TETRAPHASE PHARMACEUTICALS INC
Form 10-Q
August 12, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2013

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 Street, Suite 110,

Watertown, MA

(Address of principal executive offices)

02472

(Zip Code)

(617) 715-3600

(Registrant s telephone number, including area code)

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	¨	Accelerated filer	¨
Non-accelerated filer	x (Do not check if a smaller reporting company)	Smaller reporting company	¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

EXPLANATORY NOTE: Under the Jumpstart our Business Startups Act, the registrant qualifies as an emerging growth company. We therefore incorporate the scaled disclosures required of an emerging growth company in this Quarterly Report on Form 10-Q.

As of August 1, 2013 there were 20,671,935 shares of the registrant s common stock, par value $0.001 per share, outstanding.

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TETRAPHASE PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED June 30, 2013

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

Tetraphase Pharmaceuticals, Inc.

(A Development Stage Company)

Condensed Consolidated Balance Sheets

(In thousands except share and per share data)

(Unaudited)

	June 30, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 77,216	$ 9,079
Accounts receivable	2,912	2,452
Restricted cash	121	
Prepaid expenses and other current assets	674	850
Total current assets	80,923	12,381
Property and equipment, net	185	235
Restricted cash	40	161
Other assets	20	1,295
Total assets	$ 81,168	$ 14,072
Liabilities, convertible preferred stock and stockholders equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,963	$ 2,018
Accrued expenses	3,235	2,303
Deferred revenue		699
Current portion of term loan payable	5,682	3,641
Total current liabilities	10,880	8,661
Preferred stock warrant liability		610
Accrued final interest payment on term loan	233	128
Term loan	7,478	7,881
Commitments and contingencies		
Convertible preferred stock, par value $0.001 per share: no shares and 259,044,157 shares authorized at June 30, 2013 and December 31, 2012, respectively; no shares and 256,024,993 shares issued and outstanding at June 30, 2013 and December 31, 2012, respectively		79,841
Stockholders equity (deficit):		
Preferred stock, par value $0.001 per share; 5,000,000 shares and no shares authorized at June 30, 2013 at December 31, 2012, respectively; no shares issued and outstanding at June 30, 2013 and December 31, 2012		
Common stock, par value $0.001 per share; 125,000,000 and 317,789,510 shares authorized at June 30, 2013 and December 31, 2012, respectively; 20,671,935 and 325,243 shares issued and outstanding at June 30, 2013 and December 31, 2012, respectively	21	

Additional paid-in capital	160,858	7,036
Deficit accumulated during the development stage	(98,302)	(90,085)
Total stockholders equity (deficit)	62,577	(83,049)
Total liabilities, convertible preferred stock and stockholders equity (deficit)	$ 81,168	$ 14,072

See accompanying notes to condensed consolidated financial statements

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TETRAPHASE PHARMACEUTICALS, INC.

(A Development Stage Company)

Condensed Consolidated Statements of Operations and Comprehensive Loss

(In thousands except per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		Period from July 7, 2006 (Inception) to June 30,
	2013	2012	2013	2012	2013
Revenues	$ 3,722	$ 1,316	$ 6,422	$ 1,823	$ 14,207
Operating expenses					
Research and development	6,924	4,261	11,022	8,262	86,129
General and administrative	1,756	1,002	2,981	1,963	20,284
Total operating expenses	8,680	5,263	14,003	10,225	106,413
Loss from operations	(4,958)	(3,947)	(7,581)	(8,402)	(92,206)
Other income (expense)					
Interest income	2		2		610
Interest expense	(470)	(216)	(901)	(450)	(2,339)
Other (expense) income		(105)	263	(105)	(4,367)
Other expense, net	(468)	(321)	(636)	(555)	(6,096)
Net loss	$ (5,426)	$ (4,268)	$ (8,217)	$ (8,957)	$ (98,302)
Net loss per share applicable to common stockholders-basic and diluted	$ (0.26)	$ (13.42)	$ (0.73)	$ (28.60)	$ (96.85)
Weighted-average number of common shares used in net loss per share applicable to common stockholders-basic and diluted	20,575	318	11,263	313	1,015
Comprehensive loss	$ (5,426)	$ (4,268)	$ (8,217)	$ (8,957)	$ (98,302)

See accompanying notes to condensed consolidated financial statements

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Tetraphase Pharmaceuticals, Inc.

(A Development Stage Company)

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Six Months Ended June 30,		The Period from July 7, 2006 (inception) to June 30,
	2013	2012	2013
Operating activities			
Net loss	$ (8,217)	$ (8,957)	$ (98,302)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	72	206	2,451
Amortization of deferred financing costs and debt discount	177	67	476
Accretion of final interest payment on term loans	105		233
Fair value adjustment of warrants and investor right obligation	(263)	105	5,099
Stock-based compensation expense	335	222	1,881
Loss from disposal of property and equipment			5
Changes in operating assets and liabilities:			
Restricted cash			(161)
Accounts receivable	(460)	(844)	(2,912)
Prepaid expenses and other current assets	176	196	(643)
Accounts payable	392	204	1,964
Accrued expenses	1,135	(1,662)	3,235
Deferred revenue	(699)		
Net cash used in operating activities	(7,247)	(10,463)	(86,674)
Investing activities			
Purchases of property and equipment	(22)	(10)	(2,641)
Net cash used in investing activities	(22)	(10)	(2,641)
Financing activities			
Proceeds from sale of common stock, net of issuance costs	73,805		73,194
Proceeds from sale of convertible preferred stock, net of issuance costs			79,841
Deferred financing fees			(275)
Proceeds from issuance of term loan payable	3,000		18,750
Repayment of term loan payable	(1,409)	(857)	(5,156)
Proceeds from sale of restricted common stock and common stock to founders			20
Proceeds from exercise of stock options	10	20	157
Net cash provided by (used in) financing activities	75,406	(837)	166,531
Net increase (decrease) in cash and cash equivalents	$ 68,137	$ (11,310)	$ 77,216
Cash and cash equivalents at beginning of period	9,079	22,454	
Cash and cash equivalents at end of period	$ 77,216	$ 11,144	$ 77,216

Supplemental cash flow and noncash financing activities			
Cash paid for interest	$ 561	$ 355	$ 1,573
Fair value of warrants issued in connection with issuance of term loan	$ 115	$	$ 684
Reclassification of investors rights/liability to stockholders equity	$	$	$ 5,321
Conversion of convertible preferred stock into common stock	$ 79,832	$	$ 79,832
Reclassification of warrant liability to additional paid-in-capital	$ 462	$	$ 462
Reclassification of deferred financing costs to additional paid-in-capital	$ 1,261	$	$ 1,261

See accompanying notes to condensed consolidated financial statements

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TETRAPHASE PHARMACEUTICALS, INC.

(A Development Stage Company)

June 30, 2013

Notes to Condensed Consolidated Financial Statements

(Unaudited)

(1) Organization and Operations

Tetraphase Pharmaceuticals, Inc. (the Company), is a clinical stage biopharmaceutical company that was incorporated in Delaware on July 7, 2006 and has a principal place of business in Watertown, Massachusetts, using its proprietary chemistry technology to create novel antibiotics for serious and life-threatening multi-drug resistant infections. The Company s lead product candidate, eravacycline, is a fully synthetic tetracycline derivative that the Company is developing as a broad-spectrum intravenous and oral antibiotic for use as a first-line monotherapy for the treatment of multi-drug resistant infections, including multi-drug Gram-negative infections. The Company completed a successful Phase 2 clinical trial of eravacycline with intravenous administration for the treatment of patients with complicated intra-abdominal infections, or cIAI, in 2012. The Company plans to conduct two global Phase 3 clinical trials of eravacycline, one for the treatment of cIAI, which it expects to commence in the third quarter of 2013, and one for the treatment of complicated urinary tract infections, or cUTI, which it expects to commence in the fourth quarter of 2013. The Company is currently finalizing its plans for the Phase 3 trial of eravacycline for cUTI. The Company is also conducting a Phase 1 clinical program evaluating the pharmacokinetics and safety of oral formulations of eravacycline which it expects to complete in the second half of 2013. Subject to obtaining additional financing, the Company intends to pursue development of eravacycline for the treatment of additional indications, including acute bacterial skin and skin structure infections, or ABSSSI, acute bacterial pneumonias and other serious and life-threatening infections. The Company is also pursuing the discovery and development of additional antibiotics to target unmet medical needs.

The Company is in the development stage, and is devoting substantially all of its efforts to product research and development, initial market development, and raising capital. The Company has not generated any product revenue related to its primary business purpose to date and is subject to a number of risks similar to those of other development stage life science companies, including dependence on key individuals, competition from other companies, the need for development of commercially viable products, and the need to obtain adequate additional financing to fund the development of its product candidates. The Company is also subject to a number of risks similar to other companies in the industry, including rapid technological change, regulatory approval of products, uncertainty of market acceptance of products, competition from substitute products and larger companies, the need to obtain additional financing, compliance with government regulations, protection of proprietary technology, dependence on third parties, product liability, and dependence on key individuals.

The Company has incurred annual net operating losses in every year since its inception. The Company has not generated any product revenues related to its primary business purpose and has financed its operations primarily through public offerings of its common stock, private placements of its preferred stock, debt financings and funding from the United States government. The Company has not completed development of any product candidate and has devoted substantially all of its financial resources and efforts to research and development, including preclinical and clinical development. The Company expects to continue to incur significant expenses and increasing operating losses for at least the next several years.

As of June 30, 2013, the Company has incurred losses since inception of $98.3 million. The Company expects to continue to incur losses and require additional financial resources to advance its products to either commercial stage or liquidity events.

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

Liquidity

In May 2011, the Company executed a Loan and Security Agreement (Term Loan) with two financial institutions, Silicon Valley Bank and Oxford Finance, which provided for up to $8.0 million in funding, to be made available in two tranches. The Company borrowed the first $1.5 million in May 2011 and the second tranche for the remaining $6.5 million in

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December 2011. On December 20, 2012, the Company amended the Term Loan to provide for up to an additional $9.2 million in funding, to be made available in two tranches (2012 Term Loan). The Company borrowed the first $6.2 million under the 2012 Term Loan on December 20, 2012. The Company borrowed the second tranche of $3.0 million on February 28, 2013.

In October 2011, the National Institutes of Health s (NIH) National Institute of Allergy and Infectious Diseases (NIAID) division awarded a contract of up to $35.8 million over a five-year term for the development of TP-271, a preclinical compound, for respiratory disease caused by bacterial biothreat pathogens (NIAID Contract) (Note 3). The Company is collaborating with CUBRC Inc., or CUBRC, an independent, not for profit, research corporation that specializes in U.S. government based contracts, on this NIAID Contract and has entered into a subcontract with CUBRC which could potentially provide funding to the Company of up to approximately $13.3 million over the five year term, including committed funding of $7.5 million from the initial contract date through September 30, 2016, of which $3.4 million had been received by the Company through June 30, 2013. In addition during 2011, the Company was a subawardee under a separate grant from the NIAID (NIAID Grant) (Note 3).

In February 2012 the Biomedical Advanced Research and Development Authority (BARDA), an agency of the U.S. Department of Health and Human Services, awarded a contract of up to $67.0 million for the development of eravacycline as a potential countermeasure for the treatment of disease caused by bacterial biothreat pathogens (BARDA Contract). The Company is also collaborating with CUBRC on the BARDA Contract and has entered into a subcontract with CUBRC which could potentially provide funding to the Company of up to approximately $39.8 million including committed funding of $15.6 million from the initial contract date through April 30, 2015, of which $7.5 million had been received by the Company through June 30, 2013 (Note 3).

In March 2013, the Company completed the sale of 10,714,286 shares of common stock at a price to the public of $7.00 per share, resulting in net proceeds to the Company of $68.1 million after deducting underwriting discounts and commissions of $4.4 million and offering costs of $2.5 million (the IPO). The Company s common stock began trading on the NASDAQ Global Market under the symbol TTPH on March 20, 2013. In addition, the Company granted the underwriters a 30-day option to purchase up to 1,607,143 additional shares of common stock at the initial public offering price to cover over allotments, if any. On April 12, 2013, the Company completed the additional sale of 797,792 shares of common stock under this option at a price to the public of $7.00 per share, resulting in net proceeds to the Company of $5.2 million after deducting underwriting discounts and commissions.

The Company believes that its cash resources of approximately $77.2 million at June 30, 2013 will be sufficient to allow the Company to fund its current operating plan and continue as a going concern through at least the first quarter of 2015. The Company will be required to obtain additional funding in order to continue to fund its operations after the first quarter of 2015. There can be no assurances, however, that the current operating plan will be achieved in the timeframe anticipated by the Company, that its cash resources will fund the Company s operating plan for the period anticipated by the Company or that additional funding will be available on terms acceptable to the Company, or at all.

On February 28, 2013, the Company s board of directors approved an amendment to the Company s certificate of incorporation to effect a 1-for-29 reverse split of its Common Stock (the Reverse Split). The Company effected this amendment to its certificate of incorporation on March 5, 2013. All references to shares of Common Stock outstanding, average number of shares outstanding and per share amounts in these condensed consolidated financial statements and notes to condensed consolidated financial statements have been restated to reflect the Reverse Split on a retroactive basis.

(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 consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the accompanying notes for the year ended December 31, 2012 contained in the Company s prospectus filed with the SEC on March 20, 2013 pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended. 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 June 30, 2013 and the results of operations and comprehensive loss for the three and six months ended June 30, 2013 and 2012 and cash flows for the six months ended June 30, 2013 and 2012. Interim operating results for the three and six months ended June 30, 2013 are not necessarily indicative of the results that may be expected for future interim periods or for the fiscal year ending December 31, 2013.

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The December 31, 2012 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.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment, which is the business of developing and commercializing its proprietary chemistry technology to create novel antibiotics for serious and life-threatening multi-drug resistant infections.

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, expenses other comprehensive income and related disclosures. On an ongoing basis, the Company s management evaluates its estimates, including estimates related to clinical trial accruals, stock-based compensation expense and reported amounts of contract and grant revenues and expenses during the reported period. 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.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash, cash equivalents and restricted cash. The Company maintains its cash and cash equivalent balances in the form of money market accounts with financial institutions that management believes are creditworthy. The Company s investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk. The Company has no financial instruments with off-balance-sheet risk of loss.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Tetraphase Securities Corporation, a Massachusetts Securities Corporation. All significant intercompany balances and transactions have been eliminated in consolidation.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less from the date of purchase to be cash equivalents. Cash and cash equivalents at June 30, 2013 and December 31, 2012 consisted of cash and money market funds.

Fair Value Measurements

The Company s financial instruments consist principally of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, term loan and liabilities related to warrants to purchase preferred stock. 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.

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Financial instruments measured at fair value as of June 30, 2013 and December 31, 2012 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
June 30, 2013				
Cash	$ 5,216	$ 5,216	$	$
Money market funds, included in cash equivalents	$ 72,000	$ 72,000	$	$
December 31, 2012				
Cash	$ 5,854	$ 5,854	$	$
Money market funds, included in cash equivalents	$ 3,225	$ 3,225	$	$
Preferred stock warrant liability (Note 5)	$ (610)	$	$	$ (610)

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. The fair value of the Company s term loan payable is determined using current applicable rates for similar instruments as of the balance sheet date. The carrying value of the Company s term loan payable approximates fair value because the Company s interest rate yield is near current market rates. The Company s term loan payable is a Level 3 liability within the fair value hierarchy.

The fair value of the preferred stock warrant liability as of December 31, 2012 and March 25, 2013 was determined based on Level 3 inputs utilizing the Black-Scholes option pricing model (Note 5). On March 25, 2013, upon completion of the IPO, the warrants to purchase preferred stock converted into warrants to purchase common stock and the Company reclassified the fair value of the warrants as of March 25, 2013 to additional paid-in capital. The following table presents activity in the preferred stock warrant liability during the six months ended June 30, 2013.

	Balance
Fair value at December 31, 2012	$ 610
Value of warrants issued in 2013	115
Decrease in fair value recognized in net loss	(263)
Reclassification of fair value to additional paid-in capital	(462)
Fair value at June 30, 2013	$

Accounts Receivable

Accounts receivable at June 30, 2013 and December 31, 2012 represent amounts due from CUBRC under the Company s subcontracts under the NIAID Contract and the BARDA Contract and under the Company s subaward under the NIAID Grant. The Company s practice is to bill the prime contractor amounts for which the Company has been invoiced by third parties in the case of contract research or subcontractor costs or for internal costs incurred. Expenses directly associated with the Company s NIAID and BARDA Contracts and NIAID Grant that have been accrued at the end of the reporting period are not billed to the prime contractor until third party invoices have been received or until internal costs have been paid. Unbilled accounts receivable was approximately $1.7 million and $1.1 million at June 30, 2013 and December 31, 2012, respectively.

Property and Equipment, Net

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the respective assets, generally three to five years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful economic lives of the related assets.

Restricted Cash

At each of June 30, 2013 and December 31, 2012, the Company had $161,000 in restricted cash deposits with a bank of which $121,000 is collateral for a letter of credit issued to the landlord of the Company s leased facility. Should the Company default on its rental obligations, $121,000 will be payable to the lessor of the leased facility. In addition, the Company has $40,000 in restricted cash to secure the Company s corporate credit card issued through the same bank.

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Revenue Recognition

The Company s revenue is derived from its subcontracts with CUBRC under the BARDA Contract and the NIAID Contract and its subaward under the NIAID Grant (Note 3). The Company recognizes revenue under these best-efforts, cost-reimbursable and cost-plus-fixed-fee subcontracts and subaward as the Company performs services under the subcontracts and subaward so long as a subcontract and subaward has been executed and the fees for these services are fixed or determinable, legally billable and reasonably assured of collection. Recognized amounts reflect the Company s partial performance under the subcontracts and subaward and equal direct and indirect costs incurred plus fixed fees, where applicable. The Company does not recognize revenue under these arrangements for amounts related to contract periods where funding is not yet committed as amounts above committed funding thresholds would not be considered fixed or determinable or reasonably assured of collection. Revenues and expenses under these arrangements are presented gross on the statements of operations and comprehensive loss as the Company has determined it is the primary obligor under these arrangements relative to the research and development services it performs as lead technical expert.

Revenue under the Company s subcontract with respect to the BARDA Contract is earned under a cost-reimbursable contract in which the Company is reimbursed for direct costs incurred plus allowable indirect costs. Billings under the Company s subcontract under the BARDA Contract are based on approved provisional indirect billing rates, which permit recovery of fringe benefits and allowable general and administrative expenses. For the three months ended June 30, 2013 and 2012, the Company recognized revenue of $3.1 million and $0.9 million, respectively, from the Company s subcontract under the BARDA Contract. For the six months ended June 30, 2013 and 2012, and the period from July 7, 2006 (inception) to June 30, 2013, the Company recognized revenue of $5.0 million, $1.0 million and $9.8 million, respectively, from the Company s subcontract under the BARDA Contract.

Revenue under the Company s subcontract with respect to the NIAID Contract is earned under a cost-plus-fixed-fee contract in which the Company is reimbursed for direct costs incurred plus allowable indirect costs and a fixed-fee earned. Billings under the Company s subcontract under the NIAID Contract are based on approved provisional indirect billing rates, which permit recovery of fringe benefits, allowable overhead and general and administrative expenses and a fixed fee. For the three months ended June 30, 2013 and 2012, the Company recognized revenue of $0.5 million and $0.4 million, respectively, from the Company s subcontract under the NIAID Contract. For the six months ended June 30, 2013 and 2012 and the period from July 7, 2006 (inception) to June 30, 2013, the Company recognized revenue of $1.2 million, $0.7 million and $3.9 million, respectively, from the Company s subcontract under the NIAID Contract.

Revenue under the Company s subaward with respect to the NIAID Grant is earned under a cost-reimbursable contract in which the Company is reimbursed for direct costs incurred plus allowable indirect costs. Billings under the Company s subaward under the NIAID Grant are based on approved provisional indirect billing rates, which permit recovery of fringe benefits and allowable general and administrative expenses. During the three months ended June 30, 2013 and 2012, the Company recognized revenue of $78,000 and $43,000, respectively, from the Company s subaward under the NIAID Grant. During the six months ended June 30, 2013 and 2012 and the period from July 7, 2006 (inception) to June 30, 2013, the Company recognized revenue of $231,000, $98,000 and $506,000, respectively, from the Company s subaward under the NIAID Grant.

Organizational Costs

All organizational costs are expensed as incurred.

Research and Development Expenses

Research and development costs are charged to expense as incurred and include, but are not limited to:

- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;
- expenses incurred under agreements with contract research organizations, contract manufacturing organizations and consultants that conduct clinical trials and preclinical studies;
- payments made under the Company s license agreement with Harvard University;

the cost of acquiring, developing and manufacturing clinical trial materials;

facility, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies; and

costs associated with preclinical activities and regulatory operations.

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Costs for certain development activities, such as clinical trials, are recognized 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 the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development.

Comprehensive Loss

Comprehensive loss consists of net income or loss and changes in equity during a period from transactions and other events and circumstances generated from non-owner sources. The Company s net loss equals comprehensive loss for all periods presented.

Income Taxes

The Company uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial reporting and the tax reporting basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized. The Company has evaluated available evidence and concluded that the Company may not realize the benefit of its deferred tax assets; therefore a valuation allowance has been established for the full amount of the deferred tax assets. The Company s practice is to recognize interest and/or penalties related to income tax matters in income tax expense.

Stock-Based Compensation Expense

Stock-based compensation is recognized as expense for all stock-based awards based on estimated fair values. The Company determines equity-based compensation at the grant date using the Black-Scholes option pricing model. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period using the estimated fair market value of the stock. Any changes to the estimated forfeiture rates are accounted for prospectively.

Recent Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board (FASB) issued FASB Accounting Standards Update (ASU) No. 2013-02, *Comprehensive Income (Topic 220) Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income* (ASU 2013-02). ASU 2013-02 requires an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, an entity is required to present, either on the face of the financial statements or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income, but only if the amount reclassified is required under GAAP to be reclassified to net income in its entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional details about those amounts. ASU 2013-02 is effective prospectively for reporting periods beginning after December 15, 2012. The adoption of this ASU did not have an impact on the Company s condensed consolidated financial statements.

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

Net Loss per Common Share

Basic net loss per share is calculated by dividing the net loss applicable to common stockholders by the weighted average number of shares of Common Stock outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss applicable to common stockholders by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, preferred stock, stock options 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.

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Effective as of the completion of the IPO, all of the Company s preferred stock was converted to common stock at a 1-for-29 ratio as a result of the Reverse Split. For purposes of calculating net loss per common share for the three and six months ended June 30, 2013 and the period from July 7, 2006 (inception) to June 30, 2013, the preferred stock that converted to common stock was included in the net loss per common share calculation on a post-conversion basis as of March 25, 2013, the effective date of conversion, and the corresponding converted shares were included on a pro-rata basis for each applicable reporting period. As a result, the weighted-average common shares outstanding during the three and six months ended June 30, 2013 and the period from July 7, 2006 (inception) to June 30, 2013, was 20.6 million, 11.3 million and 1.0 million, respectively, as compared to 20.7 million shares outstanding as of June 30, 2013.

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

	June 30,		The Period from July 7, 2006 (inception) to June 30, 2013
	2013	2012	
Preferred stock		8,828,438	
Warrants	104,107	54,751	104,107
Outstanding stock options	2,686,892	1,446,491	2,686,892

(3) Significant Agreements and Contracts

License Agreement

In August 2006, the Company entered into a license agreement for certain intellectual property with Harvard University (the University). The agreement required the Company to pay a nonrefundable license fee of $250,000 and certain accrued patent expenses of approximately $61,000, and to issue 31,379 shares of common stock to the University upon the closing of a successful financing. Such consideration, which totaled $312,000, was recorded in research and development expenses in 2006.

The Company is obligated to make certain payments totaling up to, approximately $15.1 million upon achievement of certain development and regulatory milestones and royalties on net sales of products covered by the agreement. The Company made no payments to the University during the three and six months ended June 30, 2013 and June 30, 2012. The Company has made a total of $1.7 million in upfront and milestone payments to the University since inception.

In January 2007 and April 2010, the Company and the University amended the license agreement to include certain additional intellectual property. The Company paid an additional $25,000 with each amendment. In February 2011, the license agreement was further amended to include additional intellectual property in the license granted by the University without the payment of any additional consideration.

Government Grant and Contracts

BARDA Contract for Eravacycline

The Company has received funding for its lead product candidate, eravacycline, under an award from BARDA. In January 2012, BARDA awarded a five-year contract that provides for up to a total of $67.0 million in funding for the development, manufacturing and clinical evaluation of eravacycline for the treatment of disease caused by bacterial biothreat pathogens.

In connection with the BARDA Contract, in February 2012, the Company entered into a five-year cost-plus-fixed-fee subcontract with CUBRC under which it may receive funding of up to approximately $39.8 million, reflecting the portion of the BARDA 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 five-year terms, 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. As of June 30, 2013, committed funding from CUBRC under the Company s BARDA subcontract has increased by $9.3 million from $6.3 million during the original twelve-month base period ended January 31, 2013 to $15.6

million through the current contract end date, which has been extended to April 30, 2015 as a result of the exercise of several options by BARDA under the BARDA Contract. Total funds of $7.5 million have been received by the Company through June 30, 2013 under this contract.

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NIAID Grant and Contract for TP-271

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

- the NIAID Grant awarded in July 2011 that provides up to a total of approximately $2.8 million over five years; and
- the NIAID Contract awarded in September 2011 that provides up to a total of approximately $35.8 million in funding over five years.

In connection with the NIAID Grant, in November 2011, CUBRC awarded the Company a 55-month, no-fee subaward of approximately $980,000, reflecting the portion of the NIAID Grant funding that may be paid to the Company for its activities.

In connection with the NIAID Contract, in October 2011, the Company entered into a five-year cost-plus-fixed-fee subcontract with CUBRC under which the Company may receive funding of up to approximately $13.3 million, reflecting the portion of the NIAID Contract funding that may be paid to the Company for its activities.

Although the NIAID Contract, the NIAID Grant and the Company s subcontract with CUBRC under the NIAID Contract have terms of five years, and the Company s subaward under the NIAID Grant has a term of 55 months, NIAID is entitled to terminate the project for convenience at any time, and is not obligated to provide continued funding beyond September 30, 2016. To the extent NIAID ceases to provide funding of the programs to CUBRC, CUBRC has the right to cease providing funding to the Company. As of June 30, 2013, committed funding from CUBRC under the Company s subcontract with respect to the NIAID Contract has increased by $1.6 million from $5.9 million during the original 25-month base period ended October 31, 2013 to $7.5 million through the current contract end date which has been extended to September 30, 2016. Total funds of $3.4 million had been received through June 30, 2013. Committed funding from CUBRC under the Company s subaward with respect to the NIAID Grant increased by $0.1 million during the three months ending June 30, 2013 from $0.6 million to $0.7 million through the current contract end date, which was extended from May 31, 2013 to May 31, 2016. Total funds of $0.4 million had been received through June 30, 2013.

(4) Accrued Expenses

Accrued expenses at June 30, 2013 and December 31, 2012 consisted of the following (in thousands):

	June 30, 2013	December 31, 2012
Clinical	$ 1,231	$ 470
Salaries and benefits	875	963
Manufacturing	616	210
Professional fees	225	320
Other	288	340
Total	$ 3,235	$ 2,303

(5) Long-Term Debt

In May 2011, the Company executed the Term Loan with Silicon Valley Bank and Oxford Finance, which provided for up to $8.0 million funding, to be made available in two tranches. The Company borrowed the first $1.5 million in May 2011 and the second tranche for the remaining $6.5 million in December 2011. The Term Loan bears interest at 10% per annum and provides for a final payment of 2.75% of the original principal due at the maturity date of November 1, 2014. Under the terms of the Term Loan, the Company was only required to pay interest (and not principal) on the first tranche and the second tranche through February 28, 2012. Each tranche will be repaid in 33 monthly payments of equal principal, plus accrued interest, after the interest only period which ended February 28, 2012. The final payment of 2.75%

will be due at the same time as the last loan payment. The Term Loan matures on November 1, 2014. In connection with the entry into the Loan and Security Agreement, the Company issued to the lenders 10-year warrants to purchase an aggregate of 1,555,815 shares of Series C Preferred Stock at a price of $0.2571 per share.

In December 2012, the Company amended the Term Loan to provide for up to an additional $9.2 million in funding, to be made available in two tranches (2012 Term Loan). The Company borrowed the first $6.2 million under the 2012 Term Loan in December 2012 (2012 Term A Loan) and borrowed the remaining $3.0 million in February 2013 (2012 Term B Loan). Both the 2012 Term Loan A and the 2012 Term B Loan bear interest at 9% per annum.

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The Company is only required to pay interest (and not principal) for the first six months of each tranche of the 2012 Term Loan. Each tranche of the 2012 Term Loan is to be repaid in 33 equal monthly payments of principal, plus accrued interest, after the interest only period. An additional payment of 2.90% of the original principal amount of each tranche will be due at the same time as the last loan payment for the tranche. The 2012 Term A Loan matures on March 1, 2016. In connection with the funding of the 2012 Term A Loan, the Company issued to the lenders 10-year warrants to purchase an aggregate of 964,605 shares of Series C Preferred Stock with an exercise price of $0.2571 per share. The 2012 Term B Loan matures on May 1, 2016. In connection with the funding of the 2012 Term B Loan, in February 2013, the warrant the Company issued to Silicon Valley Bank automatically became exercisable for an additional 233,372 shares of Series C Preferred Stock. In addition, the Company issued to Oxford Finance a 10-year warrant to purchase an additional 233,372 shares of Series C Preferred Stock with an exercise price of $0.2571 per share. The Company initially valued the warrants issued in 2013 at $115,000 using the Black-Scholes option pricing model with the following assumptions: risk-free interest rate of 1.89%, dividend yield of zero, expected volatility rate of 59% and an expected life of ten years. The Company is expensing this value of the warrant as additional interest over the term of the loan. The warrant was classified as a liability in accordance with Accounting Standards Codification (ASC) 480 and was subject to remeasurement at each balance sheet date and changes to the fair value were recognized as a component of other income (expense) in the statement of operations and comprehensive loss.

Upon completion of the IPO, the warrants related to the Term Loan became exercisable for 53,648 shares of the Company s common stock at an exercise price of $7.46 per share, the warrants related to the 2012 Term A Loan became exercisable for 33,262 shares of the Company s common stock at an exercise price of $7.46 per share and the warrants related to the 2012 Term B Loan became exercisable for 16,094 shares of the Company s common stock at an exercise price of $7.46 per share. On the date of the conversion of the warrants, the Company revalued the outstanding warrants using the Black-Scholes option pricing model with the following assumptions: risk-free interest rate of 0.67% to 1.84%, dividend yield of zero, expected volatility rate of 59%, expected term of 5 to 10 years and stock price of $7.00. The fair value of the warrants at March 25, 2013 was $462,000. The Company recorded other income of $263,000 in the statement of operations and comprehensive loss during the three and six months ended June 30, 2013 equal to the change in fair value of the warrants from December 31, 2012 to March 25, 2013. The Company reclassified the fair value of the warrants at March 25, 2013, of $462,000, to additional paid-in capital.

The Term Loan and the 2012 Term Loan are collateralized by a blanket lien on all corporate assets, excluding intellectual property, and by a negative pledge of the Company s intellectual property. The Term Loan and the 2012 Term Loan contain customary default provisions that include material adverse events, as defined therein. The Company has determined that the risk of subjective acceleration under the material adverse events clause is remote and therefore has classified the outstanding principal in current and long-term liabilities based on scheduled principal payments.

Future principal payments on the Term Loan and the 2012 Term Loan are as follows (amounts in thousands):

Years Ending December 31:	
2013 (6 months remaining)	$ 2,823
2014	6,126
2015	3,513
2016	1,132
Total term loan principal payments	13,594
Current term loan payable	5,949
Less debt discount and issuance costs	(267)
Current term loan payable (net)	5,682
Term loan payable, less current portion	7,645
Less debt discount and issuance costs	(167)
Term loan payable, net	$ 7,478

(6) Stockholders Equity (Deficit)

Initial Public Offering

In March 2013, the Company completed its IPO, issuing 10,714,286 shares of common stock at a price to the public of $7.00 per share, resulting in net proceeds to the Company of $68.1 million after deducting underwriting discounts of $4.4 million and offering costs of $2.5 million.

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In connection with the IPO, all of the Company s outstanding preferred stock automatically converted into a total of 8,828,438 shares of its common stock, and the Company reclassified the preferred stock warrant liability of $0.5 million to additional paid-in capital upon the conversion of warrants to purchase preferred stock into warrants to purchase common stock.

On April 12, 2013, the Company completed the sale of an additional 797,792 shares of Common Stock under the underwriters option in the IPO at a price to the public of $7.00 per share, resulting in net proceeds to the Company of $5.2 million after deducting underwriting discounts and commissions.

(7) Stock-based Compensation

In August 2006, the Company adopted the Tetraphase Pharmaceuticals, Inc. Stock Incentive Plan (the 2006 Plan) under which it may grant incentive stock options, nonqualified stock options, restricted stock, and stock grants to purchase up to 1,128,183 shares of Common Stock. In May 2010, the Company amended the plan to increase the number of shares of Common Stock issuable under the 2006 Plan to 1,853,288. The options expire ten years after the grant date. As of June 30, 2013, no shares were available for future issuance under the 2006 Plan.

In February 2013, the Company s board of directors and stockholders approved, effective upon the closing of the IPO, the 2013 Stock Incentive Plan (the 2013 Plan). Under the 2013 Plan, the Company may grant incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards for the purchase of that number of shares of Common Stock equal to the sum of (i) 1,688,777 shares of Common Stock, (ii) 258,265 shares of Common Stock that were reserved for issuance under the 2006 Plan that remained available for issuance under the 2006 Plan upon the closing of the IPO, (iii) any shares of Common Stock subject to awards under the 2006 Plan which awards expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company without having been fully exercised or resulting in any Common Stock being issued. In addition, the number of shares of Common Stock that may be issued under the 2013 Plan is subject to automatic annual increases, to be added on January 1 of each year from January 1, 2014 through and including January 1, 2023, equal to the lowest of the number of shares that is the lesser of (a) 3,000,000, (b) 4% of the then outstanding shares of Common Stock or (c) an amount determined by the Company s board of directors. As of June 30, 2013, 696,102 shares were available for future issuance under the 2013 Plan.

Terms of stock award agreements, including vesting requirements, are determined by the board of directors, subject to the provisions of the 2013 Plan. Options granted by the Company typically vest over a four year period. Certain of the options are subject to acceleration of vesting in the event of certain change of control transactions. The options are exercisable from the date of grant for a period of ten years. For options granted to date, the exercise price equaled the estimated fair value of the Common Stock as determined by the board of directors on the date of grant.

The following table summarizes stock option activity at June 30, 2013 and changes during the six months then ended is presented in the table and narrative below (in thousands except share and per share data):

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2012	1,442,810	$ 1.67	7.43	$ 10,569
Granted	1,250,940	7.87		
Exercised	(6,176)	1.58		
Forfeited				
Canceled	(686)	0.87		
Options outstanding at June 30, 2013	2,686,888	$ 4.55	8.30	$ 7,703
Options vested or expected to vest at June 30, 2013 (1)	2,628,763	$ 4.52	8.28	$ 7,615
Options exercisable at June 30, 2013	1,081,022	$ 1.61	6.61	$ 5,865

(1) This represents the number of vested stock options as of June 30, 2013, plus the number of unvested stock options that the Company estimated as of June 30, 2013 would vest, based on the unvested stock options at June 30, 2013, as adjusted for the estimated forfeiture rate of 2%.

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Stock-based compensation expense recognized in the Company s condensed consolidated statements of operations for stock options granted during the periods presented was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,		The Period from July 7, 2006 (inception) to June 30, 2013
	2013	2012	2013	2012	
Research and development	$ 140	$ 121	$ 152	$ 160	$ 1,148
General and administrative	140	32	183	62	733
Total	$ 280	$ 153	$ 335	$ 222	$ 1,881

As of June 30, 2013, approximately $5.6 million of total unrecognized stock-based compensation expense related to unvested stock options is expected to be recognized over a weighted-average period of 3.7 years.

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

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, 2012, and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, contained in our prospectus filed with the United States Securities and Exchange Commission, or the SEC, pursuant to Rule 424(b)(4) on March 20, 2013, which we refer to as the Prospectus. 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 clinical stage biopharmaceutical company using our proprietary chemistry technology to create novel antibiotics for serious and life-threatening multi-drug resistant infections. Our lead product candidate, eravacycline, is a fully synthetic tetracycline derivative that we are developing as a broad-spectrum intravenous and oral antibiotic for use as a first-line empiric monotherapy for the treatment of multi-drug resistant infections, including multi-drug Gram-negative infections. We have completed a successful Phase 2 clinical trial of eravacycline with intravenous administration for the treatment of patients with complicated intra-abdominal infections, or cIAI, in 2012. We plan to conduct two global Phase 3 clinical trials of eravacycline, one for the treatment of cIAI, which we expect to commence in the third quarter of 2013, and one for the treatment of complicated urinary tract infections, or cUTI, which we expect to commence in the fourth quarter of 2013. We are currently finalizing our plans for the Phase 3 program for eravacycline. We are also conducting a Phase 1 clinical program evaluating the pharmacokinetics and safety of oral formulations of eravacycline which we expect to complete in the second half of 2013. Subject to obtaining additional financing, we intend to pursue development of eravacycline for the treatment of additional indications, including acute bacterial skin and skin structure infections, or ABSSSI, acute bacterial pneumonias and other serious and life-threatening infections. We are also pursuing the discovery and development of additional antibiotics to target unmet medical needs.

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. To date, we have not generated any product revenue and have primarily financed our operations through the public offering and private placement of our equity securities, debt financings and revenue from government awards. As of June 30, 2013, we had received an aggregate of $171.8 million in net proceeds from the issuance of equity securities and borrowings under debt facilities and an aggregate of $11.3 million from government grants and contracts. As of June 30, 2013, our principal source of liquidity was cash and cash equivalents, which totaled $77.2 million.

As of June 30, 2013, we had a deficit accumulated during the development stage of $98.3 million. Our net losses were $5.4 million and $8.2 million for the three and six months ended June 30, 2013, respectively. Our net losses were $4.3 million and $9.0 million for the three and six months ended June 30, 2012, respectively. We expect that our expenses will increase substantially as we commence our Phase 3 clinical trials of eravacycline for the treatment of patients with cIAI and cUTI, respectively, pursue development of an oral formulation of eravacycline, seek marketing approval for eravacycline, pursue development of eravacycline for additional indications, including ABSSSI, acute bacterial pneumonias and other serious and life-threatening infections, advance our other product candidates and satisfy our obligations under our license agreement with Harvard University. If we obtain marketing approval of eravacycline, we also expect to incur significant sales, marketing, distribution and outsourced manufacturing expenses, as well as ongoing research and development expenses. Furthermore, we expect to incur additional costs associated with operating as a public company and expect that our general and administrative costs will increase as we grow and operate as a public company. We will need to generate significant revenue to achieve profitability, and we may never do so.

We believe that our available funds will be sufficient to enable us to obtain top-line data from both of our planned Phase 3 clinical trials of eravacycline. We expect that these funds will not, however, be sufficient to enable us to seek marketing approval for eravacycline or commercially launch eravacycline. It is also possible that we will not achieve the progress that we expect with respect to eravacycline because the actual costs and timing of clinical development activities are difficult to predict and are subject to substantial risks and delays. In particular, we have not yet finalized our plans for our Phase 3 clinical trial of eravacycline for the treatment of cUTI. We will be required to obtain further funding through public or private equity offerings, debt financings, collaboration and licensing arrangements or other sources in order to continue to fund our operations after the first quarter of 2015. 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.

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Financial overview

Contract and Grant Revenue

We have derived all of our revenue to date from funding provided under three U.S. government awards for the development of our compounds as potential counter measures for the treatment of disease caused by bacterial biothreat pathogens through our collaborator CUBRC Inc., or CUBRC, an independent, not-for-profit, research corporation that specializes in U.S. government-based contracts:

- We have received funding for our lead product candidate, eravacycline, 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 CUBRC a five-year contract that provides for up to a total of $67.0 million in funding for the development, manufacturing and clinical evaluation of eravacycline for the treatment of disease caused by bacterial biothreat pathogens. We refer to this contract as the BARDA Contract.

- We have received funding for our preclinical compound TP-271 under two awards from the National Institute of Allergy and Infectious Diseases, or NIAID, a division of National Institutes of Health, 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:

  - a grant awarded to CUBRC in July 2011 that provides up to a total of approximately $2.8 million over five years, which we refer to as the NIAID Grant, and

  - a contract awarded to CUBRC in September 2011 that provides up to a total of approximately $35.8 million in funding over five years, which we refer to as the NIAID Contract.

We are collaborating with CUBRC because when we initially determined to seek government funding we recognized that we did not have any expertise in bidding for, or the administration and management of, government-funded contracts. CUBRC serves as the prime contractor under the BARDA Contract, the NIAID Grant and the NIAID Contract, primarily carrying out a program management and administrative role with additional responsibility for the management of preclinical studies. We serve as lead technical expert on all aspects of these awards and also serve as a subcontractor responsible for management of chemistry, manufacturing and control activities and clinical studies. We derive all of our revenue under these collaborations through subcontracts with, and a subaward from, CUBRC, with the flow of funds following the respective activities being conducted by us and by CUBRC.

- In connection with the BARDA Contract, in February 2012, we entered into a five-year cost-plus-fixed-fee subcontract with CUBRC under which we may receive funding of up to approximately $39.8 million, reflecting the portion of the BARDA Contract funding that may be paid to us for our activities.

- In connection with the NIAID Contract, in October 2011, we entered into a five-year cost-plus-fixed-fee subcontract with CUBRC under which we may receive funding of up to approximately $13.3 million, reflecting the portion of the NIAID Contract funding that may be paid to us for our activities.

- In connection with the NIAID Grant, in November 2011, CUBRC awarded us a 55-month, no-fee subaward of approximately $980,000, reflecting the portion of the NIAID Grant funding that may be paid to us for our activities.

Although the BARDA Contract, and our subcontract with CUBRC under the BARDA Contract, have five-year terms, 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. As of June 30, 2013, committed funding from CUBRC under the BARDA subcontract has increased by $9.3 million from $6.3 million during the original twelve-month base period ended January 31, 2013 to $15.6 million through the current contract end date, which has been extended to April 30, 2015 as a result of the exercise of several options by BARDA under the BARDA Contract. Total funds of $7.5 million had been received through June 30, 2013 under this contract.

Similarly, although the NIAID Contract, the NIAID Grant and our subcontract with CUBRC under the NIAID Contract have terms of five years, and our subaward under the NIAID Grant has a term of 55 months, NIAID is entitled to terminate the project for convenience at any time, and is not obligated to provide continued funding beyond the original 25-month base period ended September 30, 2016. To the extent NIAID ceases to provide funding of the programs to CUBRC, CUBRC has the right to cease providing funding to us. As of June 30, 2013, committed funding from CUBRC under our subcontract with

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respect to the NIAID Contract has increased by $1.6 million from $5.9 million during the original 25-month base period ended October 31, 2013 to $7.5 million through the current contract end date, which has been extended to September 30, 2016. Total funds of $3.4 million had been received through June 30, 2013. Committed funding from CUBRC under our subaward with respect to the NIAID Grant increased by $0.1 million during the three months ended June 30, 2013 from $0.6 million to $0.7 million through the current contract end date, which has been extended from May 31, 2013 to May 31, 2016. Total funds of $0.4 million had been received through June 30, 2013.

We have no products approved for sale. Other than the government funding described above, we do not expect to receive any revenue from any product candidates that we develop, including eravacycline, until we obtain regulatory approval and commercialize such products, which we do not expect will occur before 2016, or until we potentially enter into collaborative agreements with third parties for the development and commercialization of such product candidates. We continue to pursue government funding for other preclinical and clinical programs. If our development efforts for any of our product candidates result in clinical success and regulatory approval, or collaboration agreements with third parties, we may generate revenue from those product candidates.

We expect that our revenue will be less than our expenses for the foreseeable future and that we will experience increasing losses as we continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. 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, which include:

- employee-related expenses, including salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations, or CMOs, and consultants that conduct our clinical trials and preclinical activities;
- payments made under our license agreement with Harvard University;
- the cost of acquiring, developing and manufacturing clinical trial materials and lab supplies; and
- facility, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies.

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.

The following table identifies research and development expenses on a program-specific basis for our product candidates for the three and six months ended June 30, 2013, and 2012. 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 in the table below.

	Three Months Ended June 30,	Six Months Ended June 30,	The Period from July 7, 2006 (inception) to June 30, 2013

	2013	2012	2013	2012	
			(in thousands)		
Eravacycline	$ 2,790	$ 2,399	$ 3,781	$ 4,411	$ 34,506
BARDA Contract	3,001	544	4,721	626	9,000
NIAID Contract and NIAID Grant	568	393	1,391	794	4,101
Other development programs	262	337	394	646	20,842
Other research and development	303	588	735	1,785	17,680
Total research and development expenses	$ 6,924	$ 4,261	$ 11,022	$ 8,262	$ 86,129

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.

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As of June 30, 2013, we had incurred an aggregate of $34.5 million in research and development expenses related to the development of eravacycline. We expect that our research and development expenses will increase as we plan for and commence our two planned Phase 3 clinical trials of eravacycline, one for the treatment of cIAI, which we expect to commence in the third quarter of 2013, and one for the treatment of cUTI, which we expect to commence in the fourth quarter of 2013. We expect that our Phase 3 clinical trial for the treatment of cIAI will be a global, multi-center, randomized, double-blind trial to evaluate the efficacy and safety of eravacycline compared to ertapenem and that we will enroll 536 patients in the trial. We are currently finalizing our plans for our Phase 3 clinical trial of eravacycline for cUTI. Subject to finalizing our plans for the cUTI clinical trial, we expect that the total external costs of the Phase 3 clinical trials of eravacycline will be approximately $50.0 million, including approximately $11.8 million in 2013, exclusive of the $2.0 million milestone payment described below that would become due to Harvard University upon dosing of the first patient in the first of these Phase 3 clinical trials.

Because of the numerous risks and uncertainties associated with product development, however, we cannot determine with certainty the duration and completion costs of these or other current or future clinical trials of eravacycline or our other product candidates. We may never succeed in achieving regulatory approval for eravacycline or any of our other 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 University on an exclusive worldwide basis under a license agreement that we entered into in August 2006. Under the license agreement, we have paid Harvard an aggregate of $1.7 million in upfront license fees and development milestone payments, and issued 31,379 shares of our common stock to Harvard. In addition, we have agreed to make payments to Harvard upon the achievement of specified future development and regulatory milestones totaling up to $15.2 million per licensed product and to pay tiered royalties in the single digits based on annual worldwide net sales, if any, of licensed products by us, our affiliates and our sublicensees. We are also obligated to pay Harvard a specified share of non-royalty sublicensing revenues that we receive from sublicensees for the grant of sublicenses under the license and to reimburse Harvard for specified patent prosecution and maintenance costs. The next milestone payment that we expect to make under the license agreement is a $2.0 million payment that will become due to Harvard upon dosing of the first patient in our first Phase 3 clinical trial of eravacycline.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs such as stock-based compensation and travel expenses for personnel in executive, finance, business development, and human resource functions. Other general and administrative expenses include facility costs not otherwise included in research and development expenses, patent filing fees, and professional fees for legal, consulting, auditing and tax services.

We anticipate that our general and administrative expenses will increase for, among others, the following reasons:

- support of the anticipated expansion of our research and development activities as we continue the development of our product candidates;
- increases in payroll, expansion of infrastructure and higher consulting, legal, accounting and investor relations costs, and directors and officers insurance premiums, all associated with being a public company; and
- if and when we believe a regulatory approval of our first product candidate appears likely, anticipated increases in our payroll and expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

Interest Income

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

Interest Expense

Interest expense consists primarily of interest accrued on our outstanding indebtedness and non-cash interest related to the amortization of debt discount costs associated with our term loan facility with Silicon Valley Bank and Oxford Finance. We expect that our interest expense will increase in future periods in connection with additional indebtedness of $6.2 million that we borrowed in December 2012 under an amendment to our loan and security agreement with Silicon Valley Bank and Oxford Finance and an additional $3.0 million of indebtedness we borrowed in February 2013 under this debt facility.

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Other Income (Expense)

Other income (expense) consists of fair value adjustments on warrants for the purchase of our preferred stock, which was recorded during the three months ended March 31, 2013. We do not anticipate that we will recognize any further amounts with respect to these fair value adjustments as a result of the conversion of all outstanding warrants to purchase our preferred stock into warrants to purchase our common stock in connection with the completion of our initial public offering, or the IPO.

Critical Accounting Policies and Significant Judgments and Estimates

There have been no 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 the Prospectus, which was filed with the SEC on March 20, 2013 pursuant to Rule 424(b) under the Exchange Act.

Results of Operations

Comparison of the Three Months Ended June 30, 2013 and 2012

The following table summarizes the results of our operations for each of the three months ended June 30, 2013 and 2012, together with the changes in those items in dollars and as a percentage:

	Three Months Ended June 30,		Increase/ (decrease)	%
	2013	2012		
	(in thousands)			
Revenues	$ 3,722	$ 1,316	$ 2,406	183%
Operating expenses:				
Research and development	6,924	4,261	2,663	62%
General and administrative	1,756	1,002	754	75%
Total operating expenses	8,680	5,263	3,417	65%
Loss from operations	(4,958)	(3,947)	(1,011)	26%
Interest income	2		2	100%
Interest expense	(470)	(216)	(254)	118%
Other expense		(105)	105	(100)%
Net loss	$ (5,426)	$ (4,268)	$ (1,158)	27%

The following table sets forth our contract and grant revenue for the three months ended June 30, 2013 and 2012:

Revenue	Three Months Ended June 30,		Increase/ (decrease)	%
	2013	2012		
	(in thousands)			
BARDA	$ 3,122	$ 895	$ 2,227	249%
NIAID Contract	522	378	144	38%
NIAID Grant	78	43	35	81%
	$ 3,722	$ 1,316	$ 2,406	183%

Contract and grant revenue was $3.7 million for the three months ended June 30, 2013 compared to $1.3 million for the three months ended June 30, 2012, an increase of $2.4 million, or 183%. This increase was primarily due to an increase in the activities under our subcontract with respect to the BARDA Contract related to various clinical studies conducted during the quarter ended June 30, 2013, as well as an increase in activities under our subcontract with respect to the NIAID Contract and our subaward with respect to the NIAID Grant.

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Research and Development Expenses

Research and development expenses for the three months ended June 30, 2013 were $6.9 million compared to $4.3 million for the three months ended June 30, 2012, an increase of approximately $2.7 million or 62%. This increase was primarily due to an increase of $2.6 million in expenses related to activities having increased under our subcontracts with CUBRC with respect to the BARDA Contract and the NIAID Contract and our subaward with respect to the NIAID Grant; an increase of $1.3 million in clinical costs associated with the preparation for our Phase 3 clinical trials of eravacycline; and an increase of $0.5 million in clinical and drug manufacturing costs associated with our ongoing Phase 1 clinical program for the oral formulation of eravacycline. These increases were partially offset by a decrease in clinical and drug manufacturing costs of $1.8 million attributable to the completion of our Phase 2 clinical trial of eravacycline in the first half of 2012.

General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2013 were $1.8 million compared to $1.0 million for the three months ended June 30, 2012, an increase of approximately $0.8 million or 75%. This increase was primarily due to an increase of $0.5 million in audit, legal, insurance and consulting costs primarily due to being a public company; and an increase in personnel-related costs of $0.3 million mainly to support our increased activities related to the NIAID Contract, the BARDA Contract and the NIAID Grant.

Interest Income

Interest income for the three months ended June 30, 2013 and June 30, 2012 was immaterial.

Interest Expense

Interest expense for the three months ended June 30, 2013 was $0.5 million compared to $0.2 million for the three months ended June 30, 2012, an increase of approximately $0.3 million or 118%. The increase in interest expense was primarily attributable to an increase in debt under the term loan facility with Silicon Valley Bank and Oxford Finance associated with our borrowings in December 2012 and February 2013.

Other Income (Expense)

Other expense for the three months ended June 30, 2012 was $0.1 million, with no expense for the comparable period in 2013. Other expense during the three months ended June 30, 2012 consisted of fair value adjustments on warrants for the purchase of our preferred stock. We do not anticipate that we will recognize any further amounts with respect to these fair value adjustments as a result of the conversion of all outstanding warrants to purchase our preferred stock into warrants to purchase our common stock in connection with the completion of our IPO.

Comparison of the Six Months Ended June 30, 2013 and 2012

The following table summarizes the results of our operations for each of the six months ended June 30, 2013 and 2012, together with the changes in those items in dollars and as a percentage:

	Six Months Ended June 30,		Increase/ (decrease)	%
	2013	2012		
	(in thousands)			
Revenues	$ 6,422	$ 1,823	$ 4,599	252%
Operating expenses:				
Research and development	11,022	8,262	2,760	33%
General and administrative	2,981	1,963	1,018	52%
Total operating expenses	14,003	10,225	3,778	37%
Loss from operations	(7,581)	(8,402)	821	(10)%
Interest income	2		2	100%
Interest expense	(901)	(450)	(451)	100%

Other income (expense)	263	(105)	368	(350)%
Net loss	$ (8,217)	$ (8,957)	$ 740	(8)%

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The following table sets forth our contract and grant revenue for the six months ended June 30, 2013 and 2012:

Revenue	Six Months Ended June 30, 2013	2012	Increase/ (decrease)	%
		(in thousands)		
BARDA	$ 4,955	$ 979	$ 3,976	406%
NIAID Contract	1,236	746	490	66%
NIAID Grant	231	98	133	136%
	$ 6,422	$ 1,823	$ 4,599	252%

Contract and grant revenue was $6.4 million for the six months ended June 30, 2013 compared to $1.8 million for the six months ended June 30, 2012, an increase of $4.6 million, or 252%. This increase was primarily due to revenue associated with an increase in the activities under our subcontract with respect to the BARDA Contract, as well as an increase in activities under our subcontract with respect to the NIAID Contract and our subaward with respect to the NIAID Grant.

Research and Development Expenses

Research and development expenses for the six months ended June 30, 2013 were $11.0 million compared to $8.3 million for the six months ended June 30, 2012, an increase of approximately $2.8 million or 33%. This increase was primarily due to an increase of $4.7 million in expenses related to activities under our subcontracts with CUBRC with respect to the BARDA Contract, and the NIAID Contract and our subaward with respect to the NIAID Grant; an increase of $1.3 million in clinical costs associated with the preparation for our Phase 3 clinical trials of eravacycline; and an increase of $0.9 million in clinical and drug manufacturing costs associated with the Phase 1 clinical trial of an oral formulation of eravacycline. These increases were partially offset by a decrease in clinical and drug manufacturing costs of $2.8 million attributable to the completion of our Phase 2 clinical trial of eravacycline in the first half of 2012; a decrease of $1.1 million resulting from the allocation of research and development resources related to activities under our subcontracts with CUBRC with respect to the BARDA Contract and the NIAID Contract and our subaward with respect to the NIAID Grant; and a decrease in expenses associated with other pipeline compounds of $0.3 million.

General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2013 were $3.0 million compared to $2.0 million for the six months ended June 30, 2012, an increase of $1.0 million or 52%. This increase was primarily due to an increase of $0.6 million in audit, legal, insurance and consulting costs primarily due to being a public company; and an increase in personnel-related costs of $0.3 million mainly to support our increased activities related to the BARDA Contract, the NIAID Contract and the NIAID Grant.

Interest Income

Interest income for the six-month periods ended June 30, 2013 and June 30, 2012 was immaterial.

Interest Expense

Interest expense for the six months ended June 30, 2013 was $0.9 million compared to $0.5 million for the six months ended June 30, 2012, an increase of approximately $0.5 million or 100%. The increase in interest expense was primarily attributable to an increase in debt under the term loan facility with Silicon Valley Bank and Oxford Finance associated with our borrowings in December 2012 and February 2013.

Other Income (Expense)

Other income (expense) for the six months ended June 30, 2013 was $0.3 million compared to $(0.1) million for the six months ended June 30, 2012. The increase in other income was primarily due to a decrease in the fair value of the underlying preferred stock, which impacted the fair value of our preferred stock warrants issued in connection with various debt financings. We do not anticipate that we will recognize any further amounts with respect to these fair value adjustments as a result of the conversion of all outstanding warrants to purchase our preferred stock into

warrants to purchase our common stock in connection with the completion of our IPO.

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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 that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may obtain from additional financings, research funding, collaborations, contract and grant revenue or other sources.

Since our inception, we have funded our operations principally through the receipt of funds from the placement of equity securities, debt financings and contract research funding and research grants from the United States government. As of June 30, 2013, we had cash and cash equivalents of approximately $77.2 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 June 30, 2013, our funds were held in cash and money market funds.

In March 2013, we completed the sale of 10,714,286 shares of common stock in our IPO at a price to the public of $7.00 per share, resulting in net proceeds to us of $68.1 million after deducting underwriting discounts and commissions of $4.4 million and offering costs of $2.5 million. In addition, we granted the underwriters a 30-day option to purchase up to 1,607,143 additional shares of common stock at the initial public offering price to cover over allotments, if any. On April 12, 2013, we completed the additional sale of 797,792 shares of common stock under this option at a price to the public of $7.00 per share, resulting in net proceeds to us of $5.2 million after deducting underwriting discounts and commissions.

On December 20, 2012, we amended our existing term loan facility with Silicon Valley Bank and Oxford Finance to provide for up to an additional $9.2 million in funding, to be made available in two tranches. We borrowed the first tranche of $6.2 million of the $9.2 million term loan facility in December 2012. We borrowed the second tranche of $3.0 million in February 2013. Each tranche bears interest at 9% per annum.

We are only required to pay interest, and not principal, for the first six months of each tranche of the $9.2 million term loan facility. Each tranche is to be repaid in 33 equal monthly payments of principal, plus accrued interest, after the interest only period. An additional payment of 2.9% of the original principal amount of each tranche will be due at the same time as the last loan payment for the tranche. The first tranche of $6.2 million matures on March 1, 2016. The second tranche of $3.0 million matures on May 1, 2016. The $9.2 million term loan is collateralized by a blanket lien on all corporate assets, excluding our intellectual property, and by a negative pledge on our intellectual property. In connection with the funding of the first tranche of $6.2 million, we issued to the lenders 10-year warrants to purchase an aggregate of 964,605 shares of Series C preferred stock with an exercise price of $0.2571 per share. In connection with the funding of the second tranche of $3.0 million, the warrant we issued to Silicon Valley Bank automatically became exercisable for an additional 233,372 shares of Series C preferred stock. In addition, we issued to Oxford Finance a 10-year warrant to purchase an additional 233,372 shares of Series C preferred stock with an exercise price of $0.2571 per share. Upon completion of the IPO the warrants issued in connection with first and the second tranches became exercisable for an aggregate of 49,356 shares of our common stock at an exercise price of $7.46 per share and the related warrant liability was reclassified to additional paid-in capital.

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

	Six Months Ended June 30,	
	2013	2012
Cash Flows from Continuing Operations:		
Net cash used in operating activities	$ (7,247)	$ (10,463)
Net cash used in investing activities	(22)	(10)
Net cash provided by (used in) financing activities	75,406	(837)
Net increase (decrease) in cash and cash equivalents	$ 68,137	(11,310)

During the six months ended June 30, 2013 and 2012, our operating activities used net cash of $7.2 million and $10.5 million, respectively. The use of net cash in both periods primarily resulted from our net losses and changes in our working capital accounts. The decrease in net cash used in operations for the six months ended June 30, 2013 as compared to the six months ended June 30, 2012 was due primarily to an increase in contract and grant revenue in connection with our subcontracts under the BARDA Contract and the NIAID Contract and our subaward under the NIAID Grant, offset in part by higher operating expenses during the six months ended June 30, 2013 of $14.0 million as compared to $10.2 million for the six months ended June 30, 2012.

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During the six months ended June 30, 2013 and 2012, our investing activities used net cash of $22,000 and $10,000, respectively. The use of net cash in both periods primarily resulted from purchases of property, plant and equipment to facilitate our increased research and development activities and increased headcount. The increase in net cash used in investing activities for the six months ended June 30, 2013 as compared to the six months ended June 30, 2012 was due to an increase in equipment purchased during the six months ended June 30, 2013 compared to the comparable time period in the prior year.

During the six months ended June 30, 2013 and 2012, our net cash provided by (used in) financing activities was $75.4 million and $(0.8) million, respectively. The net cash provided by financing activities during the six months ended June 30, 2013 was primarily related to IPO offering proceeds of $73.8 million and $3.0 million in borrowings that we made under our debt facility with Silicon Valley Bank and Oxford Finance, partially offset by repayments on our debt facility of $1.4 million. The net cash used in financing activities during the six months ended June 30, 2012 was due to $0.9 million in repayments that we made in 2012 under our debt facility with Silicon Valley Bank and Oxford Finance, partially offset by proceeds from stock option exercises of $0.1 million.

Operating Capital Requirements

We expect to incur increasing operating losses for at least the next several years as we commence our Phase 3 clinical trials of eravacycline for the treatment of patients with cIAI and cUTI, pursue development of an oral formulation of eravacycline, seek marketing approval for eravacycline, pursue development of eravacycline for additional indications, including ABSSSI, acute bacterial pneumonias and other serious and life-threatening infections, advance our other product candidates and satisfy our obligations under our license agreement with Harvard University. We may not be able to complete the development and initiate commercialization of eravacycline or our other product candidates if, among other things, our preclinical research and clinical trials are not successful, the Food and Drug Administration or the European Medicines Agency does not approve eravacycline or our other product candidates when we expect, or at all, or funding under the NIAID Contract, the NIAID Grant or the BARDA Contract is discontinued.

We believe that our existing cash and cash equivalents, will be sufficient to fund our operations through at least the first quarter of 2015 and to enable us to obtain top-line data from both of our planned Phase 3 clinical trials of eravacycline. We expect that these funds will not be sufficient to enable us to seek marketing approval for eravacycline or to commercially launch eravacycline.

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, 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:

- the timing, design and costs of our planned Phase 3 clinical trials of eravacycline, including our planned Phase 3 clinical trial of eravacycline for the treatment of cUTI, the design of which we are currently finalizing;
- the progress, timing and costs of developing an oral formulation of eravacycline for intravenous-to-oral step-down therapy, including planned clinical trials;
- the timing and costs of developing eravacycline for additional indications, including ABSSSI, acute bacterial pneumonias and other serious and life-threatening infections;
- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our other product candidates and potential product candidates;
- the amount of funding that we receive under our subcontracts under the BARDA Contract and the NIAID Contract and under our subaward under the NIAID Grant, and the activities funded under the BARDA Contract, the NIAID Contract and the NIAID Grant;

the number and characteristics of product candidates that we pursue;

the outcome, timing and costs of seeking regulatory approvals;

the costs of commercialization activities for eravacycline and other product candidates if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;

subject to receipt of marketing approval, revenue received from commercial sales of eravacycline;

the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;

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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; and

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

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, 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

During the six months ended June 30, 2013, there were no material changes to our contractual obligations and commitments described under *Management s Discussion and Analysis of Financial Condition and Results of Operations* in the Prospectus, which was filed with the SEC on March 20, 2013 pursuant to Rule 424(b)(4), except as follows:

On February 28, 2013, we borrowed $3.0 million under our debt facility with Silicon Valley Bank and Oxford Finance, or the 2012 Term B Loan. The 2012 Term B Loan bears interest at 9% per annum. We are only required to pay interest (and not principal) for the first six months following the borrowing date of the 2012 Term B Loan and the 2012 Term B Loan is to be repaid in 33 equal monthly payments of principal, plus accrued interest, after the interest only period. An additional payment of 2.90% of the original principal amount of the 2012 Term B Loan will be due at the same time as the last loan payment of the 2012 Term B Loan. In connection with the 2012 Term B Loan, a warrant, previously issued by us to Silicon Valley Bank, became exercisable for an additional 233,372 shares of Series C preferred stock. In addition, we issued a 10-year warrant to Oxford Finance to purchase an additional 233,372 shares of Series C preferred stock at an exercise price of $0.2571. Upon the completion of the IPO, these warrants were converted into warrants to purchase 16,094 common shares at a price of $7.46 per share.

Recent Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board, or FASB, issued FASB Accounting Standards Update, or ASU, No. 2013-02, *Comprehensive Income (Topic 220) Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*, or ASU 2013-02. ASU 2013-02 requires an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, an entity is required to present, either on the face of the financial statements or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income, but only if the amount reclassified is required under United States generally accepted accounting principles to be reclassified to net income in its entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional details about those amounts. ASU 2013-02 is effective prospectively for reporting periods beginning after December 15, 2012. The adoption of this ASU did not have an impact on our 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 six-month period ended June 30, 2013. For additional information regarding market risk, refer to the *Qualitative and Quantitative Disclosures About Market Risk* section of the Prospectus.

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes 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 applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2013, the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to the other information included in this quarterly report. If any of the following risks actually occurs, our business, financial condition or results of operations could be adversely affected, which, in turn, could have a negative impact on the price of our common stock.

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 $21.6 million for the year ended December 31, 2011, $15.1 million for the year ended December 31, 2012 and $8.2 million for the six months ended June 30, 2013. As of June 30, 2013, we had a deficit accumulated during the development stage of $98.3 million. We have not generated any product revenues and have financed our operations primarily through the public offering and private placements of our equity securities, debt financings and revenue from U.S. government awards. We have not completed development of any product candidate and have devoted substantially all of our financial resources and efforts to research and development, including preclinical and clinical development. We expect to continue to incur significant expenses and increasing 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 increase substantially as we commence our Phase 3 clinical trials of our lead product candidate, eravacycline, for the treatment of patients with complicated intra-abdominal infections, or cIAI, and complicated urinary tract infections, or cUTI, pursue development of an oral formulation of eravacycline, seek marketing approval for eravacycline, pursue development of eravacycline for additional indications, including acute bacterial skin and skin structure infections, or ABSSSI, acute bacterial pneumonias and other serious and life-threatening infections, advance our other product candidates and satisfy our obligations under our license agreement with Harvard University. If we obtain marketing approval of eravacycline, we also expect to incur significant sales, marketing, distribution and outsourced manufacturing expenses, as well as ongoing research and development expenses. Our expenses also will increase if and as we:

- maintain, expand and protect our intellectual property portfolio;
- in-license or acquire other products and technologies;
- hire additional clinical, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we obtain marketing approval for, and commercialize, eravacycline, which will require us to be successful in a range of challenging activities, including:

- commencing and successfully completing Phase 3 clinical trials of eravacycline;
- applying for and obtaining marketing approval for eravacycline;

protecting and maintaining our rights to our intellectual property portfolio related to eravacycline;

contracting for the manufacture of commercial quantities of eravacycline; and

establishing sales, marketing and distribution capabilities to effectively market and sell eravacycline.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, 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 we are required by the United States Food and Drug Administration, or FDA, or the European Medicines Agency, or EMA, to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates.

We may be unable to develop and commercialize eravacycline or any other product candidate 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

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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 you to lose all or part of your investment.

We expect that we will need substantial 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 and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete. We expect that our expenses will increase substantially as we commence our Phase 3 clinical trials of eravacycline, pursue development of an oral formulation of eravacycline, seek marketing approval for eravacycline, pursue development of eravacycline for additional indications, including ABSSSI, acute bacterial pneumonias and other serious and life-threatening infections, advance our other product candidates and satisfy our obligations under our agreement with Harvard. Subject to finalizing our plans for our Phase 3 clinical trial of eravacycline for the treatment of cUTI, we expect that the total external costs of our planned Phase 3 clinical trials of eravacycline will be approximately $50.0 million, including approximately $11.8 million in 2013. In addition, in connection with our license agreement with Harvard, we are obligated to pay Harvard a milestone payment of $2.0 million upon commencing our first Phase 3 clinical trial of eravacycline. If we obtain marketing approval for eravacycline or any other product candidate that we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing.

We believe that our available funds will be sufficient to enable us to obtain top-line data from both of our planned Phase 3 clinical trials of eravacycline. We expect that these funds will not, however, be sufficient to enable us to seek marketing approval for eravacycline or commercially launch eravacycline. It is also possible that we will not achieve the progress that we expect with respect to eravacycline because the actual costs and timing of clinical development activities are difficult to predict and are subject to substantial risks and delays. We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. 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.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through at least the first quarter of 2015. 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. Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- the timing, design and costs of our planned Phase 3 clinical trials of eravacycline, including our planned Phase 3 clinical trial of eravacycline for the treatment of cUTI, the design of which we are currently finalizing;
- the progress, timing and costs of developing an oral formulation of eravacycline for intravenous-to-oral step-down therapy, including planned clinical trials;
- the timing and costs of developing eravacycline for additional indications, including ABSSSI, acute bacterial pneumonias and other serious and life-threatening infections;
- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our other product candidates and potential 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 the activities funded under these contracts;

the number and characteristics of product candidates that we pursue;

the outcome, timing and costs of seeking regulatory approvals;

the costs of commercialization activities for eravacycline and other product candidates if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;

subject to receipt of marketing approval, revenue received from commercial sales of eravacycline;

the terms and timing of any future collaborations, licensing 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 pursuant to our license agreement;

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- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims;

- the costs of operating as a public company; and

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

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

Our only external source of funds is funding under subcontracts and a subaward awarded to us by CUBRC pursuant to government contracts from BARDA and NIAID and a grant from NIAID. Although the BARDA contract, and our subcontract with CUBRC under the BARDA contract, have five-year terms, 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. Committed funding from CUBRC under our BARDA subcontract is $15.6 million from the initial contract date through April 30, 2015, of which $7.5 million has been received through June 30, 2013. Although the NIAID contract has a term of five years, NIAID is entitled to terminate the project for convenience at any time, and is not obligated to provide continued funding beyond September 30, 2016. 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 $7.5 million, of which $3.4 million has been received through June 30, 2013. The NIAID grant and our subcontract with CUBRC have terms of 55 months. Committed funding from CUBRC under our subaward with respect to the NIAID grant is $0.7 million from the initial grant date through May 31, 2016, of which $0.4 million has been received through June 30, 2013.

As a result, unless and until we can generate a substantial amount of revenue from our 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 interests of our existing 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 the rights of holders of our common stock. 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 actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. For example, our debt facility with Silicon Valley Bank and Oxford Finance contains restrictive covenants that, subject to certain exceptions, prohibit us from transferring all or any part of our business or property, changing our business, liquidating or dissolving, merging with or acquiring another entity, entering into a transaction that will result in a change of control, incurring additional indebtedness, creating any lien on our property, paying dividends, entering into material transactions with affiliates, changing key management or adding new offices or business locations. Future debt securities or other financing arrangements could contain similar or more restrictive negative covenants. 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 of our 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 or product candidates or to grant licenses on terms that may not be favorable to us.

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 eravacycline and other product candidates. We have not yet demonstrated an ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or 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.

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Risks Related to Product Development and Commercialization

We are dependent on the success of our lead product candidate, eravacycline, and our ability to develop, obtain marketing approval for and successfully commercialize eravacycline. If we are unable to develop, obtain marketing approval for and successfully commercialize eravacycline or experience significant delays in doing so, our business could be materially harmed.

We currently have no products approved for sale and have invested a significant portion of our efforts and financial resources in the development of eravacycline for use as a first-line empiric monotherapy for the treatment of multi-drug resistant infections. Our prospects are substantially dependent on our ability to develop, obtain marketing approval for and successfully commercialize eravacycline. The success of eravacycline will depend on several factors, including the following:

- successful completion of clinical trials;
- development of an oral formulation of eravacycline to be used with the intravenous formulation of eravacycline in intravenous-to-oral step-down therapy;
- receipt of marketing approvals from applicable regulatory authorities;
- establishment of arrangements with third-party manufacturers to obtain manufacturing supply;
- obtainment and maintenance of patent and trade secret protection and regulatory exclusivity;
- protection of our rights in our intellectual property portfolio;
- launch of commercial sales of eravacycline, if and when approved, whether alone or in collaboration with others;
- acceptance of eravacycline, if and when approved, by patients, the medical community and third-party payors;
- competition with other therapies; and
- a continued acceptable safety profile of eravacycline following approval.

Successful development of eravacycline for additional indications, including ABSSSI, acute bacterial pneumonias and other serious and life-threatening infections, will be subject to these same risks.

If we are unable to develop, receive marketing approval for, or successfully commercialize eravacycline, or experience delays as a result of any of these matters or otherwise, our business could be materially harmed.

If we do not develop an oral formulation of eravacycline, or we are delayed in developing an oral formulation of eravacycline, our business may be harmed.

Optimal development of eravacycline includes the development of an oral formulation of eravacycline to be used with the intravenous formulation of eravacycline in intravenous-to-oral step-down therapy. Our ability to successfully develop an oral formulation of eravacycline is

uncertain. While we have completed multiple Phase 1 clinical trials of oral formulations of eravacycline, we have not yet selected a formulation for advancement in clinical trials and have not demonstrated in clinical trials that the necessary doses of oral eravacycline to achieve the necessary drug exposure levels can be administered with the required safety and tolerability. We commenced a Phase 1 clinical program evaluating the pharmacokinetics and safety of oral formulations of eravacycline in the first quarter of 2013. If the data from our Phase 1 clinical program are favorable, then, subject to regulatory review, we would plan to conduct our pivotal Phase 3 clinical trial of eravacycline for the treatment of cUTI as a Phase 3 clinical trial of the intravenous and oral formulations of eravacycline used in intravenous-to-oral step-down therapy for cUTI. However, if the data from the Phase 1 clinical program are not favorable or do not otherwise warrant proceeding with a Phase 3 clinical trial, we may need to conduct additional development, which could involve reformulating the compound and conducting additional clinical trials of the oral formulation, which could cause us to incur additional expenses in the development of the oral formulation of eravacycline. In addition, in such event we may be forced to modify the design of our planned Phase 3 clinical trial for the treatment of cUTI that we are considering, which could delay the commencement of the planned trial, extend the duration of the planned trial and increase the costs of the planned trial. If we choose to proceed with the Phase 3 clinical trial in cUTI with only the intravenous formulation, we would need to conduct at least one additional Phase 3 clinical trial of the oral formulation, which would take time and be expensive. If we are unable to develop an oral formulation of eravacycline to be used in intravenous-to-oral step-down therapy, it could lower the market opportunity for eravacycline and the potential value we could receive from eravacycline, and our business may be harmed.

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If clinical trials of eravacycline or of any other 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 or eravacycline or any other 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. We have not previously submitted an NDA to the FDA or similar drug approval filings to comparable foreign regulatory authorities for any of our product candidates.

The clinical development of eravacycline and other 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, although eravacycline achieved favorable results in our Phase 2 intravenous efficacy trial, we may nonetheless fail to achieve success in Phase 3 clinical trials of the intravenous formulation of eravacycline or in clinical trials of an oral formulation of eravacycline. Moreover, the primary endpoint that we anticipate using for our planned Phase 3 clinical trial of the intravenous formulation of eravacycline for cIAI differs from the primary endpoint we successfully achieved in our Phase 2 intravenous efficacy trial. In the FDA s recent draft guidance for drug development for cIAI, the FDA suggested that the primary efficacy endpoint for a trial for cIAI should be complete resolution of baseline signs and symptoms attributable to cIAI in the microbiological intent-to-treat patient population 28 days after randomization and the absence of clinical failure including death and unplanned surgical procedures through the period ending 28 days following randomization. Our Phase 2 primary endpoint was clinical response at the test of cure visit that took place ten to 14 days after the last dose of the drug was administered (approximately 16 to 21 days after randomization) in microbiologically evaluable patients, a narrower patient population. Clinical response was defined as complete resolution or significant improvement of signs or symptoms of infection with no further systemic antibiotic treatment required.

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 the case of our clinical trials, results may differ on the basis of the type of bacteria with which patients are infected. We cannot assure you that any Phase 2, Phase 3 or 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 eravacycline or any of our other 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 delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;

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;

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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 eravacycline, either in an intravenous or oral dosage form, or any other 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 eravacycline or our other 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 assure you 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 eravacycline or any other product candidate.

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

We may not be able to initiate or continue clinical trials for eravacycline or 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 eravacycline or 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.

The inclusion and exclusion criteria for our contemplated Phase 3 clinical trials of eravacycline may adversely affect our enrollment rates for patients in these trials. In addition, many of our competitors also have ongoing clinical trials for product candidates that treat the same indications as eravacycline, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors product candidates.

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Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, slow down or halt our product development and approval process and jeopardize our ability to commence product sales and generate revenues, which would cause the value of our company to decline and limit our ability to obtain additional financing if needed.

Serious adverse events or undesirable side effects or other unexpected properties of eravacycline 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 or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. If eravacycline or any of our other 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 eravacycline, some treatment-related adverse events have been reported. The most common treatment-related adverse events observed in clinical trials of eravacycline have been nausea and vomiting. Additional adverse events, undesirable side effects or other unexpected properties of eravacycline or 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, eravacycline or our other product candidates. If such an event occurs after eravacycline or such other product candidates are 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;
- 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 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.

Even if eravacycline or any other product candidate that we develop receives marketing approval, it 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 eravacycline or other product candidates may be smaller than we estimate.

We have never commercialized a product candidate for any indication. Even if eravacycline or any other product candidates that we develop are approved by the appropriate regulatory authorities for marketing and sale, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If physicians, rightly or wrongly, associate our product candidates with the resistance issues of other products of the same class, physicians might not prescribe our product candidates for treating a broad range of infections. If eravacycline or any other 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 eravacycline, if approved, or any other product candidate that is approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;

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the potential advantages of the product compared to alternative treatments;

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;

our ability to offer the product for sale at competitive prices;

the product s convenience and ease of administration compared to alternative treatments, including, in the case of eravacycline, the availability of an oral formulation for use in intravenous-to-oral step-down therapy;

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 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 eravacycline is difficult to precisely estimate. Our estimates of the potential market opportunity are predicated on several key assumptions such as industry knowledge and publications, 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 eravacycline could be smaller than our estimates of the potential market opportunity. If the actual market for eravacycline 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 establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing eravacycline or such other product candidates that we develop if and when eravacycline or any other product candidates are approved.

We do not have a sales, marketing or distribution infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. We intend to build a commercial organization in the United States and recruit experienced sales, marketing and distribution professionals. The development of sales, marketing and distribution capabilities will require substantial resources, will be time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization costs. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire a sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we intend to target. If we are unable to establish a sales force and marketing and distribution capabilities, our operating results may be adversely affected.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future 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 creating an independent sales and marketing organization.

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We plan to commercialize eravacycline outside the United States 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 these product revenues to us are likely to be lower than if we were to directly market and sell products in those markets. 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 our product candidates.

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 eravacycline and our other 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 multi-drug resistant 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 eravacycline or any other product candidates that we are currently developing or that we may develop, which could render our product candidates obsolete and noncompetitive.

There are a variety of available therapies marketed for the treatment of multi-drug resistant infections that we would expect would compete with eravacycline, including meropenem, which is marketed by AstraZeneca as Merrem, imipenem/cilastatin, which is marketed by Merck as Primaxin, tigecycline, which is marketed by Pfizer as Tygacil, levofloxacin, which is marketed by Ortho-McNeil and Johnson & Johnson as Levaquin, and piperacillin/tazobactam, which is marketed by Pfizer as Zosyn. 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. If eravacycline is approved, it may be priced at a significant premium over other competitive products. This may make it difficult for eravacycline to compete with these products.

There are also a number of products in clinical development by third parties to treat multi-drug resistant infections, including ceftazidime/avibactam, which is being developed by AstraZeneca, and cefalozine/tazobactam, which is being developed by Cubist. If our competitors obtain marketing approval from the FDA or comparable foreign regulatory authorities for their product candidates more rapidly than us, it could result in our competitors establishing a strong market position before we are able to enter the market.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products 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 Generating Antibiotics Incentives Now Act, or 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 eravacycline and our other product candidates. In July 2013, the FDA designated the intravenous formulation of eravacycline as a qualified infectious disease product.

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

Marketing approvals, pricing 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 licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay 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 eravacycline 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 health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. 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. Moreover, eligibility for reimbursement 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 on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services.

In addition, 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. We cannot be sure that coverage will be available for eravacycline 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.

Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and limit commercialization of any 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 will face an even greater risk if we commercially sell eravacycline or any other product candidate that we develop. 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.

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Although we maintain general liability insurance of $5 million in the aggregate and clinical trial liability insurance of $3 million in the aggregate for eravacycline, 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 will need to increase our insurance coverage if and when we begin selling eravacycline or any other product candidate that receives marketing approval. 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 our product candidates, which could adversely affect our business, financial condition, results of operations and prospects.

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

Although we expect to commercialize eravacycline ourselves in the United States, we intend to seek to commercialize eravacycline outside the United States through collaboration arrangements. 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.

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 candidate that we license to a third party.

Collaborations involving our product candidates 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;

collaborators may not pursue development and commercialization of our 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;

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- 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;

- a collaborator 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 product candidates, might lead to additional responsibilities for us with respect to 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 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 candidate licensed to it by us.

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 eravacycline and our other 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 intend to utilize a variety of types of collaboration arrangements for commercialization outside the United States.

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 design or results of clinical trials;

- the likelihood of approval by the FDA or comparable foreign regulatory authorities;

- the potential market for the subject product candidate;

- the costs and complexities of manufacturing and delivering such product candidate to patients;

the potential for competing products;

our patent position protecting the 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

industry and market conditions generally.

The collaborator may also consider alternative 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 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 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

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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 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 eravacycline. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials for eravacycline and expect to rely on these third parties to conduct clinical trials of any other product candidate that we develop. 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 assure you 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 eravacycline or any other product candidates 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.

We contract with third parties for the manufacture of eravacycline for clinical trials and expect to continue to do so in connection with the commercialization of eravacycline and for clinical trials and commercialization of any other product candidates that we develop. This reliance on third parties increases the risk that we will not have sufficient quantities of our 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 eravacycline 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 eravacycline and our other product candidates, and we expect to rely on third party contract manufacturers to manufacture 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:

- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us

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- 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.

If any of our product candidates are 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 approved 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. 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, 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 eravacycline 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.

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 instance, 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.

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Our reliance on government funding for certain of our programs adds uncertainty to our research and commercialization efforts with respect to those programs and may impose requirements that increase the costs of commercialization and production of product candidates developed under those government-funded programs.

Our development of eravacycline for the treatment of disease caused by bacterial biothreat pathogens is currently being funded through a subcontract with funding from BARDA. In addition, our development of TP-271 is being funded through a subcontract and grant subaward with funding from the NIH s NIAID division.

Contracts and grants funded by the U.S. government and its agencies, including our agreements funded by BARDA and NIAID, include provisions that reflect the government s substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- terminate agreements, in whole or in part, for any reason or no reason;
- reduce or modify the government s obligations under such agreements without the consent of the other party;
- claim rights, including intellectual property rights, in products and data developed under such agreements;
- audit contract-related costs and fees, including allocated indirect costs;
- suspend the contractor or grantee from receiving new contracts pending resolution of alleged violations of procurement laws or regulations;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;
- suspend or debar the contractor or grantee from doing future business with the government;
- control and potentially prohibit the export of products;
- pursue criminal or civil remedies under the False Claims Act, False Statements Act and similar remedy provisions specific to government agreements; and
- limit the government s financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period.

We may not have the right to prohibit the U.S. government from using certain technologies developed by us, and we may not be able to prohibit third party companies, including our competitors, from using those technologies in providing products and services to the U.S. government. The U.S. government generally takes the position that it has the right to royalty-free use of technologies that are developed under U.S. government contracts.

In addition, government contracts and grants, and subcontracts and subawards awarded in the performance of those contracts and grants, normally contain additional requirements that may increase our costs of doing business, reduce our profits, and expose us to liability for failure

to comply with these terms and conditions. These requirements include, for example:

- specialized accounting systems unique to government contracts and grants;
- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of certain contract and grant information, which may enable competitors to gain insights into our research program; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination and affirmative action programs and environmental compliance requirements.

As an organization, we are relatively new to government contracting and new to the regulatory compliance obligations that such contracting entails. If we fail to maintain compliance with those obligations, we may be subject to potential liability and to termination of our contracts.

As a U.S. government contractor, we are subject to financial audits and other reviews by the U.S. government of our costs and performance on their contracts, as well as our accounting and general business practices related to these contracts. Based on the results of its audits, the government may adjust our contract- related costs and fees, including allocated indirect costs. Although adjustments arising from government audits and reviews have not had a material adverse effect on our financial condition or results of operations in the past, we cannot assure you that future audits and reviews will not have those effects.

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Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient patent protection for our technology 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 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 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 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 product candidates, our ability to develop and commercialize those 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.

As of June 30, 2013, we owned one U.S. patent, two foreign patents, ten pending U.S. patent applications, one of which is a provisional application, and 51 pending foreign patent applications in Europe and 17 other jurisdictions. In addition we have exclusively licensed from Harvard University rights under four U.S. patents, ten foreign patents, four pending U.S. patent applications and 24 pending foreign patent applications in Europe and 11 other jurisdictions. Certain of our patent applications are directed to the composition of matter and use of eravacycline and are pending in the United States, Europe, Japan and other countries.

Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which 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 be 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 preissuance 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 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

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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 product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our 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.

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 or products candidates, including 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

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costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party s intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing 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 have 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 and products, 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 have 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 registered our trademarks. Failure to secure those registrations could adversely affect our business.

We have not yet registered our trademarks in the United States or other countries. 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 have also not yet registered trademarks for any of our product candidates in any jurisdiction. When we file trademark applications for our product candidates those applications may not be allowed for registration, and registered trademarks may not be obtained, maintained or enforced. During trademark registration proceedings in the United States and foreign jurisdictions, we may receive rejections. We are given an opportunity to respond to those rejections, but we may not be able to overcome such rejections. In addition, in the United States Patent and

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Trademark Office and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings.

In addition, any proprietary name we propose to use with eravacycline or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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 eravacycline or any other product candidate that we develop, and our ability to generate revenue will be materially impaired.

Our product candidates, including eravacycline, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, 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 a product candidate will prevent us from commercializing the product candidate. We currently do not have any products approved for sale in any jurisdiction. We have only 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. We have not submitted an NDA for any of our product candidates. 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. 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. The FDA or other regulatory authorities may determine that eravacycline 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. 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 eravacycline or any other product candidate that we develop, the commercial prospects for eravacycline or such other product candidate may be harmed and our ability to generate revenues will be materially impaired.

If we are unable to obtain marketing approval in international jurisdictions, we will not be able to market our product candidates abroad.

In order to market and sell eravacycline and any other product candidate that we develop in the European Union and many other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. The approval procedure varies among countries and can involve additional testing. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis or at all.

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If we receive regulatory approval for any product candidates, including eravacycline, we will be subject to ongoing obligations and continuing regulatory review, which may result in significant additional expense. Our product candidates, including eravacycline, if approved, 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 our product candidates, when and if approved.

Any product candidate, including eravacycline, for which we obtain marketing approval, will also be subject to ongoing regulatory requirements for labeling, 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 will also be 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;
- impose restrictions on the products 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 products;

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 or withdraw marketing approvals;

refuse to permit the import or export of the products;

seize or detain supplies of the product; or

issue injunctions or impose civil or criminal penalties.

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.

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates, including eravacycline, for which we obtain marketing approval. Our future arrangements with third-party

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payors and customers may expose us 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 healthcare 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, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal false statements statute prohibits 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 Affordability Reconciliation Act, or collectively, the ACA, requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and

- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to implement compliance programs and to track and report gifts, compensation and other remuneration provided to physicians.

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. 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.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of any products that we develop, due to the trend toward managed healthcare, the

increasing influence of health maintenance organizations and additional legislative proposals.

In March 2010, the ACA became law in the United States with the goals of broadening access to health insurance, reducing or constraining the growth of healthcare spending, enhancing remedies against fraud and abuse, adding new transparency requirements for health care and health insurance industries, imposing new taxes and fees on the health industry and imposing additional health policy reforms. Further, the new law includes annual fees to be paid by manufacturers for certain branded prescription drugs, requires manufacturers to participate in a discount program for certain outpatient drugs under Medicare Part D, increases manufacturer rebate responsibilities under the Medicaid Drug Rebate Program for outpatient drugs dispensed to Medicaid recipients and expands oversight and support for the federal government s comparative effectiveness research of services and products. Despite initiatives to invalidate the ACA, the United States Supreme Court has upheld certain key aspects of the legislation, including the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the individual mandate. Although it is too early to determine its full effect, if efforts

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to repeal or amend the legislation are unsuccessful, the ACA appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs. In addition, we cannot predict whether other legislative changes will be adopted, if any, or how such changes would affect our business.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Risks Related to Employee Matters and Managing Growth

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 development, regulatory, commercialization and business development expertise of Guy Macdonald, our President and Chief Executive Officer, Patrick Horn, our Chief Medical Officer, David C. Lubner, our Senior Vice President and Chief Financial Officer, and Joyce Sutcliffe, our Senior Vice President, Biology, 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.

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 drug candidates will be limited.

We expect to grow our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales, marketing and distribution. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities to devote time to managing these growth activities. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our inability to effectively manage the expansion of our operations may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy.

If foreign approvals are obtained, we will be subject to additional risks in conducting business in international markets.

Even if we are able to obtain approval for commercialization of a product candidate in a foreign country, we will be subject to additional risks related to international business operations, including:

potentially reduced protection for intellectual property rights;

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- 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.

These and other risks may materially adversely affect our ability to attain or sustain revenue from international markets.

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. As a result of this volatility, investors may not be able to sell their common stock at or above the price they paid for it. The market price for our common stock may be influenced by many factors, including:

- the success of existing or new competitive products or technologies;

- the timing of clinical trials of eravacycline and any other product candidate;

- results of clinical trials of eravacycline and any other product candidate;

- failure or discontinuation of any of our development programs;

- 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;

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.

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An active trading market for our common stock may not be sustained, and investors may not be able to resell their shares at or above the price they paid.

Although we have listed our common stock on The NASDAQ Global 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 prices at which they acquired their shares or at the time 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 over 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 product candidates. Pending their use, we may invest our cash reserves in a manner that does not produce income or that loses value.

We are an emerging growth company, and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company for up to five years following our initial public offering in March 2013. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor s report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are currently incurring and expect to continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a newly public company, and particularly after we are no longer an emerging growth company, we are currently incurring, and expect to continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The NASDAQ Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more

difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors.

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We are currently evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K with the Securities and Exchange Commission. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps 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. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, 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.

A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. Of the 20,671,935 shares of our common stock outstanding as of August 1, 2013, 12,588,426 shares are currently subject to restrictions on transfer under 180-day lock-up arrangements with either the underwriters for our initial public offering or under stock option and restricted stock agreements entered into between us and the holders of those shares. These restrictions are due to expire on September 15, 2013, resulting in these shares becoming eligible for public sale on September 16, 2013 if they are registered under the Securities Act of 1933, as amended, which we refer to as the Securities Act, or if they qualify for an exemption from registration under the Securities Act, including under Rules 144 or 701.

Moreover, holders of an aggregate of 9,849,713 shares of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in Securities Act registration statements that we may file for ourselves or other stockholders. In addition, as of August 1, 2013, there were 2,730,888 shares subject to outstanding options under our equity incentive plans, all of which shares have been registered under the Securities Act on a registration statement on Form S-8. These shares, once vested and issued upon exercise, will be able to be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up arrangements described above.

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 our debt facility with Silicon Valley Bank and Oxford Finance preclude 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.

Our executive officers, directors and their affiliates, if they choose to act together, have the ability to significantly influence all matters submitted to stockholders for approval.

As of August 1, 2013, our executive officers and directors, and stockholders affiliated with our executive officers and directors, beneficially owned in the aggregate shares representing approximately 30% of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

- delay, defer or prevent a change in control;

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entrench our management and/or the board of directors; or

impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

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 you might otherwise receive a premium for your 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.

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Item 6. Exhibits

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

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SIGNATURES

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

Date: August 12, 2013

TETRAPHASE PHARMACEUTICALS, INC.

By: /s/ David C. Lubner
David C. Lubner
Senior Vice President and Chief Financial Officer

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EXHIBIT INDEX

		Incorporated by Reference from Date Filed			
Exhibit Number	Description of Document	Registrant s Form	with the SEC	Exhibit Number	Filed Herewith
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 Chief 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 Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101.INS	XBRL Instance Document				X
101.SCH	XBRL Taxonomy Extension Schema Document				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				X

In accordance with Rule 406T of Regulation S-T, XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not otherwise subject to liability under these sections.