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CEMPRA, INC.

FORM 10-Q
(Quarterly Report)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2017

☐ **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: 001-35405

CEMPRA, INC.

(Exact name of registrant specified in its charter)

Delaware	2834	45-4440364
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

6320 Quadrangle Drive, Suite 360
Chapel Hill, NC 27517
(Address of Principal Executive Offices)

(919) 313-6601
(Telephone Number, Including Area Code)

Securities Registered Pursuant to Section 12(b) of the Exchange Act:

Title of Each Class	Name of Exchange on which Registered
Common Stock, $0.001 Par Value	Nasdaq Global Market

Securities Registered Pursuant to Section 12(g) of the Act: None

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 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐
Emerging growth company	☐		

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

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

As of April 21, 2017 there were 52,503,483 shares of the registrant's common stock, $0.001 par value, outstanding.

CEMPRA, INC.

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P ART I—FINANCIAL INFORMATION

Item 1. Financial Statements

CEMPRA, INC.
Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	March 31, 2017	December 31, 2016
Assets		
Current assets		
Cash and equivalents	$ 202,763	$ 231,553
Receivables	6,339	6,162
Prepaid expenses	1,228	579
Total current assets	210,330	238,294
Furniture, fixtures and equipment, net	39	48
Deposits	129	173
Total assets	$ 210,498	$ 238,515
Liabilities		
Current liabilities		
Accounts payable	$ 11,783	$ 15,657
Accrued expenses	4,620	2,929
Accrued payroll and benefits	627	4,267
Current portion of long-term debt	6,667	6,667
Total current liabilities	23,697	29,520
Deferred revenue	16,987	16,987
Long-term debt	7,002	8,660
Total liabilities	47,686	55,167
Commitments and contingencies (Notes 4 and 8)		
Shareholders' Equity		
Preferred stock; $.001 par value; 5,000,000 shares authorized; no shares issued or outstanding at March 31, 2017 and December 31, 2016	-	-
Common stock; $.001 par value; 80,000,000 shares authorized; 52,448,210 and 52,392,905 issued and outstanding at March 31, 2017 and December 31, 2016, respectively	52	52
Additional paid-in capital	622,631	620,279
Accumulated deficit	(459,871)	(436,983)
Total shareholders’ equity	162,812	183,348
Total liabilities and shareholders’ equity	$ 210,498	$ 238,515

The accompanying notes are an integral part of these consolidated financial statements

CEMPRA, INC.
Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2017	**2016**
Revenue		
Contract research	$ 4,872	$ 2,679
Total revenue	4,872	2,679
Operating expenses		
Research and development	15,410	23,529
General and administrative	8,765	8,324
Restructuring	3,553	-
Total operating expenses	27,728	31,853
Loss from operations	(22,856)	(29,174)
Other income (expense)		
Interest income	211	98
Interest expense	(243)	(330)
Other income (expense), net	(32)	(232)
Net loss	$ (22,888)	$ (29,406)
Basic and diluted net loss per share	$ (0.44)	$ (0.61)
Basic and diluted weighted average shares outstanding	52,403,908	47,853,099

The accompanying notes are an integral part of these consolidated financial statements

CEMPRA, INC.
Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2017	**2016**
Operating activities		
Net loss	$ (22,888)	$ (29,406)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	9	15
Share-based compensation	2,236	2,365
Amortization of debt issuance costs	8	15
Changes in operating assets and liabilities		
Receivables	(177)	3,793
Prepaid expenses	(649)	(668)
Deposits	44	(79)
Accounts payable	(3,874)	1,557
Accrued expenses	1,691	(482)
Accrued payroll and benefits	(3,640)	(1,286)
Net cash used in operating activities	(27,240)	(24,176)
Investing activities		
Net cash used in investing activities	-	-
Financing activities		
Payment of long-term debt	(1,666)	-
Proceeds from exercise of stock options	116	239
Proceeds from issuance of common stock, net of underwriting discounts	-	94,000
Payment of offering costs	-	(219)
Net cash (used in) provided by financing activities	(1,550)	94,020
Net change in cash and equivalents	(28,790)	69,844
Cash and equivalents at beginning of the period	231,553	153,765
Cash and equivalents at end of the period	$ 202,763	$ 223,609
Supplemental cash flow information		
Cash paid for interest	$ 241	$ 322

The accompanying notes are an integral part of these consolidated financial statements

Notes to Consolidated Financial Statements
(Unaudited)

1. Description of Business

Cempra, Inc. (the "Company" or "Cempra") is the successor entity of Cempra Pharmaceuticals, Inc. which was incorporated on November 18, 2005 and commenced operations in January 2006. Cempra is located in Chapel Hill, North Carolina, and is a pharmaceutical company developing antibiotics to treat drug-resistant bacterial infections in the hospital and community.

The Company expects to continue to incur losses and require additional financial resources to advance its products to either commercial stage or liquidity events. There can be no assurance that the Company will be able to obtain additional debt or equity financing or generate revenues from collaborative partners, on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations and financial condition.

2. Basis of Presentation

Principles of Consolidation and Basis of Presentation

The accompanying consolidated financial statements include the accounts and results of operations of Cempra and its wholly owned subsidiaries. The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). All intercompany balances and transactions have been eliminated in consolidation.

Unaudited Interim Financial Data

The accompanying interim 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 U.S. GAAP for complete financial statements. These unaudited interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the accompanying notes for the year ended December 31, 2016 contained in the Company's Annual Report on Form 10-K. The unaudited interim 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 for the fair statement of the Company's financial position as of March 31, 2017 and the results of operations and cash flows for the three months ended March 31, 2017 and 2016. The December 31, 2016 consolidated balance sheet included herein was derived from audited consolidated financial statements, but does not include all disclosures including notes required by U.S. GAAP for complete financial statements.

Use of Estimates

The preparation of these consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Receivables

Receivables consist of amounts billed and amounts earned but unbilled under the Company's contract with the Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services ("BARDA"). Receivables under the BARDA contract are recorded as qualifying research activities are conducted and invoices from the Company's vendors are received. Unbilled receivables are also recorded based upon work estimated to be complete for which the Company has not received vendor invoices. The Company carries its accounts receivable at cost less an allowance for doubtful accounts. On a periodic basis, the Company evaluates its accounts receivable and establishes an allowance based on its history of collections and write-offs and the current status of all receivables. The Company does not accrue interest on trade receivables. If accounts become uncollectible, they will be written off through a charge to the allowance for doubtful accounts. The Company has not recorded an allowance for doubtful accounts as management believes all receivables are fully collectible.

Research and Development Expenses

Research and development ("R&D") expenses include direct and indirect R&D costs. Direct R&D consists principally of external costs, such as fees paid to investigators, consultants, central laboratories and clinical research organizations, including costs incurred in connection with clinical trials, and related clinical trial fees and all employee-related expenses for those employees working in research and development functions, including stock-based compensation for R&D personnel. Indirect R&D costs include insurance or other indirect costs related to the Company's research and development function to specific product candidates. R&D costs are expensed as incurred. Expenses paid but not yet incurred are recorded in prepaid expenses. The Company expenses purchases of pre-approval inventory as R&D until regulatory approval is received.

Clinical Trial Accruals

As part of the process of preparing financial statements, the Company is required to estimate its expenses resulting from its obligation under contracts with vendors and consultants and clinical site agreements in connection with conducting clinical trials. The Company's objective is to reflect the appropriate clinical trial expenses in its financial statements by matching those expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. The Company determines accrual estimates through discussion with applicable personnel and outside service providers as to the progress of trials or the services completed. During the course of a clinical trial, the Company adjusts its rate of clinical trial expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known at that time. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in the Company reporting amounts that are too high or too low for any particular period. The Company's clinical trial accrual is dependent upon the timely and accurate reporting of fee billings and passthrough expenses from contract research organizations and other third-party vendors as well as the timely processing of any change orders from the contract research organizations.

Revenue Recognition

The Company's revenue generally consists of research related revenue under federal contracts and licensing revenue related to non-refundable upfront fees, milestone payments and royalties earned under license agreements. Revenue is recognized when the following criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery of the products and/or services has occurred; (3) the selling price is fixed or determinable; and (4) collectability is reasonably assured.

For arrangements that involve the delivery of more than one element, each product, service and/or right to use assets is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has "stand-alone value" to the customer. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling prices of each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods and services are delivered, limited to the consideration that is not contingent upon future deliverables. When an arrangement is accounted for as a single unit of accounting, the Company determines the period over which the performance obligations will be performed and revenue recognized.

Milestone payments are recognized when earned, provided that (i) the milestone event is substantive; (ii) there is no ongoing performance obligation related to the achievement of the milestone earned; and (iii) it would result in additional payments. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment is non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved to achieve the milestone; and the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement, and the related risk associated with the achievement of the milestone. Contingent-based payments the Company may receive under a license agreement will be recognized when received.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers. This new guidance clarifies the principles for recognizing revenue and develops a common revenue standard for U.S. GAAP. The guidance outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes the most current revenue recognition guidance. This guidance, as amended by ASU 2015-14, is effective for fiscal years and interim periods within those years beginning after December 15, 2017, which is effective for the Company for the year ending December 31, 2018. In March 2016, the FASB issued ASU 2016-08, Revenue from Contracts with Customers: Principal versus Agent Considerations, which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU 2016-10, Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing, which clarifies an entity's identification of its performance obligations in a contract. The

update also clarifies the guidance regarding an entity's evaluation of the nature of its promise to grant a license of intellectual property and whether or not that revenue is recognized over time or at a poin t in time. In May 2016, the FASB issued ASU 2016-12, Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients, which amends the guidance in the new revenue standard on collectability, non-cash consideration, presentation o f sales tax, and transition. In December 2016, the FASB issued ASU 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers which increases shareholders' awareness of the proposals and expedites improvements to Up date 2014-09. The amendments are intended to address implementation issues that were raised by stakeholders and provide additional practical expedients to reduce the cost and complexity of applying the new revenue standard. These pronouncements have the s ame effective date as the new revenue standard.

The Company has evaluated the contract research agreement with BARDA, and does not anticipate a material impact on the financial statements. The Company is currently evaluating the license agreement with Toyama to determine the impact that the implementation of this standard will have on the financial statements, if any. The Company plans to use the full retrospective method of adoption effective January 1, 2018.

In February 2016, the FASB issued ASU 2016-02, Leases. The new guidance will increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. This guidance is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. The Company is currently evaluating the impact that the implementation of this standard will have on the Company's consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation-Stock Compensation. The new guidance simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The Company adopted this guidance as of January 1, 2017. As of December 31, 2016, the Company has accumulated excess tax benefits from temporary differences in the amount and timing of stock compensation expense and the Company's deductions on its income tax return from the award compensation that reduces the net operating loss deferred tax asset. The Company provided a full valuation allowance against its net deferred tax assets since it has been determined that it is more likely than not that all of the deferred tax assets will not be realized. Upon implementation of this standard, the stock compensation excess tax benefit will be eliminated, resulting in an increase to the net operating loss deferred tax asset, with an increase in the valuation allowance of the same. The implementation of this standard has no impact on the Company's consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments. ASU 2016-15 will make eight targeted changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. This new guidance is effective for fiscal years beginning after December 15, 2017. The Company is currently evaluating the impact that the implementation of this standard will have on the Company's consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, Business Combinations: Clarifying the Definition of a Business which revises the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. This new guidance is effective for fiscal years beginning after December 15, 2017. The Company is currently evaluating the impact that the implementation of this standard will have on the Company's consolidated financial statements.

3. Fair Value of Financial Instruments

The carrying values of cash and equivalents, receivables, prepaid expenses, and accounts payable at March 31, 2017 approximated their fair values due to the short-term nature of these items.

The Company's valuation of financial instruments is based on a three-tiered approach, which requires that fair value measurements be classified and disclosed in one of three tiers. These tiers are: Level 1, defined as quoted prices in active markets for identical assets or liabilities; Level 2, defined as valuations based on observable inputs other than those included in Level 1, such as quoted prices for similar assets and liabilities in active markets, or other inputs that are observable or can be corroborated by observable input data; and Level 3, defined as valuations based on unobservable inputs reflecting the Company's own assumptions, consistent with reasonably available assumptions made by other market participants.

At March 31, 2017 and December 31, 2016, the Company held money market funds classified as Level 1 financial instruments of $194.7 million and $228.5 million, respectively. The carrying value of the Term Loan (defined and discussed in Note 7), which is classified as a Level 2 liability, approximates its fair value. At March 31, 2017, the carrying value was $13.7 million. There were no transfers between levels of the fair value hierarchy for any assets or liabilities measured at fair value in the three months ended March 31, 2017.

4. Significant Agreements and Contracts

License Agreements

Optimer Pharmaceuticals, Inc.

In March 2006, the Company, through its wholly owned subsidiary, Cempra Pharmaceuticals, Inc., entered into a Collaborative Research and Development and License Agreement ("Optimer Agreement") with Optimer Pharmaceuticals, Inc. ("Optimer") which was acquired by Cubist Pharmaceuticals, Inc. in October 2013, which was in turn acquired by Merck in January 2015. Under the terms of the Optimer Agreement, the Company acquired exclusive rights to further develop and commercialize certain Optimer technology worldwide, excluding member nations of the Association of Southeast Asian Nations ("ASEAN").

In exchange for this license, during 2006 and 2007, the Company issued an aggregate of 125,646 common shares with a total fair value of $0.2 million to Optimer. These issuances to Optimer were expensed as incurred in research and development expense.

In July 2010, the Company paid a $0.5 million milestone payment to Optimer after the successful completion of its first solithromycin Phase 1 program. In July 2012, the Company paid a $1.0 million milestone after the successful completion of its first solithromycin Phase 2 program. Both milestones were expensed as incurred in research and development expense. Under the terms of the Optimer Agreement, the Company will owe Optimer additional payments, contingent upon the achievement of various development, regulatory and commercialization milestone events. One such milestone event would be owed upon FDA approval of solithromycin which would result in a payment to Optimer of $9.5 million. The aggregate amount of such milestone payments the Company may need to pay is based in part on the number of products developed under the agreement and would total $27.5 million (including the two milestone payments made to date and the milestone payment for FDA approval) if four products are developed and gain FDA approval. The Company will also pay tiered mid-single-digit royalties based on the amount of annual net sales of its approved products.

The Scripps Research Institute

In June 2012, the Company entered into a license agreement with The Scripps Research Institute ("TSRI"), whereby TSRI licensed to the Company rights, with rights of sublicense, to make, use, sell, and import products for human or animal therapeutic use that use or incorporate one or more macrolides as an active pharmaceutical ingredient ("API") and is covered by certain patent rights owned by TSRI claiming technology related to copper-catalysed ligation of azides and acetylenes. The rights licensed to the Company are exclusive as to the People's Republic of China (excluding Hong Kong), South Korea and Australia, and are non-exclusive in all other countries worldwide, except ASEAN member-nations, which are not included in the territory of the license. Under the terms of the agreement with TSRI, the Company paid a one-time only, non-refundable license issue fee in the amount of $0.4 million which was charged to research and development expense in the second quarter of 2012.

The Company is also obligated to pay annual maintenance fees to TSRI in the amount of (i) $50,000 each year for the first three years (beginning on the first anniversary of the agreement), and (ii) $85,000 each year thereafter (beginning on the fourth anniversary of the agreement). Each calendar year's annual maintenance fees will be credited against sales royalties due under the agreement for such calendar year. Under the terms of the agreement, the Company must pay TSRI low single-digit percentage royalties on the net sales of the products covered by the TSRI patents for the life of the TSRI patents, a low single-digit percentage of non-royalty sublicensing revenue received with respect to countries in the nonexclusive territory and a mid-single-digit percentage of sublicensing revenue received with respect to countries in the exclusive territory, with the sublicensing revenue royalty in the exclusive territory and the sales royalties subject to certain reductions under certain circumstances. TSRI is eligible to receive milestone payments of up to $1.1 million with respect to regulatory approval in the exclusive territory and first commercial sale, in each of the exclusive territory and nonexclusive territory, of the first licensed product to achieve those milestones that is based upon each macrolide covered by the licensed patents. Each milestone is payable once per each macrolide. Each milestone payment made to TSRI with respect to a particular milestone will be creditable against any payment due to TSRI with respect to any sublicense revenues received in connection with the achievement of such milestone. Pursuant to the terms of the Optimer Agreement, any payments made to TSRI under this license for territories subject to the Optimer Agreement can be deducted from any sales-based royalty payments due under the Optimer Agreement up to a certain percentage reduction of the royalties due to Optimer.

Under the terms of the agreement, the Company is also required to pay additional fees on royalties, sublicensing and milestone payments if the Company, an affiliate with the Company, or a sub licensee challenges the validity or enforceability of any of the patents licensed under the agreement. Such increased payments would be required until all patent claims subject to challenge are invalidated in the particular country where such challenge was mounted. In December 2014, the Company paid a $0.2 million milestone payment to TSRI in relation to license and milestone payments received under the license agreement with Toyama (discussed below).

The term of the license agreement (and the period during which the Company must pay royalties to TSRI in a particular country for a particular product) will end, on a country-by-country and product-by-product basis, at such time as no patent rights licensed from TSRI cover a particular product in the particular country.

TSRI may terminate the agreement in the event (i) the Company fails to cure any non-payment or default on its indemnity or insurance obligations, (ii) the Company declares insolvency or bankruptcy, (iii) the Company is convicted of a felony relating to the development, manufacture, use, marketing, distribution or sale of any products licensed under the agreement, (iv) the Company fails to cure any underreporting or underpayment by a certain amount in any 12-month period, or (v) the Company fails to cure any default on any other obligation under the agreement. The Company may terminate the agreement with or without cause upon written notice. In the event of such termination, (i) all licenses granted to the Company will terminate except in the case of any sublicensee that was not the cause of the termination, is not in default on its obligations under its sublicense, and that pays any unpaid amounts owed by the Company under the agreement with respect to the sublicense, and (ii) the Company may complete any work in progress and sell any completed inventory on hand for a period of time after termination.

Biomedical Advanced Research and Development Authority

In May 2013, the Company entered into an agreement with BARDA, for the evaluation and development of the Company's lead product candidate solithromycin for the treatment of bacterial infections in pediatric populations and infections caused by bioterror threat pathogens.

The agreement is a cost plus fixed fee development contract, with a base performance segment valued at approximately $18.7 million with contract modifications, and four option work segments that BARDA may request at its sole discretion pursuant to the agreement. If all four option segments are requested, the cumulative value of the agreement, as amended to date, would be approximately $68.2 million and the estimated period of performance would be until approximately May 2018. Three of the options are cost plus fixed fee arrangements and one option is a cost sharing arrangement without fixed fee, for which the Company is responsible for a designated portion of the costs associated with that work segment. The period of performance for the base performance segment was May 2013 through February 2016.

BARDA exercised the second option in November 2014. The value of the second option work segment is approximately $16.0 million and the estimated period of performance is November 2014 through June 2017, which was extended in April 2017 by two months from the original April 2017 date at the Company's request to allow more time to deliver the completed work product. This extension will not increase the cost of the work to be performed under the option nor does it change any other terms or provisions of the BARDA contract, including timeframes for other work options.

In February 2016, BARDA exercised the third option work segment of the agreement which is intended to fund a Phase 2/3 study of intravenous, oral capsule and oral suspension formulations of solithromycin in pediatric patients from newborn to 17 years with community acquired bacterial pneumonia. This option work segment is a cost-sharing arrangement under which BARDA will contribute $25.5 million and the Company will be responsible for an additional designated portion of the costs associated with the work segment. In September 2016, the contract was modified to increase the third option work segment by $8.0 million for increased manufacturing work related to the development of a second supply source for solithromycin. The amendment raises the value of the third option work segment to approximately $33.5 million. The estimated period of performance of this option work segment runs through May 2018.

Under the agreement, the Company is reimbursed and recognizes revenue as allowable costs are incurred plus a portion of the fixed-fee earned. The Company considers fixed-fees under cost reimbursable agreements to be earned in proportion to the allowable costs incurred in performance of the work as compared to total estimated agreement costs, with such costs incurred representing a reasonable measurement of the proportional performance of the work completed. Since inception of the agreement through March 31, 2017, the Company has recognized $44.1 million in revenue under this agreement.

The agreement provides the U.S. government the ability to terminate the agreement for convenience or to terminate for default if the Company fails to meet its obligations as set forth in the statement of work. The Company believes that if the government were to terminate the agreement for convenience, the costs incurred through the effective date of such termination and any settlement costs resulting from such termination would be allowable costs.

Any of the funding sources may request reimbursement for expenses or return of funds, or both, as a result of noncompliance by the Company with the terms of the grant. No reimbursement of expenses or return of funds for noncompliance has been requested or made since inception of the contract.

Toyama Chemical Co., Ltd.

In May 2013, Cempra Pharmaceuticals, Inc., the Company's wholly owned subsidiary, entered into a license agreement with Toyama Chemical Co., Ltd. ("Toyama"), whereby the Company licensed to Toyama the exclusive right, with the right to sublicense, to make, use and sell any product in Japan that incorporates solithromycin, the Company's lead compound, as its sole API for human therapeutic uses, other than for ophthalmic indications or any condition, disease or affliction of the ophthalmic tissues. Toyama also has a nonexclusive license in Japan and certain other countries, with the right to sublicense, to manufacture or have manufactured API for solithromycin for use in manufacturing such products, subject to limitations and obligations of the concurrently executed supply agreement discussed below. Toyama granted the Company certain rights to intellectual property generated by Toyama under the license agreement with respect to solithromycin or licensed products for use with such products outside Japan or with other solithromycin-based products inside or outside Japan.

Following execution of the agreement, the Company received a $10.0 million upfront payment from Toyama. Toyama is also obligated to pay the Company up to an aggregate of $60.0 million in milestone payments, depending on the achievement of various regulatory, patent, development and commercial milestones. Under the terms of the license agreement, Toyama must also pay the Company a royalty equal to a low-to-high first double decimal digit percentage of net sales, subject to downward adjustment in certain circumstances. In August 2014, the Company received a $10.0 million milestone payment from Toyama ("August 2014 Milestone"), which was triggered by Toyama's progress of its solithromycin clinical development program in Japan. The payment was made following Toyama's receipt of regulatory acceptance to begin a Phase 2 trial of solithromycin in Japan following successful completion of a Phase 1 trial. In March 2015, the Company recognized a $10.0 million milestone from Toyama ("March 2015 Milestone") based on the Japan Patent Office issuing a Decision of Allowance for the Company's patent covering certain crystal forms of solithromycin in Japan, which payment was received in April 2015. In October 2016, the Company received the third $10.0 million milestone from Toyama ("October 2016 Milestone"), which was triggered by Toyama's progress of the solithromycin clinical development program in Japan.

As part of the license agreement, Toyama and the Company also entered into a supply agreement, whereby the Company will be the exclusive supplier (with certain limitations) to Toyama and its sublicensees of API for solithromycin for use in licensed products in Japan, as well as the exclusive supplier to Toyama and its sublicensees of finished forms of solithromycin to be used in Phase 1 and Phase 2 clinical trials in Japan. Pursuant to the supply agreement, which is an exhibit to the license agreement, Toyama will pay the Company for such clinical supply of finished product and all supplies of API for solithromycin for any purpose, other than the manufacture of products for commercial sale in Japan, at prices equal to the Company's cost . All API for solithromycin supplied by the Company to Toyama for use in the manufacture of finished product for commercial sale in Japan will be ordered from the Company at prices determined by the Company's manufacturing costs, and which may, depending on such costs, equal, exceed, or be less than such costs. Either party may terminate the supply agreement for uncured material breach or insolvency of the other party, with Toyama's right to terminate for the Company's breach subject to certain further conditions in the case of the Company's failure to supply API for solithromycin or clinical supply, but otherwise the supply agreement will continue until the expiration or termination of the license agreement. Since inception of the agreement through March 31, 2017, the Company has recognized $6.1 million in revenue under this agreement.

The Company has determined that there are six deliverables under this agreement including (1) the license to develop and commercialize solithromycin in Japan, (2) the obligation of the Company to conduct Phase 3 studies and obtain regulatory approval in the United States and one other territory, (3) participation in a Joint Development Committee ("JDC") (4) participation in a Joint Commercialization Committee ("JCC") (5) the right to use the Company's trademark, and (6) a supply agreement. The amounts received under the license agreement have been allocated to the deliverables based on their relative fair values and will be recognized into income when the revenue recognition criteria have been achieved.

Milestone payments are recognized when earned, provided that (i) the milestone event is substantive; (ii) there is no ongoing performance obligation related to the achievement of the milestone earned; and (iii) it would result in additional payments. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment is non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved to achieve the milestone; and the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement, and the related risk associated with the achievement of the milestone. Contingent-based payments the Company may receive under a license agreement will be recognized when received.

Royalties are recorded as earned in accordance with the contract terms when third party sales can be reliably measured and collectability is reasonably assured.

The Company recognized $4.3 million in revenue associated with the delivery of the license in May 2013. Additionally, because the milestone event triggering the August 2014 and October 2016 Milestone payments were considered non-substantive for

accounting purposes, these milestone payment s are being recognized into revenue proportionately to the six deliverables in the agreement using the same allocation as the upfront payment. Therefore, $4.3 million of the August 2014 Milestone payment was recognized into revenue in August 2014 and $4.3 million of the October 2016 M ilestone payment was recognized into revenue in October 2016 . The remainder of the upfront and milestone payments which aggregate to $1 7.0 million are recorded as deferred r evenue at March 2017 and will be recognized as revenue when the revenue recognition criteria of each deliverable has been met. The Company also recognized in March 2015 a $10.0 million milestone based on the Japan Patent Office issuing a Decision of Allow ance for the Company's patent covering certain crystal forms of solithromycin in Japan. The March 2015 M ilestone payment is considered substantive for accounting purposes, and therefore the $10.0 million milestone was recognized in its entirety as revenue in March 2015.

FUJIFILM Finechemicals Co., Ltd .

In January 2016, Cempra Pharmaceuticals, Inc. entered into an API manufacturing and supply agreement with FUJIFILM Finechemicals Co., Ltd. ("FFFC"), which will provide the Company with solithromycin in sufficient quantities and at reasonable prices to help ensure it meets its obligation under the May 2013 supply agreement with Toyama. The Company will use reasonable efforts to ensure that the solithromycin supplied by FFFC is for use as the active pharmaceutical ingredient in a human drug product to be used or sold in Japan.

The Company is subject to a minimum purchase obligation for a designated number of years after the successful completion of the manufacturing facility and validation studies by FFFC. Each calendar month, the Company will submit to FFFC a projection of the anticipated volume of solithromycin that it will order for the next designated period (as set forth in the agreement) (or, if earlier, the final calendar month of the current term). Several months of each forecast are binding and the remaining months are non-binding, provided that the quantity of solithromycin ordered for any month is between designated percentages of the quantity specified in the initial forecast and between designated percentages of the most recent previous forecast.

The price of each shipment of solithromycin will be equal to the total number of kilograms in such shipment multiplied by the per-kilogram transfer price as set forth in the agreement.

For the term of the agreement plus an additional five years or until the expiration of the patents identified in the agreement, FFFC is prohibited from supplying, selling or distributing solithromycin to, or enabling the manufacture of solithromycin by, any third party for any purpose. The Company is not precluded from developing one or more alternative or additional sources of solithromycin.

The agreement's initial term runs until December 2025. After the end of the initial term, and at the end of each year thereafter, the term will automatically extend for an additional year unless either party gives written notice to the other of its intent to terminate within a designated period of time prior to the expiration of the term, in which case the agreement will terminate at the end of such term. The parties may at any time terminate the agreement by mutual written consent. Each party has the right to terminate the agreement immediately if there is a product failure in Japan, the other party becomes involved in bankruptcy, insolvency or similar proceedings or materially breaches the agreement and such breach remains uncured for a period of time following notice of the breach. A violation by the Company of the minimum purchase obligation is considered a material breach. A product failure is not considered a material breach by the Company. The Company has the right to terminate the agreement upon written notice if there is a supply failure. The Company also may terminate in the event that FFFC cannot provide the Company with solithromycin for more than a designated period of time. Upon termination, any unfulfilled binding portion of the forecast must be delivered by FFFC and paid for by the Company. The Company also may elect to purchase the remaining inventory of FFFC's solithromycin and any remaining raw materials. If FFFC terminates the agreement for a material breach by the Company and, prior to such termination, (i) FFFC has constructed a facility in Japan for the primary purpose of manufacturing API for the Company under the agreement and (ii) such facility is completed and fully operational and qualified for the manufacture of API for delivery thereunder, then, except to the extent otherwise agreed to by the parties, the Company will pay FFFC an amount equal to (a) the remaining book value of the facility less (b) the product of the number of kilograms of API ordered by the Company under the agreement prior to such termination times a designated dollar amount, provided that if the total direct costs incurred by FFFC in the construction of the facility, net of any tax credits, tax refunds, government subsidies, or similar financial, monetary, or in-kind benefits provided by any governmental agency or authority, do not equal or exceed a designated dollar amount, then the remaining book value will be reduced by a pro rata amount, based on ratios set forth in the agreement, and (z) no amount will be payable if the agreement terminates after December 31, 2025; provided, however, that if FFFC manufactures any product or performs any activities (other than the manufacture of API for the Company under the agreement) in, by, or using the facility prior to such termination and makes any profit thereby, the total amount of such profits will be subtracted from the total payment amount due from the Company to FFFC.

Macrolide Pharmaceuticals, Inc.

In January 2016, Cempra Pharmaceuticals, Inc. entered into an Option and License Agreement with Macrolide Pharmaceuticals, Inc. ("MP"), pursuant to which MP granted the Company an exclusive option to license certain of MP's patents and know-how

involving macrolides, inc luding specifically novel methods of synthesizing solithromycin (the "Compound"). Under the agreement, the Company will support research at MP focused on developing a novel, cost-competitive manufacturing approach to solithromycin. The option will run unti l the later to occur of (i) the earlier of (a) the date that the Company first obtains FDA approval for any product incorporating the Compound as an API, or (b) January 27, 2019, or (ii) the date that is six months after the earlier of (a) MP's satisfactio n of certain milestones, or (b) the Company's termination of MP's obligations under the evaluation program. Under the evaluation program called for in the agreement, MP will conduct research activities for the manufacture of the Compound, which activities the Company will evaluate to determine whether to exercise the option to license.

Upon execution of the agreement, the Company paid MP a non-refundable, non-creditable initial license fee of $0.4 million. For conducting the evaluation program, the Company paid MP a non-refundable, non-creditable fee in the amount of $0.4 million. In addition, the Company will pay MP the expected reasonable, documented, direct compensation-related costs of employees and advisors necessary to conduct MP's portion of the evaluation program in the aggregate amount of $1.5 million, which the Company will pay in 18 equal consecutive non-refundable, non-creditable monthly installments of $83,333, beginning with the first monthly anniversary of entry into the agreement. Further, the Company will pay MP up to an aggregate of $1.0 million upon the satisfaction of certain performance milestones.

If the Company exercises the option, the license will be exclusive and worldwide (other than Association of Southeast Asian Nations) and for any and all uses in human and non-human animals, and with the right to sublicense. The Company may, in its discretion, exercise the option for a reduced portion of the territory and, if the Company makes this election, may increase as it wishes within the territory, and as many times as it wishes, provided such increase is made within 60 months of the Company's exercise of the option.

If the Company exercises the option, it will pay MP a non-refundable, non-creditable license fee of $1.0 million, of which $0.5 million will be paid within 15 business days of exercise, and $0.5 million will be paid in the form of "deemed royalty" payments (up to such amount) equal to a fraction of a percent of net sales of licensed products. The Company will pay tiered royalties of a fraction of a percent on designated levels of annual net sales of license products. Further, the Company will pay a non-refundable, non-creditable additional royalty equal to a fraction of a percent on the net sales of licensed products of a designated amount sold by the Company, its sublicensees, and product partners, but the royalty will not exceed $1.0 million in the aggregate. Royalties will be paid on a country-by-country basis and product-by-product basis until the date on which there are no valid claims of any licensed MP patent covering a product in the applicable country.

If the Company exercises the option, the agreement's term will run on a country by country and product by product basis until the date on which there are no valid claims in the licensed MP patents covering a particular product in a particular country.

5. Receivables

Receivables consist of amounts billed and amounts earned but unbilled under the Company's contract with BARDA. At March 31, 2017, the Company's receivables consisted primarily of earned but unbilled receivables under the BARDA agreement.

6. Accrued Expenses

Accrued expenses are comprised of the following as of (in thousands):

	March 31, 2017	December 31, 2016
Accrued severance	$ 3,205	$ 1,999
Franchise tax	1,087	570
Lease liability	98	-
Deferred rent	84	85
Accrued interest	75	80
Other accrued expenses	71	50
Accrued professional fees	-	145
Total accrued expenses	$ 4,620	$ 2,929

In February 2017, as a consequence of the solithromycin complete response letter the Company received from the FDA, and subsequent discussions with the FDA, resulting in the delay of the potential approval of solithromycin, the Company initiated companywide cost and personnel reductions. These actions resulted in an approximately 67% reduction in the Company's workforce from 136 to 45 employees, and significant reductions in external spending related to commercial preparedness and non-essential activities. The Company also vacated two of its leased office suites that it is actively seeking to sublease. In conjunction with these activities, the Company has recorded $3.6 million related to severance, termination benefits and lease termination costs.

7. Long-term Debt

In July 2015, the Company entered into a Loan and Security Agreement (the "Loan and Security Agreement") with Comerica Bank ("Comerica"). The Loan and Security Agreement provides that the Company may borrow up to $20.0 million in a term loan (the "Term Loan") and, upon FDA approval of its New Drug Application for solithromycin, the Company may also borrow an aggregate amount equal to the lesser of (i) up to 75% of its eligible inventory and 80% of eligible accounts receivable or (ii) $10.0 million (the "Revolver"). After FDA approval of the Company's New Drug Application for solithromycin, the Company may convert the Term Loan to the Revolver, in which event the Revolver would have a maximum amount available to the Company of $25.0 million. The Loan and Security Agreement specifies the criteria for determining eligible inventory and eligible accounts receivable and sets forth ongoing limitations and conditions precedent to the Company's ability to borrow under the Revolver. The Company granted Comerica a security interest in substantially all of its personal property assets, excluding its intellectual property and its stock in its subsidiaries, to secure its outstanding obligations under the Loan and Security Agreement. The Company is also obligated to comply with various other customary covenants, including, among other things, restrictions on its ability to: dispose of assets, make acquisitions, be acquired, incur indebtedness, grant liens, make distributions to its stockholders, make investments, enter into certain transactions with affiliates, or pay down subordinated debt, subject to specified exceptions.

Amounts borrowed under the Term Loan may be repaid and reborrowed at any time without penalty or premium. The Term Loan was interest-only through April 30, 2016, followed by an amortization period of 36 months of equal monthly payments of principal plus interest, beginning on May 1, 2016 and continuing on the same day of each month thereafter until paid in full. Any amounts borrowed under the Term Loan will bear interest at a floating interest rate equal to the 30 Day LIBOR rate plus 5.2%. Amounts available to be borrowed under the Revolver may also be repaid and reborrowed at any time without penalty or premium prior to December 31, 2017, at which time all advances under the Revolver shall be immediately due and payable in full. Any amounts borrowed under the Revolver will bear interest at the 30 Day LIBOR rate plus 4.2%. Once available, the Revolver is subject to an annual unused facility fee equal to 0.25%. Under the Loan and Security Agreement, the Company is subject to certain covenants including maintaining a minimum unrestricted cash balance of $15.0 million and continuing the development or commercially launching solithromycin. The Company was in compliance with all covenants at March 31, 2017.

8. Commitments and Contingencies

Legal Proceedings

On November 4, 2016, a securities class action lawsuit was commenced in the United States District Court, Middle District of North Carolina, Durham Division, naming the Company and certain of the Company's officers as defendants, and alleging violations of the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by the defendants between May 1, 2016 and November 1, 2016 (the "Class Period"). The plaintiff seeks to represent a class comprised of purchasers of the Company's common stock during the Class Period and seeks damages, costs and expenses and such other relief as determined by the Court. Two substantially similar lawsuits were filed in the United States District Court, Middle District of North Carolina on November 22, 2016 and December 30, 2016, respectively. The Company believes it has meritorious defenses and intends to defend the lawsuits vigorously. It is possible that similar lawsuits may yet be filed in the same or other courts that name the same or additional defendants.

On December 21, 2016, a shareholder derivative lawsuit was commenced in the North Carolina Durham County Superior Court, naming certain of the Company's former and current officers and directors as defendants and the Company as a nominal defendant, and asserting claims for breach of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, and corporate waste. A substantially similar lawsuit was filed in the North Carolina Durham County Superior Court on February 16, 2017. The complaints are based on similar allegations as asserted in the securities lawsuits described above, and seeks unspecified damages and attorneys' fees. The Company believes it has meritorious defenses and intends to defend the lawsuits vigorously. It is possible that similar lawsuits may yet be filed in the same or other courts that name the same or additional defendants.

Other than as described above, the Company is not a party to any legal proceedings and is not aware of any claims or actions pending or threatened against the Company. In the future, the Company might from time to time become involved in litigation relating to claims arising from its ordinary course of business.

9. Shareholders' Equity

Common Stock

During January 2016, the Company completed a public offering of 4,166,667 shares of common stock, at a price of $24.00 per share, resulting in net proceeds to the Company of approximately $93.8 million after deducting underwriting discounts and expenses of approximately $6.2 million.

In May 2016, the Company entered into an at- the-market ("ATM") sales agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") under which the Company may, at its discretion, from time to time sell shares of its common stock, with a sales value of up to $150.0 million. The Company has provided Cowen with customary indemnification rights, and Cowen is entitled to a commission at a fixed commission rate of 3.0% of the gross proceeds per share sold. Sales of the shares under the Sales Agreement are to be made in transactions deemed to be "at the market offerings" as defined in Rule 415 under the Securities Act of 1933, as amended.

The Company began the sale of ATM shares in May 2016 and through July 2016, the Company sold 4,140,307 shares of common stock under the Sales Agreement resulting in net proceeds of $75.1 million after deducting commissions and expenses of $2.3 million. The Company has not sold any shares under the ATM since July 2016.

During the first three months of 2017, the Company issued 55,305 shares of common stock at a weighted average exercise price of $2.10 per share upon the exercise of option grants.

The following table presents common stock reserved for future issuance for the following equity instruments as of March 31, 2017:

Warrants to purchase common stock	94,912
Outstanding stock options	4,978,108
Outstanding restricted stock units	1,268,000
Available for future grants under the 2011 Equity Incentive Plan	2,528,879
Total common stock reserved for future issuance	8,869,899

10. Stock Option Plans

The Company adopted the 2006 Stock Plan (the "2006 Plan") in January 2006. The 2006 Plan provided for the granting of incentive share options, nonqualified share options and restricted shares to Company employees, representatives and consultants. As of March 31, 2017, there were options for an aggregate of 396,918 shares issued and outstanding under the 2006 Plan.

The Company's board of directors and stockholders adopted the 2011 Equity Incentive Plan (the "2011 Plan") in October 2011, which, as amended, authorizes the issuance of up to 8,697,451 shares under the 2011 Plan, and provides for an automatic annual increase in the number of shares of common stock reserved for issuance thereunder in the amount of 4% of the shares of common stock outstanding on December 31 of the preceding year. As of March 31, 2017, there were 2,528,879 options available under the 2011 Plan for future grant.

Upon adoption of the 2011 Plan, the Company eliminated the authorization for any unissued shares previously reserved under the Company's 2006 Plan. The stock awards previously issued under the 2006 Plan remain in effect in accordance with the terms of the 2006 Plan.

The following table summarizes the Company's 2006 and 2011 Plan stock option activity:

	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)	Aggregate Intrinsic Value (1)
Outstanding - December 31, 2016	3,784,346	$ 16.26		
Granted	1,896,750	3.07		
Exercised	(55,305)	2.10		
Forfeited	(639,558)	15.67		
Expired	(8,125)	34.05		
Outstanding - March 31, 2017	4,978,108	11.44	7.26	$ 1,750,048
Exercisable - March 31, 2017	2,613,027	12.90	5.38	$ 706,137
Vested and expected to vest at March 31, 2017 (2)	4,788,735	$ 11.63	7.17	$ 1,644,481

(1) Intrinsic value is the excess of the fair value of the underlying common shares as of March 31, 2017 over the weighted-average exercise price.
(2) The number of stock options expected to vest takes into account an estimate of expected forfeitures.

The following table summarizes certain information about all stock options outstanding as of March 31, 2017:

	Options Outstanding		Options Exercisable	
Exercise Price	Number of Options	Weighted Average Remaining Contractual Term (in years)	Number of Options	Weighted Average Remaining Contractual Term (in years)
$2.09 - $3.15	2,066,104	8.36	512,265	3.90
$6.63 - $11.35	1,074,496	5.28	963,840	4.80
$12.38 - $18.61	589,343	6.37	421,697	5.99
$19.25 - $31.13	1,098,526	7.89	609,717	7.39
$32.05 - $43.43	149,639	5.19	105,508	3.97
	4,978,108		2,613,027	

During the three-month periods ended March 31, 2017 and 2016, the Company recorded $2.2 million and $2.4 million in share-based compensation expense, respectively. As of March 31, 2017, approximately $10.0 million of total unrecognized compensation cost related to unvested share options is expected to be recognized over a weighted-average period of 2.65 years.

In 2016, the Company began issuing time-vested Restricted Stock Units (RSUs) from the 2011 Plan to certain employees, subject to continuous service with the Company at the vesting time. When vested, the RSU represents the right to be issued the number of shares of the Company's common stock that is equal to the number of RSUs granted.

A summary of the activity related to the Company's RSUs is as follows:

	Number of Restricted Stock Units Outstanding	Weighted Average Grant-Date Fair Value
Balance - December 31, 2016	50,000	$ 7.70
Granted	1,258,000	3.10
Vested	-	-
Forfeited	(40,000)	3.00
Expired	-	-
Balance - March 31, 2017	1,268,000	3.29

11. Income Taxes

The Company estimates an annual effective tax rate of 0% for the year ending December 31, 2017 as the Company incurred losses for the three-month period ended March 31, 2017 and is forecasting additional losses through the fourth quarter, resulting in an estimated net loss for both financial statement and tax purposes for the year ending December 31, 2017. Therefore, no federal or state income taxes are expected and none have been recorded at this time for the year ending December 31, 2016. Income taxes have been accounted for using the liability method in accordance with FASB ASC 740.

Due to the Company's history of losses since inception, there is not enough evidence at this time and it is not more likely than not that the Company will generate sufficient future income of a nature to utilize the benefits of its net deferred tax assets. Accordingly, the deferred tax assets have been reduced by a valuation allowance, since it has been determined that it is more likely than not that all of the deferred tax assets will not be realized.

12. Net Loss Per Share

Basic and diluted net loss per common share was determined by dividing net loss attributable to common shareholders by the weighted average common shares outstanding during the period. The Company's potentially dilutive shares, which include warrants, common share options and restricted stock units, have not been included in the computation of diluted net loss per share for all periods as the result would be antidilutive.

The following potentially dilutive securities have been excluded from the computat ion of diluted weighted average shares outstanding, as they would be antidilutive:

	Three Months Ended March 31,	
	2017	2016
Warrants outstanding	94,912	94,912
Stock options outstanding	4,900,441	3,453,884
Restricted stock units outstanding	773,790	-
	5,769,143	3,548,796

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

The unaudited interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the audited 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, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2016. 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. These forward-looking statements are subject to risks and uncertainties, including those set forth under "Part I. Item 1. Business - Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2016, 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 pharmaceutical company focused on developing differentiated anti-infectives for the acute care and community settings to meet critical medical needs in the treatment of bacterial infectious diseases. Our lead product, solithromycin, has completed two Phase 3 clinical trials, for which we submitted new drug applications, or NDAs, for both oral and IV formulations for the treatment of community acquired bacterial pneumonia, or CABP, in April 2016. In anticipation of potential approval on our PDUFA dates, throughout 2015 and 2016, we began preparations for potential commercial launch including building the commercial leadership team and implementing systems and processes to support the potential launch of solithromycin. In December 2016, we received a complete response letter, or CRL, from the U.S. Food and Drug Administration, or FDA, on our NDAs. The CRL stated that the FDA could not approve the NDAs in their present form and noted that additional clinical safety information and the satisfactory resolution of manufacturing facility inspection deficiencies were required before the NDAs may be approved. We met with the FDA to discuss the CRL and the FDA reiterated their request for additional clinical safety data prior to approval. Based on input from the FDA at the meeting, we have developed and provided to the FDA a protocol that proposes including fewer than 9,000 patients at the time we respond to the CRL. We plan to discuss the protocol with the FDA to determine if it could support an initial approval while we continue to accumulate a larger post-approval safety database. If we and the FDA agree on a protocol, we plan to seek non-dilutive funding to support the execution of the study. In March 2017, we announced the withdrawal of our previously filed marketing authorization application seeking European Medicines Agency, or EMA, approval of oral capsule and intravenous formulations of solithromycin for the treatment of CABP in adults. This action is to enable us to conserve considerable financial resources, and to align our strategy to provide additional data to both the EMA and FDA to support potential approval.

Our second product, fusidic acid, is an antibiotic that has been used for decades outside the U.S., including in Western Europe, but has never been approved in the U.S. We have recently completed a successful Phase 3 study evaluating fusidic acid as an oral treatment of acute bacterial skin and skin structure infections, or ABSSSI, which are frequently caused by methicillin-resistant *Staphylococcus aureus* , or MRSA. Based on the results of this study, we plan to meet with the FDA in the second quarter to discuss the next steps required to bring fusidic acid to patients in the United States. We are also exploring the potential use of fusidic acid for the long-term oral treatment of refractory bone and joint infections, or BJI, including prosthetic joint infections, or PJI, caused by staphylococci, including *S. aureus* and MRSA. Currently, there is no optimal oral, chronic antibiotic for treating these infections.

In February 2017, as a consequence of the solithromycin CRL we received, and subsequent discussions with the FDA, resulting in the delay of the potential approval of solithromycin, we initiated companywide cost and personnel reductions. These actions have resulted in an approximately 67% reduction in our workforce from 136 to 45 employees, and significant reductions in external spending related to commercial preparedness and non-essential activities. The principal objective of the reductions is to enable us to conserve our financial resources as we evaluate our path forward on our existing pipeline and potential business development opportunities. In connection with the reduction we also vacated two of our leased office spaces and have recorded a one-time charge of $3.6 million related to these actions.

As we progress ou r internal programs, we are also actively pursuing, and have engaged Morgan Stanley to assist us in , a process to evaluate and assess external late-stage assets and other potential strategic business opportunities to determine the best use of our significa nt cash resources and late stage clinical programs to deliver value to patients and shareholders through internal and/or potential external opportunities.

Financial Overview

Revenue

To date, we have not generated revenue from the sale of any products. All of our revenue to date has been derived from (1) a government contract and (2) the receipt of proceeds under our license and supply agreements with Toyama Chemical Co., Ltd., or Toyama, a portion of which has been recognized as revenue in accordance with generally accepted accounting principles in the U.S., or U.S. GAAP.

In May 2013, we entered into an agreement with the Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services, or BARDA, for the evaluation and development of solithromycin for the treatment of bacterial infections in pediatric populations and infections caused by bioterror threat pathogens, specifically anthrax and tularemia.

The agreement is a cost plus fixed fee development contract, with a base performance segment valued at approximately $18.7 million with contract modifications, and four option work segments that BARDA may request at its sole discretion pursuant to the agreement. If all four option segments are requested, the cumulative value of the agreement, as amended to date, would be approximately $68.2 million and the estimated period of performance would be until approximately May 2018. Three of the options are cost plus fixed fee arrangements and one option is a cost sharing arrangement without fixed fee, for which we are responsible for a designated portion of the costs associated with that work segment. The period of performance for the base performance segment was May 2013 through February 2016.

BARDA exercised the second option in November 2014. The value of the second option work segment is approximately $16.0 million and the estimated period of performance is November 2014 through June 2017, which was extended in April 2017 by two months from the original April 2017 date at our request to allow more time to deliver the completed work product. This extension will not increase the cost of the work to be performed under the option nor does it change any other terms or provisions of the BARDA contract, including timeframes for other work options.

In February 2016, BARDA exercised the third option work segment of the agreement, which is intended to fund a Phase 2/3 study of intravenous, oral capsule and oral suspension formulations of solithromycin in pediatric patients from two months old to 17 years with community acquired bacterial pneumonia. This option work segment is a cost-sharing arrangement under which BARDA will contribute $25.5 million and we will be responsible for an additional designated portion of the costs associated with the work segment. In September 2016, the contract was modified to increase the third option work segment by $8.0 million for increased manufacturing work related to the development of a second supply source for solithromycin. The amendment raises the value of the third option work segment to approximately $33.5 million. The estimated period of performance of this option work segment runs through May 2018.

Under the agreement, we are reimbursed and recognize revenue as allowable costs are incurred plus a portion of the fixed-fee earned. We consider fixed-fees under cost reimbursable contracts to be earned in proportion to the allowable costs incurred in performance of the work as compared to total estimated contract costs, with such costs incurred representing a reasonable measurement of the proportional performance of the work completed. Since inception of the agreement through March 31, 2017, we recognized $44.1 million in revenue under this agreement.

In May 2013, Cempra Pharmaceuticals, Inc., our wholly owned subsidiary, entered into a license agreement with Toyama, whereby we licensed to Toyama the exclusive right, with the right to sublicense, to make, use and sell any product in Japan that incorporates solithromycin as its sole active pharmaceutical ingredient, or API, for human therapeutic uses, other than for ophthalmic indications or any condition, disease or affliction of the ophthalmic tissues. Toyama also has a nonexclusive license in Japan and certain other countries, with the right to sublicense, to manufacture or have manufactured API for solithromycin for use in manufacturing such products, subject to limitations and obligations of the concurrently executed supply agreement discussed below. Toyama has granted us certain rights to intellectual property generated by Toyama under the license agreement with respect to solithromycin or licensed products for use with such products outside Japan or with other solithromycin-based products inside or outside Japan.

Following execution of the agreement, we received a $10.0 million upfront payment from Toyama. Toyama is also obligated to pay us up to an aggregate of $60.0 million in milestone payments, depending on the achievement of various regulatory, patent, development and commercial milestones. The first of these milestones was achieved in the third quarter of 2014 for which we

received a payment of $10.0 million from Toyama. The second $10.0 million milestone was recogn ized in the first quarter of 2015 which is based on the Japan Patent Office issuing a Decision of Allowance for our patent covering certain crystal forms of solithromycin in Japan. We received payment for the second milestone in April 2015. In October 20 16, we received the third $10.0 million milestone which was triggered by Toyama's decision to progress to a Phase 3 trial of solithromycin in Japan following successful completion of a Phase 2 trial. Toyama must also pay us a royalty equal to a low-to-hig h first double decimal digit percentage of net sales, subject to downward adjustment in certain circumstances. Cumulatively, through March 31, 2017, we have recognized $23.0 million in revenue under this agreement with the remaining $17.0 million received being recorded as deferred revenue. Substantially all of this deferred revenue would be recognized upon FDA approval of solithromycin in the United States and subsequent commercial launch in the United States and one additional country. As part of the lic ense agreement, we also entered into a supply agreement with Toyama, whereby we will be the exclusive supplier (with certain limitations) to Toyama and its sublicensees of API for solithromycin for use in licensed products in Japan, as well as the exclusiv e supplier to Toyama and its sublicensees of finished forms of solithromycin to be used in its clinical trials in Japan. Pursuant to the supply agreement, Toyama will pay us for such clinical supply of finished product and all supplies of API for solithrom ycin for any purpose, other than the manufacture of products for commercial sale in Japan, at prices equal to our costs. All API for solithromycin supplied by us to Toyama for use in the manufacture of finished product for commercial sale in Japan will be ordered from us at prices determined by our manufacturing costs, and which may, depending on such costs, equal, exceed, or be less than such costs. Either party may terminate the supply agreement for uncured material breach or insolvency of the other party , with Toyama's right to terminate for our breach subject to certain further conditions in the case of our failure to supply API for solithromycin or clinical supply, but otherwise the supply agreement will continue until the expiration or termination of t he license agreement.

In the future, we anticipate generating revenue from a combination of sales of our products, if approved, through our own sales force in the U.S. for solithromycin, and third parties elsewhere, and license fees, milestone payments and royalties in connection with strategic collaborations regarding any of our product candidates. We expect that any revenue we generate will fluctuate from quarter to quarter. If we or our strategic partners fail to complete the development of solithromycin or fusidic acid in a timely manner or obtain regulatory approval for them, or if we fail to develop our own sales force or find one or more strategic partners for the commercialization of approved products, our ability to generate future revenue, and our financial condition and results of operations would be materially adversely affected.

Research and Development Expenses

Since our inception, we have focused our resources on our research and development activities, including conducting pre-clinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for our product candidates. We recognize our research and development expenses as they are incurred. Our research and development expenses consist primarily of:

- employee-related expenses, which include salaries, benefits and share-based compensation expense;
- fees paid to consultants and clinical research organizations, or CROs, in connection with our clinical trials, and other related clinical trial costs, such as for investigator grants, patient screening, laboratory work and statistical compilation and analysis;
- costs related to acquiring and manufacturing clinical trial materials and costs for developing additional manufacturing sources for and the manufacture of pre-approval inventory of solithromycin;
- costs related to compliance with regulatory requirements;
- consulting fees paid to third parties related to non-clinical research and development;
- research supplies; and
- license, research and milestone payments related to in-licensed technologies.

Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical trials, and related clinical trial fees. Our internal resources, employees and infrastructure are not directly tied to any individual research project and are typically deployed across multiple projects. Through our clinical development programs, we are advancing solithromycin and fusidic acid in parallel primarily for the treatment of CABP and uncomplicated gonorrhea (for solithromycin) and ABSSSI and refractory bone and joint infections (for fusidic acid) as well as for other indications. Through our pre-clinical development programs, we are seeking to develop macrolide product candidates for non-antibacterial indications. The following table sets forth costs incurred on a program-specific basis for solithromycin and fusidic acid, excluding personnel-related costs. Macrolide research includes costs for discovery programs. All employee-related expenses for those employees working in research and development functions are included in "Research and development personnel cost" in the table, including salary, bonus, employee benefits and share-based compensation. We do not allocate insurance or other

indirect costs related to our research and development function to specific product candidates. Those expenses are included in "Indirect research a nd development expense" in the table.

	Three Months Ended March 31,	
	2017	2016
	(In thousands)	
Direct research and development expense by program:		
Solithromycin	$ 9,953	$ 15,891
Fusidic acid	2,016	2,044
Macrolide research	90	1,007
Research and development personnel cost	3,278	4,220
Total direct research and development expense	15,337	23,162
Indirect research and development expense	73	367
Total research and development expense	$ 15,410	$ 23,529

The successful development of our clinical and pre-clinical product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of any of our clinical or pre-clinical product candidates or the period, if any, in which material net cash inflows from these product candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress, expense and results of our ongoing, as well as any additional, clinical trials required and other research and development activities;
- future clinical trial costs and results;
- the costs and the timing of our regulatory submissions and any regulatory approvals; and
- changes in regulations governing drug approval, manufacturing, marketing and reimbursement.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

We have completed two pivotal trials for solithromycin in CABP, including one with oral solithromycin and one with IV solithromycin progressing to oral solithromycin. We also are conducting a Phase 2/3 trial for solithromycin in pediatric patients with CABP which is funded by BARDA.

While we are conducting an exploratory study of fusidic acid for long-term suppressive therapy of refractory bone and joint infections, including PJI, we have recently concluded our Phase 3 trial for fusidic acid in ABSSSI. We expect our research and development expenses to temporarily trend lower. However, following our discussions with the FDA with respect to the approval path for fusidic acid and solithromycin, we could decide to increase our research and development expenses.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs, including share-based compensation, for employees in executive, operational, commercial, finance and human resources functions. Other significant general and administrative expenses include professional fees for accounting, legal, and information technology services, facilities costs, expenses associated with obtaining and maintaining patents, and costs of commercial preparation activities.

We expect our general and administrative expenses to trend downward during 2017, driven primarily by reductions in personnel and expenses related to commercial preparations.

Critical Accounting Policies and Estimates

Our 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 U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in our financial statements. We evaluate our estimates and judgments, including those related to

acc rued expenses and share-based compensation, on an ongoing basis. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the bas is 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.

Our significant accounting policies are described in more detail in the notes to our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2016 that we filed with the U.S. Securities and Exchange Commission, or SEC, on February 28, 2017. We believe the following accounting policies to be most critical to the judgments and estimates used in preparation of our financial statements and such policies have been reviewed and discussed with our audit committee.

Research and Development Prepaids and Accruals

As part of the process of preparing our financial statements, we are required to estimate our expenses resulting from our obligations under contracts with vendors, consultants and clinical site agreements in connection with our research and development efforts. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts.

Our objective is to reflect the appropriate research and development expenses in our financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of our research and development efforts. We determine prepaid and accrual estimates through reviewing open contracts and purchase orders, communicating with applicable vendor personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our prepaid and accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. We do not currently anticipate the future settlement of existing accruals to differ materially from our estimates.

Revenue Recognition

Our revenue generally consists of research related revenue under federal contracts, supply revenue and licensing revenue related to non-refundable upfront fees, milestone payments and royalties earned under license agreements. Revenue is recognized when the following criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery of the products and/or services has occurred; (3) the selling price is fixed or determinable; and (4) collectability is reasonably assured.

For arrangements that involve the delivery of more than one element, each product, service and/or right to use assets is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has “stand-alone value” to the customer. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the fair value of each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods and services are delivered, limited to the consideration that is not contingent upon future deliverables. When an arrangement is accounted for as a single unit of accounting, we determine the period over which the performance obligations will be performed and revenue recognized. Management exercises significant judgment in the determination of whether a deliverable has stand-alone value, is considered to be a separate unit of accounting, and in estimating the relative fair value of each deliverable in the arrangement.

Milestone payments are recognized when earned, provided that (i) the milestone event is substantive; (ii) there is no ongoing performance obligation related to the achievement of the milestone earned; and (iii) it would result in additional payments. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment is non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved to achieve the milestone; and the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement, and the related risk associated with the achievement of the milestone. Contingent-based payments we may receive under a license agreement will be recognized when received.

Valuation of Financial Instruments

Share-Based Compensation

In accordance with Accounting Standards Codification, or ASC, Topic 718, *Stock Compensation* , as modified or supplemented, issued by the Financial Accounting Standard Board, or FASB, we measure compensation cost for share-based payment awards

granted to employees and no n-employee directors at fair value using the Black-Scholes option-pricing model. We recognize compensation expense on a straight-line basis over the service period for awards expected to vest. Share-based compensation cost related to share-based payment aw ards granted to non-employees is adjusted each reporting period for changes in the fair value of our shares until the measurement date. The measurement date is generally considered to be the date when all services have been rendered or the date that option s are fully vested.

We calculate the fair value of share-based compensation awards using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the use of subjective assumptions, including share price volatility, the expected life of options, risk-free interest rate and the fair value of the underlying common shares on the date of grant. In developing our assumptions, we take into account the following:

- we do not have sufficient history to estimate the volatility of our common share price. We calculate expected volatility based on reported data for selected reasonably similar publicly traded companies for which the historical information is available. For the purpose of identifying peer companies, we consider characteristics such as industry, market capitalization, length of trading history, similar vesting terms and in-the-money option status. We plan to continue to use the guideline peer group volatility information until the historical volatility of our common shares is relevant to measure expected volatility for future option grants;
- we determine the risk-free interest rate by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant;
- the assumed dividend yield is based on our expectation of not paying dividends in the foreseeable future;
- we determine the average expected life of options based on the mid-point between the vesting date and the contractual term; and
- we estimate forfeitures based on our historical analysis of actual option forfeitures.

Results of Operations

The following table summarizes the results of our operations for the three-month periods ended March 31, 2017 and 2016, together with the changes in those items in dollars:

	Three Months Ended March 31,		Dollar Change
	2017	2016	
	(In thousands)		
Revenue			
Contract research	$ 4,872	$ 2,679	$ 2,193
Total revenue	4,872	2,679	2,193
Research and development expense (1)	15,410	23,529	(8,119)
General and administrative expense (1)	8,765	8,324	441
Restructuring	3,553	-	3,553
Other expense, net	32	232	(200)
(1) Includes the following share-based compensation expenses:			
Research and development expense	$ 861	$ 740	$ 121
General and administrative expense	1,375	1,625	(250)

Comparison of the Three Months Ended March 31, 2017 and March 31, 2016

Contract revenue

For the three months ended March 31, 2017, contract research revenue increased $2.2 million compared to the three months ended March 31, 2016 due to increased activity in the third option period of the BARDA contract. We expect contract research revenue to begin to decrease somewhat as activity in the second option period of the BARDA contract winds down.

Research and Development Expense

For the three months ended March 31, 2017, our research and development expense decreased $8.1 million compared to the three months ended March 31, 2016. The decrease is primarily related to the following:

- a decrease in regulatory expenses of $9.0 million primarily related to the NDA expenses incurred during 2016;
- a decrease of employee costs of $0.9 million related to the reduction in headcount as a result of the delay of our planned commercial launch of solithromycin;
- a decrease of $0.5 million in the purchase of solithromycin API ordered for commercial quantities;
- a decrease in professional services related expenses of $0.2 million due to the delay of our planned commercial launch of solithromycin; and
- an increase in BARDA related expenses of $2.5 million related to the commencement of the third option period in the second quarter of 2016.

General and Administrative Expense

General and administrative expense increased $0.4 million for the three months ended March 31, 2017 compared to the three months ended March 31, 2016. There was an increase in employee costs of $1.1 million as the result of an increased headcount compared to the same period last year, before the reduction in workforce, which was offset by a decrease in professional services of $0.7 million related to the delay of our planned commercial launch of solithromycin.

Restructuring

In February 2017, as a consequence of the solithromycin complete response letter we received from the FDA, and subsequent discussions with the FDA, resulting in the delay of the potential approval of solithromycin, we initiated companywide cost and personnel reductions. These actions resulted in an approximately 67% reduction in our workforce from 136 to 45 employees, and significant reductions in external spending related to commercial preparedness and non-essential activities. We also vacated two of the leased office suites that were no longer necessary for our operations. As a result of these decisions, we recorded a one-time charge of $3.6 million.

Other Expense, Net

Other expense decreased by $0.2 million for the three months ended March 31, 2017 compared to the three months ended March 31, 2016 due to an increased balance and a higher rate of return on cash equivalents, as well as a lower interest rate and lower balance on the July 2015 Note.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception through March 31, 2017, we have funded our operations principally with $618.6 million from the sale of debt and equity instruments (common and preferred), $44.1 million of research funding from our BARDA contract, and $40.0 million of licensing and milestone payments. As of March 31, 2017, we had cash and equivalents to fund operations of approximately $202.8 million.

Cash Flows

The following table sets forth the major sources and uses of cash for the periods set forth below:

	Three Months Ended March 31,	
	2017	2016
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$ (27,240)	$ (24,176)
Financing activities	(1,550)	94,020
Net increase in cash and equivalents	$ (28,790)	$ 69,844

Operating Activities. Cash used in operating activities of $27.2 million for the three months ended March 31, 2017 was primarily a result of our $22.9 million net loss and cash used in changes in operating assets and liabilities of $6.6 million, partially offset by non-cash items of $2.3 million. Cash used in operating activities of $24.2 million for the three months ended March 31, 2016

was primarily a result of our $ 29.4 million net loss offset by changes in operati ng assets and liabilities of $ 2.8 million and non-cash item s of $ 2.4 million.

Financing Activities. Net cash used in financing activities of $1.6 million for the three months ended March 31, 2017 was the result of $1.7 million in payment of long-term debt reduced by $0.1 million in proceeds from the exercise of stock options. Net cash provided by financing activities of $94.0 million for the three months ended March 31, 2016 consisted of net proceeds of $93.8 million from the January 2016 public offering of common stock, and $0.2 million of proceeds from the exercise of stock options.

Funding Requirements

To date, we have not generated any product revenue from our clinical stage product candidates or from any other source. We do not know when, or if, we will generate any product revenue. We do not expect to generate product revenue unless and until we obtain marketing approval of and commercialize solithromycin and/or fusidic acid or any of our other product candidates. At the same time, we expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval and engage in commercial readiness activities for, solithromycin and fusidic acid and our other product candidates. In addition, subject to obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We will need substantial additional funding in connection with our continuing operations.

Based on current assumptions, we believe that our existing cash and equivalents will enable us to fund our current operating expenses and capital requirements for at least the next 12 months from the filing date of this report. Such operating and capital requirements do not contemplate incremental expenses associated with a full scale commercial launch of solithromycin or any additional clinical trials with any of our product candidates or any funds from future financings or partnerships beyond the Toyama relationship and the BARDA contract. We will need to obtain additional financing for the continued development of solithromycin and fusidic acid and our other product candidates and to support the commercialization of solithromycin and/or any of our other product candidates should any receive regulatory approval. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Due to the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of our product candidates.

Our future capital requirements will depend on many factors, including:

- the scope, progress costs, and results of pre-clinical development, laboratory testing and clinical trials for any of our product candidates including any pre- or post-approval safety studies for solithromycin and any additional clinical trials for fusidic acid;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of commercialization readiness activities for any of our product candidates, including developing manufacturing sources and building our inventory of commercial product, in anticipation of regulatory approval;
- the costs and timing of commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive regulatory approval;
- the costs of commercial and clinical supplies of any of our drug candidates;
- obtaining milestone payments from Toyama;
- receipt of payments under the BARDA contract;
- our ability to establish collaborations on favorable terms;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the acceptance in the medical community of any of our product candidates for which we receive approval;
- revenue if any, and the timing of the related payment, from the sale of our product candidates, should any receive regulatory approval;
- obtaining a commercially viable price for any of our product candidates, should any receive regulatory approval;
- the availability of adequate coverage and reimbursement from federal, state and private healthcare payors for any of our product candidates, should any receive regulatory approval;

- reimbursement and medical policy changes that may adversely affect the pricing, p rofitability or commercial appeal of any of our product candidates, should any receive regulatory approval;
- our ability to enter into any license agreements for the distribution of our product candidates outside the U.S.;
- the extent to which we acquire or invest in businesses, products and technologies; and
- our ability to obtain government or other third-party funding.

Until we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. We do not anticipate any substantial product revenue for the foreseeable future. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of any securities may include liquidation or other preferences that adversely affect our stockholders' rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or declaring dividends, such as those imposed under the Comerica loan. If we raise additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

We will need additional financing to continue development activities to obtain regulatory approval of and to commercialize solithromycin, fusidic acid and our other product candidates. We plan, as noted, to seek partners as well as equity or debt financings or other sources of third-party funding, including government grants to support the continued development and commercialization of solithromycin, fusidic acid and our other product candidates. If we are unable to raise additional funds when needed, whether on favorable terms or not, we may be required to delay, limit, reduce or terminate our development of our product candidates, or our commercialization efforts, or to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with clinical research organizations for clinical trials and clinical supply manufacturing and with vendors for pre-clinical research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice and therefore we believe that our non-cancelable obligations under these agreements are not material.

During the three months ended March 31, 2017, there have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those specified in our 2016 Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined under SEC rules.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update, or ASU, 2014-09, Revenue from Contracts with Customers. This new guidance clarifies the principles for recognizing revenue and develops a common revenue standard for U.S. GAAP. The guidance outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes the most current revenue recognition guidance. This guidance, as amended by ASU 2015-14, is effective for fiscal years and interim periods within those years beginning after December 15, 2017, which is effective for us for the year ending December 31, 2018. In March 2016, the FASB issued ASU 2016-08, Revenue from Contracts with Customers: Principal versus Agent Considerations, which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU 2016-10, Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing, which clarifies an entity's identification of its performance obligations in a contract. The update also clarifies the guidance regarding an entity's evaluation of the nature of its promise to grant a license of intellectual property and whether or not that revenue is recognized over time or at a point in time. In May 2016, the FASB issued ASU 2016-12, Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients, which amends the guidance in the new revenue standard on collectability, non-cash consideration, presentation of sales tax, and transition. In December 2016, the FASB issued ASU 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers which increases shareholders' awareness of the proposals and expedites improvements to Update 2014-09. The amendments are intended to address implementation issues that were raised by

stakeholders and provide additional practical expedients to reduce the cost and complexity of applying the new revenue standard. These pronouncements have the same effective date as the new revenue standard.

We have evaluated the contract research agreement with BARDA, and do not anticipate a material impact on our consolidated financial statements. We are currently evaluating the license agreement with Toyama to determine the impact that the implementation of this standard will have on our consolidated financial statements, if any. We plan to use the full retrospective method of adoption effective January 1, 2018.

In February 2016, the FASB issued ASU 2016-02, Leases. The new guidance will increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. This guidance is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. We are currently evaluating the impact that the implementation of this standard will have on our consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation-Stock Compensation. The new guidance simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. We adopted this guidance as of January 1, 2017. As of December 31, 2016, we had accumulated excess tax benefits from temporary differences in the amount and timing of stock compensation expense and deductions on our income tax return from the award compensation that reduces the net operating loss deferred tax asset. We provided a full valuation allowance against our net deferred tax assets since it has been determined that it is more likely than not that all of the deferred tax assets will not be realized. Upon implementation of this standard, the stock compensation excess tax benefit will be eliminated, resulting in an increase to the net operating loss deferred tax asset, with an increase in the valuation allowance of the same. The implementation of this standard has no impact on our consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments. ASU 2016-15 will make eight targeted changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. This new guidance is effective for fiscal years beginning after December 15, 2017. We are currently evaluating the impact that the implementation of this standard will have on our consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, Business Combinations: Clarifying the Definition of a Business which revises the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. This new guidance is effective for fiscal years beginning after December 15, 2017. We are currently evaluating the impact that the implementation of this standard will have on our 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 quarter ended March 31, 2017. For additional information regarding market risk, refer to “Item 7A. Quantitative and Qualitative Disclosure About Market Risk” of our 2016 Annual Report on Form 10-K.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures (as defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act), are designed only to provide reasonable assurance that information to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Acting Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer), of the effectiveness of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Acting Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report to provide the reasonable assurance discussed above.

Changes in Internal Control over Financial Reporting

No change to our internal control over financial reporting occurred during the last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1A. Risk Factors

There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016 except the additional detailed risk as set forth below.

If we effect a transaction that we believe will offer the best use of our resources and clinical programs to deliver value to patients and shareholders, the transaction may not deliver the expected benefits, which may adversely affect our operating results and business.

In February 2017, as a consequence of the solithromycin CRL we received, and subsequent discussions with the FDA, resulting in the delay of the potential approval of solithromycin, we began and are actively pursuing, and have engaged Morgan Stanley to assist us in, a process to evaluate and assess external late-stage assets and other potential strategic business opportunities to determine the best use of our significant cash resources and late stage clinical programs to deliver value to patients and shareholders through internal and/or potential external opportunities. While there can be no assurance that any transaction will result, if we were to consummate a strategic transaction, it might not yield the benefits we anticipate. There are various uncertainties and risks relating to realizing the benefits anticipated from any strategic transaction, including:

- expected benefits may not be successfully achieved for any number of reasons, including a failure to successfully combine operations resulting from the transaction;
- our cash resources could be used more rapidly than anticipated and we may pursue other opportunities post-transaction that could adversely affect the planned development of our current product candidates; and
- we might lose employees post-transaction that could adversely affect the planned development of our current product candidates and the operations of our company.

Item 6. Exhibits

Exhibit Number	Description of Document	Registrant's Form	Filed	Exhibit Number	Filed Herewith
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101	Financials in XBRL format.				X

SIGNATURES

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

CEMPRA, INC.

Dated: April 28, 2017

By: /s/ David S. Zaccardelli, Pharm.D.
David S. Zaccardelli, Pharm.D.
Acting Chief Executive Officer

Dated: April 28, 2017

By: /s/ Mark W. Hahn
Mark W. Hahn
Chief Financial Officer

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David S. Zaccardelli, Pharm.D., certify that:

(1) I have reviewed this quarterly report on Form 10-Q of Cempra, 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 the 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.

Dated: April 28, 2017

/s/ David S. Zaccardelli

David S. Zaccardelli, Pharm.D.
Acting Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark W. Hahn, certify that:

(1) I have reviewed this quarterly report on Form 10-Q of Cempra, 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 the 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.

Dated: April 28, 2017

/s/ Mark W. Hahn

Mark W. Hahn
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF THE 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 Cempra, Inc. (the "Company") for the period ended March 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David S. Zaccardelli, Pharm.D., Acting Chief Executive Officer (Principal Executive Officer) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my 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: April 28, 2017

/s/ David S. Zaccardelli
David S. Zaccardelli, Pharm.D.
Acting Chief Executive Officer (Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF THE 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 Cempra, Inc. (the "Company") for the period ended March 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark W. Hahn, Chief Financial Officer (Principal Financial Officer) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my 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: April 28, 2017

/s/ Mark W. Hahn
Mark W. Hahn
Chief Financial Officer (Principal Financial Officer)