represented by the revenues.

We believe this policy is consistent with the overarching premise in Topic 606, to ensure that we recognize revenues to reflect the transfer of promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services, even though there is no "exchange" as defined in the ASC. We believe the recognition of revenue as costs are incurred and amounts become earned/realizable is analogous to the concept of transfer of control of a service over time under ASC 606.

Prior to January 1, 2018, we recognized revenue as we performed services under the grants so long as an agreement had been executed and the fees for these services were fixed or determinable, legally billable and reasonably assured of collection. Recognized amounts reflected our partial performance under the grants and equal direct and indirect costs incurred plus fixed fees, where applicable. Revenues and expenses under these arrangements were presented gross. Revenue recognition under this new policy is not materially different than would have been calculated under the old guidance. As a result of adoption of this policy, there was no change to the amounts we have historically recorded to our financial statements.

Out-Licensing Revenue Recognition

We entered into an out-licensing agreement that is evaluated under Topic 606, through which we license certain of our product candidates' rights to a third party. Any future out-license agreement entered into by us 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, we evaluate 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, we develop 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 our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from upfront fees allocated to the license when the license is transferred to the licensee, including any associated know-how and the licensee can use and benefit from the license. For licenses that are bundled with other obligations, we use 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, we evaluate whether the milestones are considered probable and estimate 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 our 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. We

assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. If we are entitled to additional payments when the licensee exercises these options, we recognize 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, we recognize 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).

There have been no other significant changes to our critical accounting policies since the beginning of this fiscal year. Our critical accounting policies are 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 6, 2018 for the year ended December 31, 2017.

Results of Operations

Comparison of the Three Months Ended September 30, 2018 and 2017

The following table summarizes the results of our operations for the three months ended September 30, 2018 and 2017, together with the changes in those items in dollars and as a percentage:

	Three Months Ended September 30,		Increase/ (decrease)	%
	2018	2017		
	(in thousands)			
Revenues				
License revenue	$—	$—	$—	n/a
Government revenue	1,151	4,067	(2,916)	(72)%
Total revenues	1,151	4,067	(2,916)	(72)%
Operating expenses:				
Research and development	11,665	28,777	(17,112)	(59)%
Selling, general and administrative	9,481	5,600	3,881	69 %
Total operating expenses	21,146	34,377	(13,231)	(38)%
Loss from operations	(19,995)	(30,310)	10,315	(34)%
Other income	437	302	135	45 %
Net loss	$(19,558)	$(30,008)	$10,450	(35)%

Government revenue was $1.2 million for the three months ended September 30, 2018 compared to $4.1 million for the three months ended September 30, 2017, a decrease of $2.9 million, or 72%. 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.

The following table sets forth our government contract and grant revenue for the three months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Increase/ (decrease)	%
	2018	2017		
	(in thousands)			
Revenues				
NIAID Contract	$689	$1,485	$ (796)	(54)%
CARB-X Award	246	441	(195)	(44)%

BARDA Contract	216	2,141	(1,925)	(90)%
	$1,151	$4,067	$ (2,916)	(72)%

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2018 were $11.7 million compared to $28.8 million for the three months ended September 30, 2017, a decrease of $17.1 million, or 59%. This decrease was primarily due to lower clinical trial costs associated with conducting our IGNITE phase 3 clinical trials during the three months ended September 30, 2018 as compared to the three months ended September 30, 2017.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended September 30, 2018 were $9.5 million compared to $5.6 million for the three months ended September 30, 2017, an increase of $3.9 million, or 69%. This increase was primarily due to an increase in pre-commercialization expenses and launch expenses offset partially by a decrease in legal expenses.

Other Income

The increase in other income for the three months ended September 30, 2018 as compared to the three months ended September 30, 2017 was driven by improved overall yields on our money market funds.

Comparison of the Nine Months Ended September 30, 2018 and 2017

The following table summarizes the results of our operations for the nine months ended September 30, 2018 and 2017, together with the changes in those items in dollars and as a percentage:

	Nine Months Ended September 30,		Increase/ (decrease)	%
	2018	2017		
	(in thousands)			
Revenues				
License revenue	$9,500	$—	$9,500	n/a
Government revenue	5,120	7,138	(2,018)	(28)%
Total revenues	14,620	7,138	7,482	105%
Operating expenses:				
Research and development	44,162	83,237	(39,075)	(47)%
Selling, general and administrative	22,350	15,797	6,553	41 %
Total operating expenses	66,512	99,034	(32,522)	(33)%
Loss from operations	(51,892)	(91,896)	40,004	(44)%
Other income	1,215	620	595	96 %
Net loss	$(50,677)	$(91,276)	$40,599	(44)%

License revenue was $9.5 million for the nine months ended September 30, 2018 related to our license agreement with Everest Medicines. Contract and grant revenue was $5.1 million for the nine months ended September 30, 2018 compared to $7.1 million for the nine months ended September 30, 2017, a decrease of $2.0 million, or 28%. 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.

The following table sets forth our contract and grant revenue for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,		Increase/ (decrease)	%
	2018	2017		
	(in thousands)			
Revenues				
CARB-X Award	$1,597	$858	$ 739	86 %
NIAID Contract	2,280	2,678	(398)	(15)%
BARDA Contract	1,243	3,593	(2,350)	(65)%
NIAID Grant	—	9	(9)	(100)%
	$5,120	$7,138	$ (2,018)	(28)%

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2018 were $44.2 million compared to $83.2 million for the nine months ended September 30, 2017, a decrease of $39.0 million, or 47%. This decrease was primarily due to lower clinical trial costs associated with conducting our IGNITE3 and IGNITE4 phase 3 clinical trials during the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the nine months ended September 30, 2018 were $22.4 million compared to $15.8 million for the nine months ended September 30, 2017, an increase of $6.6 million, or 41%. This increase was primarily due to an increase in pre-commercialization and launch expenses offset partially by a decrease in legal expenses.

Other Income

The increase in other income was driven by improved overall yields on our money market funds for the nine months ended September 30, 2018 as compared to the same period in 2017.

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 2018 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, 2018, we had cash and cash equivalents of approximately $97.0 million. We invest cash in excess of immediate requirements in accordance with our investment policy, primarily with a view to liquidity and capital preservation. As of September 30, 2018, our funds were held in cash and money market funds.

On January 17, 2017, we entered into a Controlled Equity Offering Sales Agreement, or sales agreement, with Cantor Fitzgerald & Co., or Cantor, as sales agent. On July 7, 2017, we entered into an amendment to the sales agreement, or the amended sales agreement. In accordance with the terms of the amended sales agreement, we may offer and sell through Cantor, from time to time, shares of our common stock up to an aggregate offering price of $80,000,000 through an “at-the-market” offering program. As of September 30, 2018, we had sold an aggregate of 6,090,044 shares under the agreement at an average price of $6.50 per share and we had received aggregate cash proceeds of $38.1 million, after deducting the 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.

Between October 1, 2018 and November 8, 2018, an additional 20,402 shares had been sold under the amended sales agreement at an average price of $2.75 per share, for net proceeds of $54,000 after deducting sales commissions.

On August 2, 2017, we sold 10,000,000 shares of common stock in an underwritten public offering at an offering price to the public of $6.50 per share, resulting in net proceeds to us of $60.7 million after deducting underwriting discounts and commissions of $3.9 million and offering costs of $0.4 million. In connection with the offering, we granted the underwriters an option to purchase up to an additional 1,500,000 shares on the same terms and conditions as the offering, pursuant to which the underwriters exercised an option to purchase 107,000 additional shares on August 25, 2017 resulting in additional net proceeds to us of approximately $0.7 million after deducting underwriting discounts and commissions.

On November 2, 2018, we entered into a loan and security agreement (the “Loan Agreement”) with Solar Capital Ltd., as collateral agent and lender, and the other lenders named therein (Solar Capital Ltd. and the other lenders collectively, the “Lenders”). The Lenders have agreed to make available to us term loans in an aggregate principal amount of up to $75.0 million under the Loan Agreement. We plan to use the proceeds of the term loans to support

commercial launch of Xerava as well as for working capital and general corporate purposes. The Loan Agreement provides a term loan commitment of $50.0 million in two potential tranches: (i) a $30.0 million Term A loan facility funded on November 2, 2018 and (ii) a $20.0 million Term B loan facility to be funded at the request of the Company no later than October 31, 2020, subject to (A) the Company having unrestricted net cash proceeds of not less than $50 million from the issuance and sale of common stock and/or from other business activities and (B) the Company having product revenue greater than or equal to $14.0 million on a six month trailing basis prior to September 30, 2020. Both of these term loans have a maturity date of May 2, 2023. The Loan Agreement also provides access to an additional Term C loan facility in the amount of $25.0 million, to be funded at the Lenders' sole discretion.

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

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

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

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

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

	Nine Months Ended September 30,	
	2018	2017
Cash Flows from Operations:		
Net cash used in operating activities	$(43,203)	$(71,265)
Net cash used in investing activities	(3,105)	(685)
Net cash provided by financing activities	7,356	91,229
Net (decrease) increase in cash and cash equivalents	$(38,952)	$19,279

Cash Flows from Operating Activities. The $28.1 million decrease in cash used in operating activities for the nine months ended September 30, 2018, compared to the nine months ended September 30, 2017, was primarily due to decreased spending on the IGNITE clinical trials offset by the license payments from Everest Medicines.

Cash Flows from Investing Activities. The $2.4 million increase in cash used in investing activities for the nine months ended September 30, 2018, compared to the nine months ended September 30, 2017, was primarily 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 $83.9 million decrease in cash provided by financing activities for the nine months ended September 30, 2018, compared to the nine months ended September 30, 2017 was primarily due our public offering completed in the third quarter of 2017 and a decrease in sales of common stock under our amended sales agreement with Cantor.

Operating Capital Requirements

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

We believe that our available funds, including our recently announced debt financing with Solar Capital, will be sufficient to support our operations into the second quarter of 2020, which we believe will allow us to fund the initial launch of IV Xerava for the treatment of cIAI. We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources to fund our operations including ongoing spending to commercialize Xerava.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with

research, development and commercialization of pharmaceutical products and the variable nature of the interest-only period and funds accessibility under our new debt facility with Solar Capital, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- costs related to the sales and marking of Xerava;
- revenue received from commercial sales of Xerava;
- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our other product candidates and potential product candidates;
- the outcome, timing and costs of seeking regulatory approvals;
- the number and characteristics of product candidates that we pursue;
- the costs of commercialization activities for other product candidates if we receive marketing approval, including the timing and costs of establishing product sales, marketing, distribution and manufacturing capabilities;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish, as we did with Everest Medicines;
    - the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay to Harvard, pursuant to our license agreement;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims;
- the extent to which we in-license or acquire other products and technologies; and
- the funding, interest and repayment obligations of our debt facility with Solar Capital.

We expect that we will need to obtain substantial additional funding in order to commercialize eravacycline. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, the ownership interests of our existing stockholders may be materially diluted and the terms of these securities could include liquidation or other preferences that could adversely affect the rights of our existing stockholders. In addition, additional debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. If we are unable to raise capital when needed or on attractive terms, we could be forced to significantly delay, scale back or discontinue the development or commercialization of eravacycline or other product candidates, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, our rights to eravacycline or other product candidates that we otherwise would seek to develop or commercialize ourselves.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Contractual Obligations

In November 2018, the Company entered into a term loan with Solar Capital Ltd., with an initial draw of $30 million (see Note 10). Other than the agreement with Solar, 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 6, 2018 for the year ended December 31, 2017.

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

There have not been any material changes to our exposure to market risk during the nine months ended September 30, 2018. For additional information regarding market risk, refer to the Qualitative and Quantitative Disclosures About Market Risk section of our annual report.

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, 2018. 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, 2018, 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

With the exception of the migration of certain of our financial processing systems to an enterprise-wide systems solution, 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 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. In connection with this implementation and the resulting business process changes, we continue to enhance the design and documentation of our internal control over financial reporting processes to maintain effective controls over our financial reporting.

part ii – other information

Item 1. Legal Proceedings

In July 2018, a purported securities class action lawsuit was filed against us, our chief executive officer, our chief scientific officer and the underwriters of our July 2017 public offering, in the United States District Court for the Southern District of New York. The complaint is brought on behalf of an alleged class of those who purchased our securities pursuant and/or traceable to our July and August 2017 public offering and those who purchased our securities between March 8, 2017 and February 13, 2018. The complaint purports to allege claims arising under Sections 10 and 20 of the Exchange Act of 1934, as amended, and Sections 11 and 15 of the Securities Act of 1933, as amended. The complaint generally alleges that the defendants violated the federal securities laws by, among other things, making material misstatements or omissions concerning IGNITE3. The complaint seeks, among other relief, unspecified compensatory damages, attorneys' fees, and costs. The defendants have moved to transfer the lawsuit to the United States District Court for the District of Massachusetts. We believe we have valid defenses against these claims, and will engage in a vigorous defense of such litigation.

Item 1A. RISK FACTORS

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

Risks Relating to Our Financial Position and Need for Additional Capital

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

We have incurred annual net operating losses in every year since our inception. Our net loss was $50.7 million for the nine months ended September 30, 2018, $114.8 million for the year ended December 31, 2017, and $77.5 million for the year ended December 31, 2016. As of September 30, 2018, we had an accumulated deficit of $512.6 million. Prior to September 30, 2018, we had not generated any product revenues. We have financed our operations primarily through the public offering and private placements of our equity securities, debt financings and revenue from U.S. government grants and contract awards. In the third quarter of 2018, we received marketing approval in the United Stated 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. With approval of Xerava for cIAI, we believe that we will devote a substantial portion of our financial resources and efforts to supporting the ongoing commercialization of Xerava.

We expect to continue to incur significant expenses and operating losses for at least the next several years. The net losses we incur may fluctuate significantly from quarter to quarter. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

We expect that our expenses will decrease in 2018 compared with 2017, as the lower costs associated with the completion of the IGNITE clinical program will offset increased sales, marketing, distribution and outsourced

manufacturing expenses related to the launch of Xerava. Our expenses may also increase if and as we:

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

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

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

Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses could increase if there are any delays in the development of any of our products or product candidates or delays in the manufacture of any of our products or product candidates, particularly Xerava.

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

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

Developing pharmaceutical products, including conducting preclinical studies, clinical trials and manufacturing activities, is a time-consuming, expensive and uncertain process that takes years to complete. We expect that our expenses will decrease in 2018 compared with 2017, as the lower costs associated with the completion of the IGNITE clinical program will offset increased costs associated with sales, marketing, distribution and outsourced manufacturing expenses for the launch of Xerava.

We believe that our existing cash and cash equivalents, including our debt financing through Solar Capital completed November 2, 2018, will enable us to fund our operating expenses and capital expenditures into the second quarter of 2020. However, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources to fund our expenses after that time.

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

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

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

- revenue received from commercial sales of Xerava;
- the costs of commercialization activities for Xerava and additional product candidates if such additional product candidates receive marketing approval, including the timing and costs of establishing product sales, marketing, distribution and manufacturing capabilities;
- the timing and costs of manufacturing activities in connection with the commercialization of Xerava;
- the timing and costs of our ongoing clinical trials for our product candidates;
- the amount of funding that we receive under our subcontracts awarded to us by our collaborator CUBRC, Inc., or CUBRC, under its government contracts with the Biomedical Advanced Research and Development Authority, or BARDA, and with the National Institutes of Health's, or NIH's, National Institute of Allergy and Infectious Diseases, or NIAID, and under our subaward from CUBRC under its grant from NIAID, and our award from the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator, or CARB-X, and the activities funded under these contracts;

- the number and characteristics of product candidates that we pursue;
- the terms and timing of any future collaborations, partnerships, licensing, marketing, distribution or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay to Harvard University, or Harvard, pursuant to our license agreement;

- 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 developing Xerava and other product candidates. We obtained marketing approval for Xerava in the United States and Europe in the third quarter of 2018. We have not yet demonstrated an ability to conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

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

On November 2, 2018, we entered into a Loan and Security Agreement, or the Loan Agreement, with Solar Capital Ltd., as collateral agent and lender, and the other lenders named therein. We refer to Solar Capital Ltd. and the other lenders collectively, as the lenders. The lenders have agreed to make available to the us term loans in an aggregate principal amount of up to $75.0 million under the Loan Agreement. The Loan Agreement provides a term loan commitment of $50.0 million in two potential tranches: (i) a $30.0 million Term A loan facility funded on November 2, 2018 and (ii) a $20.0 million Term B loan facility to be funded at the request of the Company, subject to certain conditions being met, no later than October 31, 2020. Both of these term loans have a maturity date of May 2, 2023. The Loan Agreement also provides access to an additional Term C loan facility in the amount of $25.0 million, to be funded at the Lenders' sole discretion.

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

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

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

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

Currently, our only external source of funds is funding under subcontracts awarded to us by CUBRC pursuant to government contracts from BARDA and NIAID, and an award from CARB-X. Although the BARDA contract and our subcontract with CUBRC under the BARDA contract have terms which currently expire on December 31, 2018, BARDA is entitled to terminate the project for convenience at any time and is not obligated to provide continued funding beyond current-year amounts from congressionally approved annual appropriations. To the extent that BARDA ceases to provide funding of the program to CUBRC, CUBRC has the right to cease providing funding to us. Committed funding from CUBRC under our BARDA subcontract is for up to approximately $41.8 million from the

initial contract date through December 31, 2018, of which $39.5 million had been received through September 30, 2018.

Similarly, although the NIAID contract and our subcontract with CUBRC under the NIAID contract have terms which currently expire on March 31, 2019, NIAID is entitled to terminate the project for convenience at any time and is not obligated to provide continued funding beyond March 31, 2019. To the extent NIAID ceases to provide funding of the programs to CUBRC, CUBRC has the right to cease providing funding to us. Committed funding from CUBRC under our subcontract with respect to the NIAID contract is for up to $16.9 million, of which $15.1 million had been received through September 30, 2018.

Similarly, although the CARB-X Award has a term which currently expires on December 31, 2018, CARB-X is entitled to terminate the project for convenience at any time. Committed funding from the CARB-X Award is for up to $4.0 million from the initial award date through December 31, 2018, of which $0.8 million had been received through September 30, 2018.

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

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

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

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

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

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

terms that would not require us to breach the terms and conditions of our existing or future debt agreements, and our financial position and results of operations could be materially adversely affected.

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

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

- invest in our subsidiaries and make other investments;
- dispose of certain assets;
- change our lines of business;
- engage in mergers or consolidations;
- incur additional indebtedness;

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

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

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

Risks Related to Product Development and Commercialization

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

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

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

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

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

Prior to Xerava, we had never commercialized a product candidate for any indication. Efforts to educate the medical community and third-party payors on the benefits of Xerava or any additional product candidate may require significant resources and may not be successful. If Xerava or any additional product candidate that we develop does not achieve an adequate level of market acceptance, we may not generate significant product revenues and, therefore, we may not become profitable. The degree of market acceptance of Xerava, or any other product candidate that is approved for commercial sale, will depend on a number of factors, including, but not limited to:

- the efficacy and safety of the product;
- the potential advantages of the product compared to alternative treatments, including convenience and ease of administration;
- the prevalence and severity of any side effects;
- the clinical indications for which the product is approved;

- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling or an approved risk evaluation and mitigation strategy;
- our ability to offer the product for sale at competitive prices;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular infections;
- the strength of marketing and distribution support;
- the approval of other new products for the same indications;
- the timing of market introduction of our approved products as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- availability and level of coverage and amount of reimbursement from government payors, managed care plans and other third-party payors;
- the effectiveness of our sales and marketing efforts;
    - adverse publicity about the product or favorable publicity about competitive products; and
- the development of resistance by bacterial strains to the product.

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

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

To achieve commercial success for any approved product, we must successfully develop a sales and marketing organization or outsource these functions to third parties. We have built a commercial organization in the United States and recruited experienced sales, marketing and distribution professionals. If we are unable to successfully maintain the sales force and marketing and distribution capabilities, our operating results may be adversely affected.

Factors that may inhibit our efforts to commercialize Xerava or any additional product candidates that we develop and commercialize on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the ability of our sales personnel to obtain access to or persuade adequate numbers of physicians to 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; and
- unforeseen costs and expenses associated with maintaining an independent sales and marketing organization.

We plan to commercialize Xerava outside the United States and in certain European countries with the assistance of collaborators. As a result of entering 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.

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

The development and commercialization of new drug products is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to Xerava and to any additional product candidates that we may seek to develop or commercialize in the future. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products, or are pursuing the development of product candidates, for the treatment of MDR infections. Potential competitors also include academic institutions, government agencies and other public and private research organizations. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than Xerava or any product candidates that we are currently developing or that we may develop, which could render our products and product candidates obsolete or noncompetitive.

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

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

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

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

Even if we are able to commercialize Xerava or any other product candidate that we develop, the product may become subject to unfavorable pricing regulations, third-party payor coverage and reimbursement policies or healthcare reform initiatives that could harm our business.

Marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize Xerava or any other product candidate will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government authorities, private health insurers, health maintenance organizations and other third-party payors. The healthcare industry is acutely focused on cost containment, both in the

United States and elsewhere. As a result, government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidates profitably.

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

We cannot be sure that coverage will be available for Xerava or any other product candidate that we commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

If clinical trials of any product candidate that we advance to clinical trials fail to demonstrate safety and efficacy to the satisfaction of the FDA or comparable foreign regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidate.

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

The clinical development of our product candidates is susceptible to the risk of failure inherent at any stage of drug development, including failure to achieve efficacy in a trial or across a broad population of patients, the occurrence of severe adverse events, failure to comply with protocols or applicable regulatory requirements, and determination by the FDA or any comparable foreign regulatory authority that a drug product is not approvable. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. For example, in the first quarter of 2018 we reported top-line data for our IGNITE3 phase 3 clinical trial evaluating the safety and efficacy of eravacycline with intravenous, or IV, administration for the treatment of complicated urinary tract infections. IGNITE3 failed to meet the co-primary efficacy endpoints of responder rate (a combination of clinical cure and microbiological success) in the microbiological intent-to-treat population at the end-of-IV treatment visit and at the test-of-cure visit, which were evaluated using a 10% non-inferiority margin. We may fail to achieve success in any future clinical trial of any product candidate.

In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we believe that the results of our

clinical trials warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

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

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

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

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

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

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

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

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

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

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

Serious adverse events or undesirable side effects caused by, or other unexpected properties of, our product candidates could cause us, an institutional review board, or regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive label, the imposition of distribution or use restrictions or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. If any of our product candidates are associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the compound. In our clinical trials of Xerava, some treatment-related adverse events have been reported. The most common treatment-related adverse events observed in clinical trials of Xerava have been nausea and emesis. Additional adverse events, undesirable side effects or other unexpected properties of any of our other product candidates could arise or become known either during clinical development or, if approved, after the approved product has been marketed. If such an event occurs during development, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of, or deny approval of, our other 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 postmarketing studies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and limit commercialization of Xerava or of any other products that we may develop.

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

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

Although we maintain general liability insurance of $6 million in the aggregate and clinical trial liability insurance of $6 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. We intend to increase our general liability insurance coverage to $10 million effective January 1, 2019 as a result of the commercialization of Xerava. In addition, insurance coverage is becoming increasingly expensive. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of Xerava and our product candidates, which could adversely affect our business, financial condition and results of operations and prospects.

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

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

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage

against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

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

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

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

Risks Related to Our Dependence on Third Parties

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

Although we are commercializing Xerava ourselves in the United States and certain European countries, 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 complicated intra-abdominal infections and other indications, in mainland China and several other Asian territories and countries. In addition, we may seek third-party collaborators for development and commercialization of other 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;
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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 clinical trials and expect to continue to do so in connection with the commercialization of Xerava and for clinical trials and commercialization of any additional product candidates that we develop and commercialize. This reliance on third parties increases the risk that we will not have sufficient quantities of our product or product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have nor do we plan to build the internal infrastructure or capability to manufacture Xerava or our other product candidates for use in the conduct of our clinical trials or for commercial supply. We currently rely on and expect to continue to rely on third-party contract manufacturers to manufacture clinical supplies of our product candidates, and we have relied and expect to continue to rely on third-party contract manufacturers to manufacture registration batches and commercial quantities of any product candidate that we commercialize following approval for marketing by applicable regulatory authorities. Reliance on third-party manufacturers entails risks, including:

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

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

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

Third-party manufacturers are required to comply with cGMPs and similar regulatory requirements outside the United States. Facilities used by our third-party manufacturers must be inspected by the FDA after we submit 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 and any other product candidate that we develop may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

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

We will require additional funds to complete the development and potential commercialization of any additional product candidates. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. For example, we utilize a variety of types of collaboration arrangements for commercialization of Xerava outside the United States and certain European countries. We may not be able to enter into similar arrangements for any additional product candidates.

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

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

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

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

candidates or bring them to market and our business may be materially and adversely affected.

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

We do not independently conduct clinical trials of our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for clinical development activities limits our control over these activities but we remain responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and

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

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

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

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

We are a party to a license agreement with Harvard that imposes, and we may enter into additional agreements, including license agreements, with other parties in the future that impose, diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. For example, under our license agreement with Harvard, we are obligated to satisfy diligence requirements, including using commercially reasonable efforts to develop and commercialize licensed compounds and to implement a specified development plan, meeting specified development milestones and providing an update on progress on an annual basis. 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. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

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

Competitors may infringe our patents, trademarks, copyrights or other intellectual property, or those of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived

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

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

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

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our products and product candidates and use our proprietary chemistry technology without infringing the intellectual property and other proprietary rights of third parties. Numerous third-party U.S. and non-U.S. issued patents and pending applications exist in the area of antibacterial treatment, including compounds, formulations, treatment methods and synthetic processes that may be applied towards the synthesis of antibiotics. If any of 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. We are aware of a third-party U.S. patent claiming pharmaceutical compositions of tetracyclines. The third-party U.S. patent could be asserted against us with respect to Xerava. We believe we have defenses in the event that the third-party seeks to assert such patent against us, including the invalidity of the relevant claims of such patent. However, we may not be successful in asserting these defenses, including proving invalidity, and could be found to infringe the third-party's patent, which would have a material adverse effect on us.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology, products or product candidates, including patent infringement litigation with respect to the third-party U.S. patent referred to above, and Xerava. Other possible adversarial proceedings include interference proceedings before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing

evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

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

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

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

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

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

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

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

Trademark applications for TETRAPHASE PHARMACEUTICALS, our logo, and combinations of those are filed and approved for publication in the United States. These applications may be opposed. TETRAPHASE PHARMACEUTICALS is either registered or pending in twelve other jurisdictions and we have applied to register the logo in the same twelve 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 eravacycline product. A third party has threatened to oppose our application to register this mark and alleges that our use of the

Xerava trademark may create a likelihood of confusion and infringe the third party's trademark. We believe we have defenses in the event that the third party opposes our trademark application or seeks to assert its trademark against us.

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

Risks Related to Regulatory Approval and Other Legal Compliance Matters

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 revenue will be materially impaired.

Our future product candidates in addition to Xerava and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, marketing, export, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities, with regulations differing from country to country. Failure to obtain marketing approval for any such future product candidate will prevent us from commercializing such product candidate. Even after obtaining regulatory approval for Xerava, we have limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations to assist us in this process.

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

A fast track designation by the FDA does not guarantee approval and may not actually lead to a faster development, regulatory review or approval process.

If a product is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for that condition, the treatment sponsor may apply for FDA fast track designation. The FDA granted Xerava fast track designation as a qualified infectious disease product in April 2014, granted fast track designation as a qualified infectious disease product for the IV formulation of TP-271 in September 2015, and granted fast track designation as a qualified infectious disease product for the oral formulation of TP-271 in February 2017. Fast track designation does not ensure approval or a faster development, regulatory review or approval

process compared to conventional FDA procedures. Additionally, the FDA may withdraw fast track designation, if it believes that the designation is no longer supported by data from our clinical development program.

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 other product candidates, when and if approved.

Xerava is subject, and any product candidate for which we obtain marketing approval, will also be subject to ongoing regulatory requirements 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, 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 and to comply with requirements concerning advertising and promotion for our products.

In addition, even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed, may be subject to significant conditions of approval or may impose requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling and regulatory requirements. The FDA also imposes stringent restrictions on manufacturers' communications regarding off-label use 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 marketing.

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 on the product or its manufacturers or 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 and/or criminal penalties.

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Our relationships with customers and third-party payors will be 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 future arrangements with third-party payors, healthcare professionals and customers who purchase, recommend or prescribe our products and product candidates will be 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 any products for which we obtain marketing approval. These laws and regulations include, for example, the false claims and anti-kickback statutes and regulations. At such time as we market, sell and distribute any products for which we obtain marketing approval, it is possible that our business activities could be subject to challenge under one or more of these laws and regulations. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute, among other things, prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federally funded healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, which can be enforced by private citizens through civil whistleblower and qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, requires manufacturers of covered drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or track and report gifts, compensation and other remuneration provided to physicians and other health care providers; and state and foreign laws that govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, which complicates compliance efforts.

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. Even then, governmental authorities may conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Recent healthcare reform legislation has strengthened these federal and state healthcare laws. For example, the ACA amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or a specific intent to violate them. In addition, the ACA provides that the government may assert that a claim that includes items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act. 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. 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.

If we successfully commercialize Xerava or one of our product candidates, failure to comply with our reporting and payment obligations under U.S. governmental pricing programs could have a material adverse effect on our business, financial condition and results of operations.

If we participate in the Medicaid Drug Rebate Program once we successfully commercialize a drug, we will be required to report certain pricing information for our products to the Centers for Medicare & Medicaid Services, the federal agency that administers the Medicaid and Medicare programs. We may also be required to report pricing information to the Department of Veterans Affairs. If we become subject to these reporting requirements, we will be liable for errors associated with our submission of pricing data, for failure to report pricing data in a timely manner, and for overcharging government payers, which can result in civil monetary penalties under the Medicaid statute, the federal civil False Claims Act, and other laws and regulations.

Risks Related to Employee Matters

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

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the research and development, regulatory, commercialization and business development expertise of our executive management team, as well as the other principal members of our management, scientific and clinical team. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time. For instance, in December 2017, our former chief medical officer terminated his employment with us and in March 2018, our former chief financial officer terminated her employment with us.

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

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

Although our operations are based in the United States, we conduct business outside the United States and expect to continue to do so in the future. For instance, many of the sites at which our clinical trials are or may be conducted are outside the United States. In addition, we plan to seek approvals to sell our products in foreign countries. Any business that we conduct outside the United States will be subject to additional risks that may materially adversely affect our ability to conduct business in international markets, including:

- potentially reduced protection for intellectual property rights;

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

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

Our internal computer infrastructure and those of any collaborators, contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed or halted.

Risks Related to Our Common Stock

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

Our stock price may be volatile. The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. For example, our stock traded within a range of a high price of $52.90 per share and a low price of $2.01 per share for the period beginning March 20, 2013, our first day of trading on the Nasdaq Global Select Market, through November 7, 2018. As a result of this volatility, investors may not be able to sell their common stock at or above the prices they paid for it. The market price for our common stock may be influenced by many factors, including:

- revenues related to Xerava;
- the filing and approval of marketing applications for our product candidates;
- the timing of clinical trials of our product candidates;
- results of clinical trials of our product candidates;
- regulatory actions by the FDA or equivalent authorities in foreign jurisdictions with respect to Xerava and any other product candidate;
- failure or discontinuation of any of our development programs;
- the success of existing or new competitive products or technologies;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to develop, in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts or licensing or other strategic transactions;
- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;

- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;

- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

We have been, currently are and may again be subject to class action litigation and have been and may again be subject to shareholder derivative litigation, which could distract our management and could result in substantial costs or large judgments against us.

The stock market frequently experiences extreme price and volume fluctuations. We have experienced significant declines in our stock price following our announcements that our phase 3 clinical trials for eravacycline 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. In November 2017 plaintiffs withdrew a pending appeal in the United States Court of Appeals for the First Circuit. In addition, in May 2016, a shareholder derivative action was filed against our chief executive officer, certain former executive officers, all the members of our current board of directors, a former board member, and against us as nominal defendant, in Massachusetts Superior Court (Suffolk County). This case was subsequently dismissed by the court without prejudice due to the plaintiff's failure to properly perfect service of process. Furthermore, in July 2018 a class action lawsuit was filed against us, or chief executive officer, our chief scientific officer and other third parties in the United States District Court for the Southern District of New York in connection with the failure of IGNITE3 to meet its co-primary endpoints. Due to the volatility in our stock price, we may be the target of similar litigation in the future.

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

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

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

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

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

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

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

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

Section 404 of the Sarbanes-Oxley Act of 2002 requires us, on an annual basis, to review and evaluate our internal controls. To maintain compliance with Section 404, we are required to document and evaluate our internal control over financial reporting,

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

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the operation, development and growth of our business. The terms of the Loan Agreement precluded us from paying dividends, and any future debt agreements may also preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

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

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

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

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring us or merging with us, whether

or not it is desired by, or beneficial to, our stockholders.

Item 6. Exhibits

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

EXHIBIT INDEX

		Incorporated by Reference from				
Exhibit Number	Description of Document	Registrant's Form	File No.	Date Filed with the SEC	Exhibit Number	Filed Herewith
4.1	Form of Warrant to Purchase Stock entered into in connection with the Loan and Security Agreement, dated as of November 2, 2018.	8-K	001-35837	11/5/18	4.1	
10.1	Loan and Security Agreement, dated November 2, 2018, by and among Tetraphase Pharmaceuticals, Inc., Solar Capital Ltd., as collateral agent and lender, and the other lenders named therein.	8-K	001-35837	11/5/18	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						X

	XBRL Taxonomy Extension Label Linkbase Document	
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 8, 2018 TETRAPHASE PHARMACEUTICALS, INC.

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