
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2017

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
(State or other jurisdiction of
incorporation or organization)

20-5276217
(I.R.S. Employer
Identification No.)

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

02472
(Zip Code)

Registrant's telephone number, including area code: (617) 715-3600

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically 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 No

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of October 31, 2017 there were 51,414,631 shares of the registrant's common stock, par value \$0.001 per share, outstanding.

--TETRAPHASE PHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2017
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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

TETRAPHASE PHARMACEUTICALS, INC.

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

	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 161,365	\$ 142,086
Accounts receivable	3,565	1,789
Prepaid expenses and other current assets	5,493	6,582
Total current assets	170,423	150,457
Property and equipment, net	1,424	1,054
Restricted cash	199	199
Total assets	\$ 172,046	\$ 151,710
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 8,893	\$ 2,555
Accrued expenses	12,888	7,685
Deferred revenue	782	1,255
Total current liabilities	22,563	11,495
Other long term liabilities	119	162
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value \$0.001 per share; 5,000 shares authorized; no shares issued and outstanding	—	—
Common stock, par value \$0.001 per share; 125,000 shares authorized; 51,180 and 36,942 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	51	37
Additional paid-in capital	587,721	487,148
Accumulated deficit	(438,408)	(347,132)
Total stockholders' equity	149,364	140,053
Total liabilities and stockholders' equity	\$ 172,046	\$ 151,710

See accompanying notes to condensed consolidated financial statements

TETRAPHASE PHARMACEUTICALS, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues	\$ 4,067	\$ 850	\$ 7,138	\$ 4,055
Operating expenses				
Research and development	28,777	17,190	83,237	44,459
General and administrative	5,600	4,858	15,797	14,870
Total operating expenses	<u>34,377</u>	<u>22,048</u>	<u>99,034</u>	<u>59,329</u>
Loss from operations	(30,310)	(21,198)	(91,896)	(55,274)
Other income (expense)				
Other income (expense), net	302	88	620	255
Net loss	<u>\$ (30,008)</u>	<u>\$ (21,110)</u>	<u>\$ (91,276)</u>	<u>\$ (55,019)</u>
Net loss per share-basic and diluted	<u>\$ (0.63)</u>	<u>\$ (0.58)</u>	<u>\$ (2.23)</u>	<u>\$ (1.50)</u>
Weighted-average number of common shares used in net loss per share-basic and diluted	<u>47,347</u>	<u>36,692</u>	<u>40,942</u>	<u>36,640</u>
Comprehensive loss	<u>\$ (30,008)</u>	<u>\$ (21,110)</u>	<u>\$ (91,276)</u>	<u>\$ (55,019)</u>

See accompanying notes to condensed consolidated financial statements

TETRAPHASE PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2017	2016
Operating activities		
Net loss	\$ (91,276)	\$ (55,019)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	315	208
Stock-based compensation expense	9,358	10,313
Changes in operating assets and liabilities:		
Accounts receivable	(1,776)	3,406
Prepaid expenses and other assets	1,089	(2,980)
Accounts payable	6,338	764
Accrued expenses and other liabilities	5,160	(706)
Deferred revenue	(473)	168
Net cash used in operating activities	(71,265)	(43,846)
Investing activities		
Purchases of property and equipment	(685)	(197)
Net cash used in investing activities	(685)	(197)
Financing activities		
Proceeds from sale of common stock, net of issuance costs	90,863	—
Proceeds from issuance of stock under stock plans	366	207
Net cash provided by financing activities	91,229	207
Net increase (decrease) in cash and cash equivalents	\$ 19,279	\$ (43,836)
Cash and cash equivalents at beginning of period	142,086	205,912
Cash and cash equivalents at end of period	\$ 161,365	\$ 162,076

See accompanying notes to condensed consolidated financial statements

Tetraphase Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Organization and Operations

Tetraphase Pharmaceuticals, Inc. (the “Company”) is a clinical-stage biopharmaceutical company using its proprietary chemistry technology to create novel antibiotics for serious and life-threatening multidrug-resistant infections. The Company is developing its lead product candidate, eravacycline, a fully-synthetic fluorocycline, as an intravenous, or IV, and oral antibiotic for use as a first-line empiric monotherapy for the treatment of multidrug-resistant infections, including multidrug-resistant, or MDR, Gram-negative infections. The Company is also pursuing the discovery and development of additional antibiotics that target unmet medical needs, including multidrug-resistant Gram-negative bacteria.

The Company is devoting substantially all of its efforts to product research and development, and market development. The Company is subject to a number of risks similar to those of other life science companies in a similar stage of development, including rapid technological change, dependence on key individuals, competition from other companies, compliance with government regulations, protection of proprietary technology, dependence on third parties, product liability, the need for development of commercially viable products, regulatory approval of products, uncertainty of market acceptance of products, and the need to obtain additional financing to fund the development of its product candidates. 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 operating losses for at least the next several years, and expects to require additional financial resources to advance its product candidates.

The Company has incurred annual net operating losses in every year since its inception. As of September 30, 2017, the Company had an accumulated deficit of \$438.4 million. The Company has not generated any product revenues and has financed its operations primarily through public offerings and private placements of its equity securities, debt financings and funding from the United States government.

There can be no assurance that the Company will be able to generate product revenue in its anticipated amounts, on a timely basis or at all, or 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 generate revenues or obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company’s business, results of operations and financial condition.

The Company believes that its existing cash and cash equivalents will enable it to fund its operating expenses and capital expenditure requirements into at least early 2019, which it believes would allow it to file for and potentially obtain regulatory approvals in the United States and Europe for IV eravacycline for the treatment of complicated intra-abdominal infections (“cIAI”), obtain top-line complicated urinary tract infection (“cUTI”) data from its IGNITE3 clinical study, to submit a supplemental new drug application (“sNDA”) to the United States Food and Drug Administration (“FDA”) for the treatment of cUTI if warranted, and to perform pre-commercialization activities and commercially launch eravacycline for the treatment of cIAI if approved. The Company may never be profitable even if it is successful in launching eravacycline for one or more indications. Until such time as the Company is profitable, if ever, the Company will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim condensed consolidated financial statements are unaudited. These unaudited financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission (“SEC”) for interim financial information. Accordingly, they do not include all of the information and footnotes required by United States generally accepted accounting principles (“GAAP”) for complete financial statements. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the accompanying notes for the year ended December 31, 2016 contained in the Company’s annual report on Form 10-K filed with the SEC on March 13, 2017 (the “2016 Form 10-K”). The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company’s financial position as of September 30, 2017 and the results of operations and comprehensive loss and cash flows for the three and nine months ended September 30, 2017 and 2016. Interim operating results for the three and nine months ended September 30, 2017 are not necessarily indicative of the results that may be expected for future interim periods or for the fiscal year ending December 31, 2017.

The December 31, 2016 condensed consolidated balance sheet included herein was derived from audited consolidated financial statements, but does not include all disclosures including notes required by GAAP for complete financial statements.

Use of Estimates

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

Principles of Consolidation

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

Going Concern Assessment

Accounting Standards Update ("ASU") No. 2014-15, *Presentation of Financial Statements - Going Concern*, requires management to evaluate the company's ability to continue as a going concern one year beyond the filing date of the given financial statements. This evaluation requires management to perform two steps. First, management must evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern. Second, if management concludes that substantial doubt is raised, management is required to consider whether it has plans in place to alleviate that doubt. Disclosures in the notes to the financial statements are required if management concludes that substantial doubt exists or that its plans alleviate the substantial doubt that was raised. Based on a detailed cash forecast incorporating current development activities and related spending plans, the Company expects its cash to last more than one year beyond the date that the financial statements were issued. Based on this analysis, no additional disclosures are required.

Recently Issued Accounting Pronouncements

In May 2014, the Financial Accounting Standard Board ("FASB") issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. The FASB has subsequently issued ASU 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*; ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*; ASU 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*; and ASU 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*. The Company is currently evaluating the potential impact that these updates may have on its financial position, results of operations and cash flows, specifically the impact on its revenue recognized via its contracts with the Biomedical Advanced Research and Development Authority ("BARDA"), the National Institute of Allergy and Infectious Diseases ("NIAID") and the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator ("CARB-X"), an international public-private partnership focused on advancing new antimicrobial products to address the threat of antibiotic resistance. The Company is currently completing contract reviews and evaluating whether these contracts are subject to Topic 606. The Company expects these contract reviews to be completed in the fourth quarter. The Company plans to use the modified retrospective method of adoption, to be effective January 1, 2018.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The new standard will be effective for the Company on January 1, 2019. The Company is currently evaluating the potential impact that this standard may have on its financial position, results of operations and cash flows.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). This new standard provides guidance to ensure consistency in how transactions are reflected in the statement of cash flows. ASU 2016-15 will be effective for the Company for annual periods beginning after December 15, 2017. The Company is currently evaluating the potential impact that this standard may have on its statements of cash flows.

In November 2016, the FASB issued ASU No. 2016-18, *Restricted Cash* (“ASU 2016-18”). ASU 2016-18 clarifies how entities should present restricted cash and restricted cash equivalents in the statement of cash flows. The guidance will be applied retrospectively and will be effective for the Company for annual and interim periods beginning after December 15, 2017. The Company is currently evaluating the potential impact that this standard may have on its financial position, statements of operations and cash flows.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting* (“ASU 2017-09”). The new standard provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The new standard will be effective for the Company on January 1, 2018. The Company is currently evaluating the potential impact that this standard may have on its financial position, statements of operations and cash flows.

Recently Adopted Accounting Standards

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* (“ASU 2016-09”). ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, forfeiture rates, and classification on the statement of cash flows. The new guidance is effective for fiscal years beginning after December 15, 2016, including interim periods within those annual reporting periods. The Company adopted ASU No. 2016-09 as of January 1, 2017. As a result of adopting ASU No. 2016-09, the Company elected to recognize share-based award forfeitures only as they occur rather than by applying an estimated forfeiture rate as previously required. ASU No. 2016-09 requires that this change be applied using a modified-retrospective transition method by means of a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year in which the guidance is adopted. The Company did not make an adjustment to retained earnings as the amount was immaterial to the financial statements.

3. Fair Value of Financial Instruments

The Company’s financial instruments consist principally of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities. Fair value measurements are classified and disclosed in one of the following three categories:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Financial instruments measured at fair value as of September 30, 2017 and December 31, 2016 are classified below based on the three fair value hierarchy tiers described above (in thousands):

	Balance	Fair Value Measurements at Reporting Date Using		
		Level 1	Level 2	Level 3
September 30, 2017				
Cash and money market funds	\$ 161,365	\$ 161,365	\$ —	\$ —
December 31, 2016				
Cash and money market funds	\$ 142,086	\$ 142,086	\$ —	\$ —

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

4. Net Loss per Common Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of Common Stock outstanding for the period, without consideration for common stock equivalents. The Company’s potentially dilutive shares, which include outstanding stock options, unvested restricted stock units and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The amounts in the table below were excluded from the calculation of net loss per share, due to their anti-dilutive effect:

	September 30,	
	2017	2016
Warrants	1,103	1,103
Unvested restricted stock units	338,700	461,858
Outstanding stock options	6,116,217	4,053,850
Totals	6,456,020	4,516,811

5. Significant Agreements and Contracts

License Agreement

In August 2006, the Company entered into a license agreement for certain intellectual property with Harvard University (“Harvard”). Under the license agreement, as of September 30, 2017, the Company has paid Harvard an aggregate of \$6.1 million in upfront license fees and development milestone payments, and has issued 31,379 shares of common stock to Harvard. For each product covered by the license agreement, the Company is obligated to make certain payments totaling up to approximately \$15.1 million upon achievement of certain development and regulatory milestones and to pay additional royalties on net sales of such product.

Government Grant and Contracts

BARDA Contract for Eravacycline

The Company has received funding for its lead product candidate, eravacycline, under an award from BARDA, an agency of the U.S. Department of Health and Human Services. In January 2012, BARDA awarded an initial five-year contract, which has since been extended, that provides for up to a total of \$67.3 million in funding for the development, manufacturing and clinical evaluation of eravacycline for the treatment of disease caused by bacterial biothreat pathogens (“BARDA Contract”). The funding under the BARDA Contract is also being used for the development, manufacturing and clinical evaluation of eravacycline to treat certain infections caused by life-threatening multidrug-resistant bacteria.

In connection with the BARDA Contract, in February 2012, the Company entered into a cost-plus-fixed-fee subcontract with CUBRC Inc. (“CUBRC”), an independent, not for profit, research corporation that specializes in U.S. government-based contracts, which is also the direct recipient of the BARDA Contract. This subcontract, which currently expires in May 2018, granted the Company initial funding of up to \$41.6 million, reflecting the portion of the BARDA Contract funding that may be paid to the Company for its activities. The total committed funding under the BARDA subcontract has increased since the initial award in 2012 due to BARDA’s exercise of options to continue to fund specific work performed by the Company related to eravacycline.

Although the BARDA Contract and the Company’s subcontract with CUBRC under the BARDA Contract have terms which currently expire in May 2018, BARDA is entitled to terminate the project for convenience at any time, and is not obligated to provide continued funding beyond current-year amounts from congressionally approved annual appropriations. To the extent that BARDA ceases to provide funding of the program to CUBRC, CUBRC has the right to cease providing funding to the Company. Committed funding from CUBRC under the Company’s BARDA subcontract is for up to \$41.6 million through May 10, 2018, the current contract end date, as a result of the exercise of several options by BARDA under the BARDA Contract. Total funds of \$34.7 million had been received by the Company through September 30, 2017 under this contract. During the three months ended September 30, 2017 and 2016, the Company recognized revenue of \$2.1 million and \$0.6 million, respectively, from the Company’s subcontract under the BARDA Contract. During the nine months ended September 30, 2017 and 2016, the Company recognized revenue of \$3.6 million and \$2.2 million, respectively, from the Company’s subcontract under the BARDA Contract.

NIAID Grant and Contract for TP-271

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

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

In connection with the NIAID Grant, in November 2011, CUBRC, the direct recipient of the NIAID Grant, awarded the Company a no-fee subaward of approximately \$0.9 million, reflecting the portion of the NIAID Grant funding that may be paid to the Company for its activities.

In connection with the NIAID Contract, in October 2011, the Company entered into a cost-plus-fixed-fee subcontract with CUBRC, the direct recipient of the NIAID Contract, which subcontract currently expires in December 2018 under which the Company may receive funding of up to approximately \$15.1 million, reflecting the portion of the NIAID Contract funding that may be paid to the Company for its activities. The total potential committed funding under the NIAID subcontract has increased since the initial award in 2011 due to NIAID's exercise of options to continue to fund specific work performed by the Company related to TP-271.

Although the NIAID Contract and the Company's subcontract with CUBRC under the NIAID Contract have terms which currently expire on December 31, 2018, NIAID is entitled to terminate the project for convenience at any time, and is not obligated to provide continued funding beyond the respective expiration dates. To the extent that NIAID ceases to provide funding of the programs to CUBRC, CUBRC has the right to cease providing funding to the Company. As of September 30, 2017, committed funding from CUBRC under the Company's subcontract with respect to the NIAID Contract is \$15.1 million, of which \$12.9 million had been received through September 30, 2017. In addition, the NIAID Grant and the Company's subaward from CUBRC expired on May 31, 2017. Through September 30, 2017, the Company received all committed funding of \$0.9 million from CUBRC under the Company's subaward with respect to the NIAID Grant.

During the three months ended September 30, 2017 and 2016, the Company recognized revenue of \$1.5 million and \$0.2 million, respectively, from the Company's subcontract under the NIAID Contract. During the three months ended September 30, 2017, the Company recognized no revenue from its subaward under the NIAID Grant compared to revenue of \$27,000, for the three months ended September 30, 2016. During the nine months ended September 30, 2017 and 2016, the Company recognized revenue of \$2.7 million and \$1.8 million, respectively, from the Company's subcontract under the NIAID Contract. During the nine months ended September 30, 2017 and 2016, the Company recognized revenue of \$9,000 and \$90,000, respectively, from the Company's subaward under the NIAID Grant.

CARB-X Award for TP-6076

In March 2017, CARB-X selected the Company to receive up to \$4.0 million in research funding over eighteen months for TP-6076. In connection with this funding, the Company entered into a cost reimbursement Sub-Award Agreement (the "Sub-Award Agreement") with the Trustees of Boston University, the administrator of the program. The Company began recognizing revenue from the Sub-Award Agreement in April 2017. During the three months ended September 30, 2017, the Company recognized revenue of \$0.4 million under this Sub-Award Agreement. During the nine months ended September 30, 2017, the Company recognized revenue of \$0.9 million under this Sub-Award Agreement. This Sub-Award Agreement will fund certain activities through the end of 2018. This Sub-Award Agreement can be terminated for convenience at any time, subject to 30 days prior written notice.

6. Accrued Expenses

Accrued expenses at September 30, 2017 and December 31, 2016 consisted of the following (in thousands):

	September 30, 2017	December 31, 2016
Clinical trial related	\$ 4,793	\$ 1,129
Salaries and benefits	2,896	2,498
Drug supply and development	2,767	2,698
Professional fees	1,350	965
Preclinical	654	163
Other	428	232
Total	\$ 12,888	\$ 7,685

7. Stock-Based Compensation

In January 2017, the number of shares available for issuance under the Tetrphase Pharmaceuticals, Inc. Stock Incentive Plan 2013 Stock Incentive Plan, as amended ("2013 Plan") was increased by approximately 1.5 million shares as a result of the automatic increase provision of the 2013 Plan. As of September 30, 2017, the total number of shares of common stock available for issuance under the 2013 Plan was approximately 0.5 million.

Stock-Based Compensation Expense

During the three and nine months ended September 30, 2017 and 2016, the Company recognized the following stock-based compensation expense (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development	\$ 1,545	\$ 1,744	\$ 4,719	\$ 5,224
General and administrative	1,577	1,584	4,639	5,089
Total	<u>\$ 3,122</u>	<u>\$ 3,328</u>	<u>\$ 9,358</u>	<u>\$ 10,313</u>

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Stock options	\$ 2,880	\$ 2,742	\$ 8,695	\$ 8,629
Restricted stock units	211	560	579	1,551
Employee stock purchase plan	31	26	84	133
Total	<u>\$ 3,122</u>	<u>\$ 3,328</u>	<u>\$ 9,358</u>	<u>\$ 10,313</u>

Stock Options

The following table summarizes the stock option activity for the nine months ended September 30, 2017:

	Shares	Weighted-Average Exercise Price
Outstanding at December 31, 2016	4,066,411	\$ 18.42
Granted	2,278,750	\$ 4.31
Exercised	(66,076)	\$ 3.21
Forfeited	(162,868)	\$ 14.94
Outstanding at September 30, 2017	<u>6,116,217</u>	\$ 13.42
Exercisable at September 30, 2017	<u>2,884,503</u>	\$ 16.59

As of September 30, 2017, there was \$19.2 million of total unrecognized stock-based compensation cost related to employee unvested stock options granted under the 2013 Plan. The Company expects to recognize that cost over a remaining weighted-average period of 2.5 years.

Restricted Stock Units

In January 2016, the Company granted additional restricted stock units to employees. These restricted stock units vest in annual increments over three years, subject to continued employment with the Company and had a grant date fair value of \$8.47 per share, which was the closing price of the Company's common stock on the date of grant.

In January 2017, the Company issued 175,000 restricted stock units with service and performance conditions to certain employees, none of which vested during the nine months ended September 30, 2017. Vesting of these awards is contingent on the occurrence of certain milestone events and fulfillment of any remaining service condition. As a result, the related compensation cost is recognized as an expense when achievement of the milestone is considered probable over the remaining requisite service period.

The following table summarizes the restricted stock activity for the nine months ended September 30, 2017:

	Shares	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2016	254,378	\$ 8.47
Granted	175,000	\$ 3.83
Forfeited	(5,906)	\$ 8.47
Vested/Released	(84,772)	\$ 8.47
Unvested at September 30, 2017	<u>338,700</u>	<u>\$ 6.07</u>

As of September 30, 2017, there was \$1.5 million of total unrecognized stock-based compensation expense related to restricted stock units granted under the 2013 Plan. The expense is expected to be recognized over a weighted-average period of 1.8 years.

Employee stock purchase plan

Under the Company's 2014 Employee Stock Purchase Plan ("2014 ESPP"), an aggregate of 300,000 shares of common stock have been reserved for issuance pursuant to purchase rights granted to the Company's employees. As of September 30, 2017, 171,697 shares remained available for issuance. During the nine months ended September 30, 2017 and 2016, 44,785 shares and 21,178 shares of common stock were issued under the 2014 ESPP, respectively.

8. Equity

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

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

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

As of September 30, 2017, the Company had sold an aggregate of 3,935,450 shares of common stock under the Sales Agreement, at an average selling price of approximately \$7.78 per share for aggregate gross proceeds of \$30.6 million and net proceeds of \$29.5 million after deducting the sales commissions and offering expenses. An additional 222,423 shares had been sold under the Amended Sales Agreements subsequent to September 30, 2017, for net proceeds of \$1.7 million after deducting sales commissions. As of October 31, 2017, \$47.6 million of common stock remained available to be sold under the amended Sales Agreement, subject to certain conditions specified therein.

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

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

The interim financial statements included in this quarterly report on Form 10-Q and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2016, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in our annual report on Form 10-K filed with the United States Securities and Exchange Commission, or the SEC, on March 13, 2017, which we refer to as our annual report. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements are subject to risks and uncertainties, including those set forth in Part II— Other Information, Item 1A. Risk Factors below and elsewhere in this report that could cause actual results to differ materially from historical results or anticipated results.

Overview

We are a clinical-stage biopharmaceutical company using our proprietary chemistry technology to create novel antibiotics for serious and life-threatening multidrug-resistant infections. We are developing our lead product candidate, eravacycline, a fully-synthetic fluorocycline, as an intravenous, or IV, and oral antibiotic for use as a first-line empiric monotherapy for the treatment of multidrug-resistant infections, including multidrug-resistant, or MDR, Gram-negative infections. We are also pursuing the discovery and development of additional antibiotics that target unmet medical needs, including multidrug-resistant Gram-negative bacteria.

We are conducting a global phase 3 clinical program for eravacycline called IGNITE (Investigating Gram-Negative Infections Treated with Eravacycline). On July 25, 2017, we announced top-line data from our IGNITE4 trial, a global phase 3 randomized, double-blind, double-dummy, multicenter, prospective study assessing the efficacy, safety and pharmacokinetics of twice-daily IV eravacycline (1.0 mg/kg every 12 hours) compared with meropenem (1g every 8 hours) for the treatment of complicated intra-abdominal infections, or cIAI that we conducted in 500 patients. In the trial, eravacycline met the primary endpoint of statistical non-inferiority of clinical response at the test-of-cure, or TOC, visit, under the guidance set by the United States Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA. Prior to IGNITE 4, we conducted IGNITE1, a phase 3 clinical trial of twice daily IV eravacycline (1.0 mg/kg every 12 hours) compared with ertapenem (1.0g IV every 24 hours) for the treatment of cIAI. In IGNITE1, eravacycline met the primary endpoint of statistical non-inferiority of clinical response.

We designed IGNITE4 as a non-inferiority study. Under FDA guidance, the primary endpoint of the trial was clinical response at the TOC visit in the microbiological intent-to-treat, or micro-ITT, population, which consisted of randomized patients in the trial who had baseline bacterial pathogens that cause cIAI and against which eravacycline has antibacterial activity. Under EMA guidance, the primary endpoint of the trial was clinical response at the TOC visit in the modified intent-to-treat, or MITT, population, which consisted of patients in the trial who received at least one dose of study drug, and in the clinically evaluable, or CE, patient population, which consisted of patients in the trial who met key inclusion/exclusion criteria and followed other important components of the trial. Secondary endpoints included clinical response at the end-of-treatment, TOC and follow-up visits in the intent-to-treat population, the CE population, the micro-ITT population and the microbiologically evaluable, or ME, population. The ME population consisted of all micro-ITT patients who met key inclusion/exclusion criteria and followed other important components of the trial. In the trial, we also studied microbiologic response at the end-of-treatment and TOC visits in the micro-ITT and ME populations, the safety and tolerability of eravacycline in the safety population and pharmacokinetic parameters after eravacycline administration.

Eravacycline achieved high clinical cure rates in patients with cIAI, comparable to cure rates in the patients in the meropenem group. The primary efficacy analysis under the FDA guidance was conducted using a 12.5% non-inferiority margin in the micro-ITT population. Clinical cure rates in the micro-ITT population were 90.8% and 91.2% for eravacycline (n=195) and meropenem (n=205), respectively (95% CI: -6.3%,5.3%). Under the EMA guidance, the primary analysis was conducted using a 12.5% non-inferiority margin of the MITT and CE patient populations. Clinical cure rates in the MITT population were 92.4% and 91.6% for eravacycline (n=250) and meropenem (n=249), respectively (95% CI: -4.1%,5.8%). Clinical cure rates in the CE population were 96.9% and 96.1% for eravacycline (n=225) and meropenem (n=231), respectively (95% CI: -2.9%,4.5%). The secondary analyses were consistent with, and supportive of, the primary outcome.

There were no treatment-related serious adverse events in the trial. Treatment-emergent adverse event rates were similar in both treatment groups. The most commonly reported drug-related adverse events for eravacycline were infusion site reactions, nausea and vomiting, each occurring at a rate of less than 5%. The safety profile for IV eravacycline in IGNITE4 was consistent with that seen in the previously completed phase 3 IGNITE1 and phase 2 clinical trials in cIAI. In addition, the spectrum of pathogens in this trial was similar to that seen in previously completed clinical trials of third party products in this patient population. The most common Gram-negative pathogens in the study included *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas* and *Bacteroides*.

Consistent with draft guidance issued by the FDA with respect to the development of antibiotics for cIAI and our discussions with the FDA, we believe that the positive results observed in both IGNITE1 and IGNITE4 are sufficient to support submission of a new drug application, or NDA, for eravacycline for the treatment of cIAI with the FDA. We anticipate submitting an NDA by the end of the first quarter of 2018. In the third quarter of 2017 we submitted a marketing authorization application, or MAA, to the EMA for IV eravacycline for the treatment of cIAI primarily based upon the results of IGNITE1.

We are also developing eravacycline for the treatment of complicated urinary tract infections, or cUTI. In January 2017, we initiated IGNITE3, a randomized, multi-center, double-blind, phase 3 clinical trial evaluating the efficacy and safety of once-daily IV eravacycline (1.5mg/kg every 24 hours) compared to ertapenem (1g every 24 hours), the control therapy in this trial, for the treatment of cUTI. IGNITE3 enrolled 1,205 adult patients, who were randomized 1:1 to receive eravacycline or ertapenem for a minimum of five days, and are then eligible to switch to an oral antibiotic. The co-primary endpoints of responder rate (a combination of clinical cure rate and microbiological success) in the micro-ITT population at the end-of-IV treatment visit and at the TOC visit (Day 14-17 after randomization) will be evaluated using a 10% non-inferiority margin. We completed enrollment in IGNITE3 in September 2017 and expect to report top-line data from this trial in the first quarter of 2018. If IGNITE3 is successful, we plan to use the results from IGNITE3 to support submission of a supplemental new drug application, or sNDA, for IV eravacycline for the treatment of cUTI, assuming approval first of IV eravacycline for the treatment of cIAI.

In parallel with the clinical trials using IV eravacycline, we are continuing our development program for an oral formulation of eravacycline. In October 2017, we presented data from the first study of a recently completed phase 1 program designed to optimize drug exposure of oral eravacycline in an IV-to-oral dosing regimen. These results, along with data from subsequent trials in this phase 1 program, have allowed for the identification of an optimized IV-to-oral dosing regimen using the current oral formulation which we plan to advance into a phase 2 clinical trial in patients with cUTI. We expect to initiate this clinical trial in the first half of 2018.

The FDA has granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for IV and oral eravacycline for cIAI and cUTI.

In June 2017, we announced positive results from a phase 1 single-ascending dose clinical trial of the IV formulation of TP-271, a fully-synthetic fluorocycline being developed for respiratory disease caused by bacterial biothreat pathogens, in healthy volunteers. In the study, TP-271 was well tolerated at single doses that resulted in high plasma exposures. There were no clinically significant changes in lab values, ECG parameters, or physical exam findings. There were no serious or severe adverse events, or discontinuations due to an adverse event during the study. We are conducting a multiple-ascending dose trial for the IV formulation of TP-271. We also plan to initiate a multiple-ascending dose phase 1 study for the oral formulation of TP-271 in early 2018. In February 2017, we received Qualified Infectious Disease Product and Fast Track designations from the FDA.

In addition, we are developing TP-6076, a fully-synthetic fluorocycline derivative, as a lead candidate under our second-generation program to target unmet medical needs, including multidrug-resistant Gram-negative bacteria. In June 2017, we announced positive results from a phase 1 randomized, placebo-controlled, double-blind, single-ascending dose study evaluating the safety, tolerability and pharmacokinetics of IV TP-6076. In the study, TP-6076 was well tolerated, and there were no serious or severe adverse events, or discontinuations due to an adverse event. There were no clinically significant safety findings in any laboratory assessments, vital signs, ECGs or physical examinations. We also are conducting a multiple-ascending study in healthy volunteers of the IV formulation of TP-6076.

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 public offerings and private placements of our equity securities, debt financings and funding from the United States government. As of September 30, 2017, we had received an aggregate of \$551.4 million in net proceeds from the issuance of equity securities and borrowings under debt facilities and an aggregate of \$48.6 million from government grants and contracts. As of September 30, 2017, our principal source of liquidity was cash and cash equivalents, which totaled \$161.4 million.

As of September 30, 2017, we had an accumulated deficit of \$438.4 million. Our net losses were \$30.0 million and \$21.1 million for the three months ended September 30, 2017 and 2016, respectively. Our net losses were \$91.3 million and \$55.0 million for the nine months ended September 30, 2017 and 2016, respectively. We expect that our expenses will increase as we continue development of eravacycline, seek marketing approval for eravacycline, conduct pre-commercialization activities for eravacycline, pursue development of eravacycline for additional indications, manufacture drug product for our clinical and pre-clinical trials, conduct our phase 1 clinical trial of TP-271 in healthy volunteers, and our phase 1 clinical trial of TP-6076 in healthy volunteers and satisfy our obligations under our license agreement with Harvard University, or Harvard. If we obtain marketing approval of eravacycline, we also expect to incur significant sales, marketing, distribution and manufacturing expenses. Furthermore, we expect to incur ongoing research and development expenses relating to our product candidates other than eravacycline and that our general and administrative costs will increase as we grow and continue to operate as a public company, and comply with increased disclosure requirements since we are no longer an emerging growth company.

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

We believe that our cash and cash equivalents, together with the net proceeds from our underwritten public offering, will enable us to fund our operating expenses and capital expenditure requirements at least into at least early 2019, which we believe will allow us to obtain top-line data from IGNITE3 and file for and potentially obtain regulatory approvals in the United States and Europe for IV eravacycline for the treatment of cIAI, to submit an sNDA to the FDA for the treatment of cUTI if warranted, and to perform pre-commercialization activities and commercially launch eravacycline for the treatment of cIAI if approved. 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 and regulatory 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. Moreover, we will need to generate significant revenue to achieve profitability, and we may never do so.

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 an initial five-year contract, which has been extended, that provides for up to a total of \$67.3 million in funding for the development, manufacturing and clinical evaluation of eravacycline for the treatment of disease caused by bacterial biothreat pathogens. We refer to this contract as the BARDA Contract. The funding under the BARDA Contract is also being used for the development, manufacturing and clinical evaluation of eravacycline to treat certain infections caused by life-threatening multidrug-resistant bacteria. We refer to this contract as the BARDA Contract.
- We have received funding for our phase 1 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 provided up to a total of approximately \$2.9 million through May 31, 2017, 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 through December 31, 2018, which we refer to as the NIAID Contract.

We are collaborating with CUBRC on these grants and contracts, because when we initially decided to seek government funding, we recognized that we did not have any expertise in bidding for, administering or managing 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 cost-plus-fixed-fee subcontract with CUBRC which currently expires on May 10, 2018 under which we may receive funding of up to approximately \$41.6 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 cost-plus-fixed-fee subcontract with CUBRC which currently expires on December 31, 2018 under which we may receive funding of up to approximately \$15.1 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 an initial 55-month, no-fee subaward which was extended and expired on May 31, 2017 under which we received funding of up to approximately \$0.9 million, reflecting the portion of the NIAID Grant funding that was paid to us for our activities.

Although the BARDA Contract and our subcontract with CUBRC under the BARDA Contract have terms which currently expire on May 10, 2018, BARDA is entitled to terminate the project for convenience at any time, and is not obligated to provide continued funding beyond current-year amounts from congressionally approved annual appropriations. To the extent that BARDA ceases to provide funding of the program to CUBRC, CUBRC has the right to cease providing funding to us. Committed funding from CUBRC under our BARDA subcontract is up to \$41.6 million from the initial contract date through May 10, 2018, of which \$34.7 million had been received through September 30, 2017.

Similarly, although the NIAID Contract and our subcontract with CUBRC under the NIAID Contract have terms which currently expire on December 31, 2018, NIAID is entitled to terminate the project for convenience at any time, and is not obligated to provide continued funding beyond December 31, 2018. To the extent NIAID ceases to provide funding of the programs to CUBRC, CUBRC has the right to cease providing funding to us. Committed funding from CUBRC under our subcontract with respect to the NIAID Contract is for up to \$15.1 million, from the initial contract date through December 31, 2018, of which \$12.9 million had been received through September 30, 2017.

In March 2017, the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator, or CARB-X, an international public-private partnership focused on advancing new antimicrobial products to address the threat of antibiotic resistance, selected us to receive up to \$4.0 million in research funding over 18 months for TP-6076. In connection with this funding, we entered into a cost reimbursement Sub-Award Agreement with the Trustees of Boston University, the administrator of the program. We began recognizing revenue from the Sub-Award Agreement in April 2017. Of the \$4.0 million in committed funding none had been received through September 30, 2017. Although the Sub-Award Agreement has a term which currently expires on December 31, 2018, the project can be terminated for convenience at any time.

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 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, and include:

- personnel-related expenses, including salaries, benefits and stock-based compensation expense;

- expenses incurred under agreements with contract research organizations, contract manufacturing organizations, and consultants that provide preclinical, clinical, regulatory and manufacturing services;
- payments made under our license agreement with Harvard University;
- the cost of acquiring, developing and manufacturing clinical trial materials and lab supplies;
- facility, depreciation and other expenses, which include direct and allocated expenses for rent, maintenance of our facilities, insurance and other supplies; and
- costs associated with preclinical, regulatory and medical affairs activities.

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

We track external development expenses and personnel expense on a program-by-program basis and allocate common expenses, such as scientific consultants and laboratory supplies, to each program based on the personnel resources allocated to such program. Expenses related to facilities, consulting, travel, conferences, stock-based compensation and depreciation are not allocated to a program and are separately classified as other research and development expenses. The following table summarizes our research and development expenses on a program-specific basis for the three and nine months ended September 30, 2017 and 2016:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(in thousands)			
Eravacycline	\$ 21,179	\$ 10,768	\$ 63,971	\$ 23,628
BARDA Contract	2,076	583	3,420	1,785
NIAID Contract and NIAID Grant	1,394	195	2,353	1,516
CARB-X Award	434	-	832	-
TP-6076	266	1,665	1,915	4,786
Other development programs	291	582	1,272	1,682
Other research and development	3,137	3,397	9,474	11,062
Total research and development expenses	<u>\$ 28,777</u>	<u>\$ 17,190</u>	<u>\$ 83,237</u>	<u>\$ 44,459</u>

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

As of September 30, 2017, we had incurred an aggregate of \$244.8 million in research and development expenses related to the development of eravacycline, and \$34.5 million in research and development expenses related to the development of eravacycline that were funded under the BARDA Contract. We expect that our research and development expenses will continue to increase in 2017 compared to 2016 as we complete IGNITE3 and IGNITE4, incur nonclinical, regulatory and drug manufacturing costs in support of NDA-related activities, pursue development of eravacycline for additional indications, advance our other product candidates and satisfy our obligations under our license agreement with Harvard.

Because of the numerous risks and uncertainties associated with product development, however, we cannot determine with certainty the duration and completion costs of current or future clinical trials of 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 on an exclusive worldwide basis under a license agreement that we entered into in August 2006. Under our license agreement, we have paid Harvard an aggregate of \$6.1 million in upfront license fees and development milestone payments. We have also issued 31,379 shares of our common stock to Harvard under the license agreement. In addition, we have agreed to make payments to Harvard upon the achievement of specified future development and regulatory milestones totaling up to \$15.1 million for each licensed product candidate (\$4.8 million of which has already been paid with respect to eravacycline), and to pay tiered royalties in the single digits based on annual worldwide net sales, if

any, of licensed products, our affiliates and our sublicensees. We are also obligated to pay Harvard a specified share of non-royalty sublicensing revenues that we receive from sublicensees for the grant of sublicenses under the license and to reimburse Harvard for specified patent prosecution and maintenance costs. The next milestone payment due under the license agreement with respect to eravacycline would be a \$3.0 million payment upon acceptance of an NDA filing to the FDA.

General and Administrative Expenses

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

We anticipate that our general and administrative expenses will increase for a number of reasons, including:

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

Critical Accounting Policies and Significant Judgments and Estimates

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

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 our annual report, filed on form 10-K with the SEC on March 13, 2017 for the year ended December 31, 2016.

Results of Operations

Comparison of the Three Months Ended September 30, 2017 and 2016

The following table summarizes the results of our operations for the three months ended September 30, 2017 and 2016, together with the changes in those items in dollars and as a percentage:

	Three Months Ended September 30,		Increase/ (decrease)	%
	2017	2016		
	(in thousands)			
Revenues	\$ 4,067	\$ 850	\$ 3,217	378%
Operating expenses:				
Research and development	28,777	17,190	11,587	67%
General and administrative	5,600	4,858	742	15%
Total operating expenses	34,377	22,048	12,329	56%
Loss from operations	(30,310)	(21,198)	(9,112)	43%
Other income	302	88	214	243%
Net loss	\$ (30,008)	\$ (21,110)	\$ (8,898)	42%

Revenue from U.S. Government Contracts and Grants

The following table sets forth our contract and grant revenue for the three months ended September 30, 2017 and 2016:

	Three Months Ended September 30,		Increase/ (decrease)	%
	2017	2016		
	(in thousands)			
Revenues				
BARDA Contract	\$ 2,141	\$ 632	\$ 1,509	239%
NIAID Contract	1,485	191	1,294	677%
CARB-X Award	441	—	441	n/a
NIAID Grant	—	27	(27)	(100)%
	\$ 4,067	\$ 850	\$ 3,217	378%

Contract and grant revenue was \$4.1 million for the three months ended September 30, 2017 compared to \$0.9 million for the three months ended September 30, 2016, an increase of \$3.2 million, or 378%. This increase was due to the scope and timing of activities conducted under our subcontract with respect to the BARDA and NIAID Contracts and the start of activities under the CARB-X Award.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2017 were \$28.8 million compared to \$17.2 million for the three months ended September 30, 2016, an increase of \$11.6 million, or 67%. This increase was primarily due to costs associated with conducting our IGNITE3 phase 3 clinical trial during the three months ended September 30, 2017.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2017 were \$5.6 million compared to \$4.9 million for the three months ended September 30, 2016, an increase of \$0.7 million, or 15%. This increase was primarily due to an increase in legal and patent costs and an increase in headcount related costs.

Other Income

The increase in other income was driven by implementation of a new cash sweep account and improved overall yields on our money market funds for the three months ended September 30, 2017 as compared to the same period in 2016.

Comparison of the Nine Months Ended September 30, 2017 and 2016

The following table summarizes the results of our operations for the nine months ended September 30, 2017 and 2016, together with the changes in those items in dollars and as a percentage:

	Nine Months Ended September 30,		Increase/ (decrease)	%
	2017	2016		
	(in thousands)			
Revenues	\$ 7,138	\$ 4,055	\$ 3,083	76%
Operating expenses:				
Research and development	83,237	44,459	38,778	87%
General and administrative	15,797	14,870	927	6%
Total operating expenses	99,034	59,329	39,705	67%
Loss from operations	(91,896)	(55,274)	(36,622)	66%
Other income	620	255	365	143%
Net loss	\$ (91,276)	\$ (55,019)	\$ (36,257)	66%

Revenue from U.S. Government Contracts and Grants

The following table sets forth our contract and grant revenue for the nine months ended September 30, 2017 and 2016:

	Nine Months Ended September 30,		Increase/ (decrease)	%
	2017	2016		
	(in thousands)			
Revenues				
BARDA Contract	\$ 3,593	\$ 2,206	\$ 1,387	63%
NIAID Contract	2,678	1,759	919	52%
CARB-X Award	858	—	858	n/a
NIAID Grant	9	90	(81)	(90)%
	\$ 7,138	\$ 4,055	\$ 3,083	76%

Contract and grant revenue was \$7.1 million for the nine months ended September 30, 2017 compared to \$4.1 million for the nine months ended September 30, 2016, an increase of \$3.0 million, or 76%. This increase was primarily due to the scope and timing of activities conducted under our subcontracts with respect to the BARDA and NIAID Contracts and by an increase in activities related to our award with CARB-X during the nine months ended September 30, 2017 as compared to the nine months ended September 30, 2016.

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2017 were \$83.2 million compared to \$44.5 million for the nine months ended September 30, 2016, an increase of \$38.7 million, or 87%. This increase was primarily due to costs associated with conducting our IGNITE3 and IGNITE4 phase 3 clinical trials during the nine months ended September 30, 2017.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2017 were \$15.8 million compared to \$14.9 million for the nine months ended September 30, 2016, an increase of \$0.9 million, or 6%. This increase was primarily due to an increase in legal and patent costs and an increase in headcount related costs offset in part by a decrease in stock-based compensation expense.

Other Income

The increase in other income was driven by implementation of a new cash sweep account and improved overall yields on our money market funds for the nine months ended September 30, 2017 as compared to the same period in 2016.

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 public offerings and private placements of equity securities, debt financings and contract research funding and research grants from the United States government.

As of September 30, 2017, we had cash and cash equivalents of approximately \$161.4 million. We invest cash in excess of immediate requirements in accordance with our investment policy, primarily with a view to liquidity and capital preservation. As of September 30, 2017, our funds were held in cash and money market funds.

On January 17, 2017, we entered into a Controlled Equity Offering Sales Agreement, or sales agreement, with Cantor Fitzgerald & Co., as sales agent, or Cantor. On July 7, 2017, we entered into an amendment to the sales agreement, or the amended sales agreement. In accordance with the terms of the sale agreement, we may offer and sell through Cantor, from time to time, shares of our common stock up to an aggregate offering price of \$80,000,000 through an “at-the-market” offering program. As of September 30, 2017, we had sold 3,935,450 shares under the Agreement at an average price of \$7.78 per share and we had received aggregate cash proceeds of \$29.5 million, after deducting the sales commissions and offering expenses.

As of October 31, 2017, an additional 222,423 shares had been sold under the Amended Sales Agreements subsequent to September 30, 2017, for net proceeds of \$1.7 million after deducting sales commissions.

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

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

	Nine Months Ended September 30,	
	2017	2016
Cash Flows from Operations:		
Net cash used in operating activities	\$ (71,265)	\$ (43,846)
Net cash used in investing activities	(685)	(197)
Net cash provided by financing activities	91,229	207
Net (decrease) increase in cash and cash equivalents	<u>\$ 19,279</u>	<u>\$ (43,836)</u>

Cash Flows from Operating Activities. The \$27.4 million increase in cash used in operating activities for the nine months ended September 30, 2017, compared to the nine months ended September 30, 2016, was primarily due to increased spending on IGNITE 3 and IGNITE 4 clinical trials offset in part by changes in working capital.

Cash Flows from Investing Activities. The \$0.5 million increase in cash used in investing activities for the nine months ended September 30, 2017, compared to the nine months ended September 30, 2016, was due to purchases of property and equipment to facilitate our increased research and development activities.

Cash Flows from Financing Activities. The \$91.0 million increase in cash provided by financing activities for the nine months ended September 30, 2017, compared to the nine months ended September 30, 2016 was primarily due to sales of common stock under our amended sales agreement with Cantor Fitzgerald and our public offering completed in the third quarter ended 2017.

Operating Capital Requirements

We expect to incur operating losses for at least the next several years as we continue development of eravacycline, seek marketing approval for eravacycline, manufacture drug product for our clinical and pre-clinical trials, conduct pre-commercialization activities for eravacycline, conduct our phase 1 clinical trials of TP-271 in healthy volunteers, and our phase 1 clinical trials of TP-6076 in healthy volunteers and satisfy our obligations under our license agreement with Harvard. 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, our manufacturing efforts are not successful, the FDA or the EMA does not approve eravacycline or our other product candidates when we expect, or at all, or funding under the NIAID Contract or the BARDA Contract is discontinued.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into at least early 2019, which we believe will allow us to obtain top-line data from IGNITE3 and file for and potentially obtain regulatory approvals in the United States and Europe for IV eravacycline for the treatment of cIAI, to submit an sNDA to the FDA for the treatment of cUTI if warranted, and to perform pre-commercialization activities and commercially launch eravacycline for the treatment of cIAI if approved. We may never be profitable even if we are successful in launching eravacycline for one or more indications. Until such time as we become profitable, if ever, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources.

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 and costs of our clinical development program for eravacycline;
- manufacturing costs related to regulatory filings and anticipated commercial launch;
- 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 and NIAID Contracts, and the activities funded under the BARDA Contract, the NIAID Contract and our agreement with CARB-X;
- 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 timing and costs of establishing product sales, marketing, distribution and manufacturing capabilities;
- revenue received from commercial sales of eravacycline, subject to receipt of marketing approval;
- the terms and timing of any future collaborations, licensing, consulting 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;
- 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 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 nine months ended September 30, 2017, there were no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed in our annual report, filed on form 10-K with the SEC on March 13, 2017 for the year ended December 31, 2016.

Recent Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There have not been any material changes to our exposure to market risk during the nine months ended September 30, 2017. For additional information regarding market risk, refer to the *Qualitative and Quantitative Disclosures About Market Risk* section of our annual report.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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 Senior Vice President of Finance (Principal Financial Officer), has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2017, the end of the period covered by this quarterly report on Form 10-Q. Based upon such evaluation, our Chief Executive Officer and Principal 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.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

In January 2016 and March 2016, two securities class action lawsuits were filed against us, our chief executive officer, our former chief operating officer and our former chief financial officer, in the United States District Court for the District of Massachusetts. In May 2016, the court consolidated the two lawsuits and appointed lead plaintiffs and lead counsel. The lead plaintiffs filed a consolidated amended complaint in July 2016 and filed a second consolidated amended complaint in August 2016. The second amended complaint is brought on behalf of an alleged class of those who purchased our common stock between March 5, 2015 and September 8, 2015, and alleges claims arising under Sections 10 and 20 of the Exchange Act of 1934, as amended. The complaint generally alleges that the defendants violated the federal securities laws by, among other things, making material misstatements or omissions concerning IGNITE2. The complaint seeks, among other relief, unspecified compensatory damages, attorneys' fees, and costs. In October 2016, we filed a motion to dismiss the second amended complaint in its entirety, which plaintiffs have opposed. Our motion to dismiss was granted by the United States District Court for the District of Massachusetts in May 2017. In July 2017 plaintiffs appealed this decision to the United States Court of Appeals for the First Circuit. We believe we have valid defenses against these claims, and will engage in a vigorous defense of such litigation.

In addition, in May 2016, Donald Britton filed a shareholder derivative complaint against our chief executive officer, our former chief operating officer, our former chief financial officer, all the members of our current board of directors, a former board member, and against Tetrphase as nominal defendant, in Massachusetts Superior Court (Suffolk County). The complaint generally alleges that the individual defendants breached fiduciary duties owed to Tetrphase and its shareholders by disseminating materially false and misleading statements to the market concerning IGNITE2. The complaint purports to assert derivative claims against the individual defendants for breach of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets, and seeks to recover on behalf of Tetrphase for any liability Tetrphase incurs as a result of the individual defendants' alleged misconduct. The complaint seeks declaratory, equitable and monetary relief, an unspecified amount of damages, with interest, and attorney's fees and costs. In August 2016, this action was dismissed by the Massachusetts Superior Court without prejudice due to plaintiff's failure to perfect service of process in a timely manner.

Item 1A. RISK FACTORS

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

Risks Relating to Our Financial Position and Need for Additional Capital

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

We have incurred annual net operating losses in every year since our inception. Our net loss was \$91.3 million for the nine months ended September 30, 2017, \$77.5 for the year ended December 31, 2016 and \$83.2 million for the year ended December 31, 2015. As of September 30, 2017, we had an accumulated deficit of \$438.4 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 grants and contract 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 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 continue to increase in 2017 compared to 2016 as we completed our IGNITE4 trial and completed enrollment in our IGNITE3 trial, conduct pre-commercialization activities for eravacycline, seek marketing approval for eravacycline, conduct additional manufacturing process activities related to eravacycline, manufacture drug product for our clinical trials, advance our other product candidates and satisfy our obligations under our license agreement with Harvard University, or Harvard. If we obtain marketing approval of eravacycline or any other product candidate, we also expect to incur significant sales, marketing, and 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; 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:

- conducting and successfully completing IGNITE3;
- 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 U.S. Food and Drug Administration, or FDA, or the European Medicines Agency, or EMA, to perform clinical trials and non-clinical studies in addition to those that are currently being conducted or are currently expected, or if there are any delays in completing our clinical trials, the development of any of our product candidates or the manufacture 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 or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business or continue our operations. A decline in the value of our company could cause our stockholders to lose all or part of their investment in us.

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

Developing pharmaceutical products, including conducting preclinical studies, clinical trials and manufacturing activities, is a time-consuming, expensive and uncertain process that takes years to complete. We expect that our expenses will continue to increase in 2017 compared to 2016 for a number of reasons, including, but not limited to, costs associated with our IGNITE3 and IGNITE4 clinical trials, and conducting pre-commercialization activities for eravacycline. If we obtain marketing approval for eravacycline or any other product candidate that we develop, we also expect to incur significant sales, marketing, distribution and outsourced manufacturing expenses, as well as ongoing research and development expenses.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure potentially obtain regulatory approvals in the United States and Europe for IV eravacycline for the treatment of complicated intra-abdominal infections, or cIAI, to submit a supplemental new drug application, or sNDA, to the FDA for the treatment of complicated urinary tract infections, or cUTI, if warranted, and to perform pre-commercialization activities and commercially launch eravacycline for the treatment of cIAI if approved. 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 and regulatory activities are difficult to predict and are subject to substantial risks and delays. As a result, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources.

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

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

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

- the timing and costs of IGNITE3;
- the timing and costs of our ongoing clinical trials for our other product candidates;
- the timing and costs of manufacturing activities related to regulatory filings and anticipated commercial launch;
- the amount of funding that we receive under our subcontracts awarded to us by our collaborator CUBRC, Inc., or CUBRC, under its government contracts with the Biomedical Advanced Research and Development Authority, or BARDA, and with the National Institutes of Health's, or NIH's, National Institute of Allergy and Infectious Diseases, or NIAID, and under our subaward from CUBRC under its grant from NIAID, and our award from the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator, or CARB-X, and the activities funded under these contracts;
- the number and characteristics of product candidates that we pursue;
- the timing and costs of developing eravacycline for additional indications;
- 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 timing and costs of establishing product sales, marketing, distribution and manufacturing capabilities;
- revenue received from commercial sales of eravacycline, subject to receipt of marketing approval;
- the terms and timing of any future collaborations, partnerships, licensing, marketing, distribution or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights, including milestone and royalty payments and patent prosecution fees that we are obligated to pay to Harvard pursuant to our license agreement;
- the costs of maintaining and protecting our intellectual property rights and defending against intellectual property related claims; and
- the extent to which we in-license or acquire other products and technologies.

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

Currently, our only external source of funds is funding under subcontracts awarded to us by CUBRC pursuant to government contracts from BARDA and NIAID, and an award from CARB-X. Although the BARDA contract and our subcontract with CUBRC under the BARDA contract have terms which currently expire on May 10, 2018, BARDA is entitled to terminate the project for convenience at any time, and is not obligated to provide continued funding beyond current-year amounts from congressionally approved annual appropriations. To the extent that BARDA ceases to provide funding of the program to CUBRC, CUBRC has the right to cease providing funding to us. Committed funding from CUBRC under our BARDA subcontract is for up to \$41.6 million from the initial contract date through May 10, 2018, of which \$34.7 million had been received through September 30, 2017.

Similarly, although the NIAID contract and our subcontract with CUBRC under the NIAID contract have terms which currently expire on December 31, 2018, NIAID is entitled to terminate the project for convenience at any time, and is not obligated to provide continued funding beyond December 31, 2018. To the extent NIAID ceases to provide funding of the programs to CUBRC, CUBRC has the right to cease providing funding to us. Committed funding from CUBRC under our subcontract with respect to the NIAID contract is for up to \$15.1 million, of which \$12.9 million had been received through September 30, 2017. In addition, the NIAID Grant and our subaward from CUBRC expired on May 31, 2017.

Similarly, although the CARB-X Award has a term which currently expires on December 31, 2018, CARB-X is entitled to terminate the project for convenience at any time. Committed funding from the CARB-X Award is for up to \$4.0 million from the initial award date through December 31, 2018, of which none had been received through September 30, 2017.

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

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 multidrug-resistant infections. In July 2017, we announced positive top-line data from IGNITE4. We plan to use the results from IGNITE1 and IGNITE4 to support submission of an NDA for IV eravacycline for the treatment of cIAI during the first quarter of 2018. We have also completed enrollment in our IGNITE3 phase 3 clinical trial evaluating the safety and efficacy of eravacycline with IV administration for the treatment of cUTI and expect to report top-line data from this trial in the first quarter of 2018. If IGNITE3 is successful, we plan to use the results from IGNITE3 to support submission of an sNDA for IV eravacycline for the treatment of cUTI, assuming approval first of IV eravacycline for the treatment of cIAI.

In addition, we submitted a marketing authorization application, or MAA, to the EMA for IV eravacycline for the treatment of cIAI on the basis of the results of IGNITE1.

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 outcome of discussions with regulatory agencies regarding our planned marketing applications;
- favorable results of IGNITE3, and any additional clinical trials involving eravacycline that we may conduct;
- timely filing for and 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;
- successful manufacturing of commercial scale batches of eravacycline;
- commercial launch 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 the oral formulation of eravacycline and of eravacycline for additional indications 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 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 of 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, an MAA to the EMA 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 the lead-in part of IGNITE2, the pivotal portion of IGNITE2 did not meet the primary endpoint of statistical non-inferiority compared to levofloxacin. In July 2017 we announced positive top line data from IGNITE4. In January 2017, we initiated IGNITE3 and completed enrollment in September 2017. We expect to report top-line data from this trial in the first quarter of 2018. We may fail to achieve success in IGNITE3 or any other future clinical trial of eravacycline or any other product candidate.

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

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. In addition, in the case of our clinical trials, results may differ on the basis of the type of bacteria with which patients are infected. We cannot be certain that IGNITE3 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 to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

If we are required to conduct additional clinical trials or other testing of 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 be certain that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, clinical trial delays may ultimately lead to the denial of regulatory approval of 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 such other product candidate as required by the FDA or comparable foreign regulatory authorities, such as the EMA. Patient enrollment is a significant factor in the timing of clinical trials, and is affected by many factors, including:

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

Serious adverse events or undesirable side effects or other unexpected properties of 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, the imposition of distribution or use restrictions 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 emesis. 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 or impose distribution or use restrictions;
- regulatory authorities may require one or more postmarketing studies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product 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 antibiotic 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;
- 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 or an approved risk evaluation and mitigation strategy;
- 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 the oral formulation that we are developing for use in intravenous-to-oral transition 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 level of coverage and amount of reimbursement from government payors, managed care plans and other third-party payors;
- the effectiveness of our sales and marketing efforts;
- adverse publicity about the product or favorable publicity about competitive products; and
- the development of resistance by bacterial strains to the product.

In addition, the potential market opportunity for eravacycline is difficult to estimate. Our estimates of the potential market opportunity are predicated on several key assumptions such as industry knowledge, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain and the reasonableness of these assumptions has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, then the actual market for 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 as a company have little 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 develop and build a commercial organization in the United States and recruit experienced sales, marketing and distribution professionals, which 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 ability 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.

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 may 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 multidrug-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 any product candidates that we are currently developing or that we may develop, which could render our product candidates obsolete or noncompetitive.

There are a variety of available therapies marketed for the treatment of resistant or even multidrug-resistant infections that we would expect would compete with eravacycline, including meropenem/vaborbactam, which is being marketed by The Medicines Company as Vabomere, ceftazidime/avibactam, which is marketed by Allergan, Inc. as Avycaz; meropenem, which is marketed by AstraZeneca as Merrem; ceftolozane/tazobactam, imipenem/cilastatin, and ertapenem which are marketed by Merck & Co., Inc. as Zerbaxa, Primaxin and Invanz, respectively; tigecycline, which is marketed by Pfizer, Inc. as Tygacil; and piperacillin/tazobactam, which is marketed by Pfizer, Inc. 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 currently in phase 3 development by third parties to treat multidrug-resistant infections, including plazomicin, which is being developed by Achaogen, Inc., imipenem/relebactam, which is being developed by Merck & Co.,

Inc., and cefiderocol, which is being developed by Shionogi. Some of these companies may obtain marketing approval from the FDA or comparable foreign regulatory authorities for their product candidates more rapidly than we do, which 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 and obtaining regulatory approvals than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

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 coverage and reimbursement policies or healthcare reform initiatives that could harm our business.

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

Our ability to commercialize 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 authorities, private health insurers, health maintenance organizations and other third-party payors. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. As a result, government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidates profitably.

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

We cannot be sure that coverage will be available for 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.

Although we maintain general liability insurance of \$6 million in the aggregate and clinical trial liability insurance of \$6 million in the aggregate for all product candidates, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We 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.

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

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

Risks Related to Our Dependence on Third Parties

We expect to depend on collaborations with third parties for the development and commercialization of some of our 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 or in compliance with applicable regulatory requirements;
- 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;
- 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 of eravacycline outside the United States. Our ability to enter into any such collaboration may be significantly delayed, or the terms on which we enter into collaborations may be adversely affected, due to the unfavorable results of IGNITE2 or if the results from IGNITE3 are unfavorable.

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

Our reliance on these third parties for clinical development activities limits our control over these activities but we remain responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards. For example, notwithstanding the obligations of a contract research organization for a trial of one of our product candidates, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as current Good Clinical Practices, or cGCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites and institutional review boards. If we or our third-party contractors fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may

be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our product candidates, which would delay the regulatory approval process. We cannot be certain that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. We are also required to register clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time and resources to our ongoing development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for 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 registration batches and commercial quantities of any product candidate that we commercialize following approval for marketing by applicable regulatory authorities. Reliance on third-party manufacturers entails risks, including:

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

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

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

Our current and anticipated future dependence upon others for the manufacture of 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.

Our reliance on government funding for certain of our programs adds uncertainty to our research and commercialization efforts with respect to those programs.

Our development of eravacycline for the treatment of disease caused by bacterial biothreat pathogens and certain life-threatening multidrug-resistant bacteria is currently being partially funded through a subcontract with funding from BARDA. In addition, our development of TP-271 is being funded through a subcontract 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, but not limited to 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;
- 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;
- 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.

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.

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.

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

As a result of the America Invents Act of 2011, the United States transitioned to a first-inventor-to-file system in March 2013, under which, assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent. However, as a result of the lag in the publication of patent applications following filing in the United States, we are not 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 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. We are aware of a third-party U.S. patent claiming pharmaceutical compositions of tetracyclines. The third-party U.S. patent could be asserted against us with respect to eravacycline. We believe we have defenses in the event that the third party seeks to assert such patent against us, including the invalidity of the relevant claims of such patent. However, we may not be successful in asserting these defenses, including proving invalidity, and could be found to infringe the third party's patent, which would have a material adverse effect on us.

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

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

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

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

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Moreover, because we have licensed intellectual property from Harvard, we must rely on Harvard's practices with regard to the assignment of intellectual property to it. To the extent we or Harvard 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 completed registration of our trademarks. Failure to secure those registrations could adversely affect our business.

Four trademark applications for TETRAPHASE PHARMACEUTICALS, our logo, and combinations of those have been allowed in the United States, meaning that we can perfect our registrations when we have commenced use in commerce. TETRAPHASE PHARMACEUTICALS is registered in ten other jurisdictions and pending in three others. 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 completed registration of trademarks for the proposed tradename of eravacycline in two jurisdictions. Trademark applications for the proposed tradename of eravacycline are allowed and are pending in the submission of use claims in the U.S. and one other jurisdiction, but registered trademarks may not be obtained, maintained or enforced. In addition, in the United States Patent and Trademark Office and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to seek to cancel registered trademarks. Cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. We have also obtained registration for our design work in two jurisdictions, and applications remain pending for those design marks in the United States and one other jurisdiction.

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, marketing, export, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities, with regulations differing from country to country. Failure to obtain marketing approval for 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 or additional information regarding chemistry, manufacturing and controls for the product candidate. For example, our progress in the development and commercialization of eravacycline has been significantly delayed as a result of the failure of eravacycline to achieve the primary endpoint in IGNITE2 and may be further delayed as a result of additional clinical outcomes, manufacturing process challenges or other unforeseeable causes. Foreign regulatory authorities have differing requirements for approval of drug candidates with which we must comply prior to marketing. Obtaining marketing approval for marketing of a product candidate in one country does not ensure that we will be able to obtain marketing approval in other countries, but the failure to obtain marketing approval in one jurisdiction could negatively impact our ability to obtain marketing approval in other jurisdictions. Delays in approvals or rejections of marketing applications in the United States or foreign countries may be based upon many factors, including regulatory requests for additional analyses, reports, data and studies, regulatory questions regarding, or different interpretations of, data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding product candidates or related products. The FDA or equivalent foreign regulatory authorities may determine that 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. The FDA may also find during its pre-approval inspection that the facilities identified in our NDA fail to comply with cGMP requirements, thereby delaying or preventing approval. In addition, any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of 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.

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

If a product is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for that condition, the treatment sponsor may apply for FDA fast track designation. The FDA granted eravacycline fast track designation as a qualified infectious disease product in April 2014, granted fast track designation as a qualified infectious disease product for the IV formulation of TP-271 in September 2015, and granted fast track designation as a qualified infectious disease product for the oral formulation of TP-271 in February 2017. Fast track designation does not ensure approval or a faster development, regulatory review or approval process compared to conventional FDA procedures. Additionally, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

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.

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

any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

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, manufacturing, packaging, storage, distribution, advertising, promotion, record-keeping and submission of safety and other post-market information. For example, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs. As such, we and our contract manufacturers will be subject to continual review and periodic inspections to assess compliance with cGMPs. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We 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 and patients;
- impose restrictions on the product or its manufacturers or manufacturing processes;
- impose restrictions on the labeling or marketing of the product;
- impose restrictions on product distribution or use;
- require post-marketing clinical trials;
- require withdrawal of the product from the market;
- refuse to approve pending applications or supplements to approved applications that we submit;
- require recall of the product;
- require entry into a consent decree, which can include imposition of various fines (including restitution or disgorgement of profits or revenue), reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- suspend, vary, modify or withdraw marketing approvals;
- refuse to permit the import or export of the product;
- seize or detain supplies of the product; or
- issue injunctions, levy fines or impose other civil and/or criminal penalties.

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

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

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

We will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Even then, governmental authorities may conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Recent healthcare reform legislation has strengthened these federal and state healthcare laws. For example, the ACA amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or a specific intent to violate them. In addition, the ACA provides that the government may assert that a claim that includes items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act. If governmental authorities find that our operations violate any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and we may be required to curtail or restructure our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our operations and business. The extent to which future legislation or regulations, if any, relating to healthcare fraud and abuse laws or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain.

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

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

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 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, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for line extensions and for drugs that are inhaled, infused, instilled, implanted or injected and expands oversight and support for the federal government's comparative effectiveness research of services and products.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 which reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

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 our executive management team, as well as the other principal members of our management, scientific and clinical team. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time. For instance, in December 2015, both our former chief financial officer and our former chief operating officer terminated their employment with us.

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

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

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

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

We are increasingly dependent on information technology systems, infrastructure and data security. Any attack on our systems, infrastructure or data security could cause serious harm to our business.

Data privacy, security breaches or service interruptions may pose a risk that sensitive data including intellectual property, trade secrets or personal information belonging to us or our business partners may be exposed to unauthorized persons or to the public. Cyber-attacks are growing in their frequency, sophistication and intensity. Our third-party vendors face similar risks and any security breach of their systems could adversely affect us. While we have not yet experienced cyber-attacks and intrusions into our information

technology infrastructure, there can be no assurance that our efforts will prevent or detect future service interruptions or breaches in our systems. Any such future breach may adversely affect our business and operations.

Risks Related to Our Common Stock

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

Our stock price may be volatile. The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. For example, our stock traded within a range of a high price of \$52.90 per share and a low price of \$3.11 per share for the period beginning March 20, 2013, our first day of trading on the NASDAQ Global Select Market, through November 1, 2017. As a result of this volatility, investors may not be able to sell their common stock at or above the prices they paid for it. The market price for our common stock may be influenced by many factors, including:

- the timing of clinical trials of eravacycline and any other product candidate;
- results of clinical trials of eravacycline and any other product candidate;
- the filing and approval of marketing applications;
- regulatory actions by the FDA or equivalent authorities in foreign jurisdictions with respect to eravacycline and any other product candidate;
- failure or discontinuation of any of our development programs;
- the success of existing or new competitive products or technologies;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to develop, in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

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

The stock market frequently experiences extreme price and volume fluctuations. In September 2015, we experienced a significant decline in our stock price based, in large part, on our announcement that the phase 3 clinical trial for eravacycline for the treatment of patients with cUTI did not meet the primary endpoint of statistical non-inferiority compared to levofloxacin. In addition, the market prices of securities of companies in the biotechnology and pharmaceutical industry have been extremely volatile and have experienced fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. These fluctuations could adversely affect the market price of our common stock. In the past, securities class action litigation has often been brought against companies following periods of volatility in the market prices of their securities. In fact, in January 2016 and March

2016, two class action lawsuits were filed against us, our chief executive officer and certain former executives in the United States District Court for the District of Massachusetts. In addition, in May 2016, a shareholder derivative action was filed against our chief executive officer, certain former executive officers, all the members of our current board of directors, a former board member, and against us as nominal defendant, in Massachusetts Superior Court (Suffolk County). This case was subsequently dismissed by the court without prejudice due to the plaintiff's failure to properly perfect service of process. Due to the volatility in our stock price, we may be the target of similar litigation in the future.

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

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

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

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

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

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

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

We have incurred increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company we 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 Select 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 devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time-consuming and costly especially since we are no longer an "emerging growth company", as defined in the Jumpstart Our Business Startups Act of 2012, and are no longer able to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are "emerging growth companies" and that were applicable to us prior to January 1, 2016.

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

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

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the operation, development and growth of our business. The terms of our term loan facility with Silicon Valley Bank and Oxford Finance that we repaid precluded us from paying dividends, and any future debt agreements may also preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

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

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

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

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

Item 5. Other Events

Effective immediately after the Company files this Quarterly Report on Form 10-Q with the SEC, Kamalam Unninayar will become the Company’s principal financial officer and principal accounting officer. Ms. Unninayar, 50, has served as the Company’s Chief Financial Officer since October 2017. From 2005 to March 2017 Ms. Unninayar served in several roles within the financing organization of Thermo Fisher Scientific, Inc., a provider of products and services to businesses and institutions in the field of science, serving most recently as Vice President Finance, Integration Management Office. Ms. Unninayar holds a master of science in administration from Wichita State University and a master of finance and control and bachelor of commerce from the University of Delhi, India.

Pursuant to her offer letter, Ms. Unninayar receives an annual base salary of \$340,000. Ms. Unninayar is eligible to receive an annual performance-based target cash bonus equal to 40% of her annual base salary if, in the discretion of the board of directors, annual established performance criteria are satisfied. The actual cash bonus may range from 0% to 200% of the target amount. Ms. Unninayar is also eligible to receive annual equity awards, subject to approval by the board of directors or the compensation committee. Ms. Unninayar was granted by our compensation committee of the board of directors options to purchase 190,000 shares

of our common stock pursuant to Rule 5635(c)(4) of the Nasdaq Global Select Market. The option was granted as an inducement equity award outside our 2013 Plan and was made as an inducement material to Ms. Unninayar's acceptance of employment with Tetrphase. The option grant has an exercise price equal to the closing price of our common stock on November 15, 2017. The option has a ten-year term and vests over four years, with 25% of the original number of shares vesting on November 15, 2018 and an additional 6.25% of the original number of shares vesting at the end of each successive quarter thereafter, subject to Ms. Unninayar's continued service with Tetrphase through the applicable vesting dates.

In addition, if Ms. Unninayar's employment is terminated by us without cause, subject to her signing a separation agreement that will include a general release of potential claims against us, she will be entitled to continue to receive her monthly base salary for a period of 12 months and we will continue to provide medical, dental and vision benefits (to the extent that she was receiving them at the time of termination) for 12 months. Furthermore, if, within one year following a change in control, Ms. Unninayar's employment is terminated by us or the succeeding company, as applicable, without cause or she terminates her employment for good reason (as defined in her offer letter), subject to Ms. Unninayar's signing a separation agreement that will include a general release of potential claims against us, (1) she will be entitled to continue to receive her monthly base salary for a period of 12 months, (2) she will be entitled to receive a lump sum payment equal to 100% of her target bonus at the time she ceases to be employed by the company or the succeeding company, as applicable, and (3) the company or the succeeding company, as applicable, will continue to provide medical and dental benefits (to the extent that she was receiving them at the time she ceased to be employed by the company) for 12 months.

Effective as of Ms. Unninayar's appointment as the Company's principal financial officer and principal accounting officer, Christopher Watt, the Company's Senior Vice President, Finance, will no longer serve as the Company's principal financial officer and principal accounting officer. Mr. Watt will continue to serve as the Company's Senior Vice President, Finance.

Item 6. Exhibits

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

EXHIBIT INDEX

Exhibit Number	Description of Document	Incorporated by Reference from			Filed Herewith
		Registrant's Form	Form No.	Date Filed with the SEC	
10.1+	Commercial Supply Agreement, dated October 16, 2017, by and between the Registrant and Finorga SAS.				X
10.2#	Offer Letter, dated as of September 21, 2017, by and between the Registrant and Kamalam Unninayar.				X
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2	Certification of Principal 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

+ Confidential treatment requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

Indicates management contract or compensatory plan or arrangement.

SIGNATURES

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

Date: November 1, 2017

TETRAPHASE PHARMACEUTICALS, INC.

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

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

Commercial Supply Agreement

This **Commercial Supply Agreement** (the “**Agreement**”) is entered into as of the 16th day of October, 2017 (“**Effective Date**”) by and between **Tetraphase Pharmaceuticals, Inc.**, a Delaware corporation, with a place of business located at 480 Arsenal Way, Watertown, Massachusetts 02472 (“**Tetraphase**”), and **Finorga SAS**, a French corporation, with a place of business located at 497 Route de Givors, 38670 Chasse-sur-Rhône, France (“**Novasep**”) (hereinafter, each of Tetraphase and Novasep, a “**Party**” and, collectively, the “**Parties**”);

WHEREAS, Tetraphase has developed the Product (as defined below);

WHEREAS, Novasep has expertise and a manufacturing facility suitable for the Manufacture (as defined below) of the Product; and

WHEREAS, Tetraphase wishes to have Novasep Manufacture Product for commercial supply, and Novasep wishes to Manufacture Product for commercial supply for Tetraphase, each in accordance with the terms and conditions of this Agreement;

NOW, THEREFORE, in consideration of the premises and the undertakings, terms, conditions and covenants set forth below, the Parties agree as follows:

1. DEFINITIONS.

- 1.1** “**Acceptable Range**” shall have the meaning set forth in Section 4.3.
- 1.2** “**Affiliate**” of a Party shall mean any entity that controls or is controlled by such Party, or is under common control with such Party. For purposes of this definition, an entity shall be deemed to control another entity if it owns or controls, directly or indirectly, at least fifty percent (50%) of the voting equity of such other entity (or other comparable interest for an entity other than a corporation).
- 1.3** “**Background Intellectual Property**” shall have the meaning set forth in Section 12.1.
- 1.4** “**Batch**” shall mean a specific quantity of Product mutually agreed upon between Tetraphase and Novasep, and that (a) is intended to have uniform character and quality within specified limits, and (b) is manufactured by a process or series of processes so that it is expected to be homogeneous within specified limits.
- 1.5** “**Batch Records**” shall mean manufacturing and test records and documentation relating to Manufacturing, created as each Batch is processed, and relating to the release of each Batch, including but not limited to the master manufacturing formula and process, materials used, documentation, deviations, in-process and release testing records, and any additional documentation generated and/or processed as part of the manufacturing record of the related Batch.
- 1.6** “**cGMP**” shall mean applicable current good manufacturing practices pursuant to (i) the U.S. Federal Food, Drug, and Cosmetic Act as amended (21 USC 301 et seq.), (ii) relevant U.S. regulations found in Title 21 of the U.S. Code of Federal Regulations

(including but not limited to Parts 11, 210, 211, 600 and 610), (iii) Commission Directive 2003/94/EEC of 08 October 2003 and (iv) the EC Guide to Good Manufacturing Practice for Medicinal Licensed Products, including respective guidance documents and any comparable laws, rules or regulations of any agreed upon foreign jurisdiction, as each may be amended from time to time. GMP also includes adherence to any applicable product license requirements, to the current requirements of the United States Pharmacopoeia/National Formulary, the current requirements of the European Pharmacopoeia and, when requested by Tetrphase, , the Japanese Pharmacopoeia and the relevant current International Conference on Harmonization (ICH) guidance documents, including without limitation the ICH Guidance Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients.

- 1.7 “**Certificate of Analysis**” shall mean a document signed by an authorized representative of the CMO describing specifications for and testing methods applied to the Product and the results thereof.
- 1.8 “**Certificate of Compliance**” shall mean a document signed by an authorized representative of the CMO attesting that a particular Batch was Manufactured in accordance with the specifications of cGMP and all other Applicable Law.
- 1.9 “**Commercial Forecast**” shall have the meaning set forth in Section 4.2.
- 1.10 “**Components**” shall mean all components used by Novasep in Manufacturing Product under this Agreement. Components are listed in Exhibit A, and are identified as Components supplied by Tetrphase (“**Tetrphase Supplied Components**”) and Components supplied by Novasep (“**Novasep Supplied Components**”).
- 1.11 “**Confidential Information**” shall have the meaning set forth in Section 11.1.
- 1.12 “**Deficiency Cure Batch**” shall have the meaning set forth in Section 9.2.
- 1.13 “**Facility**” shall mean Novasep’s facility located at Chasse-sur-Rhone or another location as agreed to by the Parties.
- 1.14 “**FDA**” shall mean the United States Food and Drug Administration or any successor entity thereto.
- 1.15 “**Firm Order**” shall have the meaning set forth in Section 4.2.
- 1.16 “**Invention**” shall mean any creative work, invention, innovation, improvement, development, discovery, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained, and whether or not patentable or copyrightable.
- 1.17 “**Intellectual Property**” shall mean all rights, privileges and priorities provided under applicable international, national, federal, state or local law, rule, regulation, statute, ordinance, order, judgment, decree, permit, franchise, license, or other government restriction or requirement of any kind relating to intellectual property, whether registered or unregistered, in any country, including without limitation: (a) all (i) patents and patent applications (including any patent that in the future may issue in connection therewith and all divisions, continuations, continuations-in-part, extensions, additions, registrations, confirmations, reexaminations, supplementary protection certificates, renewals or

reissues thereto or thereof), (ii) copyrights and copyrightable works, including reports, software, databases and related items, and (iii) trademarks, service marks, trade names, brand names, product names, corporate names, logos and trade dress, the goodwill of any business symbolized thereby, and all common-law rights relating thereto; and (b) all registrations, applications, recordings, rights of enforcement, rights of recovery based on past infringement and any and all claims of action related thereto and licenses or other similar agreements related to the foregoing.

- 1.18** “**Master Batch Record**” or “**MBR**” shall mean the document containing the complete Manufacturing Process for the Product, including process parameters and process specifications.
- 1.19** “**Non-Conforming Product**” shall mean any Product which, at the time of delivery to Tetrphase, does not meet the Specifications.
- 1.20** “**Manufacture**” or “**Manufacturing**” shall mean all steps and activities necessary to manufacture Product to be performed by Novasep in accordance with this Agreement, including, without limitation and as applicable, the manufacturing, formulation, filling, packaging, inspection, labeling, testing, quality control, release, storage or distribution.
- 1.21** “**Manufacturing Process**” shall mean the process for Manufacturing the Product.
- 1.22** “**Manufacturing Standards**” shall have the meaning set forth in Section 6.1.
- 1.23** “**Novasep’s Project Intellectual Property**” shall have the meaning set forth in Section 12.2.
- 1.24** “**Product**” shall mean the active pharmaceutical ingredient to be Manufactured by Novasep pursuant to this Agreement.
- 1.25** “**Product Inventions**” shall have the meaning set forth in Section 12.2.
- 1.26** “**Purchase Order**” shall mean a written purchase order in substantially the form agreed in good faith based on customary arrangements in the biopharmaceutical industry between Novasep and Tetrphase, to be delivered by Customer to Novasep for Product pursuant to this Agreement. In the event of any conflict between the terms of this Agreement and any Purchase Order, the terms of this Agreement shall prevail.
- 1.27** “**Purchase Price**” shall mean the amount to be paid by Tetrphase as specified in Exhibit B, subject to adjustment from time to time in accordance with Section 5.2.
- 1.28** “**Quality Agreement**” shall mean an agreement between Novasep and Tetrphase that defines the quality roles and responsibilities of each Party in connection with Manufacture of Product.
- 1.29** “**Recall**” shall have the meaning set forth In Article 8.
- 1.30** “**Regulations**” shall have the meaning set forth in Section 6.9.
- 1.31** “**Regulatory Authority**” shall mean any agency or authority responsible for regulation of Product in the United States or any foreign regulatory jurisdiction, including but not limited to, the FDA the European Medicines Agency and the Japanese Pharmaceuticals

and Medical Devices Agency. Novasep shall have no obligation to Manufacture Product in compliance with the requirements of any non-U.S., European or Japanese Regulatory Authority, except as expressly agreed by the Parties in writing.

- 1.32** “**Released Executed Batch Record**” shall mean the completed and signed Batch Record and associated deviation reports, investigation reports, and Certificates of Analysis (or certificate of conformance) created for each Batch of Product.
- 1.33** “**Specifications**” shall mean the written specifications, characteristics, quality standards and testing specifications for a Product as set forth in Exhibit C and the MBR, which specifications may be amended by Tetraphase from time to time and shall be agreed to in writing by Novasep.
- 1.34** “**Supply Deficiency**” shall mean the difference between the Product transferred under purchase order(s) accepted by Novasep that meet the requirements under this Agreement and the number specified in such purchase order(s) in the event that Novasep has failed to transfer to Tetraphase the quantities specified in the relevant purchase order(s).
- 1.35** “**Supply Failure**” shall mean Novasep has failed to supply at least [**] percent ([**]%) of the aggregate amount of Product due to be delivered in any rolling [**] calendar month period in accordance with the applicable delivery dates, unless such failure results from a default by Tetraphase under this Agreement (including but not limited to a failure to properly provide orders). For purposes of this definition, any Product that is Non-Conforming Product shall not be considered delivered.
- 1.36** “**Term**” shall have the meaning provided in Section 17.1.
- 1.37** “**Tetraphase’s Existing Intellectual Property**” shall have the meaning set forth in Section 12.1.
- 1.38** “**Tetraphase’s Project Intellectual Property**” shall have the meaning set forth in Section 12.2.
- 1.39** **Construction.** In construing this Agreement, unless expressly specified otherwise;
- (a) references to Sections, Schedules and Exhibits are to sections of, and schedules and exhibits to, this Agreement;
 - (b) except where the context otherwise requires, use of either gender includes the other gender, and use of the singular includes the plural and vice versa;
 - (c) headings and titles are for convenience only and do not affect the interpretation of this Agreement;
 - (d) any list or examples following the word “including” shall be interpreted without limitation to the generality of the preceding words;
 - (e) except where the context otherwise requires, the word “or” is used in the inclusive sense;
 - (f) all references to “dollars” or “\$” herein shall mean U.S. dollars; and

(g) each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

2. VALIDATION; REGULATORY SUPPORT.

- 2.1 Changes in Project Scope:** If Tetrphase requests changes in the Project, or if reasonably unforeseeable technical difficulties beyond the control of the Parties require that Novasep perform either additional work or repeat work, and such additional work or repeat work is not required due to Novasep's fault or negligence, Novasep shall provide Tetrphase with cost estimates for such work. If Tetrphase approves such costs in writing, Novasep shall perform such work and Tetrphase shall pay Novasep's costs for such work within [**] days of completion of such work.
- 2.2 Validation:** Novasep shall qualify equipment (as applicable) and validate the Manufacturing Process according to the validation protocol(s) approved by both Parties in advance in writing. Such validation protocol(s) and timeline shall be attached to this Agreement and made a part of Exhibit D. The Parties hereby agree that Exhibit D may be amended in the future as the amount of Product to be manufactured is expected to increase.
- 2.3 Technical Contact and Review Right:** Each Party will appoint a "Technical Contact" having primary responsibility for day-to-day interactions with the other Party for the activities conducted hereunder. Any change to a Technical Contact will be identified in writing to the other Party. Each Party will use reasonable efforts to provide the other Party with at least [**] days prior written notice of any change in that Party's Technical Contact. All communications between the Parties regarding the conduct of the activities hereunder will be addressed to the Party's relevant Technical Contact. Tetrphase reserves the right to review each completed Batch Record and corresponding documentation with respect to API.
- 2.4 Regulatory Support:** Novasep agrees, at its reasonable sole cost and expense, to cooperate with, and provide reasonable regulatory assistance to, Tetrphase to support and provide assistance to existing, pending or new Product registrations and marketing approvals, in each case, with any relevant governmental authority; provided that if Novasep expends more than [**] hours in any given calendar year, Tetrphase shall reimburse Novasep for its reasonable costs and expenses for any hours beyond [**]. The foregoing assistance rendered by Novasep shall include: (a) assisting Tetrphase in completing and submitting new applications and/or any changes to any regulatory submissions related to the Product and (b) providing information to Tetrphase that may be required by a relevant governmental authority to support the Product, including the Manufacturing and exportation related thereto.

3. MANUFACTURE OF PRODUCT

- 3.1 Documentation:** The Master Batch Record shall be reviewed and approved in writing by Novasep and by Tetrphase prior to commencement of Manufacturing. Any major change to an approved Master Batch Record shall be reviewed and approved in writing by Novasep and by Tetrphase prior to said change being implemented. Each Batch of Product shall be Manufactured by using a copy of the Master Batch Record. Each copy of the Master Batch Record for such Batch of Product shall be assigned a unique Batch

number. Any deviation from the Manufacturing Process specified in the Master Batch Record must be documented in the Batch Record for that Batch. The Master Batch Records , will be written and executed in the local language, and Novasep shall provide translations in the English language of all documents. The Parties shall execute the Quality Agreement simultaneously with the execution of this Agreement or at another time, provided that such Quality Agreement shall be executed prior to commencement of Manufacturing.

- 3.2 Vendor and Supplier Audit and Certification:** Tetrphase shall qualify all vendors and suppliers of Tetrphase-Supplied Components. Novasep shall qualify all vendors and suppliers of Novasep -Supplied Components. Tetrphase retains the right to audit any Novasep qualified vendor. and Novasep has the right to audit any Tetrphase qualified vendor .
- 3.3** Intentionally Omitted.
- 3.4 Material Safety Data Sheet:** Tetrphase shall provide Novasep a material safety data sheet for Tetrphase-Supplied Components and for Product and Novasep shall materially conform to established safety practices and procedures set forth therein and shall store and handle Product as required by the MBR, Tetrphase's written instructions and all applicable laws and regulations.
- 3.5 Storage and Handling:** Novasep shall store and handle Components under appropriate conditions and temperature, humidity, light and cleanliness to avoid any material adverse effect on the identity, strength, quality and purity of such Components. Novasep shall store and handle the Product in accordance with the Specifications and under appropriate conditions and temperature, humidity, light and cleanliness to avoid any material adverse effect on the identity, strength, quality and purity of the Product. In addition to the foregoing, Novasep shall store and handle the Products so as to prevent the commingling of same with Novasep's own inventories and supplies, or those held by Novasep for third parties.
- 3.6 Permits and Facility:** Novasep shall secure and maintain in good order, at its sole cost and expense, such current governmental registrations, permits and licenses as are required by Regulatory Authorities in order for Novasep to perform all of its obligations under this Agreement and shall ensure sufficient capacity at the Facility to manufacture the Product in accordance with accepted Purchase Orders.
- 3.7 Subcontracting:** Novasep shall not subcontract or otherwise delegate any portion of its obligations under this Agreement without Tetrphase's prior written approval. Such prior written approval may be set forth in a statement of work or other order documentation.

4. COMMERCIAL FORECASTING AND SUPPLY

- 4.1 General:** Novasep will Manufacture Product and supply such Product ordered by Tetrphase hereunder in accordance with the terms of this Agreement and the Quality Agreement and in accordance with cGMP and all laws and regulations applicable to the Manufacture and supply of the Product. Novasep will Manufacture Product at the Facility. Novasep will deliver Product in accordance with the delivery schedules set forth in each accepted Purchase Order.

- 4.2 **[**] Forecast:** Commencing with the first calendar year after a Product is approved by a Regulatory Authority, Tetrphase shall submit to Novasep on a [**] basis on or before the first business day of each calendar quarter an [**] month rolling forecast that sets forth the total quantity of Product for commercial supply that Tetrphase either has ordered, desires to order, or expects to order from Novasep (the “**Commercial Forecast**”). The first [**] months of each Commercial Forecast shall be binding on Tetrphase and constitute a firm order (“**Firm Order**”). The remaining [**] months of each Commercial Forecast submitted by Tetrphase shall be for planning purposes only, and thus shall not be binding. Novasep will confirm the forecast within [**] working days.
- 4.3 **Amending Forecasts:** Any Commercial Forecast that is not a Firm Order is to be considered an estimated forecast to be used for planning purposes, and shall not be construed as a firm commitment by Tetrphase to Novasep; rather, it can be increased or reduced by Tetrphase from time to time, provided that, (i) Novasep shall have no obligation to manufacture Product in accordance with any Commercial Forecast that is not the subject of a Firm Order and which is increased by greater than [**] percent ([**]%) above the previously forecast amount (the “**Acceptable Range**”); and (ii) Tetrphase shall have no right or remedy with respect to any inability of Novasep to supply Product in accordance with any Commercial Forecast that is not the subject of a Firm Order and which is increased beyond the Acceptable Range. Notwithstanding the foregoing, Novasep shall use commercially reasonable efforts to fulfill any Firm Order and which is increased beyond the Acceptable Range.
- 4.4 **Purchase Order:** Each Purchase Order shall specify Product ordered and the time, manner and address of delivery, all of which shall be subject to this Article 4. Novasep shall notify Tetrphase as to whether any Purchase Order delivered pursuant to this Section 4.4 has been accepted or rejected within [**] business days following Novasep’s receipt of such Purchase Order; provided that Novasep may only reject a Purchase Order which fails to comply with the requirements of this Article 4. Novasep’s failure to affirmatively reject a Purchase Order within the [**] business day period shall be deemed an acceptance of such Purchase Order, notwithstanding the Purchase Order’s failure to comply with the requirements of this Article 4. In the event that Novasep rejects a Purchase Order hereunder, Novasep shall notify Tetrphase in writing within [**] business days of the reasons why such order was rejected by Novasep. Tetrphase may, at its option, submit a revised Purchase Order.
- 4.5 **Fulfillment of Purchase Orders:** Novasep shall deliver Product in the quantities and in accordance with the delivery dates and other terms of the relevant Purchase Order.
- 4.6 **Delivery Terms:** Novasep shall ship all released Product to Tetrphase or to Tetrphase’s designee. All shipments shall be shipped FCA Novasep’s Facility (INCOTERM 2010) , by a common carrier designated by Tetrphase, at Tetrphase’s expense. The selection of the carrier will be done in respect of regulation in Europe and country of destination and validated by Novasep prior the shipment . Tetrphase shall procure, at its cost, insurance covering damage or loss of Product during shipping. All shipping instructions of Tetrphase shall be accompanied by the name and address of the recipient and the shipping date.
- 4.7 **Certificate of Analysis:** An appropriate Certificate of Analysis shall precede the shipment of each Batch delivered to Tetrphase.

- 4.8 Shipping Instructions:** Tetrphase will provide Novasep with packaging and shipping instructions including temperature requirements, temperature monitoring instructions and packaging specifications. Notwithstanding any other provision of this Agreement, Novasep will not be liable for any loss or damage caused solely by Tetrphase's carrier.
- 4.9 Delays:** Novasep shall promptly notify Tetrphase in writing if it believes that there are likely to be delays in the delivery date(s) in any Purchase Order. Such notice shall include the reasons for such changes in the schedule and the proposed new schedule for the incomplete portion of the Purchase Order. For the avoidance of doubt, Novasep is responsible for delays due to its Facility, compliance systems, or Novasep Supplied Components and inaccurate execution of the Manufacture as outlined in the Master Batch Record.
- 4.10 Cancellation:** Tetrphase may cancel any Purchase Order and Novasep shall be relieved of its manufacturing obligations relating to such Purchase Order but, as Tetrphase's exclusive liability, Tetrphase shall remain liable for the full amount of the Purchase Order which is covered under a Firm Order, regardless of whether Novasep manufactures the Product or whether Tetrphase takes delivery of the Product.

5. PAYMENT TERMS.

- 5.1 Invoicing:** Novasep shall invoice Tetrphase upon shipment of Product. Tetrphase shall make payment on all undisputed invoices within [**] days from the date of receipt of Novasep's invoice (unless the invoice is electronically transmitted).
- 5.2 Purchase Price Changes:** From time to time, but in no event more than [**] beginning in [**], the Purchase Price shall be adjusted by Novasep based on the changes in the costs for raw materials and consumables (including but not limited to resins, solvents, anti-oxidants, silica packaging and containers), utilities (including but not limited to energy, oil, electricity and water), changes in the legal requirements or cGMPs, and changes in the Manufacturer's labor costs (not to exceed the changes in the index as published from time to time by the French Union des Industries Chimiques. For all such costs such adjustment shall not be an increase greater than [**]% of the previous calendar year's Purchase Price. Novasep shall provide at least [**] days prior written notice to Tetrphase of any such price adjustment and such price adjustment shall be effective for any Purchase Orders submitted by Tetrphase to Novasep following the notice period of such price adjustment.
- 5.3 Ongoing Productivity Efforts:** Novasep, to the extent reasonable and commercially possible, agrees to (a) study and implement ongoing productivity efforts to increase productivity [**] and (b) help generate and implement ideas to reduce [**] costs and mitigate market increases, such as improvements in quality, service, yields, price, freight, packaging, or component costs, consumption or inventory reduction. Any such reduction in [**] costs or improvements shall be documented by Novasep, verified by Tetrphase, and any such [**] cost savings shall be shared equally by both Parties.
- 5.4 Default in Payment Obligations:** Any payment due under this Agreement not received within the times noted above shall bear interest at the lesser of (a) the maximum rate permitted by law, and (b) [**]% per week on the outstanding balance compounded weekly.

5.5 Taxes: Tetrphase shall bear the cost of all national, state, municipal or other sales, use, excise, import, property, value added, or other similar taxes, assessments or tariffs assessed upon or levied against the Manufacturing and sale of Product pursuant to this Agreement or the sale or distribution of Product by Tetrphase (or at Tetrphase's sole expense, defend against the imposition of such taxes and expenses). Novasep shall notify Tetrphase of any such taxes that any governmental authority is seeking to collect from Novasep, and Tetrphase may assume the defense thereof in Novasep's name, if necessary, and Novasep agrees to fully cooperate in such defense to the extent of the capacity of Novasep, at Tetrphase's expense. Novasep shall pay all national, state, municipal or other taxes on the income resulting from the sale by Novasep of the Product to Tetrphase under this Agreement, including but not limited to, gross income, adjusted gross income, supplemental net income, gross receipts, excess profit taxes, or other similar taxes.

6. CERTIFICATES OF ANALYSIS AND MANUFACTURING COMPLIANCE.

- 6.1 Manufacturing Standards:** Novasep shall manufacture Product in conformity with the Manufacturing Process, Master Batch Record, cGMP, all applicable laws, rules and regulations, all terms and conditions contained in the applicable Purchase Order, and the Specifications (collectively, the "**Manufacturing Standards**").
- 6.2 Certificates of Analysis:** Novasep shall test, or cause to be tested by third parties, in accordance with the Specifications, each Batch of Product Manufactured pursuant to this Agreement before delivery to Tetrphase. The Certificate of Analysis shall be delivered with each Batch and shall set forth the items tested, Specifications and methods against which and by which the analyses are performed, test results and date of manufacture and expiry. Novasep shall also deliver a Released Executed Batch Record in a timely manner and indicate on the Released Executed Batch Record that all batch Manufacturing and control records have been reviewed and approved by the appropriate quality unit. Novasep shall send, or cause to be sent, such certificates to Tetrphase prior to the shipment of Product.
- 6.3 Manufacturing Compliance:** Novasep shall advise Tetrphase as soon as possible if an authorized agent of any regulatory body visits Novasep's manufacturing facility (whether or not such visit includes an inquiry regarding Novasep's Manufacture of Product for Tetrphase). Novasep also agrees to allow the FDA and any other relevant Regulatory Authority to conduct any inspection related to the manufacture of the Product and Novasep agrees to reasonably cooperate with the FDA or such Regulatory Authority in connection with such inspection. Novasep will provide Tetrphase with notice of any such inspection as soon as practicable, but no later than within [**] business days of becoming aware of such inspection.
- 6.4 Reserve Samples:** Novasep shall be responsible for obtaining and maintaining sufficient quantities of Product reserve samples pursuant to cGMP and in compliance with that Quality Agreement executed by the parties on December 3, 2015.
- 6.5 [**] Quality Review:** The Parties shall review and evaluate, at least [**], the quality standards of Product to determine the need for changes in Specifications, the Manufacturing Process, and/or controlled documents.
- 6.6 Records:** Any books and records relating to the receipt, manufacture, storage, handling or testing of the Product and Components shall be maintained under this Agreement by

Novasep in accordance with applicable laws, rules and regulations. Novasep shall maintain distribution records with respect to Product supplied hereunder that contain all of the appropriate information as specified in cGMP. Novasep shall keep all such books and records for at least [**] years.

- 6.7 Audits:** Tetrphase or its designee, at mutually agreed times during normal business hours, shall have the right to inspect, [**] (unless for cause) and during [**] business days maximum, Novasep Batch records, quality systems and the portions of the Facility used for Manufacturing of Product. If the Parties agree to audits more than [**], and/or to audit for more than [**]business days, Tetrphase agrees to reimburse Novasep for Novasep's reasonable expenses incurred in hosting the additional audit day(s). Neither Tetrphase nor its designee shall be permitted to remove or copy data without Novasep's prior consent. Notwithstanding the foregoing, Tetrphase or its designee shall also have the right to conduct "for-cause" audits to address significant Product or safety concerns as discovered through the annual audit or Product failures related to Novasep's manufacture of Product. Tetrphase shall notify Novasep in writing in advance of the audit and thereafter, Tetrphase and Novasep shall mutually determine the timing of the audit.
- 6.8 Observation by Tetrphase:** Tetrphase shall have the right, during normal business hours and at mutually agreed time, to visit the Facility to ensure that the Manufacturing Process complies with the Manufacturing Standards [**] for no more than [**] business days. At all times while in attendance at the Facility, Tetrphase agrees to comply with all Novasep health and safety protocols and other policies and procedures applicable to visitation of the Facility as notified by Novasep to Tetrphase prior to or during such attendance. Such visits shall not interfere with Novasep's operations. In the event of non-compliance Tetrphase shall have the right to revisit the Facility as reasonably necessary in order to confirm that compliance with the applicable Manufacturing Standards has been re-established. The time limitation set forth in this section shall not apply to any visits to the Facility as a result of technical issues with the Manufacture of the Product, including but not limited to issues that would jeopardize the timely supply of Product.
- 6.9 Legal Compliance:** Each Party shall comply in all material respects with applicable laws rules and regulations in the conduct of its activities under this Agreement. Unless otherwise stated, Novasep is responsible for compliance with all federal, state and local laws and regulations ("**Regulations**") as they apply generally to the Facility and Novasep's Manufacture of the Product under this Agreement. Tetrphase shall be responsible for compliance with all Regulations as they apply to the use and sale of Product, which responsibility shall include, without limitation, all contact with Regulatory Authorities regarding the foregoing.

7. ACCEPTANCE OF PRODUCT.

- 7.1 Acceptance and Non-Conforming Product:** Within [**] business days from the date of completion of testing and Novasep's release of each Batch of Product, Novasep shall promptly forward to Tetrphase, or Tetrphase's designee, copies of the Released Executed Batch Record.
- (a) If Tetrphase believes any Batch of Product contains Non-Conforming Product, Tetrphase shall notify Novasep by telephone, including a detailed explanation of the non-conformity, and shall confirm such notice in writing to Novasep within [**] business days. Tetrphase shall provide such notice of Non-Conforming

Product within (i) [**] days after Tetrphase's receipt of such Non-Conforming Product in the event of a defect discovered by Tetrphase through the use of reasonable testing methods and/or the agreed upon testing specifications or (ii) promptly upon Tetrphase's confirmation that Product is Non-Conforming Product in the event of a defect (hidden or otherwise) which was not reasonably discoverable through the use of such testing methods and/or testing specifications. Upon receipt of such notice, Novasep will investigate such alleged non-conformity, and (A) if Novasep agrees such Product is Non-Conforming Product, deliver to Tetrphase a corrective action plan within [**] calendar days after receipt of Tetrphase's written notice of non-conformity, or such additional time as is reasonably required if such investigation or plan requires data from sources other than Tetrphase or Novasep, or (B) if Novasep disagrees with Tetrphase's determination that the Batch of Product is non-conforming, Novasep shall so notify Tetrphase by telephone within the [**] calendar day period and confirm such notice in writing within [**] business days.

- (b) If the Parties dispute whether Product is Non-Conforming Product, samples of the relevant Batch of Product will be submitted to a mutually acceptable laboratory or consultant for resolution, whose determination of conformity or non-conformity, and the cause thereof if non-conforming, shall be binding upon the Parties absent manifest error. The costs of such laboratory or consultant shall be borne by the Party whose position is not upheld by such laboratory or expert's conclusion. If the dispute between the Parties relates to Novasep's ability to manufacture and deliver Product that is not Non-Conforming Product, resolve their dispute in accordance with the procedures in Section 18.7.

7.2 Remedies for Non Conforming Product: In the event Novasep agrees that the Batch of Product is Non-Conforming Product and Tetrphase rejects the Batch, then Novasep, at Tetrphase's option, shall either (i) replace such non-conforming Product within [**] calendar days from receipt of a request from Tetrphase, or (ii) refund the Purchase Price of the Non-Conforming Product. In addition, the due date for the final invoice issued at completion of Manufacturing of said non-conforming Batch of Product will be extended until the date at which replacement Product is released and determined to be conforming by Novasep and Tetrphase.

8. PRODUCT RECALLS.

In the event Tetrphase shall be required to recall any Product because such Product may violate local, state or federal laws or regulations, or the laws or regulations of any applicable foreign government or agency, or does not conform to the Manufacturing Standards, or in the event that Tetrphase elects to institute a voluntary recall, withdrawal, field alert or similar action (collectively a "Recall"), Tetrphase shall be responsible for coordinating such Recall. Tetrphase shall promptly notify Novasep if any Product is the subject of a Recall and provide Novasep with a copy of all documents relating to such Recall. Novasep shall reasonably cooperate with Tetrphase in connection with any Recall, at Tetrphase's expense. If Novasep discovers, after release and distribution of a Batch(es), any finding which impacts or could impact on the quality and safety attributes of the Product, Novasep will notify Tetrphase within [**] business days. Tetrphase shall be responsible for all of the costs and expenses of such Recall unless such recall is exclusively caused by Novasep's gross negligence or willful misconduct or the failure of Product to conform to the Manufacturing Standards at the time of delivery to Tetrphase in which case Novasep shall pay all reasonable direct costs and expenses associated with the such Recall within the limitation set forth in Section 14.2 hereafter.

9. FORCE MAJEURE; FAILURE TO SUPPLY.

9.1 Force Majeure Events: Failure of either Party to perform under this Agreement shall not subject such Party to any liability to the other if such failure is caused by acts of God, acts of terrorism, fire, explosion, flood, drought, war, riot, sabotage, embargo, strikes or other labor trouble, compliance with any order or regulation of any government entity, or by any cause beyond the reasonable control of the affected Party, whether or not foreseeable, *provided* that written notice of such event is promptly given to the other Party. In the case of a force majeure event, Novasep shall use commercially reasonable efforts to arrange for the Manufacture of Product through subcontracting or other means as appropriate to provide Product which conforms to cGMP and the Specifications. However, if Novasep is unable to provide a solution for the Manufacturing of Product reasonably acceptable to Tetrphase within sixty (60) calendar days of such event, Tetrphase may terminate this Agreement as specified in Section 17.2(c) of this Agreement.

9.2 Failure to Supply:

- (a) **Shortage of Supply:** Novasep shall notify Tetrphase immediately upon becoming aware of an event of force majeure or any other event that would render Novasep unable to supply any quantity of the Product required to be supplied hereunder. In such event, Novasep shall use commercially reasonable efforts to remedy such shortage.
- (b) **Procedure to Cure Supply Deficiencies:** If there is a Supply Deficiency, then if requested by Tetrphase Novasep shall promptly take one (1) or more of the following steps to remedy the Supply Deficiency, in the following order of preference whenever reasonably practicable : (a) increase the length of a manufacturing campaign at the Facility in order to manufacture and transfer to Tetrphase additional Batches that meet the relevant requirements under this Agreement to remedy the Supply Deficiency (each such Batch, a “**Deficiency Cure Batch**”); (b) utilize any capacity at the Facility which is not then contractually committed to the performance of services for third party customers during the applicable quarter to manufacture and transfer to Tetrphase Deficiency Cure Batches that meet the relevant requirements under this Agreement; (c) coordinate and cooperate with Tetrphase to re-schedule manufacture and transfer Batches of Product ordered hereunder that meet the relevant requirements under this Agreement in order to maximize Novasep’s ability to manufacture and transfer to Tetrphase Deficiency Cure Batches that meet the relevant requirements under this Agreement while minimizing the disruption of manufacture at the Facility then in force and any contractual commitments to third party customers; and (d) use commercially reasonable efforts to remedy the Supply Failure in subsequent quarters, if any, by utilizing and dedicating excess capacity not contractually committed to third party customers to manufacture and transfer Deficiency Cure Batches that meet the relevant requirements under this Agreement and to reserve such capacity for Tetrphase’s requirement until the issues surrounding the Supply Deficiency have been remedied to Tetrphase’s satisfaction.
- (c) **Supply Failure:**

- (i) Tetrachase may elect, in addition to all other remedies available in law, in equity or under this Agreement, either to: (A) treat the Supply Failure as a Supply Deficiency, such that the provisions of clause (b) above shall apply; or (B) use an alternative supplier for Tetrachase's requirements of Product (in which case all portions of the relevant forecast shall be deemed non-binding); or (C) terminate this Agreement as a result of Novasep's material breach.

9.3 Safety Stock: Novasep shall maintain, at its own risk and Tetrachase expense, safety stock of (1) [**] supply of Product, measured, as of any date, by the Purchase Orders delivered to Novasep by Tetrachase during the immediately preceding [**] and (2) any and all Product and intermediates (including the penultimate form of the Product) produced during the validation process set forth in Exhibit D.

9.4 Alternative Supplier: Nothing in this Agreement shall preclude Tetrachase, at any time during the Term, from qualifying an alternate supplier to manufacture and supply Product. If Tetrachase desires to establish an alternate supplier, either following a Supply Failure or to establish one or more back-up supplier(s) (where the definition of back-up is to supply at maximum [**]% Tetrachase' annual demand for the first [**] years of the Term of this Agreement and at maximum [**]% for the last [**] years of the Term of this Agreement), Novasep shall reasonably assist Tetrachase for a reasonable period of time in such transfer. For clarity, in the event that the facility or facilities selected by Tetrachase are owned or operated by a competitor of Novasep, Novasep shall not be required to communicate directly with such competitor in connection with Novasep's performance of such technology transfer activities. Tetrachase shall reimburse Novasep for all documented direct costs and expenses properly and reasonably incurred by Novasep in connection with all such technology transfer activities requested by Tetrachase.

10. CHANGES IN MANUFACTURING.

10.1 Changes to Master Batch Records and Specifications: Each Party agrees to notify the other promptly of any regulatory or other requested changes to Product, Manufacturing, Specifications or the MBR. Novasep shall notify Tetrachase of and require written approval from Tetrachase for changes to Master Batch Records or Specifications prior to the Manufacturing of subsequent Batches of Product.

10.2 Product-Specific Changes: If Facility, equipment, process or system changes are required of Novasep as a result of requirements set forth by the FDA or any other Regulatory Authority, and such regulatory changes apply only to the Manufacture and supply solely to the Product, then Tetrachase and Novasep will review such requirements and agree in writing to such regulatory changes, and Tetrachase shall bear [**]% of the reasonable costs thereof.

10.3 General Changes: If such regulatory changes apply generally to the Product as well as to other products manufactured by Novasep for itself or for third parties, then Tetrachase shall pay a pro rata amount of the reasonable cost of such regulatory changes based upon the proportion of time that such facility is dedicated to the Manufacture of Product relative to the manufacture of such other products.

10.4 Other Changes: Other changes to the Manufacturing Process and/or Specifications shall be by mutual agreement of the Parties provided that Novasep shall not unreasonably

refuse or condition any request from Tetrphase to make any changes desired by Tetrphase. Any changes to the Manufacturing Process and/or Specifications shall be implemented on terms and conditions to be agreed upon in good faith, which may include reasonable adjustments (which may be upward or downward, as appropriate) to the relevant price for Product payable to Novasep for its services hereunder.

10.5 Unused Materials In the event of changes requested by Tetrphase or to comply with any regulatory requirement, Tetrphase shall reimburse Novasep for any Novasep-Supplied Components that cannot reasonably be used by Novasep or returned for credit.

11. CONFIDENTIALITY.

11.1 Confidentiality. For purposes of this Agreement “**Confidential Information**” means all information provided by or on behalf of one Party (the “**Disclosing Party**”) to the other Party in connection with this Agreement including, without limitation, all data, inventions and information developed in or as a result of the performance of this Agreement, whether in oral, written, graphic or electronic form. Without limiting the generality of the foregoing, all Inventions and Intellectual Property of either Party shall be deemed the “**Confidential Information**” of such Party. Each Party agrees, with respect to any Confidential Information disclosed to such Party (the “**Receiving Party**”) by the Disclosing Party hereunder: (a) to use such Confidential Information only for the purposes set forth in this Agreement or to exercise its rights under this Agreement; (b) to receive, maintain and hold the Confidential Information in strict confidence and to use the same methods and degree of care (but at least reasonable care) to prevent disclosure of such Confidential Information as it uses to prevent disclosure of its own proprietary and Confidential Information and to protect against its dissemination to unauthorized parties; (c) not to disclose, or authorize or permit the disclosure of any Confidential Information to any third party, except to its Affiliates, without the prior written consent of the Disclosing Party; and (d) except as needed to fulfill its obligations hereunder, to return any Confidential Information to the Disclosing Party at the request of the Disclosing Party and to retain no copies or reproductions thereof, except that the Receiving Party may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

11.2 Limitations. The Receiving Party shall not be obligated to treat information as Confidential Information of the Disclosing Party if the Receiving Party can show by competent written evidence that such information: (a) was already known to the Receiving Party without any obligations of confidentiality prior to receipt from the Disclosing Party; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party; (c) became generally available to the public or otherwise part of the public domain after its disclosure, other than through any act or omission of the Receiving Party in breach of any obligation of confidentiality; (d) was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a third party who had no obligation not to disclose such information to others; or (e) was independently discovered or developed by the Receiving Party without the use of or reference to the Disclosing Party’s Confidential Information.

11.3 Authorized Disclosure. Notwithstanding Section 11.1, the Receiving Party may disclose Confidential Information, without violating its obligations under this Article 11, to the extent the disclosure is required by a valid order of a court or other governmental body having jurisdiction; *provided, however*; that the Receiving Party gives reasonable prior written notice to the Disclosing Party of such required disclosure and makes a

reasonable effort to assist the Disclosing Party in obtaining, a protective order preventing or limiting the disclosure and/or requiring that the Confidential Information so disclosed be used only for the purposes for which the law or regulation requires, or for which the order was issued. The Receiving Party will limit access to the Confidential Information of the Disclosing Party to only those of the Receiving Party's employees or authorized representatives having a need to know and who are bound by obligations of confidentiality and non-use consistent with those set forth herein.

11.4 Injunctive Relief. The Parties expressly acknowledge and agree that any breach or threatened breach of this Article 11 may cause immediate and irreparable harm to the Disclosing Party which may not be adequately compensated by damages. Each Party therefore agrees that in the event of such breach or threatened breach and in addition to any remedies available at law, the Disclosing Party shall have the right to seek equitable and injunctive relief, without bond, in connection with such a breach or threatened breach.

11.5 Public Announcements. All publicity, press releases and other announcements relating to this Agreement shall be reviewed in advance by, and subject to the approval of, both Parties (which approval shall not be unreasonably withheld); *provided, however*, that either Party may (a) disclose the terms of this Agreement insofar as required to comply with applicable securities laws, *provided* that in the case of such disclosures the Party proposing to make such disclosure notifies the other Party reasonably in advance of such disclosure and cooperates to minimize the scope and content of such disclosure, and (b) disclose the terms of this Agreement to such Party's investors, professional advisors or potential investors, acquirers, or merger candidates who are bound by obligations of confidentiality and non-use consistent with those set forth herein. The failure of a Party to respond in writing to a publication proposal from the other Party within [**] working days of such party's receipt of such publication shall be deemed as such Party's approval of such publication as received by such Party. Each Party agrees that it shall cooperate fully and in a timely manner with the other with respect to any disclosures to the Securities and Exchange Commission and any other governmental or regulatory agencies, including requests for confidential treatment of Confidential Information of either Party included in any such disclosure.

11.6 Duration of Confidentiality: All obligations of confidentiality and non-use imposed upon the Parties under this Agreement shall expire [**] years after the expiration or earlier termination of this Agreement; *provided, however*, that Confidential Information which constitutes the trade secrets of a Party shall be kept confidential indefinitely, subject to the limitations set forth in Sections 11.2 and 11.3.

12. INVENTIONS.

12.1 Background Intellectual Property: Except as the Parties may otherwise expressly agree in writing, each Party shall continue to own its existing Intellectual Property and Intellectual Property developed or acquired by such Party outside of this Agreement ("**Background Intellectual Property**"), without conferring any interests therein on the other Party. Without limiting the generality of the preceding sentence, Tetrphase shall retain all right, title and interest arising under the United States Patent Act, the United States Trademark Act, the United States Copyright Act and all other applicable laws, rules and regulations in and to all Product, Labeling and trademarks associated therewith (collectively, "**Tetrphase's Existing Intellectual Property**"). Neither Novasep nor any

third party shall acquire any right, title or interest in Tetrphase's Intellectual Property by virtue of this Agreement or otherwise, except to the extent expressly provided herein.

12.2 Individually Owned Inventions: Except as the Parties may otherwise agree in writing, all Inventions which are conceived, reduced to practice, or created solely or jointly by or on behalf of a Party in the course of performing its obligations under this Agreement and that pertain to the Product, but not which are of general use in pharmaceutical manufacturing ("**Product Inventions**") shall be solely owned and subject to use and exploitation by Tetrphase. Novasep hereby assigns all right and title in such Product Inventions and Intellectual Property therein, to Tetrphase. Novasep agrees to execute such assignments and other documents, to cause its employees, consultants and subcontractors to execute such assignments and other documents, and to take such other actions as may be reasonably requested by Tetrphase from time to time in order to effect to the ownership provisions of this Section 12.2. With respect to Inventions that are conceived, reduced to practice, or created by or on behalf of a Party in the course of performing its obligations under this Agreement and are not Product Inventions, the following terms of ownership shall apply: Tetrphase shall solely own all such Inventions made solely by employees, consultants and/or subcontractors of Tetrphase ("**Tetrphase's Project Intellectual Property**"); and Novasep shall solely own Inventions made solely by employees, consultants and/or subcontractors of Novasep ("**Novasep's Project Intellectual Property**").

12.3 Jointly Owned Inventions: All Inventions (other than Product Inventions) which are conceived, reduced to practice, or created jointly by the Parties and/or their respective agents (i.e., employees or agents who would be or are properly named as co-inventors under the laws of the United States on any patent application claiming such Inventions) in the course of the performance of this Agreement shall be owned jointly by the Parties. Each Party shall have full rights to exploit such Inventions for its own commercial purposes without any obligation or duty of accounting to the other. The Parties shall share equally in the cost of mutually agreed patent filings with respect to all such jointly owned Inventions. The decision to file for patent coverage on jointly owned Inventions shall be mutually agreed upon, and the Parties shall select a mutually acceptable patent counsel to file and prosecute patent applications based on such joint Inventions.

12.4 License Grants:

- (a) License to Novasep. During the Term, Tetrphase hereby grants to Novasep a fully paid, non-exclusive license under any and all of Tetrphase's Existing Intellectual Property, Product Inventions and Tetrphase's Project Intellectual Property that is necessary for Novasep to perform its obligations under this Agreement, for the sole and limited purpose of Novasep's performing its obligations under this Agreement.
- (b) License to Tetrphase. Novasep hereby grants to Tetrphase an irrevocable, fully paid, royalty-free, perpetual, worldwide, non-exclusive license, with the right to grant and authorize sublicenses, under any and all Novasep's Background Intellectual Property and Novasep's Project Intellectual Property that Novasep incorporates into the Manufacturing Process or that is otherwise necessary for the practice of the Manufacturing Process, for the sole and limited purpose of manufacturing, or having manufactured Products.

12.5 Disclaimer: Except as otherwise expressly provided herein, nothing contained in this Agreement shall be construed or interpreted, either expressly or by implication, estoppel or otherwise, as: (i) a grant, transfer or other conveyance by either Party to the other of any right, title, license or other interest of any kind in any of its Inventions or other Intellectual Property, (ii) creating an obligation on the part of either Party to make any such grant, transfer or other conveyance or (iii) requiring either Party to participate with the other Party in any cooperative development program or project of any kind or to continue with any such program or project.

12.6 Confidentiality of Inventions: Inventions shall be deemed to be the Confidential Information of the Party(ies) owning such Inventions. Any disclosure of Confidential Information by one Party to the other under the provisions of this Article 12 shall be treated as the disclosing Party's Confidential Information under this Agreement. It shall be the responsibility of the Party preparing a patent application to obtain the written permission of the other Party to use or disclose the other Party's Confidential Information in the patent application before the application is filed and for other disclosures made during the prosecution of the patent application.

13. REPRESENTATIONS AND WARRANTIES.

13.1 Mutual Representations: Each Party hereby represents and warrants to the other Party that (a) such Party is duly organized, validly existing, and in good standing under the laws of the place of its establishment or incorporation, (b) such Party has taken all action necessary to authorize it to enter into this Agreement and perform its obligations under this Agreement, (c) this Agreement will constitute the legal, valid and binding obligation of such Party, and (d) neither the execution of this Agreement nor the performance of such Party's obligations hereunder will conflict with, result in a breach of, or constitute a default under any provision of the organizational documents of such Party, or of any law, rule, regulation, authorization or approval of any government entity, or of any agreement to which it is a Party or by which it is bound.

13.2 Novasep Warranty: Novasep represents and warrants that all Product manufactured and supplied under this Agreement shall be manufactured at the Facility, conform to the Manufacturing Standards, and shall not be adulterated or misbranded within the meaning of the United States Food, Drug, and Cosmetic Act (as amended from time to time) or other applicable law, when delivered to Tetrphase in accordance with this Agreement. Novasep represents and warrants that it has obtained (or will obtain prior to Manufacturing Product), and will remain in compliance with during the Term, all permits, licenses and other authorizations (the "*Permits*") which are required under federal, state and local laws, rules and regulations applicable to the Manufacture of Product; *provided, however*, Novasep shall have no obligation to obtain Permits relating to the sale, marketing, distribution or use of Product. Novasep further represents and warrants that: (a) the Facility conforms to cGMP and the requirements of all applicable governmental and regulatory authorities; (b) all Product delivered hereunder shall be delivered to Tetrphase with good and valid title, free and clear of all liens and encumbrances; (c) neither Novasep, nor any employee, personnel or contractor of Novasep who will perform services under this Agreement, has been suspended, debarred or subject to temporary denial of approval, and to the best of its knowledge, is not under consideration to be suspended, debarred or subject to temporary denial of approval, by the FDA or any other governmental or regulatory authority from working in or providing services, directly or indirectly, to any applicant for approval of a drug product or any pharmaceutical or biotechnology company under the Generic Drug Enforcement Act of

1992 or any other similar law or regulation in any other jurisdiction; and (d) in its performance of its obligations under this Agreement, Novasep will not knowingly incorporate into the Manufacturing Process any Intellectual Property of a third party for which it does not have a license that permits it to do so. Novasep makes no representation or warranty with respect to the sale, marketing, distribution or use of the Product.

13.3 Tetrphase Warranties: Tetrphase represents and warrants that (a) it has the right to give Novasep any tetrphase-supplied material and information provided by Tetrphase hereunder, and that Novasep has the right to use such information for the Manufacture of Product, and (b) as of the Effective Date, Novasep's manufacture of Product in accordance with the Specifications and this Agreement does not, to Tetrphase's knowledge, infringe any patents or other intellectual property rights belonging to third parties.

13.4 Disclaimer of Warranties: Except as expressly set forth in this Agreement, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF TITLE, NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

14. EXCLUSION AND LIMITATION OF LIABILITY AND WAIVER.

14.1 Exclusion of Liability: EXCEPT WITH RESPECT TO A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 15.1 OR 15.2 OR WITH RESPECT TO A BREACH OF THE CONFIDENTIALITY OR NON-USE OBLIGATIONS UNDER ARTICLE 11, UNDER NO CIRCUMSTANCES SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY HEREUNDER FOR LOSS OF USE OR PROFITS, COLLATERAL, SPECIAL, CONSEQUENTIAL, PUNITIVE OR OTHER INDIRECT DAMAGES.

14.2 Limitation of liability: Notwithstanding any other terms of this Agreement, the aggregate liability of Novasep arising out of any term or condition of the present Agreement with respect to any batch of Product shall be in any case limited to twice the sum paid by Tetrphase to Novasep for such batch of Product.

15. INDEMNIFICATION.

15.1 Tetrphase Indemnification: Tetrphase hereby agrees to defend, indemnify and hold harmless Novasep and its Affiliates and their respective officers, directors, employees, contractors, consultants and agents (each, a "**Novasep Indemnatee**") from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees ("**Losses**"), to which any Novasep Indemnatee may become subject as a result of any claim, demand, action or other proceeding by any third party including, without limitation, property damage, death or personal injury of third parties (a "**Claim**") against an Novasep Indemnatee arising or resulting, directly or indirectly, from (a) Tetrphase's storage, promotion, labeling, marketing, distribution, use or sale of Product, (b) Tetrphase's negligence or willful misconduct, or (c) Tetrphase's breach of this Agreement, except to the extent any such Loss(es) are caused by the negligence or willful misconduct of the Novasep Indemnitees or by the breach of this Agreement by Novasep.

15.2 Novasep Indemnification: Novasep hereby agrees to defend, indemnify and hold harmless Tetrphase and its Affiliates and any of their respective directors, officers, employees, subcontractors and agents (each, a “**Tetrphase Indemnitee**”) from and against any and all Losses to which any Tetrphase Indemnitee may become subject as a result of any Claim arising from (a) any Novasep Indemnitee’s negligence or willful misconduct or (b) the breach of this Agreement by Novasep, except to the extent any such Loss(es) are caused by the negligence or willful misconduct of the Tetrphase Indemnitees or by the breach of this Agreement by Tetrphase.

15.3 Indemnitee Obligations: A Party that makes a claim for indemnification under this Article 15 shall promptly notify the other Party (the “**Indemnitor**”) in writing of any action, claim or other matter in respect of which such Party, intends to claim such indemnification; *provided, however,* that failure to provide such notice within a reasonable period of time shall not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is prejudiced by such failure. The indemnified Party shall permit the Indemnitor, at its discretion, to settle any such action, claim or other matter, and the indemnified Party agrees to the complete control of such defense or settlement by the Indemnitor. Notwithstanding the foregoing, the Indemnitor shall not enter into any settlement that would adversely affect the indemnified Party’s rights hereunder, or impose any obligations on the indemnified Party in addition to those set forth herein, in order for it to exercise such rights, without the indemnified Party’s prior written consent, which shall not be unreasonably withheld or delayed. No such action, claim or other matter shall be settled without the prior written consent of the Indemnitor, which shall not be unreasonably withheld or delayed. The indemnified Party shall fully cooperate with the Indemnitor and its legal representatives in the investigation and defense of any action, claim or other matter covered by the indemnification obligations of this Article 15. The indemnified Party shall have the right, but not the obligation, to be represented in such defense by counsel of its own selection and at its own expense.

16. INSURANCE.

16.1 Tetrphase Insurance: Tetrphase shall procure and maintain, from the Effective Date through the date that is one year after the expiration date of all Product Manufactured under this Agreement, commercial general liability insurance, including without limitation, Product Liability and Contractual Liability coverage. Such insurance shall cover amounts not less than \$[**] combined single limit and shall be with an insurance carrier reasonably acceptable to Novasep.

16.2 Novasep Insurance: Novasep shall procure and maintain, from the Effective Date through the date that is one year after the expiration date of all Product Manufactured under this Agreement, Commercial General Liability Insurance, including without limitation, Product Liability and Contractual Liability coverage. Such insurance shall cover amounts not less than \$[**] combined single limit.

17. TERM AND TERMINATION.

17.1 Term: This Agreement shall commence on the Effective Date and will continue for five (5) years after the Effective Date (the “**Initial Term**”). Unless otherwise terminated in accordance with this Article 17, this Agreement shall be automatically extended for an indefinite period (the “**Renewal Term**” and together with the Initial Term, the “**Term**”). Notwithstanding any of the foregoing, either Party may terminate this Agreement at the

end of the Initial Term or during the Renewal Term provided, however, that it has given the other Party at least eighteen (18) months prior written notice of termination.

17.2 Termination: This Agreement may be terminated at any time upon the occurrence of any of the following events:

- (a) **Termination for Breach:** Either Party may terminate this Agreement upon the material breach (which shall include any breach of payment terms) of any provision of this Agreement by the other Party if such breach is not cured by the breaching Party within [**] days (or such additional time reasonably necessary to cure such breach *provided* the breaching Party has commenced a cure within the [**]-day period and is diligently pursuing completion of such cure) after receipt by the breaching Party of written notice of such breach.
- (b) **Termination for Financial Matters:** This Agreement may be terminated immediately by either Party by giving the other Party written notice thereof in the event such other Party makes a general assignment for the benefit of its creditors, or proceedings of a case are commenced in any court of competent jurisdiction by or against such Party seeking (a) such Party's reorganization, liquidation, dissolution, arrangement or winding up, or the composition or readjustment of its debts, (b) the appointment of a receiver or trustee for or over such Party's property, or (c) similar relief in respect of such Party under any law relating to bankruptcy, insolvency, reorganization, winding up or composition or adjustment of debt, and such proceedings shall continue undismissed, or an order with respect to the foregoing shall be entered and continue unstayed, for a period of more than sixty (60) days.
- (c) **Termination for Force Majeure:** Tetrphase shall have the right to terminate this Agreement with thirty (30) days written notice to Novasep in the event that Novasep experiences a force majeure event.
- (d) **Termination for Regulatory Action:** Tetrphase may terminate this Agreement upon thirty (30) days' prior written notice if any Regulatory Authority takes any action, or raises any objection, that prevents Tetrphase from importing, exporting, purchasing, or selling the Product.

17.3 Effects of Termination:

- (a) In the event this Agreement is terminated, other than by Novasep pursuant to Section 17.2(a), (i) Novasep shall, at Tetrphase's sole cost and expense, make reasonable effort to convey to Tetrphase all manufacturing know-how and other information related to the Manufacturing Process sufficient to enable Tetrphase to manufacture Product (including assay methods, SOPs, detailed equipment requirements and specifications, materials and all know-how contained in the Master Batch Record), and (ii) Novasep shall promptly, upon request by Tetrphase and at Tetrphase's sole cost and expense, provide such other assistance as Tetrphase may reasonably request (including access to and assistance from employees with knowledge of the Manufacturing Process during any transition period). Such know-how and information shall include, without limitation, records and reports related to (A) the Manufacturing Process, (B) testing for compliance with the Specifications, and (C) Batch records for previously supplied Product. In addition, Novasep shall refund to Tetrphase

Project Manager [**]

Quality Control and Assurance [**]

For specific inquiries, the following Tetraphase responsible parties may be contacted directly:

Project Manager: [**]

- 18.2** Quality Control and Assurance: [**]**Entire Agreement; Amendment:** The Parties acknowledge that this Agreement sets forth the entire agreement and understanding of the Parties and supersedes all prior written or oral agreements or understandings with respect to the subject matter hereof. No modification of any of the terms of this Agreement, or any amendments or Appendices, shall be deemed to be valid unless in writing and signed by an authorized agent or representative of both Parties hereto. No course of dealing or usage of trade shall be used to modify the terms and conditions herein.
- 18.3** **Waiver:** None of the provisions of this Agreement shall be considered waived by any Party hereto unless such waiver is agreed to, in writing, by authorized agents of both Parties. The failure of a Party to insist upon strict conformance to any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law shall not be deemed a waiver of any rights of either Party.
- 18.4** **Assignment:** This Agreement may not be assigned or transferred by either Party without the prior written consent of the other, which consent will not be unreasonably withheld or delayed; *provided, however,* that either Party may assign this Agreement without the other Party's consent to an Affiliate or in connection with the transfer or sale of all or substantially all of the business of such Party to which this Agreement relates, whether by merger, sale of stock, sale of assets or otherwise. Any attempted assignment of this Agreement not in compliance with this Section 18.4 shall be null and void. No assignment shall relieve either Party of the performance of any accrued obligation that such Party may then have under this Agreement. This Agreement shall inure to the benefit of and be binding upon each Party signatory hereto, its successors and permitted assigns, subsidiaries and Affiliates.
- 18.5** **Independent Contractor:** Novasep shall act as an independent contractor for Tetraphase in providing the services required hereunder and shall not be considered an agent of, or joint venturer with, Tetraphase. Unless otherwise provided herein to the contrary, Novasep shall furnish all expertise, labor, supervision, machining and equipment necessary for performance hereunder and shall obtain and maintain all building and other permits and licenses required by public authorities.
- 18.6** **Governing Law; Limitations:** This Agreement is made under and will be construed in accordance with the laws of the State of New York without giving effect to that jurisdiction's choice of law rules. The United Nations Convention on Contracts for the International Sale of Goods will not apply to this Agreement or to transactions processed under this Agreement.
- 18.7** **Dispute Resolution:** In case of disputes between the Parties arising from the enforcement and/or the interpretation of the Agreement, the Parties shall try to settle amicably and rapidly such dispute. It is expressly agreed between the Parties that if no settlement can be found between them within a reasonable period of time, and in any case

no later than [**] months following the receipt by one Party of the written claim of the other Party, any disputes shall be brought in the Federal or State courts of New York which shall have exclusive jurisdiction.

18.8 Attorney's Fees: The successful Party in any litigation or other dispute resolution proceeding to enforce the terms and conditions of this Agreement shall be entitled to recover from the other Party reasonable attorney's fees and related costs involved in connection with such litigation or dispute resolution proceeding.

18.9 Severability: In the event that any one or more of the provisions contained herein, or the application thereof in any circumstances, is held invalid, illegal or unenforceable in any respect for any reason, the Parties shall negotiate in good faith with a view to the substitution therefor of a suitable and equitable provision in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid provision; *provided, however*, that the validity, legality and enforceability of any such provision in every other respect and of the remaining provisions contained herein shall not be in any way impaired thereby, it being intended that all of the rights and privileges of the Parties hereto shall be enforceable to the fullest extent permitted by law.

IN WITNESS WHEREOF, the Parties have each caused this Agreement to be executed by their duly-authorized representatives as of the Effective Date above.

TETRAPHASE PHARMACEUTICALS, INC.

FINORGA S.A.S.

By: /s/ Guy Macdonald

By: /s/ Laurent Castel

Name: Guy Macdonald

Name: Laurent Castel

Title: CEO

Title: President Finorga SAS

Exhibit A
Components

Components Used in the Commercial Process for []**

Table 1 shows the batch input size for each of the steps that will be carried for the commercial manufacture of [**]

Table 1 – Batch Input Size

Reaction Step	Input Material (Limiting)	Batch Size ¹ (kg)	
		Minimum	Maximum
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]

¹ Amounts refer to the quantity of the input material used in the step.

The tables below list the target quantities of materials used in the manufacture of [**]. The proven acceptable ranges (PAR) for material charges are provided and for some reagents are expressed in molar ratios with respect to the starting material. Material amounts required, including solvent quantities, may vary depending upon batch size and equipment configuration but will be within ranges to ensure the quality of the drug substance.

Table 2 – Materials Used in the Manufacture of []**

Process Step	Material	Target Quantity (PAR)	Molar Ratio (PAR)
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Process Step	Material	Target Quantity (PAR)	Molar Ratio (PAR)
[**]	[**]	[**]	[**]
	[**]	[**]	[**]
	[**]	[**]	[**]
	[**]	[**]	[**]
	[**]	[**]	[**]
	[**]	[**]	[**]
	[**]	[**]	[**]
[**]	[**]	[**]	[**]
	[**]	[**]	[**]
	[**]	[**]	[**]
	[**]	[**]	[**]
	[**]	[**]	[**]
	[**]	[**]	[**]
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	[**]	[**]	[**]
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[**]	[**]	[**]	[**]
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[**]	[**]	[**]	[**]
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[**]	[**]	[**]	[**]

[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
	[**]	[**]	[**]
	[**]	[**]	[**]

Exhibit B

Purchase Price

1. Quantity / Number of Batches / Pricing

Product	Number of Batches per Year	Quantity (kg)	Price (USD/kg)
Tesla St4	[**]	[**]	[**]
	[**]	[**]	[**]
	[**]	[**]	[**]

- Pricing is inclusive of all raw materials with the exception of [**].
- Tetraphase will provide [**]
- Manufacturing will be performed in the same workshops as the PPQ campaign.
- The pricing above is based on the production performance of the process validation campaign. Should process improvements (whether they be operational or otherwise) be achieved through additional development work and recognized on scale, the pricing will be re-evaluated at that time and the parties will use commercially reasonable efforts to determine a mutually agreed upon new pricing.

2. Currency Exchange Rate

The price offered is based on a Euro-USD exchange rate of [**]

Exhibit C
Specifications

Confidential
ActiveUS 165292859

P | 30 a g e

Tetraphase Pharmaceuticals, Inc. 480 Arsenal Street, Suite 110 Watertown, MA 02472	 TETRAPHASE PHARMACEUTICALS
SPECIFICATION	Document No: [**]
Title: Material Specification for [**]	Version: 01
	Stage: Commercial

MATERIAL SPECIFICATION

Material Name: [**]

Material Description: [**]

Compound Number [**]

Material Code: [**]

Storage Conditions: [**]

Shipping Conditions: [**]

Retest Period: [**]

Expiry Period: [**]

Container Closure System: [**]

Material Type:

Drug Substance (DS) Drug Product (DP) Intermediate (IN)
 Starting Material (SM) Seed Material (SD) Other [OT]

Release Specifications:

Test	Method	Method Number	Acceptance Criteria
Appearance ²	Visual	[**]	[**]
Identification	HPLC Method 1	[**]	[**]
Identification	IR	[**]	[**]
Chloride content	IC (%w/w)	[**]	[**]
Polymorph ²	XRPD	[**]	[**]

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INFORMATION ONLY

Tetraphase Pharmaceuticals, Inc. 480 Arsenal Street, Suite 110 Watertown, MA 02472	 TETRAPHASE PHARMACEUTICALS
SPECIFICATION	Document No: [**]
Title: Material Specification for [**]	Version: 01
	Stage: Commercial

Test	Method	Method Number	Acceptance Criteria	
Impurities ²	HPLC (area%) Method 1	[**]	[**]	[**]
Impurities ²	HPLC (area%) Method 2	[**]	[**]	[**]
Impurities	HPLC (%w/w) Method 3	[**]	[**]	[**]
Assay ² (anhydrous, solvent free)	HPLC (% w/w) Method 1	[**]	[**]	
Residual Solvents ²	GC	[**]	[**]	[**]
			[**]	[**]
1-Methyl 1-2-pyrrolidone	HPLC (ppm) Method 4	[**]	[**]	
Methyl Chloride ² (MeCl)	GC-MS (ppm)	[**]	[**]	
Ethyl Chloride ² (EtCl)	GC-MS (ppm)	[**]	[**]	
Moisture Content ²	Karl Fisher (% w/w) Ph. Eur. 2.5.32, USP <921> Method 1c	[**]	[**]	
Heavy Metals	USP <231> Method II (ppm)	[**]	[**]	
Palladium	ICP-MS (ppm)	[**]	[**]	
Specific Rotation	Ph. Eur. 2.2.7 USP <781S>	[**]	[**]	
Endotoxin	Ph. Eur. 2.6.14 method D USP <85>	[**]	[**]	

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INFORMATION ONLY

Tetraphase Pharmaceuticals, Inc. 480 Arsenal Street, Suite 110 Watertown, MA 02472	 TETRAPHASE PHARMACEUTICALS
SPECIFICATION	Document No: [**]
Title: Material Specification for [**]	Version: 01
	Stage: Commercial

Test	Method	Method Number	Acceptance Criteria
Bioburden ² Total Viable Aerobic Count, Bacteria	Ph. Eur. 2.6.12 USP <61>	[**]	[**]
Total Viable Aerobic Count, Fungi			

[**]

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INFORMATION ONLY

Tetraphase Pharmaceuticals, Inc. 480 Arsenal Street, Suite 110 Watertown, MA 02472	 TETRAPHASE PHARMACEUTICALS
SPECIFICATION	Document No: [**]
Title: Material Specification for [**]	Version: 01
	Stage: Commercial

Prepared by:

Date:

/s/ Anne Fornicola

07 APR 2017

Anne Fornicola, Director, CMC PM
Tetraphase Pharmaceuticals, Inc.

Approved by:

Date:

/s/ Jonathan Walker

7th April 2017

Jonathan Walker, VP, Manufacturing
Tetraphase Pharmaceuticals, Inc.

/s/ Robert Costanzo

11 Apr 2017

Robert Costanzo, Director, Quality Control
Tetraphase Pharmaceuticals, Inc.

/s/ Steven Ferris

11 Apr 2017

Steven Ferris, Senior Director, Quality Assurance
Tetraphase Pharmaceuticals, Inc.

VERSION SUMMARY

Brief Summary of Changes to this Document:

DCR #	Version	Summary of Changes
17-014	00	[**]
17-017	01	[**]

Tetraphase Pharmaceuticals, Inc documentation is considered CONFIDENTIAL and PROPRIETARY. Distribution to third parties without prior permission is prohibited.

INFORMATION ONLY

Exhibit D

Validation Protocols

**Confidential Materials omitted and filed separately with the
Securities and Exchange Commission. A total of 160 pages were omitted. [**]**

Confidential
ActiveUS 165292859

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Tetraphase Pharmaceuticals, Inc.
480 Arsenal Street, Suite 110
Watertown, MA 02472

September 21, 2017

Kamalam Unninayar

Dear Kam:

On behalf of Tetraphase Pharmaceuticals, Inc. (the "Company"), I am very pleased to offer you employment with the Company. The purpose of this letter is to summarize the terms of your employment with the Company, should you accept our offer.

- 1. Employment.** You will be employed to serve on a full-time basis in the position of Chief Financial Officer, reporting to Guy Macdonald, President and Chief Executive Officer, Tetraphase Pharmaceuticals, Inc. Your start date will be mutually agreed upon, but no later than October 16, 2017. As Chief Financial Officer, you will have such duties and responsibilities as are customary for such position and such other duties and responsibilities as may be assigned to you by the Company. You agree to devote your full business time, best efforts, skill, knowledge, attention, and energies to the advancement of the Company's business and interests and to the performance of your duties and responsibilities as an employee of the Company.
 - 2. Base Compensation.** Your base salary will be at the rate of \$13,076.93 per bi-weekly pay period (equivalent to an annualized rate of \$340,000), less all applicable federal, state, and local taxes and withholdings, such base salary to be paid in installments in accordance with the Company's standard payroll practices. Such base salary may be adjusted from time to time in accordance with normal business practices and in the sole discretion of the Company.
 - 3. Bonus.** If the Board of Directors approves an annual bonus for fiscal year 2018 or any fiscal year thereafter, you may be eligible for a discretionary retention and performance bonus award of up to 40% of your annualized base salary in such year (the "Target Bonus"). The bonus award, if any, will be based on both individual and corporate performance and will be determined by the Board of Directors of the Company in its sole discretion. You will not be eligible to receive any bonus for fiscal year 2017. In any event, in order to be eligible for and to earn a bonus, if any, you must be an active employee of the Company on the date such bonus is distributed, as it also serves as an incentive to remain employed by the Company. Any bonus that the Board determines to be payable for a fiscal year will be paid before March 15th of the next fiscal year. Your annual bonus is subject to the terms and conditions set forth in the Company's Employee Bonus Plan
 - 4. Benefits.** You may participate in any and all benefit programs that the Company establishes and makes available to its employees from time to time, provided that you are eligible under (and subject to all provisions of) the plan documents governing those programs. Such benefits may include: participation in group medical and dental insurance programs, term life insurance, long-term disability insurance and participation in the Company's 401(k) plan. The benefits made
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available by the Company, and the rules, terms, and conditions for participation in such benefit programs, may be changed by the Company at any time and from time to time without advance notice (other than as required by such programs or under law). With respect to vacation time, you will accrue vacation at 1.67 days/month or the equivalent of a maximum of 4 weeks per calendar year. Vacation may be taken at such times as may be approved by the Company. Your accrual and use of vacation time will also be subject to any and all vacation policies and procedures that the Company establishes from time to time.

5. **Stock Incentive Program.** You will be eligible to participate in the Company's stock incentive program. Subject to approval by the Company's Board of Directors, the Company will grant to you an option to purchase 190,000 shares of the Company's Common Stock (subject to adjustment for stock splits, combinations, or other recapitalizations) which will vest (i.e., become exercisable) as to 25% of the shares on the first anniversary of your first day of employment and as to 6.25% of the shares every three-months thereafter, subject to your continued employment by the Company. The option exercise price will be equal to the fair market value of one share of Common Stock on the date of grant of the option as determined by the Company's Board of Directors.
6. **At-Will Employment.** This letter shall not be construed as an agreement, either express or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at will, under which both you and the Company remain free to terminate the employment relationship at any time, for any reason, with or without cause, and with or without notice. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at-will" nature of your employment may only be changed by a written agreement signed by you and the principal executive officer of the Company, which expressly states the intention to modify the at-will nature of your employment. Similarly, nothing in this letter shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company, except to the extent explicitly set forth in Section 8 hereof.
7. **Non-Solicitation, Non-Disclosure and Developments Agreement.** As a condition of your employment, you will be required to execute the Company's Non-Solicitation, Non-Disclosure and Developments Agreement (the "Non-Solicitation Agreement"), a copy of which is enclosed with this letter.
8. **Severance Benefits.** Notwithstanding your status as an at-will employee, in the event that the Company (or, as may be applicable, an acquiring or succeeding company) terminates your employment without "Cause," or you terminate your employment with the Company (or, as may be applicable, an acquiring or succeeding company) for "Good Reason" (each term as defined in Exhibit A and in either case a "Qualifying Termination"), you will be eligible for the benefits outlined in either sub-section A or subsection B (the "Severance Benefits"), subject to the terms set forth in this letter agreement:

(A) If a Qualifying Termination occurs prior to or more than twelve months following a Change in Control Event (as defined in Exhibit A), the Company will provide to you as severance pay an amount equal to twelve (12) months of your then-current base salary (subject to

all applicable federal, state and local taxes and withholdings and payable over a twelve -month period in accordance with the Company's regular payroll practices). In addition, should you timely elect and be eligible to continue receiving group medical coverage pursuant to applicable "COBRA" law, and so long as the Company can provide such benefit without violating the nondiscrimination requirements of applicable law, the Company will, until the earlier of (x) the date that is twelve (12) months following your termination date and (y) the date you (or, as applicable, your beneficiaries) become eligible for coverage through a new employer, continue to pay the share of the premium for such coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage (provided that the Company will not pay more each month than the monthly amount it was paying for your coverage when your employment ended). The remaining balance of any premium costs shall timely be paid by you on a monthly basis (or such other basis as is required by the Company) for as long as, and to the extent that, you remain eligible for COBRA continuation.

(B) If a Qualifying Termination occurs upon or during the twelve month period commencing upon a Change in Control Event, the Company will provide to you as severance pay an amount equal to the sum of (i) twelve (12) months of your then-current base salary (subject to all applicable federal, state and local taxes and withholdings and payable over a twelve -month period in accordance with the Company's regular payroll practices) and (ii) an amount equal to 100% of your then-current annual Target Bonus (subject to all applicable federal, state and local taxes and withholdings and payable in a lump sum). In addition, should you timely elect and be eligible to continue receiving group medical coverage pursuant to applicable "COBRA" law, and so long as the Company can provide such benefit without violating the nondiscrimination requirements of applicable law, the Company will, until the earlier of (x) the date that is twelve (12) months following your termination date and (y) the date you (or, as applicable, your beneficiaries) become eligible for coverage through a new employer, continue to pay the share of the premium for such coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage (provided that the Company will not pay more each month than the monthly amount it was paying for your coverage when your employment ended). The remaining balance of any premium costs shall timely be paid by you on a monthly basis (or such other basis as is required by the Company) for as long as, and to the extent that, you remain eligible for COBRA continuation. Further, the vesting of all stock options held by you on the date of termination shall be accelerated, such that such stock options shall become 100% fully vested and exercisable.

Your receipt of severance pay and benefits as set forth in this Section 8 is conditioned upon your full compliance with the Non-Solicitation Agreement, your timely execution of a separation and release of claims agreement prepared by and satisfactory to the Company (which will include, at a minimum, a release by you of all releasable claims, non-disparagement and cooperation obligations, and reaffirmation of your continuing obligations under the Non-Solicitation Agreement) (the "Release"), and any applicable revocation period with respect to the Release expiring without revocation within 60 days (or such shorter period as may be directed by the Company) following your termination date. If the Release has been executed and any applicable revocation period has expired prior to the 60th day following your termination, then the severance payments and benefits shall commence (or in the case of any lump sum payment, be paid) on the first regular pay date after any applicable revocation period has expired (but no earlier than the 30th day following your termination date); provided, however, that if the 60th day following your

termination occurs in the calendar year following the calendar year during which your termination occurs, then the severance payments shall commence (or in the case of any lump sum payment, be paid) no earlier than January 1 of such subsequent calendar year. The provision of severance pay and benefits hereunder shall be subject to the terms and conditions set forth in Section 12 hereto. In the event you breach your obligations under the Release or the Non-Solicitation Agreement, you will have no right to receive, and the Company shall not provide to you, any severance pay or benefits following the date of such breach. Such cessation of payments and benefits shall be in addition to, and not in lieu of, any and all other remedies, whether at law or in equity, available to the Company for such breach.

9. **Proof of Legal Right to Work.** For purposes of federal immigration law, you will be required to provide the Company with documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to the Company within three (3) business days of your date of hire, or our employment relationship with you may be terminated. You may need to obtain a work visa in order to be eligible to work in the United States. If that is the case, your employment with the Company will be conditioned upon your obtaining a work visa in a timely manner as determined by the Company.
10. **Company Policies and Procedures.** As an employee of the Company, you will be required to comply with all Company policies and procedures. Violations of the Company's policies may lead to immediate termination of your employment. Further, the Company's premises, including all workspaces, furniture, documents, and other tangible materials, and all information technology resources of the Company (including computers, data and other electronic files, and all internet and email) are subject to oversight and inspection by the Company at any time. Company employees should have no expectation of privacy with regard to any Company premises, materials, resources, or information.
11. **Other Agreements and Governing Law.** You represent that you are not bound by any employment contract, restrictive covenant or other restriction preventing you from entering into employment with or carrying out your responsibilities for the Company, or which is in any way inconsistent with the terms of this letter. Please note that this offer letter is your formal offer of employment and supersedes any and all prior or contemporaneous agreements, discussions and understandings, whether written or oral, relating to the subject matter of this letter or your employment with the Company. The resolution of any disputes under this letter will be governed by Massachusetts law.

12. **Section 409A of the Code.**

Subject to the provisions in this Section 12, any severance payments or benefits under this letter will begin only upon the date of your "separation from service" (determined as set forth below) which occurs on or after the date of termination of your employment. The following rules shall apply with respect to distribution of the payments and benefits, if any, to be provided to you under this letter.

- (a) It is intended that each installment of the severance payments and benefits provided under this letter shall be treated as a separate "payment" for purposes of Section 409A of the Internal Revenue Code and the guidance issued thereunder ("Section 409A"). Neither you nor the
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Company will have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A.

(b) The determination of whether and when your separation from service from the Company has occurred shall be made and in a manner consistent with and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of this paragraph, “Company” shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Internal Revenue Code.

(c) If, as of the date of your separation from service from the Company, you are not a “specified employee” (within the meaning of Section 409A), then each installment of the severance payments and benefits provided under this letter shall be made on the dates and terms set forth in this letter.

(d) If, as of the date of your separation from service from the Company, you are a “specified employee” (within the meaning of Section 409A), then:

(i) Each installment of the severance payments and benefits due under this letter that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when your separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid on the dates and terms set forth in this letter; and

(ii) Each installment of the severance payments and benefits due under this letter that is not described in Section 12(d)(i) and that would, absent this subsection, be paid within the six-month period following your separation from service from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, your death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following your separation from service and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of payments or benefits if and to the maximum extent that that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of your second taxable year following the taxable year in which the separation from service occurs.

(e) All reimbursements and in-kind benefits provided under this letter shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses incurred during your lifetime (or during a shorter period of time specified in your offer letter), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred and (iv) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.

(f) Notwithstanding anything herein to the contrary, the Company makes no representation or warranty and shall have no liability to you or to any other person if the payments and benefits provided in this letter are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.

If this letter correctly sets forth the initial terms under which you will be employed by the Company, please sign the enclosed duplicate of this letter in the space provided below and return it to my attention at the Company. This offer is effective through September 27, 2017. If you do not accept this offer by such date, it will be deemed revoked. This offer is contingent on satisfactory reference checks.

On behalf of Tetrphase Pharmaceuticals, Inc.

/s/ Paul Fanning
Paul Fanning
Senior Vice President, Human Resources

The foregoing correctly sets forth the terms of my at-will employment by the Company. I am not relying on any representations pertaining to my employment other than those set forth above.

/s/ Kamalam Unninayar

Date: _____ September 25, 2017 _____

Kamalam Unninayar

EXHIBIT A

Definitions

For the purposes of this Offer Letter:

(1) **“Cause”** shall mean: (a) a good faith finding by the Board of Directors of the Company in its sole discretion that you have (i) failed or refused to substantially perform your assigned duties for the Company, or failed or refused to comply in any material respect with the Company’s material policies or procedures, which failure or violation is not cured (provided that the Company deems that such failure or violation is curable) within 20 days following written notice from the Company to you specifying the duties not performed or the nature of the violation, (ii) engaged in dishonesty, gross negligence or misconduct, or (iii) breached any employment agreement, confidentiality agreement, non-solicitation agreement, or other agreement entered into between you and the Company; or (b) your conviction of, or the entry of a pleading of guilty or *nolo contendere* by you to, any crime involving dishonesty or moral turpitude or any felony.

(2) **“Change in Control Event”** shall mean

(a) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) (a “Person”) of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 promulgated under the Exchange Act) 50% or more of the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the “Outstanding Company Voting Securities”); provided, however, that for purposes of this subsection (a), the following acquisitions shall not constitute a Change in Control Event: (i) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for common stock or voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), or (ii) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company; or

(b) the consummation of a merger, consolidation, reorganization, recapitalization or statutory share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company (a “Business Combination”), unless, immediately following such Business Combination all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company’s assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership of the Outstanding Company Voting Securities immediately prior to such Business Combination:

provided that, where required to avoid additional taxation under Section 409A, the event that occurs must also be a “change in the ownership or effective control of a corporation, or a change in the

ownership of a substantial portion of the assets of a corporation” as defined in Treasury Regulation Section 1.409A-3(i)(5).

(3) **“Good Reason”** shall occur if a Cause event has not occurred or has not been cured, to the extent curable, and if (x) you provide written notice to the Company of the event or change you consider to constitute “Good Reason” within 30 calendar days following its occurrence, (y) you provide the Company with a period of at least 30 calendar days to cure the event or change, and (z) the “Good Reason” persists following the cure period, and you actually resign within 60 calendar days following the event or change. An event or change constituting “Good Reason” shall be limited to any of the following that occur without your prior written consent: (a) a material diminution of your duties, authority or responsibilities, provided, however, that the assignment of different duties to you by the Company involving a reasonably comparable level of responsibility shall not, by itself, constitute “Good Reason,” and provided, further, that a change in your duties, authority or responsibilities solely as a result of the Company’s acquisition by or merger with another entity, if you continue to have a comparatively senior role relative to the Company or its successor following such event, shall not, by itself, constitute “Good Reason”; (b) a material diminution in your base compensation, or (c) the relocation of the principal place at which you provide services to the Company by at least 50 miles and to a location such that your daily commuting distance is increased.

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

I, Guy Macdonald, certify that:

- (1) I have reviewed this quarterly report on Form 10-Q of Tetrphase Pharmaceuticals, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 1, 2017

/s/ Guy Macdonald

Guy Macdonald

Chief Executive Officer (Principal Executive Officer)

**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**

I, Christopher Watt, certify that:

- (1) I have reviewed this quarterly report on Form 10-Q of Tetrphase Pharmaceuticals, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d015(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 1, 2017

/s/ Christopher Watt

Christopher Watt

Senior Vice President, Finance

(Principal Financial Officer and Principal Accounting Officer)

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

In connection with the quarterly report on Form 10-Q of Tetrphase Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Guy Macdonald, as Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 1, 2017

/s/ Guy Macdonald

Guy Macdonald
Chief Executive Officer

**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**

In connection with the quarterly report on Form 10-Q of Tetrphase Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Christopher Watt, as Principal Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 1, 2017

/s/ Christopher Watt

Christopher Watt

Senior Vice President, Finance

