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 September 30, 2016

☐ **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, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

As of October 24, 2016 there were 52,381,530 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)

	September 30, 2016	December 31, 2015
Assets		
Current assets		
Cash and equivalents	$ 248,917	$ 153,765
Receivables	4,531	7,639
Prepaid expenses	792	573
Total current assets	254,240	161,977
Furniture, fixtures and equipment, net	59	90
Deposits	146	73
Total assets	$ 254,445	$ 162,140
Liabilities		
Current liabilities		
Accounts payable	$ 12,531	$ 9,635
Accrued expenses	2,090	1,475
Accrued payroll and benefits	3,679	2,337
Current portion of long-term debt	6,667	4,444
Total current liabilities	24,967	17,891
Deferred revenue	11,326	11,326
Long-term debt	10,300	15,258
Total liabilities	46,593	44,475
Commitments and contingencies		
Shareholders' Equity		
Preferred stock; $.001 par value; 5,000,000 shares authorized; no shares issued or outstanding at September 30, 2016 and December 31, 2015	-	-
Common stock; $.001 par value; 80,000,000 shares authorized; 52,381,530 and 43,990,751 issued and outstanding at September 30, 2016 and December 31, 2015, respectively	52	44
Additional paid-in capital	613,345	436,643
Accumulated deficit	(405,545)	(319,022)
Total shareholders’ equity	207,852	117,665
Total liabilities and shareholders’ equity	$ 254,445	$ 162,140

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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue				
Contract research	$ 3,972	$ 2,497	$ 10,071	$ 7,744
License	-	-	-	10,000
Supply	-	-	-	3,770
Total revenue	3,972	2,497	10,071	21,514
Operating expenses				
Research and development	21,096	23,541	60,643	73,334
General and administrative	15,021	5,848	35,333	16,230
Total operating expenses	36,117	29,389	95,976	89,564
Loss from operations	(32,145)	(26,892)	(85,905)	(68,050)
Other income (expense)				
Interest income	128	-	330	4
Interest expense	(295)	(679)	(948)	(1,910)
Other income (expense), net	(167)	(679)	(618)	(1,906)
Net loss and comprehensive loss	$ (32,312)	$ (27,571)	$ (86,523)	$ (69,956)
Basic and diluted net loss attributable to common shareholders per share	$ (0.62)	$ (0.63)	$ (1.74)	$ (1.61)
Basic and diluted weighted average shares outstanding	52,072,536	43,910,908	49,616,785	43,427,114

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

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

	Nine Months Ended September 30,	
	2016	**2015**
Operating activities		
Net loss	$ (86,523)	$ (69,956)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	40	54
Share-based compensation	7,518	4,427
Amortization of debt issuance costs	44	405
Loss on extinguishment of debt	-	153
Changes in operating assets and liabilities		
Receivables	3,108	(748)
Prepaid expenses	(219)	2,012
Deposits	(73)	288
Accounts payable	2,896	3,025
Accrued expenses	615	468
Accrued payroll and benefits	1,342	360
Net cash used in operating activities	(71,252)	(59,512)
Investing activities		
Purchases of furniture, fixtures and equipment	(9)	(46)
Net cash used in investing activities	(9)	(46)
Financing activities		
Proceeds from borrowing on long-term debt	-	20,000
Payment of long-term debt	(2,779)	(18,995)
Payment of debt issuance costs	-	(327)
Proceeds from exercise of stock options and warrants	364	2,953
Proceeds from issuance of common stock, net of underwriting discounts	169,112	139,044
Payment of offering costs	(284)	(213)
Net cash provided by financing activities	166,413	142,462
Net change in cash and equivalents	95,152	82,904
Cash and equivalents at beginning of the period	153,765	99,113
Cash and equivalents at end of the period	$ 248,917	$ 182,017
Supplemental cash flow information		
Cash paid for interest	$ 916	$ 1,226

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, 2015 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 September 30, 2016 and the results of operations and cash flows for the three and nine months ended September 30, 2016 and 2015. The December 31, 2015 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 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. 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.

Due to the potential launch in 2017 of solithromycin for the treatment of community acquired bacterial pneumonia, the Company anticipates early adoption of the new revenue recognition guidance effective January 1, 2017. The Company's ability to early adopt is dependent on system readiness and the evaluation of potential impacts on current revenue streams. The Company is currently evaluating the impact that the implementation of this standard will have on the Company's consolidated financial statements. The Company plans to complete this analysis by the end of the 2016 calendar year.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements-Going Concern. The guidance addresses management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. The standard will be effective for the year ending December 31, 2016, with early adoption permitted. The Company does not expect that the adoption of this guidance will have a material impact on its consolidated financial statements.

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. This guidance is effective for fiscal years beginning after December 15, 2016, 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 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.

3. Fair Value of Financial Instruments

The carrying values of cash and equivalents, receivables, prepaid expenses, and accounts payable at September 30, 2016 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 September 30, 2016 and December 31, 2015, the Company held money market funds classified as Level 1 financial instruments of $243.3 million and $129.0 million, respectively. The Term Loan (defined and discussed in Note 6), which is classified as a Level 2 liability, has a variable interest rate and, accordingly, its carrying value approximates its fair value. At September 30, 2016, the carrying value was $17.0 million. There were no transfers between levels of the fair value hierarchy for any assets or liabilities measured at fair value in the nine months ended September 30, 2016.

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 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. 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. If all option segments are requested, this estimated period of performance would be extended until approximately May 23, 2018.

The estimated period of performance for the base performance segment was May 24, 2013 through February 29, 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 14, 2014 through November 30, 2016.

On February 29, 2016, the Company entered into an amendment to its existing agreement with BARDA, for the evaluation and development of its lead product candidate solithromycin for the treatment of bacterial infections in pediatric populations and infections caused by bioterror threat pathogens, specifically anthrax and tularemia. The amendment evidences the authorization by BARDA of a third option work segment of the agreement. The value of this option work segment is approximately $25.5 million, 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. The estimated period of performance for this option work segment is February 29, 2016 through May 23, 2018. This option is a cost sharing arrangement for which 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 remains as running through May 23, 2018.

Under the agreement, the Company is reimbursed and recognizes revenue as allowable costs are incurred plus a portion of the fixed-fee earned, excluding the cost sharing option segment. 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 September 30, 2016, the Company has recognized $35.6 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.

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 active

pharmaceutical ingredient (“ 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 gene rated 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 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.

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 September 30, 2016, 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 Milestone payment was considered non-substantive for accounting purposes, this milestone payment is 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. The remainder of the upfront and milestone payments which aggregate to $11.3 million are recorded as deferred revenue at September 2016 and will be recognized as revenue when the revenue recognition criteria of each deliverable has been met. The Company also recognized a $10.0 million 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. The March 2015 milestone 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 .

On January 18, 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 8, 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 16, 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, 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.

On January 29, 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, including 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 until 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 satisfaction 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 Comp any 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 September 30, 2016, the Company's receivables consisted primarily of earned but unbilled receivables under the BARDA agreement.

6. 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.

At closing, the Company received the full $20.0 million under the Term Loan and paid a facility fee of $0.1 million for the Term Loan and a facility fee of $0.2 million for the Revolver. The Company immediately used proceeds from the Term Loan to pay all of its $17.7 million outstanding principal and interest and $1.2 million in end of term and prepayment fees under the loan and security agreement ("December 2011 Note") with Hercules Technology Growth Capital, Inc. ("Hercules") and terminated the Hercules Loan. The Company recorded a charge of $0.3 million on the early extinguishment of the December 2011 Note.

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 of 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.

7. Shareholders' Equity

Common Stock

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. Through September 30, 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.

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.

During the first nine months of 2016, the Company issued 83,805 shares of common stock at a weighted average exercise price of $4.34 per share upon the exercise of option grants.

During January 2015, the Company completed a public offering of 6,037,500 shares of common stock, at a price of $24.50 per share, resulting in net proceeds to the Company of approximately $138.8 million after deducting underwriting discounts, commissions and expenses of approximately $9.1 million.

The following table presents common stock reserved for future issuance for the following equity instruments as of September 30, 2016:

Warrants to purchase common stock	94,912
Options:	
Outstanding under the 2006 Stock Plan	451,525
Outstanding under the 2011 Equity Incentive Plan	3,219,998
Available for future grants under the 2011 Equity Incentive Plan	3,074,428
Total common stock reserved for future issuance	6,840,863

8. 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 September 30, 2016, there were options for an aggregate of 451,525 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 6,601,735 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 September 30, 2016, there were 3,074,428 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 activity:

	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)	Aggregate Intrinsic Value [1]
Outstanding - December 31, 2015	2,813,765	$ 12.80		
Granted	998,158	26.88		
Exercised	(83,805)	4.34		
Forfeited	(53,225)	21.72		
Expired	(3,370)	23.95		
Outstanding - September 30, 2016	3,671,523	16.68	7.28	$ 34,064,353
Exercisable - September 30, 2016	2,259,658	12.07	6.32	$ 29,492,630
Vested and expected to vest at September 30, 2016 [2]	3,581,925	$ 16.47	7.24	$ 33,837,681

(1) Intrinsic value is the excess of the fair value of the underlying common shares as of September 30, 2016 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 options outstanding as of September 30, 2016:

	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 - $2.47	451,525	3.27	451,525	3.27
$6.63 - $7.86	850,217	6.06	839,530	6.05
$8.70 - $13.71	643,438	7.20	421,118	7.10
$15.69 - $19.25	224,625	9.55	-	-
$22.11 - $43.43	1,501,718	8.87	547,485	8.63
	3,671,523		2,259,658	

During the three-month periods ended September 30, 2016 and 2015, the Company recorded $2.5 million and $1.6 million in share-based compensation expense, respectively. During the nine-month periods ended September 30, 2016 and 2015, the Company recorded $7.5 million and $4.4 million in share-based compensation expense, respectively. As of September 30, 2016, approximately $19.6 million of total unrecognized compensation cost related to unvested share options is expected to be recognized over a weighted-average period of 2.76 years.

9. Income Taxes

The Company estimates an annual effective tax rate of 0% for the year ending December 31, 2016 as the Company incurred losses for the nine-month period ended September 30, 2016 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, 2016. 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.

10. 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

and common share options, have not been included in the computation of diluted net los s per share for all periods as the result would be antidilutive.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Warrants outstanding	94,912	125,246	94,912	145,119
Stock options outstanding	3,605,373	2,847,922	3,517,324	2,938,101
	3,700,285	2,973,168	3,612,236	3,083,220

11. Subsequent Events

In October 2016, the Company recognized the third $10.0 million milestone from Toyama ("October 2016 Milestone"), which was triggered by Toyama's progress of solithromycin clinical development program in Japan. The milestone relates to Toyama's receipt of regulatory acceptance to begin a Phase 3 trial of solithromycin in Japan following successful completion of a Phase 2 trial. The milestone event triggering the October 2016 Milestone was considered non-substantive for accounting purposes. Therefore, the milestone is being recognized into revenue proportionately to the six deliverables in the agreement using the same allocation as the upfront payment. An amount of $4.3 million of the October 2016 Milestone was recognized into revenue in October 2016. The remainder is recorded as deferred revenue at October 2016 and will be recognized as revenue when the revenue recognition criteria of each deliverable has been met.

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, 2015, 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, 2015. 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, 2015, 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 antibiotics for the acute care and community settings to meet critical medical needs in the treatment of bacterial infectious diseases, particularly respiratory tract infections and acute and chronic staphylococcal infections. Our lead product, solithromycin, has completed two Phase 3 clinical trials, for which topline results were reported in January and October 2015. Additionally, we are conducting a Phase 1B clinical trial, as well as a Phase 2/3 registrational trial, for solithromycin with pediatric patients. We are developing solithromycin in oral capsules, intravenous, or IV, and suspension formulations, initially for the treatment of community acquired bacterial pneumonia, or CABP, one of the most serious infections of the respiratory tract, for which we recently completed two new drug applications, or NDAs, to the U.S. Food and Drug Administration, or FDA, in the second quarter of 2016. We also completed our submission of the Marketing Authorization Application, or MAA, for solithromycin to the European Medicines Agency, or EMA, for the treatment of CABP. The MAA is for the IV and oral capsule formulations. Solithromycin is a potent new fourth generation macrolide and the first fluoroketolide in clinical development. We also are conducting a Phase 3 trial of solithromycin in uncomplicated gonorrhea. In September 2015, we began exploring solithromycin's anti-inflammatory properties by initiating Phase 2 studies of solithromycin treating chronic obstructive pulmonary disease, or COPD, and nonalcoholic steatohepatitis, or NASH patients. Our second program is Taksta, which we are developing exclusively in the U.S. as an oral treatment for acute bacterial skin and skin structure infections, or ABSSSI, and refractory bone and joint infections caused by staphylococci, including *S. aureus* and methicillin-resistant *S. aureus* , or MRSA. Based on our discussions with the FDA in 2015, we are conducting a Phase 3 trial for the treatment of ABSSSI that we began in November 2015 as well as a refractory bone and joint infection study that we began in March 2016.

On August 30, 2016, we announced that the FDA has scheduled a meeting of the Antimicrobial Drugs Advisory Committee on November 4, 2016 in Silver Spring, Maryland to discuss the safety and efficacy of solithromycin to treat CABP. We have conducted two pivotal Phase 3 global registration studies of solithromycin. The first study was conducted with solithromycin oral capsules, and the second study tested IV solithromycin progressing to oral solithromycin. Both Phase 3 studies met their primary endpoints that

were aligned with FDA guidance. Solithromycin was granted qualified infectious diseases product, or QIDP, designation which entitled the NDAs to eight-month priority reviews, resulting in PDUFA dates of December 27, and December 28, 2016, respectively, for the oral and IV NDAs.

As part of the priority reviews, we made a rolling submission of the chemistry, manufacturing, and controls, or CMC, section of the NDAs beginning in January of 2016. In addition to evaluating the safety and efficacy of solithromycin, as is customary, the FDA is evaluating the CMC section of the solithromycin NDAs. Based on an import alert placed on a Wockhardt Limited, or Wockhardt, manufacturing facility in August 2016, several months after our NDA had been submitted and accepted for review by the FDA, Cempra began an active dialog with the FDA to determine if the active pharmaceutical ingredient, or API, produced at Wockhardt prior to the import alert was adequate for the NDA.

Based on an in person meeting held with the FDA in late October, we currently believe the FDA may not allow us to use API produced by Wockhardt for approval and commercial supply of solithromycin, and we are preparing to provide the FDA with data from API that we are manufacturing with another API supplier.

We believe that the FDA's concerns with Wockhardt's operations and facilities are related to the GMP quality systems at Wockhardt, and not specifically focused on Cempra's product or processes. Solithromycin API manufacturing at Wockhardt was closely supervised by our personnel and we continue to have confidence in the solithromycin manufacturing process and the quality of our drug product.

As disclosed previously, as part of our commercialization plans for the anticipated demand for solithromycin for the treatment of CABP we have been developing various additional supply sources for the API of solithromycin. This includes manufacturing activities at Uquifa in Cuernavaca, Mexico, which we began in the second quarter of 2014. Based on our recent discussions with the FDA, we have accelerated our API manufacturing activities with Uquifa. We expect to provide data from Uquifa to the FDA over the next several months, which, if acceptable to the FDA, would allow us to launch solithromycin for the 2017-2018 influenza/pneumonia season.

Based on our discussions with the FDA, we believe their concerns are specific to Wockhardt rather than with any aspect of our API process and that providing satisfactory drug substance from Uquifa will address these concerns. The FDA could withhold or defer potential approval until they are satisfied that commercial supplies of solithromycin meet their CMC requirements.

Assuming FDA approval, we plan to sell solithromycin in the U.S. through our own specialty sales and marketing teams that will focus on the continuum of care for CABP focused in the outpatient setting, primarily on emergency rooms, urgent care centers, outpatient clinics and other high CABP antibiotic prescribing physician offices, and in the hospital, focused primarily on key academic medical centers and teaching hospitals with significant influence in a given geography.

We expect to build an antibiotic specialty sales force of between 200 and 300 representatives to be able to address the high prescribing centers we have identified as our primary targets. According to data we have generated, we believe this team can address the prescribers writing approximately 60% of the prescriptions for azithromycin and levofloxacin to treat CABP. In the third quarter of 2016, we completed hiring our core sales leadership team, consisting of three area sales directors and more than 20 regional sales managers. We have also hired 12 medical science liaisons who are responsible for communicating medical information to physicians and two national account directors who are responsible for establishing and maintaining our relationships with payors.

We believe a strong position on commercial and hospital formularies could support the adoption rate for solithromycin. Immediately following approval, we plan to begin discussions with commercial payors and hospital formularies in an effort to secure favorable positions. These discussions can take three to six months, or longer. We also anticipate that the committee responsible for updating the IDSA/ATS Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults may consider the published Phase 3 clinical data from solithromycin and could proceed to update the guidelines in 2017, if solithromycin is approved. We believe that an update to the guidelines to include solithromycin could further support the adoption rate for solithromycin.

Based on our market research to assess physician perspectives on the need for new CABP therapies and their potential adoption of solithromycin, we believe physicians will begin prescribing solithromycin fairly quickly once we make the product available and we want to have sufficient supplies of solithromycin available to support potential demand at launch. We further believe that having both the oral and the intravenous formulations readily available at launch will enhance physician and patient acceptance of solithromycin and, therefore, the trajectory of launch.

As we have continued to consider the timing of o ur PDUFA dates in late December, the seasonal nature of the influenza/pneumonia season typically creating declining demand for CABP therapy in the spring, the potential commercial advantages of launching solithromycin after securing potential formulary acc eptance, potential inclusion in treatment guidelines, the costs associated with hiring, training and deploying a 200-300 person sales force at the tail end of the 2016-2017 influenza/pneumonia season, and the potential time required for FDA to approve the material we are producing at Uquifa, we now believe that focusing our commercial launch activities on the 2017-2018 influenza/pneumonia season is the best timing to support the most successful launch of solithromycin.

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 in accordance with generally accepted accounting principles in the U.S., or U.S. GAAP.

In May 2013, we entered into an agreement with 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. 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 estimated period of performance for the base performance segment was May 24, 2013 through February 29, 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 14, 2014 through November 30, 2016. If all option segments are requested, this estimated period of performance would be extended until approximately May 23, 2018.

On February 29, 2016, we entered into an amendment to our agreement with BARDA for the evaluation and development of our lead product candidate solithromycin for the treatment of bacterial infections in pediatric populations and infections caused by bioterror threat pathogens, specifically anthrax and tularemia. The amendment evidences the authorization by BARDA of a third option work segment of the agreement. The value of this option work segment is approximately $25.5 million, 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. The estimated period of performance for this option work segment is February 29, 2016 through May 23, 2018. This option is a cost sharing arrangement for which 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 remains as running through May 23, 2018.

Under the agreement, we are reimbursed and recognize revenue as allowable costs are incurred plus a portion of the fixed-fee earned, excluding the cost sharing option segment. We consider 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 September 30, 2016, we have recognized $35.6 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 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 recognized 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 2016, we recognized the third $10.0 million milestone which was triggered by Toyama's re ceipt of regulatory acceptance to begin a Phase 3 trial of solithromycin in Japan following successful completion of a Phase 2 trial. We expect to receive payment for the third milestone in the fourth quarter of 2016. Under the terms of the license agree ment, Toyama must also pay us a royalty equal to a low-to-high first double decimal digit percentage of net sales, subject to downward adjustment in certain circumstances. Cumulatively, through September 30 , 2016, we have recognized $18.7 million in revenu e under this agreement with the remaining $11.3 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.

As part of the license 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 exclusive 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 solithromycin 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 the license agreement.

In January 2016, we entered into a supply agreement with FUJIFILM Finechemicals Co., Ltd., or FFFC, which is intended to provide us with solithromycin in sufficient quantities and at reasonable prices to ensure we meet our obligation to Toyama under the supply agreement. We are subject to a minimum purchase obligation for a designated number of years after the successful completion of a manufacturing facility to be built and validation studies to be conducted by FFFC. 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. We are not precluded from developing one or more alternative or additional sources of solithromycin. The agreement's initial term runs until December 16, 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, 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 us of the minimum purchase obligation is considered a material breach. A product failure is not considered a material breach by us. We have the right to terminate the agreement upon written notice if there is a supply failure. We also may terminate in the event that FFFC cannot provide us 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 us. We 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 us and, prior to such termination, (i) FFFC has constructed a facility in Japan for the primary purpose of manufacturing API for us 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, we 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 us 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 us 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 us to FFFC.

In the future, we anticipate generating revenue from a combination of sales of our products, if approved, whether through our own or a third-party sales force, 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 Taksta 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, activities related to regulatory filings for our product candidates, and activities related to the planned commercial launch of solithromycin as a treatment for CABP. 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;
- activities and supplies related to preparing solithromycin for commercial launch in the U.S. for the treatment of CABP;
- research supplies; and
- license fees 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 Taksta in parallel primarily for the treatment of CABP and uncomplicated gonorrhea (for solithromycin) and ABSSSI and refractory bone and joint infections (for Taksta) 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 Taksta, 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 and development expense" in the table.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(In thousands)		(In thousands)	
Direct research and development expense by program:				
Solithromycin	$ 13,036	$ 15,305	$ 36,943	$ 58,812
Taksta	3,829	4,818	9,122	5,108
Macrolide research	425	9	1,886	183
Research and development personnel cost	3,599	3,133	11,885	8,423
Total direct research and development expense	20,889	23,265	59,836	72,526
Indirect research and development expense	207	276	807	808
Total research and development expense	$ 21,096	$ 23,541	$ 60,643	$ 73,334

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 and expense of our ongoing, as well as any additional, clinical trials required and other research and development activities;
- ongoing and future clinical trial results; and

- the costs and the timing of our regulatory submissions and any regulatory approvals.

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 or completion of 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, including one with oral solithromycin and one with IV solithromycin progressing to oral solithromycin. We are also conducting a Phase 3 trial for solithromycin in patients with uncomplicated gonorrhea.

We are also conducting a Phase 3 trial for the treatment of ABSSSI and a refractory bone and joint infection study to determine Taksta's safety and efficacy as a long-term suppressive therapy of refractory bone and joint infections, including PJI.

We expect research and development expense in the last quarter of 2016 will be similar to research and development expense in the preceding quarters of 2016, excluding the costs of manufacturing of commercial product and the potential payment of any milestones tied to FDA approval of solithromycin for CABP. If approved by the FDA, we will owe a milestone payment of $9.5 million through our licensing agreement with Optimer Pharmaceuticals, Inc. In 2017, unless we add new compounds to our clinical pipeline, we expect research and development expenses to decline.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs, including share-based compensation, for employees in executive, operational, 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 commercialization activities.

We expect that our general and administrative expenses will continue to increase with the continued development of and in preparation for commercialization of our product candidates. Specifically, we anticipate general and administrative expenses to increase for the next several quarters as we further expand our commercial team, build out our sales infrastructure, conduct market research and develop and execute marketing programs. We also believe that these increases will likely include increased costs related to the hiring of additional personnel and increased fees for outside consultants, lawyers and accountants. We also expect to incur significant costs to comply with corporate governance, internal controls, information technology and similar requirements applicable to public companies.

Other Income (Expense), Net

Interest income consists of interest earned on our cash and equivalents.

Interest expense consists of interest incurred on the loan and security agreement with Hercules Technology Growth Capital, Inc. ("December 2011 Note"), which was paid in full in July 2015, using the proceeds from the loan and security agreement with Comerica Bank ("July 2015 Note"), which was entered into in July 2015.

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 accrued 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 basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

For a description of our critical accounting policies and estimates, please refer to the "Critical Accounting Policies and Estimates" section of the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section in our Annual Report on Form 10-K for the year ended December 31, 2015 filed with the Securities and Exchange Commission, or SEC, on February 25, 2016. 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.

Accrued Expenses

As part of the process of preparing our financial statements, we are required to estimate accrued expenses. This process involves 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 accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued expenses include:

- fees paid to CROs in connection with pre-clinical or clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- milestone payments; and
- unpaid salaries, wages and benefits.

We accrue our expenses related to clinical trials based on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. 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 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, 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.

Res ults of Operations

The following table summarizes the results of our operations for each of three and nine-month periods ended September 30, 2016 and 2015, together with the changes in those items in dollars:

	Three Months Ended September 30,		Dollar Change	Nine Months Ended September 30,		Dollar Change
	2016	2015		2016	2015	
	(In thousands)			(In thousands)		
Revenue						
Contract research	$ 3,972	$ 2,497	$ 1,475	$ 10,071	$ 7,744	$ 2,327
License	-	-	-	-	10,000	(10,000)
Supply	-	-	-	-	3,770	(3,770)
Total revenue	3,972	2,497	1,475	10,071	21,514	(11,443)
Research and development expense (1)	21,096	23,541	(2,445)	60,643	73,334	(12,691)
General and administrative expense (1)	15,021	5,848	9,173	35,333	16,230	19,103
Other expense, net	167	679	(512)	618	1,906	(1,288)
(1) Includes the following share-based compensation expenses:						
Research and development expense	$ 627	$ 535	$ 92	$ 2,348	$ 1,459	$ 889
General and administrative expense	1,851	1,030	821	5,169	2,968	2,201

Comparison of the Three Months Ended September 30, 2016 and September 30, 2015

Contract revenue

For the three months ended September 30, 2016, contract research revenue increased $1.5 million compared to the three months ended September 30, 2015 due to increased activity in the second option period and the commencement of the third option period of the BARDA contract. We expect contract research revenue to continue to increase as activity increases in the third option period of the BARDA contract.

Research and Development Expense

For the three months ended September 30, 2016, our research and development expense decreased $2.4 million compared to the three months ended September 30, 2015. The decrease is primarily related to the following:

- a decrease in solithromycin clinical trial expenses of $5.7 million related to completion of the IV-to-Oral Phase 3 clinical trial;
- a decrease of $2.4 million in purchases of clinical trial supplies for Taksta due to timing of the comparator purchase for the Phase 3 ABSSSI trial;
- a decrease of $0.7 million in the purchase of API ordered for commercial quantities in preparation for the planned commercial launch of solithromycin;
- an increase in BARDA related expenses of $2.2 million as developmental activity increases;
- an increase in Taksta clinical trial expenses of $1.4 million primarily related to the ongoing Phase 3 ABSSSI trial and the ongoing refractory bone and joint study;
- an increase in clinical trial supplies of $1.0 million for validation batches;
- an increase in regulatory expenses of $0.8 million for the preparation for the FDA Antimicrobial Drugs Advisory Committee meeting;
- an increase of $0.5 million in expenses related to research for other potential indications of solithromycin; and
- an increase in employee cost of $0.5 million primarily from increased headcount.

General and Administrative Expense

General and administrative expense increased by $9.2 million for the three months ended September 30, 2016 compared to the three months ended September 30, 2015. The increase is primarily related to the following:

- an increase in employee cost of $4.3 million primarily from increased headcount;
- an increase in professional service expenses of $2.2 million primarily related to our commercial readiness activities for the planned commercial launch; and
- an increase of information technology services, medical affairs expenses and conference and travel fees of $2.7 million related to our commercial readiness activities for the planned commercial launch.

Other Income (Expense), Net

Other expense decreased by $0.5 million for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 due to an increased balance and a higher rate of return on cash equivalents, as well as a lower interest rate on the July 2015 Note compared to the December 2011 Note.

Comparison of the Nine Months Ended September 30, 2016 and September 30, 2015

Contract revenue

For the nine months ended September 30, 2016, contract research revenue increased approximately $2.3 million compared to the nine months ended September 30, 2015 due to increased activity in the second option period and the commencement of the third option period of the BARDA contract. We expect contract research revenue to continue to increase as activity increases in the third option period of the BARDA contract.

License revenue

For the nine months ended September 30, 2016, license revenue decreased $10.0 million compared to the nine months ended September 30, 2015. During the nine months ended September 30, 2015, we received a $10.0 million payment from Toyama. No such payments have been received thus far in 2016.

Supply revenue

For the nine months ended September 30, 2016, supply revenue decreased $3.8 million compared to the nine months ended September 30, 2015, as no shipments to Toyama have occurred in 2016.

Research and Development Expense

For the nine months ended September 30, 2016, our research and development expense decreased $12.7 million compared to the nine months ended September 30, 2015. The decrease is primarily related to the following:

- a decrease in solithromycin clinical trial expenses of $24.3 million related to completion of the IV-to-Oral Phase 3 clinical trial;
- a decrease of $6.9 million in the purchase of API ordered for commercial quantities in preparation for the planned commercial launch of solithromycin;
- a decrease of $2.8 million in purchases of API for Toyama's clinical trials in Japan;
- a decrease of $2.4 million in purchases of clinical trial supplies for Taksta due to timing of the comparator purchase for the Phase 3 ABSSSI trial;
- an increase in regulatory expenses of $7.9 million for submission fees related to the NDA and MAA filings as well as the preparation for the FDA Antimicrobial Drugs Advisory Committee meeting;
- an increase in Taksta clinical trial expenses of $6.4 million primarily related to the ongoing Phase 3 ABSSSI trial and the ongoing refractory bone and joint study;
- an increase in employee cost of $3.5 million primarily from increased headcount;
- an increase in BARDA related expenses of $3.4 million as developmental activity increases;

- an increase of $1.7 million in exp enses related to research for other potential indications of solithromycin; and
- an increase in clinical trial supplies of $0.8 million for ongoing clinical studies.

General and Administrative Expense

General and administrative expense increased by $19.1 million for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015. The increase is primarily related to the following:

- an increase in employee cost of $8.8 million primarily from increased headcount; and
- an increase in commercial readiness activities for the planned commercial launch of $10.3 million from our commercial primarily from professional services, conference, travel, and IT systems expenses.

Other Income (Expense), Net

Other expense decreased by $1.3 million for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 due to an increased balance and a higher rate of return on cash equivalents, as well as a lower interest rate on the July 2015 Note compared to the December 2011 Note.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in November 2005 through September 30, 2016, we have funded our operations primarily with an aggregate of $618.6 million from debt and the sale of convertible notes, convertible preferred shares, common shares and common stock, including net proceeds of $93.8 million from our January 2016 public offering and $75.1 million in 2016 from the at-the-market ("ATM") sales agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen"). As of September 30, 2016, we had cash and equivalents of approximately $248.9 million.

Cash Flows

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

	Nine Months Ended September 30,	
	2016	2015
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$ (71,252)	$ (59,512)
Investing activities	(9)	(46)
Financing activities	166,413	142,462
Net increase in cash and equivalents	$ 95,152	$ 82,904

Operating Activities. Cash used in operating activities of $71.3 million for the nine months ended September 30, 2016 was primarily a result of our $86.5 million net loss offset by changes in operating assets and liabilities of $7.6 million and non-cash items of $7.6 million. Cash used in operating activities of $59.5 million for the nine months ended September 30, 2015 was primarily a result of our $69.9 million net loss offset by changes in operating assets and liabilities of $5.4 million and non-cash items of $5.0 million.

Investing Activities. Net cash used in investing activities was $9,000 and $46,000 for the nine months ended September 30, 2016 and 2015, respectively related to purchases of equipment.

Financing Activities. Net cash provided by financing activities of $166.4 million for the nine months ended September 30, 2016 consisted of net proceeds of $169.1 million from the issuance of common stock, $0.4 million of proceeds from the exercise of stock options reduced by $2.8 million in payment of long-term debt and $0.3 million of offering costs. Net cash provided by financing activities was $142.5 million for the nine months ended September 30, 2015 and consisted of net proceeds of $139.0 million from the January 2015 public offering of common stock, offset by $0.2 million in offering costs, $20.0 million of gross proceeds from Comerica under the Term Loan which was used to pay off the outstanding debt balance to Hercules of $18.9 million offset by debt issuance costs of $0.3 million, and $2.9 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 Taksta 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 of and engage in commercial readiness activities for, solithromycin and Taksta and our other product candidates. In addition, subject to obtaining regulatory approval of any of our product candidates, including solithromycin for CABP, 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 expect that our existing cash and equivalents, including the proceeds of the January 2016 offering and the ATM program, will enable us to fund our operating expenses and capital expenditure through 2017, including the completion of our Phase 3 trial for solithromycin for the treatment of gonorrhea, and the cost of preparing for and executing the planned 2017 launch of solithromycin in the U.S.. This projection does not include 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 Taksta and our other product candidates and to support the ongoing commercialization of solithromycin and any of our other product candidates. 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 progress, costs and results of our ongoing Phase 3 uncomplicated gonorrhea trial, our ongoing Taksta Phase 3 trial for ABSSSI and exploratory study for bone and joint infections and any future trials for solithromycin and Taksta;
- the costs and timing of commercialization readiness activities for solithromycin for CABP including developing additional manufacturing sources for solithromycin and building our inventory of commercial product;
- the costs of commercial launch activities, including product sales, marketing, manufacturing and distribution, for solithromycin for CABP;
- the progress, costs and results of our ongoing Phase 2 trials for solithromycin for COPD and NASH;
- the scope, progress costs, and results of pre-clinical development, laboratory testing and clinical trials for our other product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our other product candidates for which we receive regulatory approval;
- the costs of commercial and clinical supplies of solithromycin and our other 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 solithromycin for the treatment of CABP and any other product candidate for which we receive approval;
- revenue if any, and the timing of the related payment, from the sale of our product candidates, if approved by the FDA;
- obtaining a commercially viable price for solithromycin for the treatment of CABP, and for any other product candidate, for which we receive approval;
- the availability of adequate coverage and reimbursement from federal, state and private healthcare payors for solithromycin and any other product candidate for which we receive approval;

- reimbursement and medical policy changes that may adversely affect th e pricing, profitability or commercial appeal of solithromycin and any other product candidate for which we receive 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 until we launch solithromycin in the U.S., assuming approval of our NDA for the treatment for CABP. Assuming FDA approval, we do not expect to be able to launch solithromycin for CABP until sometime in 2017 at the earliest. The FDA Prescription Drug User Fee Act ("PDUFA") dates for our applications are December 27 (Oral) and December 28 (IV), 2016, assuming there are no unexpected developments with our applications. We do not have any committed external source of funds except for the potential $10.0 million revolver available under the Comerica loan we entered into in July 2015, which will be available to us in the event of FDA approval of our NDA for solithromycin for CABP. 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 support the ongoing commercialization of solithromycin, any development for other indications for solithromycin, as well as to continue development activities to obtain regulatory approval of and to commercialize Taksta. 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, Taksta 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 nine months ended September 30, 2016, there have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those specified in our 2015 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 Financial Accounting Standards Board, or 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. The amendments are intended to address implementation issues that were raised by stakeholders and provi de 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.

Due to the potential launch in 2017 of solithromycin for the treatment of CABP, we anticipate early adoption of the new revenue recognition guidance effective January 1, 2017. Our ability to early adopt is dependent on system readiness and the evaluation of potential impacts on current revenue streams. We are currently evaluating the impact that the implementation of this standard will have on our consolidated financial statements. We plan to complete this analysis by the end of the 2016 calendar year.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements-Going Concern. The guidance addresses management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. The standard will be effective for the year ending December 31, 2016, with early adoption permitted. We do not expect that the adoption of this guidance will have a material impact on our consolidated financial statements

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. This guidance is effective for fiscal years beginning after December 15, 2016, 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 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.

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 September 30, 2016. For additional information regarding market risk, refer to "Item 7A. Quantitative and Qualitative Disclosure About Market Risk" of our 2015 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 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 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, 2015 except the additional detailed risk as set forth below.

Our planned commercialization of solithromycin for the treatment of community acquired bacterial pneumonia could be delayed or denied if our third party manufacturers do not meet regulatory requirements.

Each component of our planned solithromycin products, both the oral and intravenous formulations that are the subjects of our new drug applications, or NDAs, for the treatment of community acquired bacterial pneumonia, or CABP, on file with both the U.S. Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, as well as the manufacturer of each component, must meet all applicable regulatory requirements in order to receive regulatory approval as well as maintain regulatory compliance after approval. Any of the following could have a material adverse impact on our business, financial condition, results of operations or prospects:

- If any manufacturer we employ for the production of solithromycin cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, in which event we would not receive approval from the FDA for solithromycin for the treatment of CABP;
- Even if our manufacturers are successful in ultimately meeting FDA requirements for our NDAs, compliance issues that arise prior to receipt of approval of the NDAs could cause significant and expensive delays prior to receiving approval;
- A delay in receiving approval of the NDAs could negatively impact our pre-launch activities for solithromycin;
- If approval is received, the failure of our third party manufacturers to continue to meet applicable regulatory requirements could result in the loss of those manufacturing sources, which could cause shortages of commercial product.

These same risks apply to our current application to the EMA for solithromycin for the treatment of CABP.

Item 6. Exhibits

Exhibit Number	Description of Document	Registrant's Form	Filed	Exhibit Number	Filed Herewith
10.1	Amendment, dated September 26, 2016, to contract by and between Cempra Pharmaceuticals, Inc. and the Biomedical Advanced Research and Development Agency, dated May 24, 2013, as amended.				X
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: October 27, 2016

By: /s/ Prabhavathi Fernandes, Ph.D.
Prabhavathi Fernandes, Ph.D.
President and Chief Executive Officer

Dated: October 27, 2016

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

Dated: October 27, 2016

By: /s/ Shane M. Barton
Shane M. Barton
Chief Accounting Officer

Exhibit 10.1

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE		PAGE 1 OF PAGES 33
2. AMENDMENT/MODIFICATION NO. 0017	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO. OS185824	5. PROJECT NO. *(If applicable)*	
6. ISSUED BY CODE ASPR-BARDA		7. ADMINISTERED BY *(If other than Item 6)* CODE ASPR-BARDA01		
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201		ASPR-BARDA 330 Independence Ave, SW, Rm G644 Washington DC 20201		
8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)* CEMPRA PHARMACEUTICALS, INC. 1425009 CEMPRA PHARMACEUTICALS, INC. BUILDING 2 QUADRANGLE 6320 QUADRANGLE DRIVE, SUITE 360 CHAPEL HILL NC 27517		☒	9A. AMENDMENT OF SOLICITATION NO.	
			9B. DATED *(SEE ITEM 11)*	
		☒	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201300009C	
			10B. DATED *(SEE ITEM 13)* 05/24/2013	
CODE 1425009	FACILITY CODE			

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

£ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers £ is extended, £ is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing items 8 and 15, and returning ____copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)* **Net Increase: $ 8,000,000.00**

2016.1992016.25103

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER *(Specify type of modification and authority)*
X	Bilateral: Mutual Agreement of the Parties.

E. IMPORTANT: Contractor £ is not, ☒ is required to sign this document and return __0__copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (***Organized by UCF section headings, including solicitation/contract subject matter where feasible.)***

Tax ID Number: 20-3905814
DUNS Number: 623713034
see the Attached Pages.
Delivery: 05/23/2018
Delivery Location Code: HHS
HHS
200 Independence Avenue, SW
Washington DC 20201 US

Appr. Yr.: 2016 CAN: 1992016 Object Class: 25103
FOB: Destination
Continued …

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
Prabhavathi Fernandes, President & CEO		ETHAN J. MUELLER	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
Prabhavathi Fernandes *(Signature of person authorized to sign)*	Sept 26 2016	ETHAN J. MUELLER *(Signature of Contracting Officer)*	9/26/16

NSN 7540-01-152-8070
Previous edition unusable

STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

NAME OF OFFEROR OR CONTRACTOR

CEMPRA PHARMACEUTICALS, INC. 1425009

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Period of Performance: 05/24/2013 to 05/23/2018				
	Change Item 4 to read as follows (amount shown is the obligated amount):				
4	Phase 2/3 Clinical Evaluation and Phase 1 Suspension Relative Bioavailability Study.				8,000,000.00
	Reports and Other Data Deliverables.				
	Amount: $25,521,725.48				
	Amount: $8,000,000.00				

A. The purpose of this modification is for the Government and the Contractor to bilaterally mo d i fy the Statement of Work requirements for Option 3 CLIN 0004 for the purposes of adding within scope changes to the Statement of Work for the purposes of adding to Option 3 CLIN 0004, **Paragraph 4.6.1.2 Manufacture Key Starting Material (Stage 5) and validation batches of solithromycin drug substance (API) batches that will be used to manufacture drug product batches to support commercial launch and the manufacture of POS registration batches** and the following revised **Paragraph 4. 6 . 5. 1 POS Phase 2/3 CTM /Registration Batch and capsule CTM Stability Studies, including Phase 1 POS CTM stability for supportive expiry (WBS 4 . 6.5.1)** in order to comply with FDA Guidance. These within scope changes to Option 3 CLIN 0004 are all necessary for compliance with FDA G u i dance and the full completion of Option 3 CLIN 000 4 .

1. Unde r , **ARTICLE B . 3 . OPTION PRICES,** Option 3 , CLIN 0004 is hereby modified as follow s :

1. Option 3 , CLIN 0004 , is a cost-sharing CLIN. Monies shall be provided for the total cost of performance from the Department of Health and Human Services, and the Contractor, Cempra Pharmaceuticals , Incorpo r ate d .

2. The Government shall provide mo n i es for Option 3 , CLIN 0004 in an amount not to e x ceed $33,521,725.4 8 . The total amount obligated by the Government for Option 3 , CLIN 0004 shall not exceed the Total Estimated Cost of $3 3 , 521,725.48 and the Government will not be responsible for any Contractor incurred costs that exceed this amount under Option 3 , CLIN 0004 unless a modification to the contract is signed by the Contracting Officer which e x pressly increases th i s amount. The Contractor's share for Option 3 , CLIN 0004 is estimated at $13,03 6 , 22 6 . 46.

3. For Option 3 , CLIN 000 4 , the Contractor shall maintain records of all contract costs (including costs claimed by the Contractor as being its share) and such records shall be subject to the Audit and Records-Negotiation and Final Decisions on Audit Findings clauses of the General Clauses.

4. For Option 3 , CLIN 000 4 , costs contributed by the Contractor shall not be charged to the Government under any other contrac t , grant, or cooperative agreement (including allocation to other grant s , c ontracts , or cooperative agreements as part of an independent research and development program) . The Contractor shall report the organization's share of the costs e x pended by category, on the Financial Repor t , as referenced in the CONTRACT FINANCIAL REPORT Article in SECTION G of this contrac t .

5. The following clause contained in Article I .]Section I CONTRACT CLAUSES i s applicable ONLY to Option 3 , CLIN 0004:

FAR Clause No.	Date	Title
52.216-12	Apr 1984	Cost Sharing Contract – no fee **(Applicable to Option 3, CLIN 0004 ONLY)**

CLIN	**Estimated Period of Performance**	**Supplies/Services**	**Total Estimated USG Cost**	**Total Estimated Cempra Cost Sharing**	**Total Estimated Cost**
0004	29 February 2016 through 23 May 2018.	Phase 2/3 Clinical Evaluation and Phase 1 Suspension Relative Bioavailability Study. Reports and Other Data Deliverables.	$33,521,725.48	$13,036,226.46	$46,557,951.94

2. This modification results in the following increases to Option 3 CLIN 0004 of the contract:

Total Estimated USG Cost (USG Share ONLY) of Option 3 CLIN 4: From $25,521,725.48 By $8,00 0 ,000.00 To $33,521,725.4 8 .

Total Estimated Cempra Cost Sharing (Cempra's Share ONLY) of Option 3 CLIN 4: From $9,925,115.46 By $3,111,111.00 To $13,036,22 6 . 46.

Total Estimated Cost (USG Share and Cempra's Share) of Option 3 CLIN 0004: From $35,446,84 0 . 94 By $11,111]11.00 To $46,557,951.94.

3. This modification also results in an increase in the total amount of the contract From $60,226,535.10 By $8,000,000.00 To $68,226,535.10 as well as the following:

Total Estimated Cost of the Contrac t : From $58,021,194.94 By $8,000,00 0 .00 To $66,021,19 4 . 9 4 .

No Change to the Total Fixed Fee of the Contract of $2,205,34 0 . 16.

Total Estimated Cost Plus Fixed Fee of the Contract: From $60,226,535.10 By $8,000,000.00 To $68,226,535.10

4. In Block 14 of the SF 26 , the following CAN Number is added: Appropriation Year: 2016 , Object Class: 25103, CAN# 1992016 $8,000,000.00

5. In Block 15G of the SF 26, the amount of $60,226,535.10 is hereby changed to $68,226,535.10.

6 . The Government and the Contractor bilaterally modify Attachment 1, Statement of Work dated 16 January 2015, under PART III, LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS , SECTION J LIST OF ATTACHMENTS for the purposes of adding to Option 3 CLIN 0004 , **Paragraph 4.6.1.2 Manufacture Key Starting Material (Stage 5) and validation batches of solithromycin drug substance (API) batches that will be used to manufacture drug product batches to support commercial launch and the manufacture of POS registration batches** and the following revised **Paragraph 4.6.5. 1 POS Phase 2/3 CTM / Registration Batch and capsule CTM Stability Studies, including Phase 1 POS CTM stability for supportive expiry (WBS 4 .6. 5 .1)** under Option 3 CLIN 0004 that are within the general scope of both the contract and Option 3 CLIN 4 and are required for both the full completion of Option 3 CLIN 0004 and also are required per recent FDA Guidance. As such, Attachment 1, Statement of Work dated 16 January 2015 , under PART I II , LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS , SECTION J - LIST OF ATTACHMENTS is hereby deleted and replaced with the attached Statement of Work dated 7 September 2016 (27 Pages attached herein) . The efforts within Option 3 CLIN 0004 that involve clinical human trials/studies and non-clinical animal studies cannot be performed until the receipt and approval of all required Protocols by BARDA inclusive of all IRB, OHRP approvals and any required Ethics Approvals for any clinical trials/studies and any required approved OLAW Assurances and II A approvals from OLAW for any non clinical animal studies.

7. Under Section F.2 Deliverables , 3. Contract WBS Milestones & Related Deliverables Milestone 16 ONLY is hereby deleted and replaced with the attache d . (See Attached Page).

8. Under Article I .1, Section I Contract Clauses of the contract, the asterisk associated with HHSAR 352.231-70 Salary Rate Limitation (Aug 2012) is deleted and replaced with the following:

The provisions set forth by this clause will only apply if and when any funds are obligated from HHS funding appropriated in the 2012, 2013, 2014, 2015 and 2016 Government Fiscal Year s .

9. The period of performance of Option 3 , CLIN 0004 from 29 February 2016 through 23 May 2018 herby remains unchanged.

10. The total amount , scope and period of performance of all other CLIN(s) that are currently being performed under the contract remain unchange d . This modification does not exercise any unexercised Option CLINs under the contract and does not authorize any performance of efforts under any unexercised Option CLINs under the contract. I n addition , the total amount , scope and period of performance of all unexercised Option CLINs under the contract remain unchanged.

B . This is a bilateral modification. All other terms and conditions remain unchanged.

3. STATEMENT OF WORK

3.1 Preamble

Independently and not as an agent of the Governmen t , the Contractor shall be required to furnish all the nec e ssary service s , qualified pe r s o nne l , material, equipment, and faciliti e s, not otherwise provided by the Governmen t , as needed to perform the Statement of Work s ubmitted in r e s ponse to Broad Agency Announcement (BAA) BARDA CBRN BAA-12-100-SOL-00011.

The Government reserves the right to modify the milestones, progress, schedul e , budge t , or product to add or delete product s , proces s , or s c hedule as need may arise. Because of the nature of th i s (R&D) contract and complexities inherent in this and prior prog r ams, at designated mil e s tones the Government will evaluate whether work should be redirected, remove d , or whether schedule or budget adjustments s hould be made. In any even t , the Government reserves the right to change product, proce ss, s c hedul e , or event to add or delete part or all of these elements as the need arise s.

3.2 Overall Objectives and Scope

The overall objective of this contract i s to advance the development of solithromycin (SOLI) as an intravenous (IV) and orally-delivered antibiotic for use in the pediatric population for the treatment of community-acquired bacterial pneumonia (CABP) and for protection against biothreat organisms, including *Bacillus anthracis* and *Francisella tularensis.* The scope of work is organized in 5 severable phases (Clinical Line Item Number [CLI N] 1 through 5):

1. CLIN 1

The C o ntractor will carry out the following t a sks and subtasks and in accordance with the agreed upon Integrated Master Schedul e , which further d e tai l s the c o nduct of the specific tasks and s u b tasks.

1.1 Program Management (WBS 1.1)

The Contractor outsources a majority of th e work to established pr ac titioners in each discipline, with the Contractor team providing experienced program m a na geme nt , coordination, and oversight. All selected purchased commercial service providers for the BARDA project have pro ve n their ability to deliver quality wo rk cost -effecti ve ly a nd on schedule . The Contractor shall provide for the following program management activities as outlined below:

1 . 1 .1 The Contractor w ill provide overa ll management, integration and coordination of all contract activities , including a technical and administrative infrastructure to ens ur e the efficient planning , initiation , implementation , and direction of a ll contract activities .

1 . 1 .2 The Principal Investigator is r espo nsibl e for overall leader s hip for project management , communication , trackin g, monitoring and rep orting on s tatus and p r ogress, and modifi c a tion to the p r o ject requirements and timeline s , including projects undertaken by s u bcontracto r s.

1.1.3 The Project Manager w i ll oversee the monitoring and tracking day-to-day progress and timelines, coord i n ating communication and project activities; costs incurre d ; and program management.

1.1.4 The Principal Investigator and t h e Project Manager will act as the BARDA Liaison with responsibility for effective communication with the Project O ffic e r and Contracting Officer.

1.1.5 The Contractor has adequate ad m i nistrative staff and legal consultants to provide development of compliant subcontract s , consulting, and other legal agreements, and ensure timely acquisition of all proprietary right s , including IP rights, and reporting all inventions made in the performance of t h e project.

1.1.6 The Contractor's Project Management Team along with support from the Finance department h a s r esponsib i l ity for financial management and reporting on all activities conducted by the C o ntr a c t or and any subcontractors and service provider s.

1.1 . 7 Contract Review Meetings

1.1. 7.1 The Contractor's team will participate in regu lar face-to-face meetings on a quarterly basis to coordinate and oversee the contract effort as directed by the Contracting and Project Officers. Such meetings may include, but are not limited to , meeting of the Contractor and subcontracto r s to discuss clinica l manufacturing progress , product development, product assay development, scale up manufacturing development , clinical sample assays development , preclinical/clinical study designs and regu l atory issues; meetings with individual Contractors and othe r HHS officials to discuss the technical, regulatory, and ethical aspects of the program; and meeting with technical consultants to discuss technical data provided by the Contractor.

1 .1.7.2 The Contractor will participate in teleconferences every 2 weeks between the Contractor and BARDA to review technical progress . The Contractor will include subcontractors and service providers as necessary. If additional teleconferences or face - to - face meetings are requested by BARDA , the Contractor will be available.

1.1.8 I n tegrated Master Schedule (IMS)

1.1.8.1 Within 30 ca l endar days of the effective date of the contract, the Contractor will submit a first d r aft of an updated IMS in a format agreed upon by BAR D A to the Project Officer and the Contracting Officer for review and comment. The Integrated Master Schedule will be incorporated into the contrac t , and will b e used to monitor performance of the contract. The Contractor will include the key milestones and Go/No Go decision g a tes. The IMS for the period of performance will be reviewed and accepted b y BARDA at the PMBR.

1.1.9 I n t egrated Master P l an (IMP)

1.1. 1 0 Work Breakdown Structure: The Contractor w i ll utilize a WBS template agreed up o n by BAR D A for reporting on the contact. The Contractor w i ll expand and delineate the Contract Work Breakdown Structure (CWBS) to a level agreed upon by BARDA as part of their Integrated Master Plan for contract reporting. The CWBS will be discernible and consistent. At BARDA's reques t , the Contractor will furnish WBS data at the work package l e vel or at a lower level if there is significant complexity and risk associated with the task.

1 . 1.11 G O / NO-GO Decision Gate s /C o ntract Milestones: The IMP will outline key milestones with "Go/No Go" decision criteria (entrance and exit criteria for each phase of the project). The project plan should include, but not be limited t o , milestones in manufacturing, non-clinical and clinical studies, and regulatory submissions.

1.1 . 12 Earned Value Management System Plan: Subject to the requirements under HHSAR Clause 352.234-4, the Contractor will use principles of Earned Value Management System (EVMS) in the management of this contract. The Contractor will follow the Seven Principles:

I. The Contractor will plan all work scope for the program to completion.

II. The Contractor will break down the program work s cope into finite pieces that can be assigned to a responsible person or organ i z a tion for contr o l of technica l , schedul e , and cost objectives.

III. The Contractor will integrate program work scope, schedule, and cost objectives into a performance measurement baseline plan against which accomplishments may be measured.

IV. The Contractor will use actual cost incurred and recorded in accomplishing the work performed.

V. The Contractor will objectively assess accomplishments at the work performance level.

VI. The Contractor will analyze significant variances from the plan , forecast impacts, and prepare an estimate at completion based on performance to date and work to be performed.

VII. The Contractor will use earned value information in the company's management processes.

1.1.13 We understand that elemen t s of EVMS will be applied to all applicable projects as part of the IMP. In addition, the Contractor will submit a written summary of the management procedures that will be used to establish, maintain and comply with EVMS requirements.

1. 1 .1 3 .1 Decision Gate Reporting: On completion of a stage of the product developmen t , as defined in the agreed upon IMS and IM P , the Contractor will prepare and submit to the Project Officer and the Contracting Officer a Decision Gate Report that contains (i) sufficient detai l , docu m e ntation and analysis to support successfu l completion of the stage according to the predetermined qualitative and quantitative criteria that were established for Go/No Go decision making; and (ii) a description of the next s tage of product development to be initiated and a request for approval to proceed to the next stage of product development.

1.1.14 Risk Management Plan: The Contractor will develop a risk management plan within 90 days of contract award highlighting potential problems an d / or issues that may arise during the life of the contract, their impact on cost, schedule and performanc e , and appropriate remediation plan s . This plan will reference relevant WBS elements where appropriate. Updates to this plan will be included every 3 months (quarterly) in the monthly Project Status Report.

1.1.15 Performance Measurement Baseline Review (PMBR): The Contractor will submit a plan for a PMBR to occur within 90 days of contract award. At the PMB R , the Contractor and BARDA will mutually agree upon the budge t , schedule and technical plan baselines (Performance Measurement Baseline). These baselines will be the basis for monitoring and reporting progress throughout the life of the contract. The PMBR is conducted to achieve confidence that the baselines accurately capture the entire technical scope of wor k , are consistent with contract schedule requirements, are reasonably and logically planne d , and have adequate resourc e s assigned. The goals of the PMBR are as follows:

I. Jointly assess areas such as the Contractor's planning for complete coverage of the SOW, logical scheduling of the work activities, adequate resource s , and identification of inherent risks

II. Confirm the integrity of the Performance Measurement Baseline (PMB)

III. Foster the use of EVM as a means of communication

IV. Provide confidence in the validity of the Contractor's reporting

V. Identify risks associated with the PMB

VI. Present any revised PMBs for mutual agreement

VII. Present an IMS: The Contractor will deliver an initial program IMS that rolls up all time-phased WBS elements down to the activity level. This IMS will include the dependencies that exist between tasks. This IMS will be agreed to and finalized at the PMBR.

VIII. Present the Risk Management Plan

1.1 .16 Deviation Request: During the course of contract performance, in response to a need to change IMS activities as baselined at the PMB R , the Contractor will submit a Deviation Report. This report will be used to request a change in the agreed-upon IMS and timeline s , if necessary. This report will include: (i) discussion of the justification/rationale for the proposed chang e ; (ii) options for addressing the needed changes from the agreed upon timelines, including a cost benefit analysis of each option; and (iii) recommendations for the preferred option that includes a full analysis and discussion of the effect of the change on the entire product development program , timeline s , and budget.

1.1.17 Monthly and Annual Report s : The Contractor will deliver Project Status Reports on a monthly basis. The repor t s will address th e items below cross referenced to the WBS, SO W , IMS, and EVMS:

I. Executive summary highlighting the progress, issue s , and rel e v ant activities in manufacturin g , non-clinica l , clinical, and regulator y ;

II. Progress in meeting contract milestone s , detailing the planned progr e ss and actual progress during the reporting perio d , explaining any differences between the two and corrective steps;

III. Updated IM S ;

IV. Updated EVMS;

V. Updated Risk Management Plan (Every 3 months);

VI. Three month rolling forecast of planned activities;

VII. Progress of regulatory submissions;

VIII. Estimated and actual expenses;

1.1.18 Data Management: The Contractor will develop and implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data;

1.1.18.1 Provide for the statistical design and analysis of data resulting from the research;

1.1.18.2 Provide raw data or specific analyses of data generated with contract funding to the Project Officer, upon request.

1.2 Non-Clinical Development (WBS 1.2)

1.2.1 PK/PD (WBS 1.2.1 - reserved)

1.2.2 Safety (WBS 1.2.2)

1.2.2.1 Segment 3 toxicology (WBS 1.2.2.1): A Segment 3 toxicology study will be conducted to evaluate effects of SOLI on gestation, parturition, and lactation.

1.2.2.2 Juvenile toxicology (WBS 1.2.2.2): This study is designed to characterize postnatal developmental toxicities that would not be detected in routine peri-natal/post-natal toxicity study designs. NOTE: Segment II toxicology generally provides sufficient data to proceed with pediatric studies for antibiotics in the macrolide class. Therefore, although the Contractor has budgeted for juvenile toxicology in the Cost Proposal, the Contractor does not propose to do this study unless specifically requested by the FDA.

1.3 Non-Clinical Biodefense (WBS 1.3)

1.3.1 Agent Characterization (WBS 1.3.1 - reserved)

1.3.2 Model Development (WBS 1.3.2)

1.3.2.1 Determination of Protein Binding in Monkey Plasma (WBS 1.3.2.1): When modeling IV doses in monkeys that equate to the human therapeutic oral dose (for CABP), the degree of protein binding of SOLI in monkey plasma must be taken into consideration.

1.3.2.2 Reverse PK/PD Modeling for Non-Human Primate (NHP) Dose (WBS 1.3.2.1): IV dosing of monkeys is necessary to overcome the first pass metabolism that SOLI undergoes after oral administration in monkeys, which is unlike that seen in human oral studies. The pharmacokinetic (PK) data from a previously completed 28-day IV toxicology/toxicokinetic study in non-infected cynomolgus monkeys administered various SOLI dosing regimens will be used to develop a structural population PK model describing the disposition of SOLI. Using this population PK model, SOLI dosing regimens will be identified which provide concentration-time profiles similar to those for dosing regimens being developed for treatment of patients with community-acquired bacterial pneumonia (CABP).

1.3.2.3 Pilot NHP efficacy study in cynomolgus macaques for treatment of inhalational anthrax (WBS 1.3.2.2): In this non-GLP study, an established monkey model will be used to determine the effective dose & duration of SOLI necessary for treatment of inhalational anthrax.

1.3.2.4 Pilot NHP efficacy study in cynomolgus macaques for treatment of pneumonic tularemia (WBS 1.3.2.3): In this non-GLP study, an established monkey model will be used to determine the effective dose & duration of SOLI necessary for treatment of inhalational tularemia.

1.3.2.5 PKIPD Confirmation Modeling and Determination of Dose for Pivotal Efficacy Studies (WBS 1.3.2.1): Using the data from the pilot treatment efficacy studies in NHPs, population PK and PK / PD analyses will be conducted. The population PK model based on data from non-infected cynomolgus monkeys will be refined as necessary to describe the data from cynomolgus monkeys infected with biothreat agents including *B. anthracis or F. tularensis* .This refined population PK model will be used to predict exposures for the humanized SOLI dosing regimens studied. PK-PD analyses for efficacy will then be conducted and PK-PD relationships based on these analyses will be used to guide selection of SOLI dosing regimens for further evaluation in pivotal studies.

1.3.3 Efficacy and Safety (WBS 1.3.3)

1.3.3.1 RESERVED.

1.3.3.2 RESERVED.

1.4 Clinical Studies (WBS 1.4)

1.4.1 Phase 1 (WBS 1.4.1)

1.4.1.1 Pediatric Dose Determination (WBS 1.4.1.1 and WBS 1.4.1.2): Compartmental PK/PD modeling and simulation of doses that takes into account body weight, height and the volume of distribution differences in pediatrics will be conducted. In addition, pediatric dose-determination studies will be performed to determine dose adjustments from the adult dose that are related to differences in CYP-based metabolism and drug elimination pathways in young children. Population variability in the pediatric age groups as well as the potential for drug-drug interactions will be taken into consideration.

1.4.1.2 Phase 1a Adolescents PK and Safety Study (WBS 1.4.1.1): The doses determined by the modeling experiments will be tested to determine safety and PK of SOLI in adolescents. Since Phase 1 studies in pediatrics are performed as an add-on to standard therapy in patients, a multiple day dosing strategy is proposed as it can be beneficial to current therapy, while a single dose will have limited added benefit. The Phase 1a safety and PK study will be performed with oral capsules in an open-label study in adolescents (12-17 years) receiving concomitant antibiotic treatment. Each cohort will contain 8-16 subjects. SOLI bioanalytical method development and validation in small volumes of human plasma and using dried blood spots (DBS) will be performed to support analysis of SOLI plasma levels in pediatric populations. Validation of DBS analysis will be performed if feasible and only if sufficient volume is available in blood draws.

1.4.1.3 Phase 1 Suspension Bioavailability Study (WBS 1.4.1.3): The relative bioavailability of the SOLI suspension formulation (relative to capsules) will be determined in healthy adult volunteers in an open-label, randomized, cross-over study.

1.4.1.4 Phase 1b Pediatric PK and Safety Study site startup activities, including protocol development, site selection and startup activities, and shipment of drug and PK kits (WBS 1.4.1.2): The Phase 1b safety and PK study will be designed for administration of oral capsules, suspension, and IV solution in children <12 years, and administration of IV solution-only in adolescents (12-17 years) receiving concomitant antibiotic treatment.

1.4.2 Phase 2/3 (WBS 1.4.2 - reserved)

1.5 Regulatory (WBS 1.5)

1.5.1 IND (WBS 1.5.1)

1.5.1.1 Pediatric Study Plan: The Contractor will submit a pediatric plan to the FDA within 60 days after the EOP2 meeting for the adult CABP and gonorrhea (GC) indications. The Contractor will submit an Agreed Initial PSP within 90 days of a meeting with FDA or receipt of written comments from FDA on the PSP.

1.5.1.2 Meeting with FDA regarding Pediatric Development: When the Contractor submits the Pediatric Study Plan to FDA, a request will be made to hold a meeting with FDA to discuss the proposed pediatric studies.

1.5.1.3 The Contractor will submit the Phase 1a protocol (Adolescent PK study) to FDA for review and comment.

1.5.1.4 The Contractor will submit a new IND for SOLI Powder for Oral Suspension (POS) including full CMC information on the suspension formulation, an updated Investigator Brochure and the final protocol for the Phase 1 suspension bioavailability study. The new IND will cross-reference data in the oral capsule and IV INDs. The Contractor will provide BARDA with all data submitted with the new IND.

1.5.2 NDA Activities (WBS 1.5.2)

1.5.2.1 The Contractor will submit a CMC Amendment for newly manufactured capsules (to be used in the Phase 1a/1b Pediatric PK and Safety Studies).

1 5.2.2 The Contractor will submit a CMC Amendment for the new IV formulation containing tri-amino acid buffer (to be used in the Nonclinical Biodefense animal studies and Phase 1b Pediatric PK and Safety Studies).

1.5.2.3 After completion of each study, the Contractor will update relevant IND modules/summaries and submit all data and reports to the IND.

1.5.2.4 RESERVED.

1.5.2.5 RESERVED.

1.5.2.6 The Contractor will submit the Phase 1a Adolescent PK Study protocol to the SOLI capsule IND prior to enrollment of the first patient.

1.5.2.7 The Contractor will submit a Phase 1b Pediatric Study protocol including PK/PD modeling of IV and capsules to FDA for review. Prior to enrollment of the first patient, the Contractor will submit the Phase 1b protocol to the IND. If necessary, after determination of the relative bioavailability of the suspension formulation, and prior to enrollment of suspension cohorts, the Contractor will submit a Phase 1b Study protocol amendment.

1.6 CMC (WBS 1.6)

1.6.1 Chemistry (Formulation Studies) (WBS 1.6.1)

1.6.1.1 Obtain API: Drug substance will be sourced from the Contractor's current API supplier.

1.6.1.2 Preformulation Studies: Preformulation studies will include pH solubility profiling, pH stability profiling, taste threshold evaluation and stress testing of SOLI. Part of the formulation development will be a study to assess excipients compatibility with SOLI. Commonly used pharmaceutical excipients suitable for a POS dosage formulation of SOLI, such as diluents, sugars, sugar alcohols, hydroxypropyl cellulose, viscosity improvers (xanthan gum, etc.) and preservatives (potassium sorbate, etc.) will be evaluated for compatibility with SOLI. Mixtures of SOLI and the excipients will be prepared and exposed to several stress conditions and placed on short term stability. Samples will be pulled after storage and stability will be assessed. To support the taste masking efforts the solubility of SOLI in the preferred suspending vehicles including water will be evaluated. SOLI In this study the water can be buffered to a pH in the range of 6-8, because SOLI solubility is low in this pH range.

1.6.1.3 Formulation development and stability studies: The target POS will be formulated to consist of approximately 10-20% SOLI as powder and to deliver approximately 30-70 mg/mL of SOLI as suspension upon reconstitution. Considerations for development of the POS formulation are: taste of suspension, suspendability, uniformity of dosage form (POS blend uniformity / sample from

reconstituted suspension), powder flow, particle size, bulk density and moisture content. During trial formulations, the main considerations are: taste of suspension, suspendability, uniformity of dosage form and moisture content. Stability studies on prototype POS formulations in bottle packaging will be conducted. Stability studies on prototype reconstituted suspension will also be conducted. The need for an antioxidant in the formulation will be evaluated as part of the development.

1.6.1.4 Taste-masking formulation development: For initial approach, organoleptic method will be tried, which includes non-reducing sugars, sugar alcohols, other sweetener and other excipients to mask the bitter taste of the API. Initial taste masking development work may include a wet granulation technique using nonreducing sugars (e.g. powdered sucrose) and/or sugar alcohols as diluents and binders (e.g. hydroxypropyl cellulose). This approach will also establish a suspendability upon reconstitution, content uniformity, and flowability of the powder. If it is difficult to improve taste by organoleptic method, a POS formulation would be developed by physical taste masking method or combination of organoleptic method and physical method. Taste-masking sensory panels will evaluate the taste of the reconstituted suspension from the POS, and provide feedback to the formulation team. Studies will also include the selection of the appropriate container size for the POS and evaluation of the ability of the dose measurement device (syringe or dose cup to deliver the required dose). Compatibility of the container closure with the POS and compatibility of the dosing device (syringe or Dosing cup) with the reconstituted POS will also be evaluated.

1.6.2 Pre-Clinical Manufacturing (WBS 1.6.2)

1.6.2.1 POS Feasibility Lots: The formulation and process variables that are critical to meet the target product profile will be reconfirmed and used to guide the manufacture of clinical trial material (CTM) for Phase 1. A stability study will be conducted on the drug product from the feasibility lot.

1.6.3 Pilot Scale Manufacturing (WBS 1.6.3)

1.6.3.1 Contractor will manufacture, package, label and release Capsule and IV drug product for shipment to Phase 1 clinical sites. Executed batch records will be sent to BARDA.

1.6.3.2 Contractor will manufacture, package, label and release applicable IV drug product supplies for the NHP pilot studies.

1.6.3.3 Phase 1 clinical trial material (CTM) lots of POS: Current plans are to manufacture CTM for Phase 1 studies. Excipients complying with the standard of USP/NF/EP and excipients that have already been used in commercially available drug products in US/EU will be used. A stability study will be performed at Toyama Chemical according to the ICH guidelines. Clinical (primary) packaging is planned. The POS for clinical studies will be packaged in wide-mouthed HDPE bottles with each bottle containing a 5 day course of therapy for Phase 1b. The higher strength formulation will be packaged and shipped first to support the Bioavailability study. The bottles will be labeled based on English text provided by Cempra. Supplies should be shipped in time to start clinical trials in the US. A full Certificate of Analysis for the CTM batch will be provided.

1.6.4 Commercial (WBS 1.6.4 - reserved)

1.6.5 Controls/Analytical Validation (WBS 1.6.5)

1.6.5.1 Analytical methods will be set with the same conditions and concentration of sample/standard solution as those of the current SOLI 200 mg capsule drug product. Appropriate diluents will be selected to extract SOLI from the powder for oral suspension drug product. For method validation, Specificity, Linearity, Detection Limit, Quantitation Limit, Accuracy and Repeatability will be performed before the pediatric pharmacokinetic (PK) studies (early clinical stage) and Intermediate Precision and Robustness will be performed before completion of registration batches. The analytical methods required include:

- Appearance and Identification by HPLC
- Product Assay and Related Substances Assay
- Dissolution
- Moisture Content
- Microbial Limit Testing (MLT)
- Preservative Assay (as appropriate)
- Anti-oxidant Assay (as appropriate)

2. CLIN 2

2.1 Program Management (WBS 2.1)

The Contractor outsources a majority of the work to established practitioners in each discipline, with the Contractor team providing experienced program management, coordination, and oversight. All selected purchased commercial service providers for the BARDA project have proven their ability to deliver quality work cost-effectively and on schedule. The Contractor shall provide for the following program management activities as outlined below:

2.1.1 The Contractor will provide overall management, integration and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities.

2.1.2 The Principal Investigator is responsible for overall leadership for project management, communication, tracking, monitoring and reporting on status and progress, and modification to the project requirements and timelines, including projects undertaken by subcontractors.

2.1.3 The Project Manager will oversee the monitoring and tracking day-to-day progress and timelines, coordinating communication and project activities; costs incurred; and program management.

2.1.4 The Principal Investigator and the Project Manager will act as the BARDA Liaison with responsibility for effective communication with the Project Officer and Contracting Officer.

2.1.5 The Contractor has adequate administrative staff and legal consultants to provide development of compliant subcontracts, consulting, and other legal agreements, and ensure timely acquisition of all proprietary rights, including IP rights, and reporting all inventions made in the performance of the project.

2.1.6 The Contractor's Project Management Team along with support from the Finance department has responsibility for financial management and reporting on all activities conducted by the Contractor and any subcontractors and service providers.

2.1.7 Contract Review Meetings

2.1.7.1 The Contractor's team will participate in regular face-to-face meetings on a quarterly basis to coordinate and oversee the contract effort as directed by the Contracting and Project Officers. Such meetings may include, but are not limited to, meeting of the Contractor and subcontractors to discuss clinical manufacturing progress, product development, product assay development, scale up manufacturing development, clinical sample assays development, preclinical/clinical study designs and regulatory issues; meetings with individual Contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program; and meeting with technical consultants to discuss technical data provided by the Contractor.

2.1.7.2 The Contractor will participate in teleconferences every 2 weeks between the Contractor and BARDA to review technical progress. The Contractor will include subcontractors and service providers as necessary. If additional teleconferences or face-to-face meetings are requested by BARDA, the Contractor will be available.

2.1.8 Integrated Master Schedule (IMS)

2.1.8.1 Within 30 calendar days of the effective date of the contract, the Contractor will submit a first draft of an updated IMS to the Project Officer and the Contracting Officer for review and comment. The Integrated Master Schedule will be used to monitor performance of the contract. The Contractor will include key milestones and Go/No Go decision gates. The IMS for the period of performance will be reviewed and accepted by BARDA at the PMBR.

2.1.8.2 Changes to the IMS: During the course of contract performance, in response to a need to change IMS activities as baselined at the PMBR, the Contractor will submit a Baseline Change Request. This report will be used to request a change in the agreed-upon IMS and timelines, if necessary.

2.1.9 Work Breakdown Structure: The Contractor will utilize a WBS template agreed upon by BARDA for reporting on the contact. The Contractor will expand and delineate the Contract Work Breakdown Structure (CWBS) to a level agreed upon by BARDA.

2.1.10 GO/ NO-GO Decision Gates/Contract Milestones: The Go/No Go Milestones will outline key objectives with "Go/No Go" decision criteria (entrance and exit criteria for each phase of the project). The milestones should include, but not be limited to, objectives in manufacturing, non-clinical and clinical studies, and regulatory submissions.

2.1.11 Earned Value Management System: Subject to the requirements under HHSAR Clause 352.234-4, the Contractor will use principles of Earned Value Management System (EVMS) in the management of this contract. The Contractor will follow the Seven Principles:

VIII. The Contractor will plan all work scope for the program to completion.

IX. The Contractor will break down the program work scope into finite pieces that can be assigned to a responsible person or organization for control of technical, schedule, and cost objectives.

X. The Contractor will integrate program work scope, schedule, and cost objectives into a performance measurement baseline plan against which accomplishments may be measured.

XI. The Contractor will use actual cost incurred and recorded in accomplishing the work performed.

XII. The Contractor will objectively assess accomplishments at the work performance level.

XIII. The Contractor will analyze significant variances from the plan, forecast impacts, and prepare an estimate at completion based on performance to date and work to be performed.

XIV. The Contractor will use earned value information in the company's management processes as it relates to the BARDA contract.

2.1.12 Risk Management Plan: The Contractor will develop a risk management plan within 90 days of contract award highlighting potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans. This plan will reference relevant WBS elements where appropriate. Updates to this plan will be made as deemed necessary.

2.1.13 Performance Measurement Baseline Review (PMBR): The Contractor will submit a plan for a PMBR to occur within 90 days of contract award. At the PMBR, the Contractor and BARDA will mutually agree upon the budget, schedule and technical plan baselines (Performance Measurement Baseline). These baselines will be the basis for monitoring and reporting progress throughout the life of the contract. The PMBR is conducted to achieve confidence that the baselines accurately capture the entire technical scope of work, are consistent with contract schedule requirements, are reasonably and logically planned, and have adequate resources assigned. The goals of the PMBR are as follows:

IX. Jointly assess areas such as the Contractor's planning for complete coverage of the SOW, logical scheduling of the work activities, adequate resources, and identification of inherent risks

X. Confirm the integrity of the Performance Measurement Baseline (PMB)

XI. Foster the use of EVM as a means of communication

XII. Provide confidence in the validity of the Contractor's reporting

XIII. Identify risks associated with the PMB

XIV. Present any revised PMBs for mutual agreement

XV. Present an IMS: The Contractor will deliver an initial program IMS that rolls up all time-phased WBS elements down to the activity level. This IMS will include the dependencies that exist between tasks. This IMS will be agreed to and finalized at the PMBR.

XVI. Present the Risk Management Plan

2.1.14 Monthly and Annual Reports: The Contractor will deliver Project Status Reports on a monthly basis. The reports will address the items below cross referenced to the WBS, SOW, IMS, and EVMS:

IX. Executive summary highlighting the progress, issues, and relevant activities in manufacturing, non-clinical, clinical, and regulatory

X. Progress in meeting contract milestones, detailing the planned progress and actual progress during the reporting period, explaining any differences between the two and corrective steps

XI. Updated IMS

XII. Updated EVMS

XIII. Two month rolling forecast of planned activities

XIV. Progress of regulatory submissions

XV. Estimated and actual expenses

2.2 Non-Clinical Development (WBS 2.2 - reserved)

2.3 Non-Clinical Biodefense (WBS 2.3 - reserved)

2.4 Clinical (WBS 2.4)

2.4.1 Phase 1 (WBS 2.4.1)

2.4.1.1 Phase 1b Pediatric PK Study (WBS 2.4.1.1): The Contractor will conduct a multiple dose PK and safety study in pediatrics. This open-label study will be performed with oral capsules, suspension or IV solution in children less than 12 years, and with IV solution-only in adolescents (12-17 years). Each cohort can contain up to 16 subjects. PK and safety data may be published in a peer-reviewed scientific journal. Changes to the clinical design may occur based on the Cempra's assessment with input from BARDA.

2.4.1.2 PK/PD-modeling for pediatric therapeutic dose justification for Phase 2/3 trial (WBS 2.4.1.2): Using PK data from Phase 1a/b studies, the population PK will be modeled. Pediatric therapeutic doses will be selected based upon the target attainment PK/PD modeling based on plasma and pulmonary levels in adult subjects.

2.4.2 Phase 2/3 (WBS 2.4.2)

2.4.2.1 Phase 2/3 pediatric CABP study Startup activities (WBS 2.4.2.1): The Phase 2/3 safety study will be designed for administration of oral capsules, suspension, and IV solution in pediatric CABP patients receiving concomitant antibiotic treatment. The Phase 2/3 study startup activities will include but are not limited to: development of a protocol and SAP, site feasibility/selection and activation activities, development of an Informed Consent Form, Clinical Monitoring Plan, Regulatory Binder, Safety Reporting Plan, Data Management Plan and other study documentation (to include any foreign regulatory submission documents), establishing a DSMC and charter, and shipment of CTM and PK kits. Changes to the clinical design may occur based on Cempra's assessment with input from BARDA.

2.5 Regulatory (WBS 2.5)

2.5.1 IND (WBS 2.5.1 - reserved)

2.5.2 NDA (WBS 2.5.2)

2.5.2.1 The Contractor will submit IND Amendments for CTM batches (WBS 2.5.2.1)

2.5.2.2 The contractor will submit IMPDs for Pediatric studies (multiple countries)

2.5.2.3 The contractor will submit taste optimization/ DOE work to FDA for POS formulation

2.5.2.4 The Contractor will submit the Pediatric Phase 2/3 protocol and Clinical Study Regulatory Documents to FDA (WBS 2.5.2.2)

2.5.2.5 The Contractor will submit an NDA for IV and oral capsules in adults for CABP and GC indications, including adolescent GC patients. PDUFA fees for these NDAs will be covered by the Contractor (WBS 2.5.2.3).

2.5.2.6 The Contractor will submit the Phase 1b CSR to the FDA (WBS 2.5.2.4).

2.5.2.7 The Contractor will submit other BARDA related Regulatory/Ethics Committee amendments and summaries as deemed necessary by Cempra's Regulatory team.

2.6 CMC (WBS 2.6)

2.6.1 Chemistry (Formulation Studies) (WBS 2.6.1)

2.6.1.1 Obtain API: Drug substance will be sourced from the Contractor's current API supplier. The API will be used for: formulation and/or process optimization, clinical supply manufacturing, scale up studies, registration batches and other activities deemed necessary by the Contractor's CMC team

2.6.1.2 Formulation studies will be conducted at a CMO. These include but are not limited to:

2.6.1.2.1 Excipient compatibility: Several studies will be performed to evaluate the effect of different excipients on the formulation. The excipients include but are not limited to: sucralose, magna-sweet, sodium chloride, flavor, colorant and citric acid.

2.6.1.2.2 Formulation optimization: Several studies to optimize the formulation composition identified from taste evaluation work will be conducted at Catalent. A Design of Experiments (DoE), or similar approach, will be used. Studies will include, but are not limited to:

- Determination of buffer capacity
- Determine the amount of anti-forming agent required
- The amount of shaking to re-suspend the powder
- The level of preservative in the formulation
- The addition of a colorant to improve aesthetic appeal
- The amount of water required for reconstitution to a target concentration
- A method for reconstitution

2.6.2 Pre-Clinical Manufacturing (WBS 2.6.2)

2.6.2.1 POS Process Optimization: After the formulation optimization DoE work is completed, manufacturing process development and optimization to support the manufacture of clinical supplies for the Phase 2/3 studies will be conducted. The key requirements of the process include, but are not limited to, these items listed below:

- The process should consistently yield a homogeneous blend
- The POS blend should flow sufficiently well for machine processing
- The process should be scalable
- The process should be efficient with just enough steps to yield a consistent product

The formulation and process variables that are critical to meet the target product profile will be determined and used to guide the manufacture of clinical trial material (CTM) for Phase 1. A stability study will be conducted on the POS manufactured at target parameters.

2.6.2.2 Process confirmation: At least one process confirmation batch will be manufactured at the 20-50 kg scale. The batch(es) will be packaged and set on stability. The results from the process confirmation batch(es) will guide manufacture of a clinical batch for the phase 2/3 studies.

2.6.3 Pilot Scale Manufacturing (WBS 2.6.3)

2.6.3.1 Capsules and IV vials will be acquired and packaged for the pediatric Phase 2/3 study (WBS 2.6.3.2).

2.6.3.2 Phase 2/3 POS CTM (WBS 2.6.3.4): Manufacturing, packaging, quality studies, and stability study will be conducted at a CMO. Phase 2/3 CTM will be manufactured at an appropriate scale and, if possible, will suffice as 1 of the 3 registration batches needed for NDA submission. (Registration batch manufacturing, packaging and testing originally planned for CLIN 2 will now be conducted in a future CLIN). SOLI will be compared to the Standard of Care (SOC) treatment. If necessary, Cempra will have to procure SOC comparator products as well.

2.6.4 Commercial (WBS 2.6.4 - reserved)

2.6.5 Controls/Analytical Validation (WBS 2.6.5).

2.6.5.1 POS Phase 1 CTM Stability Study (WBS 2.6.5.1)

2.6.5.2 Analytical methods to support formulation and process optimization will be adapted from those used in the manufacture of phase 1 clinical supplies. These methods will be further developed and validated to support the phase 2/3 study. The analytical methods required include, but are not limited to:

- Appearance and Identification by HPLC
- Product Assay and Related Substances Assay
- Dissolution
- Moisture Content
- Microbial Limit Testing (MLT)
- Preservative Assay (as appropriate)
- Microbial Effectiveness Test (AET) methods

3. CLIN 3

3.1 Program Management (WBS 3.1)

3.1.1 Program management scope is consistent with that outlined in CLIN 2.

3.2 Non-Clinical Development (WBS 3.2 - reserved)

3.3 Non-Clinical Biodefense (WBS 3.3)

3.3.1 Agent Characterization (WBS 3.3.1 - reserved)

3.3.2 Model Development (WBS 3.3.2 - reserved)

3.3.3 Efficacy and Safety (WBS 3.3.3)

3.3.3.1 Pivotal NHP Efficacy Study in cynomolgus macaques for treatment of inhalational anthrax (WBS 3.3.3.1): The therapeutic dose selected based on the pilot NHP study and PK/PD modeling will be tested in the pivotal GLP study to determine the efficacy of SOLI in the therapeutic model of inhalational anthrax in cynomolgus monkeys.

3.3.3.2 Pivotal NHP Efficacy Study in cynomolgus macaques for treatment of inhalational tularemia (WBS 3.3.3.2): The dose selected based on the pilot NHP study and PK/PD modeling will be tested in a pivotal GLP study to determine the efficacy of SOLI in the therapeutic model of inhalational tularemia in cynomolgus monkeys.

3.3.3.3 PK/PD Modeling and Translation to Human Dose for Treatment of lnhalational Anthrax and Tularemia (WBS 3.3.3.3): The plasma concentration-time data from the infected cynomolgus monkeys will be evaluated using a similar structural population PK model as that previously developed for the non-infected animals, and individual SOLI exposure measures (AUC) will be generated for each animal. These individual exposure measures will then be utilized in subsequent PK/PD analyses for both animal survival and SOLI microbiologic response. The relationship between the AUC:MIC ratio and the efficacy endpoints, animal survival, and the microbiological response to therapy measured at the end-oftherapy, will be examined. If trends for PK/PD relationships for efficacy are observed, initial graphical analyses of efficacy endpoints will be followed by univariable and multivariable logistic or other nonlinear regression modeling techniques. In addition, a survival analysis (i.e., time-to-event analysis) may be conducted if appropriate. These pharmacokinetic parameters will be used to calculate the therapeutic doses for inhalational anthrax and inhalational tularemia in human adults. Upon completion of pediatric PK studies, the therapeutic doses for children for biodefense indications will be extrapolated from the pediatric PK/PD results.

3.4 Clinical (WBS 3.4)

3.4.1 Phase 1 (WBS 3.4.1)

3.4.1.1 Phase 1 Multiple dose PK and Safety study in Human (Adult) Volunteers (WBS 3.4.1.1): The multidose study is planned for 21 days, but could be shortened if efficacy is demonstrated with a shorter duration of SOLI treatment in the NHP studies.

3.4.2 Phase 2/3 (WBS 3.4.2 - reserved)

3.5 Regulatory (WBS 3.5)

3.5.1 IND (WBS 3.5.1 - reserved)

3.5.2 NDA (WBS 3.5.2)

3.5.2.1 After completion of the NHP pilot studies, the Contractor will submit a meeting request to FDA to discuss submission of the supplemental NDA for the Animal Rule indications (WBS 3.5.2.1).

3.5.2.2 The Contractor will submit supplemental NDAs for use of SOLI capsule and IV formulations for the biodefense indications under the Animal Rule (WBS 3.5.2.2).

3.6 CMC (WBS 3.6)

3.6.1 Chemistry (Formulation Studies) (WBS 3.6.1 - reserved)

3.6.1.1 Obtain API: Drug substance will be sourced from the Cempra's current API supplier. Registration grade API is required for POS registration batches.

3.6.2 Pre-Clinical Manufacturing (WBS 3.6.2 - reserved)

3.6.3 Pilot Scale Manufacturing (WBS 3.6.3)

3.6.3.1 POS registration batches will be manufactured.

3.6.3.2 IV drug product supplies will be packaged for NHP pivotal studies (WBS 3.6.3.1)

3.6.4 Commercial (WBS 3.6.4 - reserved)

3.6.5 Controls/Analytical Validation (WBS 3.6.5)

3.6.5.1 POS Phase 2/3 CTM Stability Study (WBS 3.6.5.1)

4. CLIN 4 (GOVERNMENT/CONTRACTOR COST-SHARE)

4.1 Program Management (WBS 4.1)

The Contractor outsources a majority of the work to established practitioners in each discipline, with the Contractor team providing experienced program management, coordination, and oversight. All selected purchased commercial service providers for the BARDA project have proven their ability to deliver quality work cost-effectively and on schedule. The Contractor shall provide for the following program management activities as outlined below:

4.1.1 The Contractor will provide overall management, integration and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities.

4.1.2 The Principal Investigator is responsible for overall leadership for project management, communication, tracking, monitoring and reporting on status and progress, and modification to the project requirements and timelines, including projects undertaken by subcontractors.

4.1.3 The Project Manager will oversee the monitoring and tracking day-to-day progress and timelines, coordinating communication and project activities; costs incurred; and program management.

4.1.4 The Principal Investigator and the Project Manager will act as the BARDA Liaison with responsibility for effective communication with the Project Officer and Contracting Officer.

4.1.5 The Contractor has adequate administrative staff and legal consultants to provide development of compliant subcontracts, consulting, and other legal agreements, and ensure timely acquisition of all proprietary rights, including IP rights, and reporting all inventions made in the performance of the project.

4.1.6 The Contractor's Project Management Team along with support from the Finance department has responsibility for financial management and reporting on all activities conducted by the Contractor and any subcontractors and service providers.

4.1.7 Contract Review Meetings

4.1.7.1 The Contractor's team will participate in regular face-to-face meetings on a quarterly basis to coordinate and oversee the contract effort as directed by the Contracting and Project Officers. Such meetings may include, but are not limited to, meeting of the Contractor and subcontractors to discuss clinical manufacturing progress, product development, product assay development, scale up manufacturing development, clinical sample assays development, preclinical/clinical study designs and regulatory issues; meetings with individual Contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program; and meeting with technical consultants to discuss technical data provided by the Contractor.

4.1.7.2 The Contractor will participate in teleconferences every 2 weeks between the Contractor and BARDA to review technical progress. The Contractor will include subcontractors and service providers as necessary. If additional teleconferences or face-to-face meetings are requested by BARDA, the Contractor will be available.

4.1.8 Integrated Master Schedule (IMS)

4.1.8.1 Within 30 calendar days of the effective date of the contract, the Contractor will submit a first draft of an updated IMS to the Project Officer and the Contracting Officer for review and comment. The Integrated Master Schedule will be used to monitor performance of the contract. The Contractor will include key milestones and Go/No Go decision gates. The IMS for the period of performance will be reviewed and accepted by BARDA at the PMBR.

4.1.8.2 Changes to the IMS: During the course of contract performance, in response to a need to change IMS activities as baselined at the PMBR, the Contractor will submit a Baseline Change Request. This report will be used to request a change in the agreed-upon IMS and timelines, if necessary.

4.1.9 Work Breakdown Structure: The Contractor will utilize a WBS template agreed upon by BARDA for reporting on the contact. The Contractor will expand and delineate the Contract Work Breakdown Structure (CWBS) to a level agreed upon by BARDA.

4.1.10 GO/ NO-GO Decision Gates/Contract Milestones: The Go/No Go Milestones will outline key objectives with "Go/No Go" decision criteria (entrance and exit criteria for each phase of the project). The milestones should include, but not be limited to, objectives in manufacturing, non-clinical and clinical studies, and regulatory submissions.

4.1.11 Earned Value Management System: Subject to the requirements under HHSAR Clause 352.234-4, the Contractor will use principles of Earned Value Management System (EVMS) in the management of this contract. The Contractor will follow the Seven Principles:

XV. The Contractor will plan all work scope for the program to completion.

XVI. The Contractor will break down the program work scope into finite pieces that can be assigned to a responsible person or organization for control of technical, schedule, and cost objectives.

XVII. The Contractor will integrate program work scope, schedule, and cost objectives into a performance measurement baseline plan against which accomplishments may be measured.

XVIII. The Contractor will use actual cost incurred and recorded in accomplishing the work performed.

XIX. The Contractor will objectively assess accomplishments at the work performance level.

XX. The Contractor will analyze significant variances from the plan, forecast impacts, and prepare an estimate at completion based on performance to date and work to be performed.

XXI. The Contractor will use earned value information in the company's management processes as it relates to the BARDA contract.

4.1.12 Risk Management Plan: The Contractor will develop a risk management plan within 90 days of contract award highlighting potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans. This plan will reference relevant WBS elements where appropriate. Updates to this plan will be made as deemed necessary.

4.1.13 Performance Measurement Baseline Review (PMBR): The Contractor will submit a plan for a PMBR to occur within 90 days of contract award. At the PMBR, the Contractor and BARDA will mutually agree upon the budget, schedule and technical plan baselines (Performance Measurement Baseline). These baselines will be the basis for monitoring and reporting progress throughout the life of the contract. The PMBR is conducted to achieve confidence that the baselines accurately capture the entire technical scope of work, are consistent with contract schedule requirements, are reasonably and logically planned, and have adequate resources assigned. The goals of the PMBR are as follows:

XVII. Jointly assess areas such as the Contractor's planning for complete coverage of the SOW, logical scheduling of the work activities, adequate resources, and identification of inherent risks

XVIII. Confirm the integrity of the Performance Measurement Baseline (PMB)

XIX. Foster the use of EVM as a means of communication

XX. Provide confidence in the validity of the Contractor's reporting

XXI. Identify risks associated with the PMB

XXII. Present any revised PMBs for mutual agreement

XXIII. Present an IMS: The Contractor will deliver an initial program IMS that rolls up all time-phased WBS elements down to the activity level. This IMS will include the dependencies that exist between tasks. This IMS will be agreed to and finalized at the PMBR.

XXIV. Present the Risk Management Plan

4.1.14 Monthly and Annual Reports: The Contractor will deliver Project Status Reports on a monthly basis. The reports will address the items below cross referenced to the WBS, SOW, IMS, and EVMS:

XVI. Executive summary highlighting the progress, issues, and relevant activities in manufacturing, non-clinical, clinical, and regulatory

XVII. Progress in meeting contract milestones, detailing the planned progress and actual progress during the reporting period, explaining any differences between the two and corrective steps

XVIII. Updated IMS

XIX. Updated EVMS

XX. Two month rolling forecast of planned activities

XXI. Progress of regulatory submissions

XXII. Estimated and actual expenses

4.1.15 Quality Assurance (QA) and Quality Control (QC): The Contractor will perform QA activities such as the auditing of vendors and clinical sites to ensure that work is completed in compliance with all regulations. Review of all batch records and study documentation will be performed. Pharmacovigilance activities throughout the Phase 2/3 clinical study will also be conducted.

4.2 Non-Clinical Development (WBS 4.2 - reserved)

4.3 Non-Clinical Biodefense (WBS 4.3 - reserved)

4.4 Clinical Studies (WBS 4.4)

4.4.1 Phase 1 (WBS 4.4.1)

4.4.1.1 Phase 1 Suspension Relative Bioavailability Study (WBS 4.4.1.1): The bioavailability of the Phase 2/3 SOLI suspension formulation (relative to Phase 1 suspension formulation) will be determined in healthy adult volunteers in an openlabel, randomized, cross-over study.

4.4.2 Phase 2/3 (WBS 4.4.2)

4.4.2.1 Phase 2/3 Pediatric CABP Trial (WBS 4.4.2.1): Since CABP infection in children is similar to that documented in adults, results of microbiological efficacy in adults could be extrapolated to children with similar antimicrobial exposure. Therefore, a Phase 2/3 study will be conducted following interim results from the Phase 1 studies. These studies will be conducted after successful completion of adult CABP trials and concurrent to the submission of the NDA for adult CABP. Sparse PK sampling will be collected and used in Pop PK modeling. The outline of this study has been approved in the PSP and the PIP.

4.5 Regulatory (WBS 4.5)

4.5.1 IND (WBS 4.5.1 - reserved)

4.5.2 NDA Activities (WBS 4.5.2)

4.5.2.1 The Contractor will submit Regulatory/ Ethics Committee/ IMPD amendments and summaries as deemed necessary by the Contractor's regulatory team (WBS 4.5.2.1).

4.5.2.2 The Contractor will submit any Pediatric Phase 2/3 protocol amendments and clinical study regulatory documents to FDA or international regulatory agencies (WBS 4.5.2.2)

4.5.2.3 The Contractor will update the Pediatric Study Plan (PSP) and Pediatric Investigational Plan (PIP) and communicate with FDA/EMA as deemed necessary by the Contractor's regulatory team (WBS 4.5.2.3).

4.5.2.4 The Contractor will submit to applicable regulatory agencies any Phase 2/3 CTM and POS registration batch documentation, as deemed necessary by the Contractor's regulatory team (WBS 4.5.2.4)

4.5.2.5 The Contractor will submit the Phase 2/3 CSR to the FDA (WBS 4.5.2.5).

4.6 CMC (WBS 4.6)

4.6.1 Chemistry (Formulation Studies) (WBS 4.6.1)

4.6.1.1 Obtain API: Drug substance will be sourced from Cempra's current API supplier. Registration grade API is required for POS registration batches.

4.6.1.2 Manufacture Key Starting Material (Stage 5) and validation batches of solithromycin drug substance (API) batches that will be used to manufacture drug product batches to support commercial launch and the manufacture of POS registration batches.

4.6.2 Pre-Clinical Manufacturing (WBS 4.6.2)

4.6.2.1 Scale-up and tech transfer batches will be manufactured for each POS formulation (160 mg/5 mL and 320 mg/5 mL).

4.6.3 Pilot Scale Manufacturing (WBS 4.6.3)

4.6.3.1 Capsules, IV vials and Powder for Oral Suspension (POS) will be acquired, packaged, stored and distributed for resupply during the pediatric Phase 2/3 study and for the Phase 1 Relative Bioavailability study. Components for IV kits will be procured. At the completion of the clinical study, all CTM from clinical sites will be dispositioned (WBS 4.6.3.1).

4.6.3.2 POS registration batches will be manufactured to support resupply of POS in the Phase 2/3 study (WBS 4.6.3.2).

4.6.4 Commercial (WBS 4.6.4 - reserved)

4.6.5 Controls/ Analytical Validation (WBS 4.6.5)

4.6.5.1 POS Phase 2/3 CTM / Registration Batch and capsule CTM Stability Studies, including Phase 1 POS CTM stability for supportive expiry (WBS 4.6.5.1)

4.6.5.2 Analytical methods to support formulation of registration grade API will be adapted from those used in the manufacture of Phase 2/3 POS clinical supplies. These methods will include, but are not limited to:

- Product Assay and Related Substances Assay
- Dissolution
- Quantitative X-ray Powder Diffraction
- Shipping Studies
- Temperature Excursion Studies
- Photostability Studies

5. CLIN 5

5.1 Program Management (WBS 5.1)

5.1.1 Program management scope is consistent with that in CLIN 4.

5.2 Non-Clinical Development (WBS 5.2 - reserved)

5.3 Non-Clinical Biodefense (WBS 5.3 - reserved)

5.4 Clinical (WBS 5.4 - reserved)

5.5 Regulatory (WBS 5.5)

5.5.1 IND (WBS 5.5.1 - reserved)

5.5.2 NDA (WBS 5.5.2)

5.5.2.1 At the completion of the Phase 2/3 pediatric CABP trial, the Contractor will submit an NDA for oral suspension for CABP in adults and pediatric populations to the FDA, including a biodefense indication under the Animal Rule (WBS 5.5.2.1).

5.5.2.2 The Contractor will submit supplemental NDAs for use of SOLI capsule and IV formulations for the CABP and biodefense indications in pediatric patients (WBS 5.5.2.2).

5.6 CMC (WBS 5.6 - reserved)

6. OTHER ITEMS

6.1 Facilities, Equipment, and Other Resources

The Contractor confirms the subcontractor and all purchased commercial service providers provide equipment, facilities and other resources under Federal and HHS regulations.

3. Contract WBS Milestones & Related Deliverables

No.	GO/NO-GO Decision Gates	GO Criteria	NO-GO Criteria	Deliverable	WBS/SOW#	CLIN #
16.	POS Phase 2/3 CTM Registration Batch and capsule CTM Stability Studies, including Phase I POS CTM stability for supportive expiry and Analytical Methods	Successful Demonstration of Stability and Analytical Methods Formulation	Stability and Analytical Methods Formulation not demonstrated	Final Stability Studies and Analytical Methods Reports	4.6.5/4.6.5	Option 3 CLIN 0004

Exhibit 31.1

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

I, Prabhavathi Fernandes, Ph.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: October 27, 2016

/s/ Prabhavathi Fernandes, Ph.D.

Prabhavathi Fernandes, Ph.D.
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: October 27, 2016

/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 September 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Prabhavathi Fernandes, Ph.D., 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: October 27, 2016

/s/ Prabhavathi Fernandes, Ph.D.
Prabhavathi Fernandes, Ph.D.
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 September 30, 2016, 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: October 27, 2016

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