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TRIUS THERAPEUTICS INC

FORM 10-Q
(Quarterly Report)

Filed 11/07/12 for the Period Ending 09/30/12

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2012

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the transition period from to

Commission file number 001-34828

TRIUS THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	2834	20-1320630
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

6310 Nancy Ridge Drive, Suite 105
San Diego, California 92121
(858) 452-0370
(Address, including zip code and telephone number, including area code, of registrant's principal executive offices)

(Former Name, Former Address and Former Fiscal Year, If Changed Since Last Report)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

Large accelerated filer ☐ Accelerated filer ☒

Non-accelerated filer ☐ (do not check if a smaller reporting company) Smaller reporting company ☐

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

The number of shares outstanding of the issuer's common stock, par value $.0001 per share, as of November 1, 2012 was 39,406,671.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Trius Therapeutics, Inc.

Balance Sheets
(In thousands except share and per share data)

	September 30, 2012 (unaudited)	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 13,496	$ 11,381
Short-term investments, available-for-sale	57,404	47,762
Accounts receivable	4,785	4,272
Prepaid expenses and other current assets	3,134	3,272
Total current assets	78,819	66,687
Property and equipment, net	1,131	1,037
Restricted cash	150	150
Other assets	152	251
Total assets	$ 80,252	$ 68,125
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,378	$ 3,774
Accrued liabilities	7,666	6,959
Common stock warrant liability	5,571	7,124
Current portion of deferred revenue	293	377
Total liabilities	18,908	18,234
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at September 30, 2012 and December 31, 2011; no shares issued and outstanding at September 30, 2012 and December 31, 2011	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized at September 30, 2012 and December 31, 2011; 38,791,538 and 28,663,548 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively	5	4
Additional paid-in capital	196,422	145,272
Accumulated other comprehensive income	9	7
Accumulated deficit	(135,092)	(95,392)
Total stockholders' equity	61,344	49,891
Total liabilities and stockholders' equity	$ 80,252	$ 68,125

See accompanying notes.

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Trius Therapeutics, Inc.

Statements of Operations
(In thousands except per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenues:				
Contract research	$ 2,270	$ 2,995	$ 7,501	$ 8,568
Collaborations	2,919	1,733	11,010	1,733
License	784	25,708	3,518	25,708
Total revenues	5,973	30,436	22,029	$36,009
Operating expenses:				
Research and development	19,332	14,903	52,557	35,722
General and administrative	4,427	3,731	10,742	8,550
Total operating expenses	23,759	18,634	63,299	44,272
Income (loss) from operations	(17,786)	11,802	(41,270)	(8,263)
Other income (expense):				
Interest income	13	5	20	19
Fair value adjustment of common stock warrant liability	91	2,504	1,553	2,504
Other income (expense)	—	—	(3)	1
Total other income	104	2,509	1,570	2,524
Net income (loss)	$(17,682)	$14,311	$(39,700)	$ (5,739)
Net income (loss) per share, basic	$ (0.46)	$ 0.50	$ (1.06)	$ (0.22)
Weighted-average shares outstanding, basic	38,781	28,527	37,568	25,816
Net income (loss) per share, diluted	$ (0.46)	$ 0.49	$ (1.06)	$ (0.22)
Weighted-average shares outstanding, diluted	38,781	29,477	37,568	25,816

See accompanying notes.

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Trius Therapeutics, Inc.

Statements of Comprehensive Loss
(In thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net income (loss)	$(17,682)	$14,311	$(39,700)	$(5,739)
Unrealized gain on available-for-sale securities, net	12	1	2	10
Comprehensive income (loss)	$(17,670)	$14,312	$(39,698)	$(5,729)

See accompanying notes.

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Trius Therapeutics, Inc.

Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2012	2011
Operating activities		
Net loss	$(39,700)	$ (5,739)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	480	372
Share-based compensation	2,241	1,994
(Gain) loss on fair value adjustment of stock warrant liability	(1,553)	(2,504)
Amortization of investment premiums	643	462
Deferred revenue	(83)	193
Changes in operating assets and liabilities:		
Accounts receivable	(512)	(2,889)
Prepaid expenses and other current assets	138	(435)
Accounts payable	1,604	1,710
Accrued liabilities	711	3,541
Other assets	100	216
Net cash used in operating activities	(35,931)	(3,079)
Investing activities		
Purchases of investments	(62,842)	(40,995)
Sales and maturities of investments	52,558	34,287
Purchases of property and equipment	(575)	(601)
Net cash used in investing activities	(10,859)	(7,309)
Financing activities		
Proceeds from issuance of common stock, net of offering costs	48,374	28,013
Proceeds from exercise of stock options and stock issuances under employee stock purchase plan	531	307
Net cash provided by financing activities	48,905	28,320
Net increase in cash and cash equivalents	2,115	17,932
Cash and cash equivalents at beginning of period	11,381	14,515
Cash and cash equivalents at end of period	$ 13,496	$ 32,447

See accompanying notes.

Trius Therapeutics, Inc.

NOTES TO FINANCIAL STATEMENTS

Note 1. Organization and Summary of Significant Accounting Policies

Organization

Trius Therapeutics, Inc., or the Company, is a biopharmaceutical company focused on the discovery, development and commercialization of innovative antibiotics for life-threatening infections. The Company was originally incorporated in California in June 2004 and reincorporated in Delaware in December 2007.

Use of Estimates

The preparation of financial statements in conformity with United States generally accepted accounting principles, or GAAP, requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less from the date of purchase to be cash equivalents.

Investments Available-for-Sale

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in accumulated other comprehensive income (loss). The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization of premiums and accretion of discounts is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income (expense). The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash and cash equivalents and marketable securities. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. Additionally, the Company has established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

Accounts Receivable

Accounts receivable at September 30, 2012 and December 31, 2011 represent amounts due under the Company's Collaboration and License Agreement with Bayer Pharma AG, or the Bayer Agreement, and from federal funding sources based upon federal contracts with the National Institute of Allergy and Infectious Diseases, or NIAID, a part of the National Institutes of Health, or NIH, the Defense Threat Reduction Agency, or DTRA, an agency within the U.S. Department of Defense, and Lawrence Livermore National Laboratory, or LLNL, a part of the U.S. Department of Energy's National Nuclear Security Administration. The Company's accounts receivable consists of both billed and unbilled amounts. The Company's practice is to bill its customers and collaborators amounts for which the Company has been invoiced by third parties in the case of contract research or subcontractor costs or for internal costs incurred. Unbilled accounts receivable consist of expenses directly associated with the Company's contracts that have been accrued at the end of the reporting period but have not been billed to its customers and collaborators.

Property and Equipment, Net

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

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment, long-term investments and long term deposits. The Company will record impairment losses on long-lived assets used in operations when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. While the Company's current and historical operating losses and cash flows are indicators of impairment, the Company believes the future cash flows to be received support the carrying value of its long-lived assets and, accordingly, the Company has not recognized any impairment losses through September 30, 2012.

Restricted Cash

The Company's corporate credit card arrangement requires that the Company maintain a deposit of $150,000 with the issuer of its credit cards. This security deposit is maintained in an interest bearing certificate of deposit and is recorded as restricted cash on the Balance Sheet.

Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, marketable securities, accounts receivable, accounts payable, accrued liabilities and warrants to purchase common stock. Fair value estimates of these instruments are made at a specific point in time based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision. The carrying amount of cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities are generally considered to be representative of their respective fair values because of the short-term nature of those instruments. The fair value of marketable securities is based upon market prices quoted on the last day of the fiscal period. The fair value of the common stock warrants is determined using a Black-Scholes model.

Revenue Recognition

The Company's revenues are derived from the Bayer Agreement and federal contracts with NIAID, DTRA and LLNL. The Company recognizes revenues when all four of 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.

The Company's license and collaboration agreements contain multiple elements, including non-refundable upfront fees, payments for reimbursement of internal and third-party development and regulatory costs, payments associated with achieving specific milestones and royalties based on specified percentages of net product sales, if any. The Company considers a variety of factors in determining the appropriate method of revenue recognition under these arrangements, such as whether the elements are separable, whether there are determinable fair values and whether there is a unique earnings process associated with each element of a contract.

Revenue recognition for agreements with multiple deliverables is based on the individual units of accounting determined to exist in the agreement. A delivered item is considered a separate unit of accounting when the delivered item has value to the customer on a stand-alone basis. Items are considered to have stand-alone value when they are sold separately by any vendor or when the customer could resell the item on a stand-alone basis.

Effective January 1, 2011, the Company adopted the provisions of Accounting Standards Update 2009-13 which codified modifications to Accounting Standards Codification, or ASC, 605-25 *Revenue Recognition—Multiple Element Arrangements* . As a result of this change in accounting principle, consideration received from multiple-element arrangements is allocated at the inception of the agreement to all deliverables based on their relative selling price. The relative selling price for each deliverable is determined using vendor specific objective evidence, or VSOE, of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, the Company uses its best estimate of the selling price for the deliverable.

The Company recognizes revenue for delivered elements only when it determines there are no uncertainties regarding customer acceptance. Changes in the allocation of the sales price between delivered and undelivered elements can impact revenue recognition but do not change the total revenue recognized under an agreement.

Cash received in advance of services being performed is recorded as deferred revenue and recognized as revenue as services are performed over the applicable term of the agreement.

When a payment is specifically tied to a separate earnings process, revenues are recognized when the specific performance obligation associated with the payment is completed. Performance obligations typically consist of significant and substantive milestones pursuant to the related agreement. Revenues from milestone payments may be considered separable from funding for development and regulatory services because of the uncertainty surrounding the achievement of milestones for products in early stages of development. Accordingly, these payments are allowed to be recognized as revenue if and when the performance milestone is achieved if they are determined to be substantive milestones. Milestones do not include events that occur solely upon the passage of time or as a result of a counterparty's performance.

When determining whether or not to account for transactions under the milestone method, the Company makes a determination at the inception of the agreement of whether or not each milestone is considered substantive. During this assessment process, the Company considers if achievement of the milestone is based in whole or in part on the Company's performance or on the occurrence of a separate outcome resulting from the Company's performance, if there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and if achievement will result in additional payments being due. In order for milestone consideration to be deemed substantive, it should:

1. Be commensurate with either the vendor's performance to achieve the milestone or the enhancement of value of the item delivered as a result of the specific outcome resulting from the vendor's performance to achieve the milestone

2. Relate solely to past performance; and

3. Be reasonable relative to all deliverables and payment terms in the arrangement.

With respect to revenues derived from reimbursement of direct out-of-pocket expenses for research costs associated with federal contracts,

where the Company acts as a principal, with discretion to choose suppliers, bears credit risk and performs part of the services required in the transaction, the Company records revenue for the gross amount of the reimbursement. The costs associated with these reimbursements are reflected as a component of research and development expense in the Statements of Operations.

Research and Development Expenses

Research and development expenses include related salaries, benefits, share-based compensation, costs to third-party contractors to perform research, conduct clinical trials and develop drug materials, research supplies, associated overhead expenses, facilities costs and license fees paid to third parties for use of their intellectual property. Research and development costs are expensed as incurred.

Patent Costs

Costs related to filing and pursuing patent applications are expensed as incurred, as recoverability of such expenditures is uncertain.

Share-Based Compensation

The Company accounts for share-based compensation by measuring and recognizing compensation expense for all share-based payments made to employees and directors based on estimated grant date fair values. The Company allocates compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period, and estimates the fair value of share-based awards to employees and directors using the Black-Scholes option valuation model. The Black-Scholes model requires the input of subjective assumptions, including volatility, the expected term and the fair value of the underlying common stock on the date of grant, among other inputs.

Stock options granted to non-employees are accounted for using the fair value approach. Stock options granted to non-employees are subject to periodic revaluation over their vesting terms.

Comprehensive Income (Loss)

Comprehensive income or loss consists of net income or loss and changes in equity during a period from transactions and other events and circumstances generated from non-owner sources. The Company's other comprehensive loss consisted of the net loss and unrealized gains and losses on the changes in fair value of investments.

Income Taxes

The Company uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial reporting and the tax reporting basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized. The Company has evaluated available evidence and concluded that the Company may not realize the benefit of its deferred tax assets; therefore a valuation allowance has been established for the full amount of the deferred tax assets at September 30, 2012 and December 31, 2011. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense.

Unaudited Interim Financial Data

The accompanying balance sheet as of September 30, 2012, statements of operations for the three and nine months ended September 30, 2012 and 2011, statements of comprehensive loss for the three and nine months ended September 30, 2012 and 2011 and statements of cash flows for the nine months ended September 30, 2012 and 2011 are unaudited. These unaudited financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission for interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. These financial statements should be read in conjunction with the audited financial statements and the accompanying notes for the year ended December 31, 2011 contained in the Company's Annual Report on Form 10-K. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company's financial position as of September 30, 2012 and the results of operations and comprehensive loss for the three and nine months ended September 30, 2012 and 2011 and cash flows for the nine months ended September 30, 2012 and 2011. The December 31, 2011 balance sheet included herein was derived from audited financial statements, but does not include all disclosures including notes required by GAAP for complete financial statements.

The financial data and other information disclosed in these notes to the financial statements related to the three and nine months ended September 30, 2012 and 2011 are unaudited. Interim results are not necessarily indicative of results for an entire year.

Net Income (Loss) per Common Share

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net income (loss) per share is computed by dividing the net income (loss) by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net income (loss) per share when their effect is dilutive.

The following table presents the computation of basic and diluted net income (loss) per common share (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net income (loss) per share				
Numerator				
Net income (loss)	$(17,682)	$14,311	$(39,700)	$ (5,739)
Denominator				
Weighted-average common shares outstanding	38,781	28,536	37,569	25,840
Less: Weighted-average shares subject to repurchase	—	(9)	(1)	(24)
Denominator for basic net income (loss) per share	38,781	28,527	37,568	25,816
Basic net income (loss) per share	$ (0.46)	$ 0.50	$ (1.06)	$ (0.22)
Denominator for diluted net income (loss) per share	38,781	29,477	37,568	25,816
Diluted net income (loss) per share	$ (0.46)	$ 0.49	$ (1.06)	$ (0.22)

Potentially dilutive securities not included in the calculation of diluted net income (loss) per common share because to do so would be anti-dilutive are as follows (in common equivalent shares):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Common stock warrants	1,678,884	—	1,678,884	12,200
Common stock options	3,888,163	354,192	3,888,163	1,107,508
	5,567,047	354,192	5,567,047	1,119,708

Segments

The Company operates in only one segment. Management uses cash flows as the primary measure to manage its business and does not segment its business for internal reporting or decision making.

Note 2. Significant Agreements and Contracts

License Agreements

In January 2007, the Company entered into a license agreement whereby the Company acquired the rights to certain proprietary materials and information related to DA-7128 (now known as tedizolid phosphate) from Dong-A Pharmaceuticals. The agreement requires payments of up to an aggregate of $13.0 million between completion of Phase 2 and registration of the product in various regions, of which $1.5 million was paid to Dong-A upon completion of the clinical study report in July 2012 for the Company's first Phase 3 trial of tedizolid phosphate. The agreement terminates upon the expiration of the last royalty term for a licensed product. Either party may terminate the agreement upon 90 days' prior written notice to the other upon or after a material, uncured default by the other party. The Company may terminate the agreement by sending Dong-A Pharmaceuticals 90 days' advance written notice where the Company decides to discontinue development or commercialization of products for any reason. Dong-A Pharmaceuticals may terminate the agreement by sending 90 days' advance written notice to the Company in the event that the Company fails to meet specified development and commercialization efforts within specified time periods.

Contract Research

In September 2008, the Company entered into a five-year federal contract with NIAID under which the Company is advancing the development of a novel broad spectrum antibiotic. This is a cost reimbursement contract with total potential payments of up to $27.7 million. The Company recognizes revenues under this contract as the services are performed. The Company recorded revenues under this contract of $2.0 million and $1.7 million for the three months ended September 30, 2012 and 2011, respectively, and $5.3 million and $5.1 million for the nine months ended September 30, 2012 and 2011, respectively. NIAID can terminate the contract upon delivering notice to the Company for default or convenience. Upon receipt of a notice of termination, the Company must discontinue contract activities and NIAID must pay the Company a final settlement based on eligible expenses incurred under the contract. As of September 30, 2012, the Company has not received a notice of termination relative to contract activities. Amounts received in advance of services performed are recorded as deferred revenue until earned. Billed receivables due under the Company's contract with NIAID at September 30, 2012 and December 31, 2011 were $856,000 and $644,000, respectively. Unbilled receivables were $1.7 million and $994,000 at September 30, 2012 and December 31, 2011, respectively. From contract inception through September 30, 2012, the Company has recognized $24.3 million in revenues related to the research performed under the NIAID contract.

In April 2011, the Company entered into a three-year research contract with LLNL, a part of the U.S. Department of Energy's National Nuclear Security Administration, for the development of novel antibiotics directed against gram negative multi-drug resistant bacterial pathogens. This is a cost-plus-fixed-fee contract with total potential payments of up to $3.0 million which the Company may receive over three years in support of its development efforts. The Company recognizes revenue under this contract as the services are performed. The Company recorded revenues under this contract of $0.2 million and $0.3 million for the three months ended September 30, 2012 and 2011, respectively,

and

$1.0 million and $0.5 million for the nine months ended September 30, 2012 and 2011, respectively. LLNL can terminate the contract upon delivering notice to the Company for default or convenience. Upon receipt of a notice of termination, the Company must discontinue contract activities and LLNL must pay the Company a final settlement based on eligible expenses incurred under the contract. As of September 30, 2012, the Company has not received a notice of termination relative to contract activities. Amounts received in advance of services performed are recorded as deferred revenue until earned. Billed receivables due under the Company's contract with LLNL at September 30, 2012 and December 31, 2011 were $183,000 and $81,000, respectively. Unbilled receivables were $124,000 and $154,000 at September 30, 2012 and December 31, 2011, respectively. From contract inception through September 30, 2012, the Company has recognized $1.7 million in revenues related to the research performed under the LLNL contract.

In April 2010, the Company entered into a four and one-half-year federal contract with DTRA, an agency within the U.S. Department of Defense, for the development of novel antibiotics directed against gram-negative bacterial pathogens. Due to programmatic priorities toward later stage programs, on May 3, 2012, DTRA elected not to exercise its option to extend funding under the four and one-half-year federal contract with the Company for the development of novel antibiotics directed against gram-negative bacterial pathogens, and therefore, the contract would not be extended beyond July 20, 2012. As a result, the Company has chosen to discontinue its marine natural products discovery program, which was solely funded by the DTRA contract. The Company recognized revenue under this contract as the services were performed. The Company recorded revenues under this contract of $0 million and $1.0 million for the three months ended September 30, 2012 and 2011, respectively, and $1.3 million and $3.0 million for the nine months ended September 30, 2012 and 2011, respectively. There were no billed receivables due under the Company's contract with DTRA at September 30, 2012 or December 31, 2011. Unbilled receivables were $0 and $795,000 at September 30, 2012 and December 31, 2011, respectively. From contract inception through the termination of the contract in the second quarter of 2012, the Company recognized $7.3 million in revenues related to the research performed under our DTRA contract.

Collaborations

In July 2011, the Company entered into the Bayer Agreement with Bayer which is an exclusive agreement to develop and commercialize the Company's lead antibiotic, tedizolid phosphate, in China, Japan and substantially all other countries in Asia, Africa, Latin America and the Middle East, excluding North and South Korea, which the Company refers to as the Bayer Licensed Territory. Under the Bayer Agreement, the Company retains full development and commercialization rights outside the Bayer Licensed Territory, including the United States, Canada and the European Union. In exchange for development and commercialization rights in the Bayer Licensed Territory, Bayer paid the Company $25.0 million upfront and agreed to support approximately 25% of the future development costs of tedizolid required for global approval for treatment of acute bacterial skin and skin structure infections, or ABSSSI, and pneumonia, subject to certain adjustments and limitations. In addition, Bayer agreed to support 100% of the future development costs required for local approval in the Bayer Licensed Territory. The Company is also eligible to receive up to $69.1 million upon the achievement of certain development, regulatory, and commercial milestones and will receive double-digit royalties on net sales of tedizolid in the Bayer Licensed Territory. None of the payments that the Company has received from Bayer to date, whether recognized as revenue or deferred, are refundable even if the related program is not successful. Revenues recognized in connection with the Bayer Agreement were $3.7 million and $14.5 million for the three and nine months ended September 30, 2012 and $27.4 million for the three and nine months ended September 30, 2011, as further discussed in Note 8.

Note 3. Investments in Marketable Securities

Investments classified as available-for-sale at September 30, 2012 and December 31, 2011 consisted of the following (in thousands):

	September 30, 2012	December 31, 2011
U.S. Treasury securities	$ 57,404	$ 47,762
Total available-for-sale investments	$ 57,404	$ 47,762

The following is a summary of investments classified as available-for-sale securities (in thousands):

	Amortized Cost	Gross Unrealized Gains (1)	Gross Unrealized Losses (1)	Aggregate Estimated Fair Value
September 30, 2012				
U.S. Treasury securities with unrealized gains	$ 54,638	$ 9	$ —	$ 54,647
U.S. Treasury securities with unrealized losses	2,757	—	—	2,757
Total available-for-sale securities	$ 57,395	$ 9	$ —	$ 57,404
December 31, 2011				
U.S. Treasury securities with unrealized gains	$ 30,175	$ 9	$ —	$ 30,184
U.S. Treasury securities with unrealized losses	17,580	—	(2)	17,578
Total available-for-sale securities	$ 47,755	$ 9	$ (2)	$ 47,762

Unrealized gains and losses on available-for-sale securities are included as a component of comprehensive loss. The three securities in unrealized loss positions have not been in a continuous unrealized loss position for more than 12 months. The Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases which may be at maturity. The Company reviews its investments to identify and evaluate investments that have an indication of possible other-than-temporary impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value.

The amortized cost and estimated fair value of debt securities classified as available-for-sale by contractual maturity at September 30, 2012 and December 31, 2011 are presented below (in thousands):

	Maturing in 12 months or less		Maturing in more than 12 months	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
September 30, 2012				
U.S. Treasury securities	$ 57,395	$ 57,404	$ —	$ —
Total available-for-sale securities	$ 57,395	$ 57,404	$ —	$ —
December 31, 2011				
U.S. Treasury securities	$ 47,755	$ 47,762	$ —	$ —
Total available-for-sale securities	$ 47,755	$ 47,762	$ —	$ —

The proceeds from sales of available-for-sale securities during the three and nine months ended September 30, 2012 were $1.3 million and $7.6 million, respectively, and resulted in realized gains of less than $1,000. The proceeds from sales of available-for-sale securities during the three and nine months ended September 30, 2011 were $2.5 million and $3.0 million, respectively, and resulted in realized gains of less than $1,000.

Note 4. Fair Value Measurements

The Company's financial instruments consist principally of cash and cash equivalents, marketable securities, accounts receivable, accounts payable, accrued liabilities, and long-term warrant liabilities related to warrants to purchase common stock. Fair value measurements are classified and disclosed in one of the following three categories:

Level 1 —Quoted prices in active markets for identical assets or liabilities.

Level 2 —Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 —Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Financial instruments measured at fair value as of September 30, 2012 and December 31, 2011 are classified below based on the three fair value hierarchy tiers described above (in thousands):

	Total	Fair Value Measurements at Reporting Date Using		
		Level 1	Level 2	Level 3
September 30, 2012				
Assets:				
Money Market funds, included in cash equivalents	$ 7,083	$ 7,083	$ —	$ —
U.S. Treasury securities, available-for-sale	57,404	—	57,404	—
Total	$64,487	$ 7,083	$ 57,404	$ —
Liabilities:				
Common stock warrant liability	5,571	—	—	5,571
Total	$ 5,571	$ —	$ —	$ 5,571
December 31, 2011				
Assets:				
Money Market funds, included in cash equivalents	$ 4,587	$ 4,587	$ —	$ —
U.S. Treasury securities, included in cash equivalents	850	—	850	—
U.S. Treasury securities, available-for-sale	47,762	—	47,762	—
Total	$53,199	$ 4,587	$ 48,612	$ —
Liabilities:				
Common stock warrant liability	7,124	—	—	7,124
Total	$ 7,124	$ —	$ —	$ 7,124

The fair value of the common stock warrant liability was determined based on “Level 3” inputs and utilizing the Black-Scholes option pricing model. The following table presents activity for the common stock warrant liability measured at fair value using significant unobservable Level 3 inputs during the nine months ended September 30, 2012 and 2011 (in thousands):

	Nine Months Ended September 30,	
	2012	2011
Beginning balance	$(7,124)	$ —
Purchases	—	—
Issuances	—	(8,682)
Settlements	—	—
Gains included in other income (expense)	1,553	2,504
Transfers (to) from Level 3	—	—
Ending balance	$(5,571)	$(6,178)

The Company performed an analysis to determine the sensitivity to changes in the unobservable input used in the calculation of the estimated fair value of the common stock warrant liability. If the volatility rate used in the calculation of the estimated fair value of the liability-classified common stock warrants at September 30, 2012 were to decrease by 10%, the liability would have decreased approximately $0.6 million. If the volatility rate were to increase by 10%, the liability would have increased approximately $0.6 million. These changes would have been recognized in the related component of other income (expense) in the Statement of Operations.

Note 5. Common Stock Warrants

Equity-classified warrants

During 2004, in connection with a financing arrangement, the Company issued warrants to purchase 140,909 shares of Series A-1 convertible preferred stock at $0.55 per share. After giving effect to the 1 for 8.6 reverse stock split approved in February 2010, 16,384 warrants remain outstanding at $4.73 per share.

The preferred stock warrants were accounted for as a liability and recorded at fair value with increases or decreases in the fair value of such warrants recorded separately within other income (expense) in the Statement of Operations. Upon the closing of the Company’s initial public offering on August 6, 2010, all preferred stock converted into common stock and warrants to purchase preferred stock converted into warrants to purchase common stock. The Company reassessed the fair value accounting for the preferred stock warrants due to their conversion on August 6, 2010 to common stock warrants and determined that fair value measurement was no longer appropriate and that recognition as a component of additional paid-in capital was proper.

Liability-classified warrants

On May 31, 2011, the Company closed a private placement transaction with certain accredited investors pursuant to which an aggregate of 4,750,000 units were sold at a purchase price of $6.35 per unit, with each unit consisting of one share of common stock and a warrant to purchase an additional 0.35 shares of common stock. Each warrant is exercisable in whole or in part for a period of five years commencing on November 27, 2011 at a per share exercise price of $8.50, subject to certain adjustments as specified in the warrant. The Company valued the warrants as derivative financial instruments as of the date of issuance and recorded them as a liability. The Company will continue to value the warrants at each reporting date, with any changes in fair value being recorded within other income (expense) in the Statement of Operations. The fair value of the warrants decreased by approximately $1.6 million during the nine months ended September 30, 2012 primarily due to the decline in the Company’s stock price since the December 31, 2011 measurement date. The warrants have been recorded at an estimated fair value of $5.6 million at September 30, 2012.

The determination that the warrants should be recorded as a liability is due to the fact that the warrants contain a net cash settlement provision under which the warrant holders may require the Company to purchase the warrants in exchange for a cash payment following the announcement of specified events defined as Fundamental Transactions involving the Company (e.g., merger, sale of all or substantially all assets, tender offer, or share exchange) or a Delisting, which is deemed to occur when the common stock is no longer listed on a national securities exchange. The net cash settlement provision requires use of the Black-Scholes model in calculating the cash payment value in the event of a Fundamental Transaction or a Delisting.

The net cash settlement value at the time of any future Fundamental Transaction or Delisting will depend upon the value of the following inputs at that time: the price per share of the Company's common stock, the volatility of the Company's common stock, the expected term of the warrant, the risk-free interest rate based on U.S. Treasury security yields, and the Company's dividend yield. The warrant requires use of a volatility assumption equal to the greater of (i) 100%, (ii) the 30-day volatility determined as of the trading day immediately following announcement of a Fundamental Transaction or Delisting, or (iii) the arithmetic average of the 10, 30, and 50-day volatility determined as of the trading day immediately following announcement of a Fundamental Transaction or Delisting.

The fair value of the warrants is determined using a Black-Scholes model. The valuation of warrants is subjective and is affected by changes in inputs to the valuation model including the price per share of the Company's common stock, the historical volatility of the stock prices of the Company's peer group, risk-free rates based on U.S. Treasury security yields, the expected term of the warrants and the Company's dividend yield. Changes in these assumptions can materially affect the fair value estimate. The Company could ultimately pay amounts to settle the warrant under the net cash settlement value that are significantly different than the carrying value of the liability in the financial statements. The Company will continue to classify the estimated fair value of the warrants as a liability until the warrants are exercised, expire, or are amended in a way that would no longer require these warrants to be classified as a liability.

Warrants Exercised and Outstanding

No warrants to purchase common stock were exercised during the nine months ended September 30, 2012. During the three months ended September 30, 2011, 14,174 equity-classified warrants were net exercised resulting in the issuance of 6,431 shares of common stock. During the nine months ended September 30, 2011, 49,691 warrants were net exercised resulting in the issuance of 21,560 shares of common stock. At September 30, 2012 and December 31, 2011, there were 1,678,884 common stock warrants outstanding all of which were exercisable. The common stock warrants outstanding will expire between three years and five years from September 30, 2012 and have a weighted average exercise price of $8.46.

The fair value of the liability-classified common stock warrants was estimated using the Black-Scholes option pricing model based on the following assumptions at September 30, 2012:

Expected volatility	90%
Expected term (in years)	4.2
Risk-free interest rate	0.47%
Expected dividend yield	0%

Note 6. Common Stock Reserved for Issuance

The following table summarizes shares of common stock reserved for future issuance:

	September 30, 2012	December 31, 2011
Common stock warrants	1,678,884	1,678,884
Shares available for purchase under the 2010 Employee Stock Purchase Plan	439,189	529,159
Common stock options outstanding	3,888,163	2,550,589
Common stock options available for future grant	1,199,250	1,770,844
Total common shares reserved for issuance	7,205,486	6,529,476

Note 7. Share-based Compensation

The Company granted 1,532,500 stock options to certain employees of the Company with a weighted average exercise price of $5.04 per share during the nine months ended September 30, 2012. The Company granted 524,000 stock options to certain employees and consultants of the Company with a weighted average exercise price of $6.53 per share during the nine months ended September 30, 2011. The stock options granted by the Company had an exercise price equal to the closing market price of the Company's common stock on the date of grant.

The following table summarizes stock option activity during the nine months ended September 30, 2012:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Options outstanding at December 31, 2011	2,550,589	$ 3.63	8.15	
Granted	1,532,500	$ 5.04		
Exercised	(148,020)	$ 1.59		$ 539
Canceled	(46,906)	$ 6.26		
Options outstanding at September 30, 2012	3,888,163	$ 4.24	8.21	$ 6,968
Options vested or expected to vest at September 30, 2012	3,875,090	$ 4.23	8.21	$ 6,957
Options exercisable at September 30, 2012	1,746,060	$ 3.35	7.22	$ 4,754

At September 30, 2012 and December 31, 2011, there was approximately $6.8 million and $3.8 million, respectively, of total unrecognized compensation costs related to outstanding options granted which is expected to be recognized over a weighted average period of 2.89 years and 2.79 years, respectively.

During the three months ended September 30, 2012 and 2011, approximately 25,000 and 18,000 stock options were exercised, respectively, resulting in cash proceeds to the Company of approximately $68,000 and $16,000, respectively. During the nine months ended September 30, 2012 and 2011, approximately 148,000 and 46,000 stock options were exercised, respectively, resulting in cash proceeds to the Company of approximately $235,000 and $55,000, respectively. Upon option exercise, the Company issues new shares of common stock.

Compensation cost for stock options granted to employees is based on the estimated grant-date fair value and is recognized ratably over the vesting period of the applicable option. The estimated per share-weighted average fair value of stock options granted to employees during the nine months ended September 30, 2012 was $3.38.

As share-based compensation expense recognized is based on options ultimately expected to vest, the expense has been reduced for estimated forfeitures. The fair value of each employee option grant during the nine months ended September 30, 2012 was estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions:

	Nine Months Ended September 30, 2012
Expected volatility	78%
Expected term (in years)	5.98
Risk-free interest rate	1.10%
Expected dividend yield	0%

Expected Volatility. The expected volatility rate used to value stock option grants is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the pharmaceutical and biotechnology industry in a similar stage of development to the Company.

Expected Term. The Company elected to utilize the “simplified” method for “plain vanilla” options to value stock option grants. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.

Risk-free Interest Rate. The risk-free interest rate assumption was based on zero-coupon U.S. Treasury instruments that had terms consistent with the expected term of our stock option grants.

Expected Dividend Yield. The Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future.

Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates. The Company estimates forfeitures based on its historical experience. Groups of employees that have similar historical forfeiture behavior are considered separately for expense recognition.

Stock options granted to non-employees are accounted for using the fair value approach. The fair value of non-employee option grants is estimated using the Black-Scholes option-pricing model and is remeasured over the vesting term as earned. The estimated fair value is expensed over the applicable service period. No stock options were granted to non-employees during the nine months ended September 30, 2012. The Company granted 5,000 stock options to non-employees during the nine months ended September 30, 2011.

In connection with non-employee options, the Company recognized expense of less than $1,000 and $(3,000) during the three months ended September 30, 2012 and 2011, respectively. The Company recognized expense related to non-employee options of less than $1,000 and $9,000 during the nine months ended September 30, 2012 and 2011, respectively.

Share-based Compensation Summary. Share-based compensation expense is recognized for stock options granted to employees and non-employees as well as employee participation in the 2010 Employee Stock Purchase Plan and has been reported in the Company’s Statements of Operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Research and development	$ 357	$ 336	$1,057	$ 967
General and administrative	384	416	1,184	1,027
Total	$ 741	$ 752	$2,241	$1,994

Since the Company had a net operating loss carryforward as of September 30, 2012, no excess tax benefits for the tax deductions related to share-based awards were recognized in the Statements of Operations. Additionally, no incremental tax benefits were recognized from stock options exercised during the nine months ended September 30, 2012 and 2011 that would have resulted in a reclassification to reduce net cash provided by operating activities with an offsetting increase in net cash provided by financing activities.

Note 8. Revenue Recognition Under Multiple Element Arrangements

In July 2011, the Company entered into the Bayer Agreement which is an exclusive agreement to develop and commercialize the Company's lead antibiotic, tedizolid phosphate in the Bayer Licensed Territory which includes China, Japan and substantially all other countries in Asia, Africa, Latin America and the Middle East, excluding North and South Korea. Under the Bayer Agreement, the Company retains full development and commercialization rights outside the Bayer Licensed Territory, including the United States, Canada and the European Union. In exchange for development and commercialization rights in the Bayer Licensed Territory, Bayer paid the Company $25.0 million upfront and agreed to support approximately 25% of the future development costs of tedizolid phosphate required for global approval for the treatment of ABSSSI and pneumonia, subject to certain adjustments and limitations. In addition, Bayer agreed to support 100% of the future development costs required for local approval in the Bayer Licensed Territory. The Company is also eligible to receive up to $69.1 million upon the achievement of certain development, regulatory and commercial milestones and will receive double-digit royalties on net sales of tedizolid phosphate in the Bayer Licensed Territory.

Pursuant to the accounting guidance under ASC 605-25, which governs revenue recognition for multiple element arrangements, the Company evaluated the two material non-contingent deliverables under the Bayer Agreement and determined that each meets the criteria for separation and therefore both will be treated as separate units of accounting, as follows:

- The license, referred to as the License, to develop and commercialize tedizolid in the Bayer Licensed Territory; and
- Certain Global Development Plan Services, referred to as Global Development Plan Services, which are expected to be conducted by the Company through December 2017.

The Bayer Agreement requires that the Company manufacture and supply bulk drug product for commercial use for up to five years from the first commercial sale of tedizolid phosphate in the Bayer Licensed Territory. Since these manufacturing efforts are contingent upon regulatory approvals for commercialization and there were no firm orders for commercial supply at or near the execution of the agreement, this obligation is deemed a contingent deliverable and was not valued at the inception of the arrangement.

The Company allocated the estimated arrangement consideration based on the percentage of the relative selling price of each unit of accounting. The Company estimated the selling price of the License using the relief from royalty method income approach. The assumptions were based on the estimated after-tax income related to a hypothetical license agreement with a third-party pharmaceutical partner company, which would jointly develop tedizolid phosphate with the Company and hold the rights outside of the U.S., the European Union and Canada. The significant inputs used to determine the selling price were estimates of product sales in the licensed territory, the royalties to be received by the Company from these sales, contractual milestone payments to be received by the Company, total expenses expected to be incurred by the Company, the Company's income tax rate in future years, and the discount rate used to discount the cash flows to their present values. If the Company's best estimate of the selling price of the License had been less than the estimate made at the time of initial assessment, then less of the arrangement consideration would have been allocated to the License, while an equal amount would have been allocated to the Global Development Plan Services. If the amount allocated to the License had been less than the upfront payment, then that difference would not have been recorded immediately but would have been deferred until the future periods over which the Global Development Plan Services would be performed. Assuming a constant selling price for the Global Development Plan Services, if there was an assumed 10% decrease in the estimated selling price of the License, or approximately $2.9 million, the Company determined that this change in estimated selling price would have reduced the allocation of the initial arrangement consideration allocated to the License agreement by about $1.6 million.

The Company estimated the selling prices of the Global Development Plan Services using estimated development costs, which consist primarily of costs to be paid to third parties. The significant assumptions and inputs include estimated timeframes to NDA approval, the number of internal hours to be spent performing these services, the estimated number of studies to be performed, the estimated number of patients to be included in the studies, the costs of clinical research organizations helping to conduct the studies, the estimated patient costs in conducting the studies, the estimated cost of drug product, the estimated regulatory costs of preparing NDA filings, and the estimated milestone payments to Dong-A, from whom the Company licensed tedizolid phosphate. If the selling price of the Global Development Plan Services were to increase, then more of the expected arrangement consideration would be allocated to the Global Development Plan Services, and an equal amount would be deducted from the License. Assuming a constant estimated selling price for the License and a 10% increase in the estimated selling price of the Global Development Plan Services, or approximately $4.5 million, then the Company would have allocated an additional $1.4 million of the initial arrangement consideration to the Global Development Plan Services, which would have been recorded over the period of performance of such services.

Revenues recognized related to the Bayer Agreement were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Collaborations	$2,919	$ 1,733	$11,010	$ 1,733
License	784	25,708	3,518	25,708
Total	$3,703	$27,441	$14,528	$27,441

In January 2012, the Company and Bayer agreed on the achievement of all efficacy and safety objectives for Trius' first global Phase 3 study of tedizolid phosphate for the treatment of ABSSSI. This event triggered a $5.0 million payment to the Company under the Bayer Agreement. At the inception of the Bayer Agreement, the Company determined that this milestone would be substantive when earned. Therefore, the $5.0 million payment was recognized as revenue during the quarter ended March 31, 2012 with $2.0 million recorded as License revenues and $3.0 million recorded as Collaboration revenues in accordance with the ratio of the estimated selling prices of each unit of accounting determined at inception of the Bayer Agreement.

In both May 2012 and August 2012, the Company earned $2.0 million milestone payments for progress made on its second Phase 3 clinical trial of tedizolid phosphate for the treatment of ABSSSI. The Company determined each of these $2.0 million milestones to be substantive at the inception of the Bayer Agreement. As such, the $2.0 million milestone earned in May 2012 was recognized as revenue in the quarter ended June 30, 2012 with $0.8 million recorded as license revenues and $1.2 million recorded as collaboration revenue. The $2.0 million milestone earned in August 2012 was recognized as revenue in the quarter ended September 30, 2012 with $0.8 million recorded as license revenues and $1.2 million recorded as collaboration revenue. Both of these milestones were allocated in accordance with the ratio of the estimated selling prices of each unit of accounting determined at inception of the Bayer Agreement.

The Global Development Plan Services are expected to be performed through December 2017, with no general right of return. From inception of the contract through September 30, 2012, the Company has provided certain Global Development Plan Services to Bayer. Under the Bayer Agreement, the Company is entitled to be reimbursed for certain costs associated with the performance of these services. At September 30, 2012, the Company calculated its percentage of completion estimate by taking its total actual costs for Global Development Plan Services since inception of the agreement and dividing it by the Company's estimate of the expected total costs to be incurred to provide the Global Development Plan Services for the remainder of the Global Development Period. The expected arrangement consideration was multiplied by the percentage of completion to determine the maximum amount that could be recognized as revenue. Collaboration revenue was recognized for the lesser of (a) the total amounts billed and billable to Bayer for the Global Development Plan Services during the period, or (b) the product of the percentage of completion and the expected arrangement consideration less cumulative revenues previously recognized. For the three and nine months ended September 30, 2012, the Company recognized $1.4 million and $4.7 million, respectively, in Collaboration revenues related to performance of Global Development Plan Services. For the three and nine months ended September 30, 2011, the Company recognized $0.4 million in Collaboration revenues related to performance of Global Development Plan Services.

Development expenses incurred by Trius that pertain to the Global Development Plan Services are being charged to research and development expense. At Bayer's election, Trius may perform certain services directly related to the Bayer Licensed Territory that are outside the scope of the Global Development Plan Services, or Bayer Licensed Territory Services. These services vary but may include contract research and intellectual property maintenance activities and are fully reimbursable to the Company. Expenses for these services are classified in the Statement of Operations on a basis consistent with the nature of the services. Amounts earned in connection with the performance of such services are recognized as Collaboration revenues in the period the services are performed. Collaboration revenues recognized for the performance of Bayer Licensed Territory Services during the three and nine months ended September 30, 2012 consisted of $255,000 and $751,000, respectively, in contract research and $33,000 and $90,000, respectively, of intellectual property support fees.

The Company may receive up to $69.1 million upon the achievement of certain development, regulatory and commercial events. Approximately $34.1 million of the future payments that the Company may receive are related to the achievement of certain development and regulatory events and $35.0 million if certain commercial sales thresholds are met. The Company has determined that $19.1 million of the development and regulatory payments are based upon its efforts. In September 2011, the Company earned $2.0 million of this total for dosing the first patient in its second Phase 3 clinical trial of tedizolid phosphate. In January 2012, the Company earned an additional $5.0 million for the successful completion of its first Phase 3 trial. The Company earned a $2.0 million milestone in May 2012 and another $2.0 million milestone in August 2012, both of which were tied to progress made on the Company's second Phase 3 clinical trial of tedizolid phosphate for the treatment of ABSSSI. The remaining $15.0 million of the development and regulatory payments and all $35.0 million of potential payments for the achievement of the commercial sales thresholds are based upon the efforts of Bayer.

Bayer has the ability to terminate the Bayer Agreement in its entirety by providing at least six months notice to the Company within the first two years of the Bayer Agreement. After two years, Bayer must provide at least 90 days notice. In addition, Bayer has the right to terminate the Bayer Agreement within 30 days of determining that the Company's second ongoing Phase 3 clinical trial of tedizolid phosphate for the treatment of ABSSSI has not been completed successfully or of becoming aware of any material toxicity and/or material drug safety event or issue concerning tedizolid phosphate.

Note 9. Stockholders' Equity

Public Offering of Common Stock

On January 31, 2012, the Company completed a public offering in which an aggregate of 9,890,000 shares of its common stock were sold at a purchase price of $5.25 per share. The Company raised a total of $48.4 million in net proceeds after deducting underwriting discounts and commissions of $3.1 million and offering expenses of $0.4 million.

Committed Equity Line of Credit

In August 2012, the Company entered into a committed equity line of credit with Terrapin Opportunity, L.P., or Terrapin, pursuant to which the Company may sell up to the lesser of $25.0 million of its common stock or 7,757,607 shares of its common stock over an approximately 24-month period pursuant to the terms of a Common Stock Purchase Agreement, or the Terrapin Purchase Agreement. The

Company is not obligated to utilize any portion of the facility. The Company will determine, at its sole discretion, the timing, the dollar amount and the price per share of each draw under this facility, subject to certain conditions. When and if the Company elects to utilize the facility by delivery of a draw down notice to Terrapin, the Company will issue shares to Terrapin at a discount ranging from 3.00% to 5.30% of the volume weighted average price of the Company's common stock over a preceding period of trading days, or the Draw Down Period. The Terrapin Purchase Agreement also provides that from time to time, at the Company's sole discretion, it may grant Terrapin an option to purchase additional shares of the Company's common stock during each Draw Down Period for an amount of shares specified by the Company based on the trading price of its common stock. Upon Terrapin's exercise of such an option, the Company will sell to Terrapin the shares subject to the option at a price equal to the greater of (i) the daily volume weighted average price of the Company's common stock on the day Terrapin notifies the Company of its election to exercise its option or (ii) the threshold price for the option determined by the Company, in each case less a discount ranging from 3.00% to 5.30%. Terrapin is not required to purchase any shares at a pre-discounted purchase price below $1.00 per share, and any shares sold under this facility will be sold pursuant to a shelf registration statement declared effective by the Securities and Exchange Commission on September 11, 2012. The Terrapin Purchase Agreement will terminate on September 1, 2014.

In October 2012, the Company sold 612,133 shares of its common stock under the Terrapin Purchase Agreement and received net proceeds of $3.4 million after deducting estimated expenses.

Note 10. Commitments

The Company's amended facility lease will expire on June 30, 2014 and the Company has options to extend the lease on or before December 31, 2013. In addition to the minimum lease payments, the Company is required to pay a pro-rata share of certain building expenses. Rent expense for the three months ended September 30, 2012 and 2011 was $203,000 and $163,000, respectively. Rent expense for the nine months ended September 30, 2012 and 2011 was $584,000 and $449,000, respectively.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited financial statements and related notes included in this Quarterly Report on Form 1O-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2011 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 filed by us with the Securities and Exchange Commission, or SEC, on March 14, 2012.

Forward-Looking Statements

The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words "anticipates", "believes", "estimates", "expects", "intends", "may", "plans", "projects", "will", "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item IA, "Risk Factors" in this Quarterly Report on Form 10-Q and in our other filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements.

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of innovative antibiotics for life threatening infections. We are developing tedizolid phosphate, an intravenous, or IV, and oral antibiotic, for the treatment of serious Gram-positive bacterial infections, for acute bacterial skin and skin structure infections, or ABSSSI, and pneumonia, and subsequently for other indications, including bacteremia. ABSSSI is a new classification for complicated skin and skin structure infections, or cSSSI. Tedizolid phosphate, the Company's lead product candidate, is a once daily IV and orally administered second generation oxazolidinone being developed

for the treatment of serious Gram-positive infections, including those caused by methicillin-resistant *staphylococcus aureus* (MRSA). In addition, we are discovering antibiotics for broad spectrum infections using our proprietary discovery platform under two government contracts: one funded by the National Institute of Allergy and Infectious Diseases, or NIAID, a part of the National Institutes of Health, or NIH; and a second contract with Lawrence Livermore National Laboratory, or LLNL, a part of the U.S. Department of Energy's National Nuclear Security Administration.

In December 2011, we completed our first Phase 3 clinical trial, the ESTABLISH-1 (TR-701-112) study, of the oral dosage form of tedizolid phosphate for the treatment of ABSSSI, and in September 2011, we initiated our second Phase 3 clinical trial, the ESTABLISH-2 (TR-701-113) study, of the IV to oral transition therapy for the treatment of ABSSSI and we expect to report top-line data on this second Phase 3 clinical trial in early 2013. We currently expect to submit a New Drug Application, or NDA, to the Food & Drug Administration, or FDA, for tedizolid phosphate for the treatment of ABSSSI during the second half of 2013. We have also completed a Phase 1 clinical trial which evaluated the ability of tedizolid phosphate to penetrate into the lung, for potential use in treating lung infections. Based on the results of the study, we plan to initiate a Phase 3 program of tedizolid phosphate for the treatment of pneumonia in the first half of 2013 using the same 200 mg, once daily dose of tedizolid phosphate that we are currently testing for skin infections.

In July 2011, we signed an exclusive collaboration and license agreement, the Bayer Agreement, with Bayer Pharma AG, or Bayer, to develop and commercialize tedizolid phosphate in China, Japan and substantially all other countries in Asia, Africa, Latin America and the Middle East, excluding North and South Korea, which we refer to as the Bayer Licensed Territory. We are evaluating potential strategic alliances for tedizolid phosphate in Europe.

Preclinical activities for our GyrB/ParE dual target development program, or Gyrase-B, are funded through Phase 1 clinical trials, subject to achievement of program milestones, by our NIAID contract. We are conducting Investigational New Drug, or IND, enabling studies for Gyrase-B which has potent activity against Gram-negative and Gram-positive bacterial pathogens. We expect to initiate a Phase 1 clinical trial of Gyrase-B in 2013.

In January 2012, we raised approximately $48.4 million in net proceeds from the public offering of our common stock in which we sold 9,890,000 shares of common stock at an offering price of $5.25 per share.

As of September 30, 2012, we had an accumulated deficit of $135.1 million. These losses have resulted principally from costs incurred in connection with research and development activities, including the costs of clinical trial activities associated with tedizolid phosphate, license fees and general and administrative expenses. We expect to continue to incur operating losses for the next several years as we pursue the clinical development and commercialization of tedizolid phosphate and work to discover and develop additional product candidates through our research and discovery program. As a result, we will seek to fund our operations through public or private equity or debt financings or other sources, such as collaborations and government contracts. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategies.

Financial Overview

Revenues

We have recognized $82.0 million of revenues from inception through September 30, 2012. We have derived substantially all of our revenues from our Bayer Agreement and government contracts, small business innovation research, or SBIR, grants funded by the NIH, and collaborations with other third parties for the research and development of certain preclinical programs. We have no products approved for sale, and we have not generated any revenues from product sales. We expect to recognize revenues from our contracts with NIAID and LLNL as well as through our license and collaboration agreement with Bayer. We continue to pursue government contract funding for our nonclinical, preclinical and clinical programs. If our development efforts for any of our product candidates result in clinical success and regulatory approval, or other collaboration agreements with third parties, we may generate revenues from those product candidates.

On May 3, 2012, the Defense Threat Reduction Agency, or DTRA, notified us that, due to programmatic priorities toward later stage programs, it elected not to exercise its option to extend funding under the four and one-half-year federal contract with us for the development of novel antibiotics directed against gram-negative bacterial pathogens, and the contract was not extended beyond July 20, 2012. As a result, we discontinued our marine natural products discovery program, which was solely funded by the DTRA contract. We have shifted our internal resources from the marine natural products discovery program to our other later stage programs and do not expect any associated negative impact on our cash requirements as a result of this decision.

Research and Development Expenses

The majority of our operating expenses to date have been for research and development activities related to tedizolid phosphate and our nonclinical and preclinical programs. Research and development expenses consist of: (1) expenses incurred under agreements with contract research organizations, or CROs, and investigative sites, which conduct a substantial portion of our nonclinical and preclinical studies, and all of our clinical trials; (2) employee-related expenses, which include salaries, benefits and share-based compensation; (3) payments to third-party manufacturers, which produce our active pharmaceutical ingredient and finished drug product; (4) license fees paid to third parties for use of their intellectual property; (5) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements and equipment and laboratory and other supplies; and (6) payments to consultants.

The following table presents our research and development expenses for the periods indicated (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Clinical and nonclinical research and development (including manufacturing)	$16,253	$11,857	$43,409	$27,224
Preclinical research and development	3,079	3,046	9,148	8,498
Total	$19,332	$14,903	$52,557	$35,722

At this time, due to the inherently unpredictable nature of nonclinical, preclinical and clinical development and given the early stage of our preclinical programs, we are unable to estimate with any certainty the costs we will incur in the continued development of tedizolid phosphate and our preclinical programs for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. While we are currently focused on advancing tedizolid phosphate and our preclinical programs, our future research and development expenses will depend on the clinical success of each product candidate that we develop, as well as ongoing assessments of the commercial potential of such product candidates. In addition, other than our collaboration agreement with Bayer, we cannot forecast with any degree of certainty which product candidates may be subject to future collaborations or contracts, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. We expect to incur increased research and development expenses as we continue our Phase 3 clinical program for tedizolid phosphate. In addition, we expect to incur significant research and development costs as we perform additional clinical trials necessary to obtain regulatory approval of tedizolid phosphate for additional indications, as well as to advance our preclinical programs.

The costs of clinical trials may vary significantly over the life of a project owing to but not limited to the following:

- Per patient trial costs;
- The number of sites included in the trials;
- The countries in which the trials are conducted;
- The length of time required to enroll eligible patients;
- The number of patients that participate in the trials;
- The number of doses that patients receive;
- The cost of comparative agents used in trials;
- The drop-out or discontinuation rates of patients;
- Potential additional safety monitoring or other studies requested by regulatory agencies;
- The duration of patient follow-up; and
- The efficacy and safety profile of the product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related expenses for personnel in administration, finance, commercial strategy and business development. Other significant expenses include professional fees for general legal services, legal expenses to pursue patent protection of our intellectual property, accounting fees, director fees, directors' and officers' insurance premiums, fees for investor relations services, share-based compensation and allocated facility costs. We expect our general and administrative expense to increase as we continue to operate as a public company and build our corporate infrastructure in support of continued development of tedizolid phosphate and our preclinical programs. These increases likely will include additional salaries and related expenses, consultant fees, and expenses related to enhanced business systems.

Interest Income

Interest income consists of interest earned on our cash, cash equivalents and investments in marketable securities.

Income Taxes

We assess income tax positions and record tax benefits for all years subject to examination based upon our evaluation of the facts, circumstances and information available at the reporting date. For those tax positions where there is a greater than 50% likelihood that a tax benefit will be sustained, we have recorded the largest amount of tax benefit that may potentially be realized upon ultimate settlement with a taxing authority that has full knowledge of all relevant information. For those income tax positions where there is less than 50% likelihood that a tax benefit will be sustained, no tax benefit has been recognized in the financial statements.

We have had federal and state net operating loss carryforwards and federal and state research and development tax credit carryforwards. Under Section 382/383 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, substantial changes in our ownership may limit the amount of net operating loss carryforwards and development tax credit carryforwards that could be utilized annually in the future to offset taxable income. Any such annual limitation may significantly reduce the utilization of the net operating losses and tax credits before they expire. We recently completed an updated Section 382/383 study to ascertain whether the public offering of common stock that was completed in January 2012 may have triggered an "ownership change," which could limit the future use of our net operating loss and tax credit carryforwards. Based upon this updated study, we have determined that an "ownership change" did occur but that the annual limitation would not have a material impact on our ability to use net operating loss and tax credit carryforwards. In each period since our inception, we have recorded a valuation allowance for the full amount of our net deferred tax asset, as the realization of such net deferred tax asset is uncertain.

Change in Fair Value of Common Stock Warrants Liability

We have issued warrants to purchase our common stock that may require us to purchase unexercised warrants for a cash amount equal to their fair value following the announcement of specified events defined as Fundamental Transactions involving us (e.g., merger, sale of all or substantially all assets, tender offer, or share exchange) or a delisting, which is deemed to occur when the common stock is no longer listed on a national securities exchange. The cash settlement provisions require use of the Black-Scholes model in calculating the cash payment value in the event of a Fundamental Transaction or a delisting. As a consequence of these provisions, the warrants are classified as a liability on our balance sheets. The cash settlement value at the time of any future Fundamental Transaction or delisting will depend upon the value of the following inputs at that time: the price per share of our common stock, the volatility of our common stock, the expected term of the warrant, the risk-free interest rate based on U.S. Treasury security yields, and our dividend yield.

The fair value of the warrants is determined using a Black-Scholes model. The valuation of warrants is subjective and is affected by changes in inputs to the valuation model including the price per share of our common stock, the historical volatility of the stock prices of companies included in our peer group, risk-free rates based on U.S. Treasury security yields, the expected term of the warrants and our dividend yield. Changes in these assumptions can materially affect the fair value estimate. We could ultimately incur amounts to settle the warrant at a cash settlement value that is significantly different than the carrying value of the liability on our financial statements. We will continue to classify the fair value of the warrants as a liability until the warrants are exercised, expire, or are amended in a way that would no longer require these warrants to be classified as a liability. Changes in the fair value of the common stock warrants liability are recognized as a component of other income (expense) in the Statement of Operations.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments related to preclinical, nonclinical and clinical development costs and drug manufacturing costs. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We discussed accounting policies and assumptions that involve a higher degree of judgment and complexity within Note 1 to our financial statements in our Annual Report on Form 10-K for the year ended December 31, 2011. There have been no material changes to our critical accounting policies and estimates as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2011.

Results of Operations

Comparison of the Three Months Ended September 30, 2012 and 2011

Revenues

The following table summarizes our revenues for the three months ended September 30, 2012 and 2011 (in thousands, except percentages):

	Three Months Ended September 30,		$	%
	2012	2011	Change	Change
Contract research	$2,270	$ 2,995	$ (725)	(24)%
Collaborations	2,919	1,733	1,186	68%
License fees	784	25,708	(24,924)	(97)%
Total	$5,973	$30,436	(24,463)	(80)%

Contract research revenues decreased for the three months ended September 30, 2012 as compared to the three months ended September 30, 2011 primarily due to decreased research performed under our DTRA contract as a result of DTRA's election in May 2012 not to extend the contract. This decrease was partially offset by an increase in research performed under our NIAID contract.

License and collaboration revenues for the three months ended September 30, 2012 relate to activities performed under our collaboration and license agreement with Bayer that we entered into in July 2011. We performed certain development and regulatory services under the Bayer collaboration and license agreement during the three months ended September 30, 2012 for which we recognized $1.7 million as collaboration revenues. In addition, we earned a $2.0 million milestone payment for progress made on our second Phase 3 clinical trial of tedizolid phosphate. At the inception of the Bayer Agreement, we determined that this milestone would be substantive when earned. Therefore, the $2.0 million payment was recognized as revenue during the quarter ended September 30, 2012 with $0.8 million recorded as License revenues and $1.2 million recorded as Collaboration revenues in accordance with the ratio of the estimated selling prices of each unit of accounting determined at inception of the Bayer Agreement.

License and collaboration revenues for the three months ended September 30, 2011 relate to commencement of activities under our collaboration and license agreement with Bayer. Upon entry into the license and collaboration agreement, Bayer made an upfront payment of $25.0 million. Approximately $24.9 million of the upfront payment was allocated to the License and was recorded as license revenue during the three months ended September 30, 2011. The remaining $0.1 million was allocated to the Global Development Plan Services and was recorded as collaboration revenue during the three months ended September 30, 2011. We also performed certain development and regulatory services under the Bayer collaboration and license agreement during the three months ended September 30, 2011 for which we recognized $441,000 as collaboration revenues. In addition, we earned a $2.0 million payment that was contingent upon the first patient being dosed in our second Phase 3 clinical trial of tedizolid phosphate. We increased the allocable arrangement consideration when the contingent payment was earned and recognized $1.2 million of collaboration revenues and $0.8 million of license revenues during the three months ended September 30, 2011.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2012 and 2011 (in thousands, except percentages):

	Three Months Ended September 30,		$	%
	2012	2011	Change	Change
Research and development expenses	$19,332	$14,903	$4,429	30%

During the three months ended September 30, 2012 our research and development costs related primarily to our clinical trials of tedizolid phosphate as well as research under our NIAID and LLNL contracts and other preclinical activities. Development expenses for tedizolid phosphate increased by approximately $4.4 million during the three months ended September 30, 2012 primarily due to clinical and nonclinical costs to support our planned NDA filing with the FDA.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended September 30, 2012 and 2011 (in thousands, except percentages):

	Three Months Ended September 30,		$	%
	2012	2011	Change	Change
General and administrative expenses	$ 4,427	$ 3,731	$ 696	19%

The increase in general and administrative expenses was primarily due to additional commercial planning activities for tedizolid phosphate. This increase was partially offset by a decrease in costs related to partnering activities due to finalizing the collaboration and license agreement with Bayer during the three months ended September 30, 2011.

Other Income (Expense)

The following table summarizes our other income for the three months ended September 30, 2012 and 2011 (in thousands, except percentages):

	Three Months Ended September 30,		$	%
	2012	2011	Change	Change
Interest income	$ 13	$ 5	$ 8	160%
Fair value adjustment of common stock warrant liability	91	2,504	(2,413)	(96)%
Total Other Income (Expense)	$ 104	$ 2,509	(2,405)	(96)%

Other income and expense for the three months ended September 30, 2012 resulted primarily from the remeasurement of the estimated fair value of the common stock warrant liability. This liability is remeasured at each reporting date with changes in estimated fair value recorded as other income or expense. There were no significant changes in the inputs to the valuation model during the three months ended September 30, 2012. During the three months ended September 30, 2011, a decrease in the price of our common stock caused a corresponding decrease in the estimated fair value of the warrant liability. This decrease resulted in $2.5 million of other income.

Comparison of the Nine Months Ended September 30, 2012 and 2011

Revenues

The following table summarizes our revenues for the nine months ended September 30, 2012 and 2011 (in thousands, except percentages):

	Nine Months Ended September 30,		$	%
	2012	2011	Change	Change
Contract research	$ 7,501	$ 8,568	$ (1,067)	(12)%
Collaborations	11,010	1,733	9,277	535%
License fees	3,518	25,708	(22,190)	(86)%
Total	$22,029	$36,009	(13,980)	(39)%

Contract research revenues decreased for the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011 primarily due to decreased research performed under our DTRA contract. This decrease was partially offset by an increase in work performed under our NIAID and LLNL contracts.

License and collaboration revenues for the nine months ended September 30, 2012 relate to activities performed under our collaboration and license agreement with Bayer that we entered into in July 2011. We performed certain development services under the Bayer Agreement during the nine months ended September 30, 2012 for which we recognized $5.5 million as collaboration revenues. In addition, we earned a $5.0 million payment that was contingent upon the successful completion of our first Phase 3 clinical trial of tedizolid phosphate and two $2.0 million payments for progress made on our second Phase 3 clinical trial of tedizolid phosphate. At the inception of the Bayer Agreement, we determined that these milestones would be substantive when earned. Therefore, these payments were recognized as revenue when earned with $3.5 million recorded as License revenues and $5.5 million recorded as Collaboration revenues in accordance with the ratio of the estimated selling prices of each unit of accounting determined at inception of the Bayer Agreement.

License and collaboration revenues for the nine months ended September 30, 2011 relate to commencement of activities under our collaboration and license agreement with Bayer. Upon entry into the license and collaboration agreement, Bayer made an upfront payment of $25.0 million. Approximately $24.9 million of the upfront payment was allocated to the License and was recorded as License revenue during the three months ended September 30, 2011. The remaining $0.1 million was allocated to the Global Development Plan Services and was recorded as Collaboration revenue during the three months ended September 30, 2011. We also performed certain development and regulatory services under the Bayer collaboration and license agreement during the three months ended September 30, 2011 for which we recognized $441,000 as Collaboration revenues. In addition, we earned a $2.0 million payment that was contingent upon the first patient being dosed in our second Phase 3 clinical trial of tedizolid phosphate. We increased the allocable arrangement consideration when the contingent payment was earned and recognized $1.2 million of Collaboration revenues and $0.8 million of License revenues during the three months ended September 30, 2011.

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2012 and 2011 (in thousands, except percentages):

	Nine Months Ended September 30,		$	%
	2012	2011	Change	Change
Research and development expenses	$52,557	$35,722	$16,835	47%

During the nine months ended September 30, 2012, our research and development costs related primarily to our clinical trials of tedizolid phosphate as well as research under our NIAID, DTRA, LLNL contracts and other preclinical activities. During the nine months ended September 30, 2011, our research and development costs related primarily to our clinical trials of tedizolid phosphate as well as research under our NIAID, DTRA and LLNL contracts. Development expenses for tedizolid phosphate increased by approximately $16.2 million during the nine months ended September 30, 2012 primarily due to clinical and nonclinical costs to support our planned NDA filing with the FDA.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2012 and 2011 (in thousands, except percentages):

	Nine Months Ended September 30,		$	%
	2012	2011	Change	Change
General and administrative expenses	$10,742	$8,550	$2,192	26%

The increase in general and administrative expenses was primarily due to additional commercial planning activities for tedizolid phosphate. This increase was partially offset by a decrease in costs related to partnering activities which were incurred in connection with the collaboration and license agreement entered into with Bayer in 2011.

Other Income (Expense)

The following table summarizes our other income (expense) for the nine months ended September 30, 2012 and 2011 (in thousands, except percentages):

	Nine Months Ended September 30,		$	%
	2012	2011	Change	Change
Interest income	$ 20	19	$ 1	5%
Fair value adjustment of common stock warrant liability	1,553	2,504	(951)	(38)%
Other income (expense)	(3)	1	(4)	(400)%
Total Other Income (Expense)	$1,570	$2,524	(954)	(38)%

Other income for the nine months ended September 30, 2012 was $1.6 million and resulted primarily from the remeasurement of the estimated fair value of the common stock warrant liability. This liability was recognized upon the issuance of warrants in connection with a private placement of stock in May 2011 and is remeasured at each reporting date with changes in estimated fair value recorded as other income or expense. The decrease in the estimated fair value of the common stock warrant liability during the nine months ended September 30, 2012 was due primarily to the decrease in our stock price since December 31, 2011. The fair value adjustment recorded during the nine months ended September 30, 2011 resulted from a decrease in our stock price from the value recorded when the warrants were issued.

Liquidity and Capital Resources

We have incurred losses since our inception and we anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may obtain from financings, research funding, collaborations, contract revenues or other sources.

Since our inception, we have funded our operations principally through the receipt of funds from the placement of equity securities and convertible notes payable, contract research funding under our government contracts, our collaboration and license agreement with Bayer and research grants. As of September 30, 2012, we had cash and cash equivalents and investments of approximately $70.9 million. Cash in excess of immediate requirements is invested in accordance with our investment policy primarily with a view to liquidity and capital preservation. As of September 30, 2012, our funds are held in cash, money market funds and United States Treasury securities.

	Nine Months Ended September 30,	
	2012	2011
	(In thousands)	
Cash Flows from Continuing Operations:		
Net cash used in operating activities	$(35,931)	$ (3,079)
Net cash used in investing activities	(10,859)	(7,309)
Net cash provided by financing activities	48,905	28,320
Net increase in cash and cash equivalents	$ 2,115	$17,932

During the nine months ended September 30, 2012 and 2011 our operating activities used cash of $35.9 million and $3.1 million, respectively, primarily resulting from our net losses and changes in our working capital accounts. The increase in cash used in operations during the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was primarily due to increased expenses associated with our clinical program for tedizolid phosphate which were partially offset in 2011 by the receipt of a $25.0 million payment from Bayer upon entering into the Bayer Agreement. During the nine months ended September 30, 2012, our investing activities used cash of $10.9 million primarily due to purchases of investments in excess of proceeds from sales and maturities of investments. During the nine months ended September 30, 2012, financing activities provided cash of $48.9 million which was primarily derived from proceeds received from our public offering of common stock in January 2012 from which we raised a total of $48.4 million in net proceeds after deducting underwriting discounts, commissions and offering expenses. Cash provided by financing activities during the nine months ended September 30, 2011 was primarily derived from a private placement of stock in May 2011 from which we received net proceeds of approximately $28.0 million.

Operating Capital Requirements

We anticipate we will continue to incur net losses for the next several years as we incur expenses for our clinical and nonclinical studies of tedizolid phosphate, complete preclinical studies and initiate clinical development of our preclinical programs, build commercial capabilities and expand our corporate infrastructure. We may not be able to complete the development and initiate commercialization of these programs if, among other things, our preclinical research and clinical trials are not successful, the FDA does not approve tedizolid phosphate or any other product candidates arising out of our current preclinical programs when we expect, or at all, or funding under our NIAID or LLNL contracts or collaboration and license agreement with Bayer is discontinued.

On May 31, 2011, we closed a private placement transaction, or Private Placement, with certain accredited investors in which we sold an aggregate of 4,750,000 units at a price of $6.35 per unit, with each unit consisting of one share of common stock and a warrant to purchase an additional 0.35 shares of common stock. As a result of the Private Placement, we raised a total of $28.0 million in net proceeds after deducting underwriting discounts and commissions of $1.9 million and offering expenses of $0.3 million.

On July 26, 2011, we signed our collaboration and license agreement with Bayer. In exchange for development and commercialization rights in the Bayer Licensed Territory, Bayer paid us $25.0 million upfront and agreed to support approximately 25% of the development and regulatory costs of tedizolid phosphate required for global approval in ABSSSI and pneumonia. In addition, Bayer agreed to support 100% of the development and regulatory costs required for local approval of tedizolid phosphate in the Bayer Licensed Territory. We are also eligible to receive up to $69.1 million upon the achievement of certain development and regulatory milestones and commercial milestones and are entitled to receive double-digit royalties on net sales of tedizolid phosphate in the Bayer Licensed Territory.

On January 31, 2012, we closed our public offering whereby we sold 9,890,000 million shares of common stock at an offering price of $5.25 per share. We raised approximately $48.4 million in net proceeds after deducting underwriting discounts and commissions of $3.1 million and offering expenses of $0.4 million.

On May 3, 2012, DTRA notified us that, due to programmatic priorities toward later stage programs, it elected not to exercise its option to extend funding under the four and one-half-year federal contract with us for the development of novel antibiotics directed against gram-negative bacterial pathogens, and therefore, the contract will not be extended beyond July 20, 2012. As a result, we discontinued our marine natural products discovery program, which was solely funded by the DTRA contract. We shifted our internal resources from the marine natural products discovery program to our other later stage programs and do not expect any associated negative impact on our cash runway as a result of this decision.

On August 30, 2012, we entered into a committed equity line of credit with Terrapin Opportunity, L.P., or Terrapin, under which we may sell up to the lesser of $25.0 million of common stock or 7,757,607 shares of our common stock over an approximately 24-month period pursuant to a Common Stock Purchase Agreement, the Terrapin Purchase Agreement. We are not obligated to utilize any of the facility and we remain free to enter into and consummate other equity and debt financing transactions. We will determine, at our sole discretion, the timing, the dollar amount and the price per share of each draw under this facility, subject to certain conditions. When and if we elect to use the facility, we will issue shares to Terrapin at a discount ranging from 3.00% to 5.30% of the volume weighted average price of our common stock over a preceding period of trading days. Terrapin is not required to purchase any shares at a pre-discounted purchase price below $1.00 per share. Any shares sold under this facility will be sold pursuant to a shelf registration statement declared effective by the Securities and Exchange Commission on September 11, 2012. In October 2012, we sold 612,133 shares of our common stock under the Terrapin Purchase Agreement and received net proceeds of $3.4 million after deducting estimated expenses of $0.1 million.

We believe that we have sufficient cash and cash equivalents to fund our operations for at least the next twelve months. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed in Part II, Item 1A, “Risk Factors.”

We do not anticipate that our existing working capital alone will be sufficient to fund our operations through the successful development and commercialization of tedizolid phosphate or any other products we develop. As a result, we will need to raise additional capital to fund our operations and continue to conduct clinical and nonclinical activities to support potential regulatory approval of tedizolid phosphate and any other product candidates. To raise additional capital, we may seek to sell additional equity or convertible debt securities or incur indebtedness. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may also seek funding through collaborations or other similar arrangements with third parties.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- The progress of our tedizolid phosphate clinical program, including expenses to support the clinical trials;
- The costs and timing of regulatory approvals;
- Our progress in advancing our preclinical programs through preclinical development into clinical trials;
- The costs and timing of clinical and commercial manufacturing supply arrangements for our product candidates;
- The costs of establishing sales or distribution capabilities;
- The success of the commercialization of our products;
- Our ability to maintain existing, and be awarded new, government research contracts;
- Our ability to maintain our current collaboration and license agreement with Bayer and establish potential future strategic collaborations, including licensing and other arrangements; and
- The costs involved in enforcing or defending patent claims or other intellectual property rights.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Contractual Obligations

The following table summarizes our outstanding contractual obligations as of payment due date by period at September 30, 2012:

	Payment by Period				
	Total	Less Than 1 Year	1 - 3 Years	3-5 Years	More Than 5 Years
			(In thousands)		
Operating leases	$1,280	$ 721	$ 559	$ —	$ —

Upon completion of the clinical study report in July 2012 for our first Phase 3 clinical trial of tedizolid phosphate, we paid a $1.5 million milestone under our license agreement with Dong-A. We may be required to make up to an aggregate of $11.5 million in additional payments to Dong-A upon the achievement of specified development and regulatory approval milestones. We are unable at this time to estimate with certainty the amount or timing of future costs we will incur under this agreement.

Recent Accounting Pronouncements

Occasionally, new accounting standards are issued or proposed by the Financial Accounting Standards Board, or FASB, or other standard-setting bodies that we adopt by the effective date specified within the standard. Unless otherwise discussed, standards that do not require adoption until a future date are not expected to have a material impact on our financial statements upon adoption.

In June 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2011-05, Presentation of Comprehensive Income (Topic 220) . This standard eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. The standard is intended to enhance comparability between entities that report under GAAP and those that report under International Financial Reporting Standards, or IFRS, and to provide a more consistent method of presenting non-owner transactions that affect an entity's equity. Under the ASU, an entity can elect to present items of net income and other comprehensive income in one continuous statement, referred to as the statement of comprehensive income, or in two separate, but consecutive, statements. Each component of net income and each component of other comprehensive income, together with totals for comprehensive income and its two parts, net income and other comprehensive income, would need to be displayed under either alternative. The statement(s) would need to be presented with equal prominence as the other primary financial statements. This ASU does not change items that constitute net income and other comprehensive income, when an item of other comprehensive income must be reclassified to net income or the earnings-per-share computation (which will continue to be based on net income). The new U.S. GAAP requirements are effective for public entities as of the beginning of a fiscal year that begins after December 15, 2011 and interim and annual periods thereafter. Effective January 1, 2012, we adopted ASU 2011-05.

Item 3. Qualitative and Quantitative Disclosures About Market Risk

Our cash equivalents and available-for-sale investments consisted of money market funds and debt instruments of agencies of the U.S. government at September 30, 2012. The investments in these financial instruments are made in accordance with an investment policy approved by our board of directors which specifies the categories, allocations, and ratings of securities we may consider for investment. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Some of the financial instruments that we invest in could be subject to market risk. This means that a change in prevailing interest rates may cause the value of the instruments to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of that security will probably decline. To minimize this risk, we intend to maintain a portfolio which may include cash, cash equivalents and investment securities available-for-sale in a variety of securities which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Based on our current investment portfolio, we do not believe that our results of operations would be materially impacted by an immediate change of 10% in interest rates.

We do not hold or issue derivatives, derivative commodity instruments or other financial instruments for speculative trading purposes. Further, we do not believe our cash equivalents and investment securities have significant risk of default or illiquidity. We made this determination based on discussions with our investment advisors and a review of our holdings. While we believe our cash equivalents and investment securities do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. All of our investments are held at fair value.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) and Rule 15d-15(b) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control

As required by Rule 13a-15(d) and Rule 15d-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded no such changes during the period covered by this Quarterly Report on Form 10-Q materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

You should consider carefully the following information about the risks described below, together with the other information contained in this Quarterly Report and in our other public filings in evaluating our business. The risk factors set forth below with an asterisk (*) next to the title contain changes to the description of the risk factors associated with our business previously disclosed in Item 1A. of our annual report on Form 10-K for the year ended December 31, 2011. Additional risks and uncertainties that we are unaware of may also become important factors that affect us. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future. We may never become profitable.*

As of September 30, 2012, we had an accumulated deficit of $135.1 million. We have funded, and plan to continue to fund, our operations from the sale of our securities, through research funding and from collaboration and license payments, including payments under the Bayer collaboration. However, we have generated no revenues from product sales to date. We expect that the uncertainty of our ability to achieve milestones under the Bayer collaboration and any other collaboration agreements we may enter into in the future and the timing of those payments will lead to significant fluctuations in our earnings and profitability. However, even with these funds, we expect to continue to incur substantial additional operating losses for the next several years as we advance tedizolid phosphate and our preclinical programs. In addition, if we obtain regulatory approval for tedizolid phosphate, we may incur significant sales, marketing, licensing and outsourced manufacturing expenses. As a result, we expect to continue to incur significant and increasing losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical drugs, we are unable to predict the extent of any future losses. We may never successfully commercialize any products and thus may never have any significant future revenues or achieve and sustain profitability.

We have limited sources of revenues and have not to date generated any revenues from product sales.*

We are a biopharmaceutical company with no products approved for commercial sale. To date, substantially all of our revenues have been derived from federal contract and grant revenues and fees for development and regulatory services from license or collaboration agreements, and we have not generated any revenues from product sales. We do not anticipate generating revenues, if any, from sales of tedizolid phosphate for at least two years from the date hereof. Our ability to generate future revenues from product sales depends heavily on our success in:

- Obtaining favorable results for and advancing the development of tedizolid phosphate for the treatment of ABSSSI, including successfully completing our Phase 3 clinical program;
- Obtaining United States and/or foreign regulatory approvals for tedizolid phosphate;
- Commercializing tedizolid phosphate and any other product candidates for which we obtain FDA approval, including by building a hospital-directed sales force and/or collaborating with third parties;
- Achieving broad market acceptance of tedizolid phosphate in the medical community and with third-party payers;
- Pursuing clinical development of tedizolid phosphate for the treatment of pneumonia and potentially for other indications, including bacteremia;
- Generating a pipeline of innovative product candidates using our drug discovery platform or through licensing strategies;
- Maintaining our current federal contracts that support our current drug discovery efforts and obtaining new federal contracts to help pay for future drug discovery efforts; and
- Maintaining our collaboration and license agreement with Bayer to support our continuing development and regulatory efforts for tedizolid phosphate for the treatment of ABSSSI and pneumonia.

Tedizolid phosphate will require extensive additional clinical study and evaluation, regulatory approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote tedizolid phosphate, or any other antibiotic product candidates that we develop, before we obtain regulatory approval from the FDA or comparable foreign regulatory authorities. If we do not obtain regulatory approval for and successfully commercialize tedizolid phosphate, we may not generate any revenues from product sales, and we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market tedizolid phosphate, our revenues are dependent upon the size of the markets in the territories for which we obtain regulatory approval and have commercial rights, as well as our ability to gain market acceptance and achieve commercial success. If we do not generate revenues, or the markets for the treatment of ABSSSI are not as significant as we estimate, our business and prospects will be materially harmed.

If we fail to obtain additional financing, we may not be able to complete the development and commercialization of tedizolid phosphate or any other product candidates.*

Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts to:

- Complete the clinical development of tedizolid phosphate, initially for treatment of ABSSSI, which will obligate us to pay substantial additional milestone payments to Dong-A;
- Launch and commercialize tedizolid phosphate and any other product candidates for which we obtain regulatory approval, including by building a hospital-directed sales force and/or collaborating with third parties;
- Pursue clinical development of tedizolid phosphate for the treatment of pneumonia and potentially for other indications, including bacteremia; and
- Continue our discovery and development programs to advance our preclinical product pipeline.

In May 2011, we completed a private placement, raising $28.0 million in net proceeds. In July 2011, we signed a collaboration agreement with Bayer where they agreed to pay us $25.0 million in upfront fees, and agreed to support approximately 25% of our development costs of tedizolid phosphate for ABSSSI and pneumonia, pay us up to $69.1 million upon the achievement of certain milestones, and pay us royalties on net sales of tedizolid phosphate in the Bayer Licensed Territory. In addition, Bayer agreed to pay for 100% of the development efforts in the Bayer Licensed Territory. In January 2012, we completed our public offering, raising $48.4 million in net proceeds. In August 2012, we entered into a committed equity line of credit under which we may sell up to $25.0 million of our common stock from time to time to Terrapin over a 24-month period. To date, we have received aggregate net proceeds of $3.4 million under the committed equity line of credit. We expect that the net proceeds from our public offerings, revenues under our Bayer collaboration and our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our capital requirements through at least the next twelve months. However, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. For example, our clinical trials may encounter technical, enrollment or other issues that could cause our development costs to increase more than we expected. We may also need to raise additional funds sooner if we choose to initiate clinical trials for indications in addition to ABSSSI more rapidly than we presently anticipate. In any event, we expect that we will require additional capital to obtain regulatory approval of and to commercialize tedizolid phosphate. Securing additional financing will require a substantial amount of time and attention from our management and may divert a disproportionate amount of its attention away from our day-to-day activities, which may adversely affect our management's ability to conduct our day-to-day operations. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- Significantly delay, scale back or discontinue the development or commercialization of tedizolid phosphate or our preclinical programs;
- Seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- Relinquish or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may not be able to maintain our collaboration and license agreement with Bayer and we will be prevented from pursuing discovery, development and commercialization efforts and our ability to generate revenues and achieve or sustain profitability will be substantially harmed. In addition, if the United States government stops funding our preclinical programs, we may not be able to continue our preclinical programs, and our business and prospects may be materially harmed.

To raise additional funds to support our business operations, we may sell additional equity or convertible debt securities, which would result in dilution to our stockholders, or incur indebtedness which could result in restrictive covenants that adversely impact the operation of our business.

The sale of additional equity or convertible debt securities would result in the issuance of additional shares of our capital stock and dilution to our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

The timing of the milestone and royalty payments we are required to make to Dong-A Pharmaceutical Co., Ltd., or Dong-A, is uncertain and could adversely affect our cash flows and results of operations.*

In January 2007, we entered into a license agreement with Dong-A pursuant to which we acquired an exclusive license to certain patent applications and other intellectual property related to the oral and injectable forms of tedizolid phosphate to develop and commercialize licensed products, including tedizolid phosphate, outside of Korea. In addition to milestone payments we have already made to Dong-A, we have an obligation to make up to an aggregate of $11.5 million in additional payments upon achievement of specified development and regulatory approval milestones. We are also required to pay Dong-A mid-single digit tiered royalties on net sales of tedizolid phosphate. The timing of our achievement of these events and corresponding milestone payments to Dong-A is subject to factors relating to the clinical and regulatory development and commercialization of tedizolid phosphate, many of which are beyond our control. We may become obligated to make a milestone payment when we do not have the cash on hand to make such payment, which could require us to delay our clinical trials, curtail our operations, scale back our planned commercialization and marketing efforts or seek funds to meet these obligations on terms unfavorable to us. In addition, if we are unable to make any payment to Dong-A when due or if we fail to use commercially reasonable efforts to achieve certain development and commercialization milestones within the timeframes required by our license agreement with Dong-A, Dong-A has the right to terminate the license agreement and all of our rights to develop and commercialize tedizolid phosphate upon 90 days written notice of our failure to make any such payment or to timely achieve the specified development and commercialization milestones.

The timing of the milestone and royalty payments we are entitled to receive from Bayer is uncertain and could adversely affect our cash flows and results of operations.*

The timing of the up to $58.1 million remaining that we are entitled to receive upon the achievement of certain milestones under our collaboration and license agreement with Bayer is inherently uncertain. The receipt of milestone payments under the Bayer collaboration and license agreement can have a significant impact on our cash flows and results of operations for the periods of time in which such payments are made. However, while receipt of milestone and royalty payments would result in significant income, the absence of collaboration revenues in

subsequent quarters could result in significant reductions in net income and could cause our stock price to drop.

Our limited operating history makes it difficult to evaluate our business and prospects.

We were incorporated in 2004. Our operations to date have been limited to organizing and staffing our company, conducting product development activities for tedizolid phosphate and performing research and development with respect to our preclinical programs. We have not yet demonstrated an ability to obtain regulatory approval for or commercialize a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

Risks Related to our Business

We are heavily dependent on the success of tedizolid phosphate, which is still under clinical development. We cannot assure you that we will obtain regulatory approval for tedizolid phosphate. If we fail to obtain regulatory approval for tedizolid phosphate, our business will be materially harmed.*

To date, we have not marketed, distributed or sold any products. Our near-term prospects are substantially dependent on our ability to develop and commercialize tedizolid phosphate. To date, we have completed one Phase 3 study, one Phase 2 study and thirteen Phase 1 studies of tedizolid phosphate. In October 2009, we completed our end of Phase 2 meeting with the FDA. Based on the feedback and guidance we received from the FDA as well as the SPA agreement we reached with the FDA on the protocol for our first Phase 3 clinical trial of tedizolid phosphate for the treatment of ABSSSI, we conducted our first Phase 3 clinical trial of tedizolid phosphate. We completed our first Phase 3 trial in ABSSSI and, in December 2011, announced the positive results on both the early endpoints used by the FDA and the post-treatment assessment used by the European Medicines Agency, or EMA. In addition, we obtained a SPA agreement for our second Phase 3 clinical trial of tedizolid phosphate in August 2011 and commenced enrollment in September 2011. If our second Phase 3 clinical trial of tedizolid phosphate is also successful, we plan to use both Phase 3 trials as a basis for our NDA and Marketing Authorization Application submissions, seeking approvals to commercialize the IV and oral dosage forms of tedizolid phosphate for the treatment of ABSSSI. Additional clinical safety and special population Phase 1 clinical trials necessary for registration are also being performed. We cannot commercialize tedizolid phosphate prior to obtaining FDA approval. However, tedizolid phosphate is susceptible to the risks of failure inherent at any stage of drug development, including the appearance of Adverse Events, or AEs, failure to maintain efficacy across a broad population of patients and the FDA's determination that a drug product is not approvable. We cannot assure you that our clinical trials for tedizolid phosphate will be completed timely or at all, or that we will be able to obtain FDA or EMA approvals for this product. If we are not able to commercialize tedizolid phosphate for ABSSSI or for any other indications, we will not be able to generate product revenues in the foreseeable future, or at all. Tedizolid phosphate is the only product candidate for which we have conducted clinical trials, and we cannot be certain that we will advance any other product candidates into clinical trials. As a company, we have never obtained regulatory approval for or commercialized a drug. It is possible that the FDA may refuse to accept our NDA for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval of tedizolid phosphate. If the FDA does not accept or approve our NDA, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit that data before it will reconsider our application. Depending on the extent of these or any other FDA required studies, approval of any NDA or application that we submit may be delayed by several years, or may require us to expend more resources than we have available. In addition, increased scrutiny by the United States Congress of the FDA's approval process, particularly in our areas of focus, may significantly delay or prevent regulatory approval, as well as impose more stringent product labeling and post-marketing testing and other requirements. Any delay in obtaining, or an inability to obtain, regulatory approvals would prevent us from commercializing tedizolid phosphate, generating revenues and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDA. If any of these outcomes occur, we may be forced to abandon our NDA for tedizolid phosphate, which would materially adversely affect our business and could potentially cause us to cease operations.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is highly uncertain. Failure can occur at any time during the clinical trial process due to inadequate performance of a drug or inadequate adherence by patients or investigators to clinical trial protocols, leading to poor data quality. The results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of later-stage clinical trials. For example, the positive results we have seen to date in our Phase 2 clinical trial of tedizolid phosphate in patients with complicated skin and skin structure infections, or cSSSI, and in our first Phase 3 clinical trial of the oral dosage form of tedizolid phosphate do not ensure that later clinical trials, such as our ongoing second Phase 3 study of the IV to oral transition therapy for the treatment of ABSSSI, will demonstrate similar results. Investigational drugs in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed satisfactorily through preclinical studies and initial clinical testing. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in Phase 3 studies, even after seeing promising results in earlier clinical trials. Despite the results reported in clinical trials for tedizolid phosphate so far, we do not know whether any upcoming Phase 3 or other clinical and nonclinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market tedizolid phosphate. In addition, based on our discussions and agreement with the FDA, the design of our ongoing and planned Phase 3 studies of tedizolid phosphate differ in certain ways from our Phase 2 study. Those design changes may lead to unexpected results in our Phase 3 studies.

The FDA regulatory approval process is lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for tedizolid phosphate, our business will be substantially harmed.

The time required to obtain approval for commercialization from the FDA and similar foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials, depending upon numerous factors. In addition, approval policies, regulations, or the type and amount of clinical data necessary to obtain regulatory approval may change during the course of a product's clinical development.

We may fail to obtain regulatory approval for tedizolid phosphate or any other product candidates for many reasons, including the following:

- We may not be able to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for any indication;
- The results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- The FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- We may not be able to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- We may not be able to demonstrate that a product candidate provides an advantage over current standard of care, future competitive therapies in development, or over placebo in any indications for which the FDA requires a placebo-controlled trial;
- The FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- The FDA or comparable foreign regulatory authorities may not accept data generated at our clinical trial sites;
- The data collected from clinical trials of any product candidates that we develop may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- The FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators enter into agreements for clinical and commercial supplies; and
- The approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market tedizolid phosphate or any future product candidates, which would significantly harm our business, results of operations and prospects.

We have previously applied to the FDA for Fast Track designation based on the results of our in vitro nonclinical data and Phase 1 study data from healthy volunteers. Fast track designation is a process designed to facilitate the development and expedite the review of drugs to treat serious diseases with an unmet medical need. The applications were denied as the FDA was unable to conclude based on the submitted data and our proposed development plan at that time whether tedizolid phosphate would meet an unmet medical need given that alternative therapies were available for cSSSI, including infections with MRSA as a pathogen. Based on future clinical trial data, or on other future data, we may consider submitting a new request for Fast Track designation. However, we cannot guarantee that we will ever receive Fast Track designation, or that tedizolid phosphate will qualify for other FDA programs for expediting the development, review or approval process.

Delays in clinical trials are common and have many causes, and any such delays could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales as currently contemplated.*

We may experience delays in clinical trials of our product candidates. To date, tedizolid phosphate has completed one Phase 3 study for the treatment of ABSSSI, and a second Phase 3 study is currently ongoing. The first patient was enrolled in our second Phase 3 study in September 2011. In parallel with the ongoing Phase 3 trial, we are conducting additional safety, pharmacology and special population clinical studies necessary for registration. If both of our Phase 3 studies are successful, we intend to use these trials as a basis to submit an NDA and EMA submission for the approval of the IV and oral dosage forms of tedizolid phosphate for the treatment of ABSSSI. We do not know whether our planned clinical trials will begin on time, need to be redesigned, enroll a sufficient number of patients or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including the following:

- Delays in obtaining regulatory approval to commence a trial;
- Delays in reaching agreement with the FDA on any SPAs we submit;
- Imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- Delays in reaching agreement on acceptable terms with prospective Clinical Research Organizations, or CROs, and clinical trial sites;
- Delays in obtaining required institutional review board approval at each clinical trial site;
- Delays in recruiting suitable patients to participate in a clinical trial;
- Delays in having patients complete participation in a trial or return for post-treatment follow-up;
- Clinical trial sites dropping out of a trial to the detriment of enrollment;

- Time required to add new sites;
- Delays in obtaining sufficient supplies of clinical trial materials; or
- Delays resulting from negative or equivocal findings of a data safety monitoring board, or DSMB, for a clinical trial.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, enrollment criteria imposed by the FDA, the proximity of patients to clinical sites, the eligibility criteria for participating in the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. For example, we could encounter delays in our clinical trials of tedizolid phosphate if participating physician investigators encounter unresolved ethical issues associated with enrolling patients in clinical trials of tedizolid phosphate in lieu of prescribing approved antibiotics that have established safety and efficacy profiles. In addition, because we are the first sponsor to enroll an ABSSSI Phase 3 study under new regulatory guidance, we do not have a reliable basis from which to project or otherwise predict enrollment rates or timing for our ongoing Phase 3 study. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. Any of these delays in completing our clinical trials could increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenues.

We may be required to suspend or discontinue clinical trials due to adverse side effects or other safety risks that could preclude approval of tedizolid phosphate or any of our future product candidates.

Our clinical trials may be suspended at any time for a number of reasons. A clinical trial may be suspended or terminated by us, our collaborators, the FDA or other regulatory authorities due to a failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, unforeseen safety issues including adverse side effects, failure to demonstrate a benefit from using the investigational drug, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or negative or equivocal findings of a DSMB, an Institutional Review Board or an Independent Ethics Committee for a clinical trial. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to participants. If we elect or are forced to suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues, if at all, from any of these product candidates will be delayed or eliminated. Any of these occurrences may harm our business, financial condition and prospects significantly.

To date, the drug-related adverse events experienced by patients while being treated with tedizolid phosphate were mostly mild or moderate side effects that included nausea, diarrhea, vomiting and headache. However, our ongoing Phase 3 and other future clinical trials will involve broader populations and could reveal a high prevalence or different severity of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Any of these occurrences may harm our business and prospects significantly.

The SPAs for our Phase 3 studies of tedizolid phosphate do not guarantee any particular outcome from regulatory review of our Phase 3 studies.*

The FDA's SPA process creates a written agreement between the sponsoring company and the FDA regarding clinical trial design and data analysis and other clinical trial issues that can be used to support approval of a product candidate. The SPA is intended to provide assurance that if the agreed upon clinical trial protocols are followed, the clinical trial endpoints are achieved, and there is a favorable risk-benefit profile, the data may serve as the primary basis for an efficacy claim in support of an NDA. However, SPA agreements are not a guarantee of an approval of a product candidate or any permissible claims about the product candidate. In particular, SPAs are not binding on the FDA if previously unrecognized public health concerns arise during the performance of the clinical trial, other new scientific developments regarding product candidate safety or efficacy arise or if the sponsoring company fails to comply with the agreed upon clinical trial protocols. We do not know how the FDA will interpret the commitments under the agreed upon SPAs, how it will interpret the data and results or whether it will approve tedizolid phosphate for the treatment of ABSSSI. In addition, although the FDA has provided us with feedback as to the adequacy of the proposed size of our safety population to support an NDA, it may, require us to conduct additional clinical trials. As a result, we cannot guarantee any particular outcome from regulatory review of these planned Phase 3 studies.

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be delayed in obtaining or ultimately not be able to obtain regulatory approval for or commercialize tedizolid phosphate or any other product candidates.

We have relied and plan to continue to rely upon CROs to monitor and manage data for our on-going clinical programs for tedizolid phosphate as well as the execution of our preclinical and nonclinical studies, and control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with the FDA's current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA for all of our products in clinical development. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials will require an

adequately large number of test subjects to evaluate the safety and effectiveness of tedizolid phosphate. Accordingly, if our CROs fail to comply with these regulations or recruit a sufficient number of patients, the FDA may require us to repeat clinical trials, which would delay the regulatory approval process. In addition, our CROs are not our employees, and we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize tedizolid phosphate or any other product candidates that we develop. As a result, our financial results and the commercial prospects for tedizolid phosphate and any other product candidates that we develop would be harmed, our costs could increase and our ability to generate revenues could be delayed.

We plan to maintain our relationships with existing CROs and enter into agreements with additional CROs to obtain additional resources and expertise in an attempt to accelerate our progress with regard to on-going clinical, nonclinical and preclinical programs and specifically, the compilation of clinical trial data for submission with an NDA for tedizolid phosphate. Switching or entering into new relationships with CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our operating results, financial condition or future prospects.

Our dependence upon third parties for the manufacture and supply of tedizolid phosphate and any future product candidates and products may cause delays in, or prevent us from, successfully developing and commercializing products.

We do not currently have nor do we plan to implement the infrastructure or capability internally to manufacture tedizolid phosphate for use in the conduct of our clinical trials. We employ the services of Albany Molecular Research, Inc., or AMRI, to produce tedizolid phosphate active pharmaceutical ingredient, or API, and Patheon Inc., or Patheon, to produce the solid oral and sterile IV tedizolid phosphate finished products. We have entered into clinical supply master services agreements with AMRI and Patheon for our short-term clinical supply needs, but we do not have long-term or commercial agreements for the supply of tedizolid phosphate or any future product candidates with AMRI, Patheon or any other third party.

With respect to the manufacturing for our commercial scale product, we intend to pursue long term agreements with our current manufacturers or transfer the manufacturing to other larger manufacturers. However, tedizolid phosphate is a new chemical entity that has never been produced at commercial scale, and, as such, there are underlying risks associated with its manufacture, which could include cost overruns, new impurities, difficulties in scaling up or reproducing manufacturing processes and lack of timely availability of raw materials. Any of these risks may prevent or delay us from successfully developing and commercializing tedizolid phosphate. If we are unable to arrange for third-party manufacturing sources, or do so on commercially reasonable terms, we may not be able to complete development of any product candidates or market them. Reliance on third-party manufacturers entails many risks, including regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us.

Our third-party manufacturers are required to comply with applicable FDA current good manufacturing practice, or cGMP, regulations. In addition, our manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our product candidates. We do not have control over our manufacturers' compliance with these regulations and standards. Failure by any of our manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market our product candidates, delays, suspensions or withdrawals of approvals, operating restrictions, and interruptions in supply and criminal prosecutions, any of which could significantly and adversely affect our business.

We could also experience manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates. If AMRI, Patheon or any alternate supplier of finished drug product, experiences any significant difficulties in its respective manufacturing processes for tedizolid phosphate API or finished drug product, we could experience significant interruptions in the supply of tedizolid phosphate. Our inability to coordinate the efforts of our third-party manufacturing partners, or the lack of capacity available at our third-party manufacturing partners, could impair our ability to supply tedizolid phosphate at the levels required for successful commercialization. If our current suppliers are unable or unwilling to perform under their agreements, we could experience significant interruptions in the supply of tedizolid phosphate because of the significant regulatory requirements that we would need to satisfy in order to qualify a new tedizolid phosphate API or finished drug product supplier.

If for any reason we are unable to use our currently available supply of tedizolid phosphate, the inability to acquire additional quantities of tedizolid phosphate in a timely manner from third parties could delay clinical trials of tedizolid phosphate or result in product shortages and prevent us from developing and commercializing tedizolid phosphate in a cost-effective manner or on a timely basis.

In addition, we do not currently have the capability to package tedizolid phosphate finished drug product for distribution to hospitals and other customers. Prior to commercial launch, we intend to enter into agreements for the commercial supply of tedizolid phosphate so that we can ensure proper supply chain management if and when we are authorized to make commercial sales of tedizolid phosphate. If we are unable to

enter into an agreement with a commercial supplier on satisfactory terms, or at all, our commercialization of tedizolid phosphate may be significantly delayed.

The failure to maintain our collaboration with Bayer or the failure of Bayer to perform its obligations under this collaboration, could negatively impact our business.*

Pursuant to the terms of our collaboration and license agreement with Bayer, we granted to Bayer exclusive rights to develop and commercialize tedizolid phosphate in the Bayer Licensed Territory. Consequently, our ability to generate any revenues from tedizolid phosphate in the Bayer Licensed Territory depends on our ability to maintain our collaboration with Bayer and Bayer's ability to obtain regulatory approvals for and to successfully commercialize tedizolid phosphate in the Bayer Licensed Territory. We have limited control over the amount and timing of resources that Bayer will dedicate to these efforts.

We are subject to a number of other risks associated with our collaboration and license agreement with Bayer, including:

- Bayer has the right to terminate the Agreement within 30 days of determining that our second Phase 3 ABSSSI study has not been completed successfully or of becoming aware of any material toxicity and/or material drug safety event or issue concerning tedizolid.
- Bayer may not comply with applicable regulatory guidelines with respect to developing or commercializing tedizolid phosphate, which could adversely impact future development or sales of tedizolid phosphate in the Bayer Licensed Territory and elsewhere;
- We and Bayer could disagree as to current or future development plans for tedizolid phosphate for the treatment of ABSSSI or pneumonia and Bayer may delay clinical trials or stop a clinical trial;
- There may be disputes between us and Bayer, including disagreements regarding the collaboration and license agreement, that may result in (1) the delay of or failure to achieve regulatory and commercial objectives that would result in milestone or royalty payments, (2) the delay or termination of any future development or commercialization of tedizolid phosphate for the treatment of ABSSSI or pneumonia, and/or (3) costly litigation or arbitration that diverts our management's attention and resources;
- Bayer may not provide us with timely and accurate information regarding supply forecasts, which could adversely impact our ability to comply with our supply obligations to Bayer and manage our own inventory of tedizolid phosphate, as well as our ability to generate accurate financial forecasts;
- Business combinations or significant changes in Bayer's business strategy may adversely affect Bayer's ability or willingness to perform its obligations under our collaboration agreement;
- Inability to raise additional capital in sufficient amounts or on terms acceptable to us, business combinations or significant changes in our business strategy may adversely affect our ability or willingness to perform our obligations under our collaboration agreement;
- The royalties we are eligible to receive from Bayer may be reduced or eliminated based upon Bayer's and our ability to maintain or defend our intellectual property rights and the presence of generic competitors in the Bayer Licensed Territory;
- Limitations on our or an acquirer's ability to maintain or pursue development or commercialization of products that are competitive with tedizolid phosphate could deter a potential acquisition of us that our stockholders may otherwise view as beneficial; and
- If Bayer is unsuccessful in obtaining regulatory approvals for or commercializing tedizolid phosphate in the Bayer Licensed Territory, we may not receive certain additional milestone payments or any royalty payments under the collaboration and license agreement and our business prospects and financial results may be materially harmed.

The collaboration and license agreement is subject to early termination, including through Bayer's right to terminate without cause upon advance notice to us. If the agreement is terminated early, we may not be able to find another collaborator for the further development and commercialization of tedizolid phosphate in the Bayer Licensed Territory on acceptable terms, or at all, and we may be unable to pursue continued development and commercialization of tedizolid phosphate in the Bayer Licensed Territory on our own.

We may enter into additional collaboration and license agreements for the development and commercialization of tedizolid phosphate or other of our drug candidates, and may be similarly dependent on the performance of third parties with similar risk.

Other than our collaboration and license agreement with Bayer, we may not be able to enter into acceptable agreements to develop and commercialize tedizolid phosphate or, if needed, adequately build our own marketing and sales capabilities.

We intend to pursue the development and commercialization of tedizolid phosphate through collaboration and license arrangements with third parties, such as our collaboration and license agreement with Bayer. We may be unable to enter into additional collaboration and license arrangements outside of the Bayer Licensed Territory. In addition, there can be no guarantee that Bayer or any other parties that we may enter into collaboration and license arrangements with will be successful or generate more revenues than we could obtain by developing and commercializing tedizolid phosphate on our own. If we are unable to enter into additional collaboration and license arrangements for tedizolid phosphate or develop an effective international sales force, our ability to generate product revenues would be limited, which would adversely affect our business, financial condition, results of operations and prospects. If we are unable to enter into such collaboration arrangements for development of tedizolid phosphate in areas outside of the Bayer Licensed Territory, we may need to develop our own marketing and sales force to market tedizolid phosphate in these territories, for which currently we do not have sufficient funds to develop an adequate sales force in these regions. There is no guarantee that we will be able to develop an effective international sales force to successfully commercialize tedizolid phosphate or any other future products in these markets. If we cannot commercialize tedizolid phosphate in any territory that represents a significant market opportunity, our ability to achieve and sustain profitability will be substantially limited.

If the FDA does not approve the manufacturing facilities of AMRI, Patheon or any future manufacturing partners for commercial production, we may not be able to commercialize tedizolid phosphate.

After we submit our NDA to the FDA and before approval of tedizolid phosphate, the facilities used by AMRI, Patheon and any of our future manufacturers to manufacture tedizolid phosphate must be approved by the FDA. We do not control the manufacturing process of tedizolid phosphate and are completely dependent on these third-party manufacturing partners for compliance with the FDA's requirements for manufacture of tedizolid phosphate API and finished product. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's strict regulatory requirements, they will not be able to secure FDA approval for their manufacturing facilities. If the FDA does not approve these facilities for the commercial manufacture of tedizolid phosphate, we may need to find alternative manufacturing facilities, which would result in significant delays of up to several years in obtaining FDA approval for tedizolid phosphate.

If approved, tedizolid phosphate will face competition from less expensive generic versions of branded antibiotics of competitors and, if we are unable to differentiate the benefits of tedizolid phosphate over these less expensive alternatives, we may never generate meaningful product revenues.

Generic antibiotic therapies are typically sold at lower prices than branded antibiotics and are generally preferred by hospital formularies and managed care providers of health services. We anticipate that, if approved, tedizolid phosphate will face increasing competition in the form of generic versions of branded products of competitors that have lost or will lose their patent exclusivity. For example, tedizolid phosphate, if approved, will initially face competition from the inexpensive generic forms of vancomycin that are currently available and, in the future, would face additional competition from a generic form of linezolid when the patents covering it are expected to expire in 2015, or earlier if the patents are successfully challenged. If we are unable to demonstrate to physicians and payers that the key differentiating features of tedizolid phosphate translate to overall clinical benefit or lower cost of care, we may not be able to compete with generic antibiotics.

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies and universities and other research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and drug products that are more effective or less costly than tedizolid phosphate or any other drug candidate that we are currently developing or that we may develop, which could render our products obsolete and noncompetitive.

The competition in the market for antibiotics is intense. If approved, tedizolid phosphate will face competition from commercially available antibiotics such as vancomycin, marketed as a generic by Abbott Laboratories and others; daptomycin, marketed by Cubist Pharmaceuticals, Inc. as Cubicin; linezolid, marketed by Pfizer Inc. as Zyvox; ceftaroline, marketed by Forest Laboratories, Inc. and AstraZeneca PLC as Teflaro; ceftobiprole, under development by Basilea Pharmaceutica AG; quinupristin/dalfopristin, marketed by King Pharmaceuticals, Inc, a subsidiary of Pfizer, as Synercid; tigecycline, marketed by Wyeth, a subsidiary of Pfizer, as Tygacil; and telavancin, marketed by Theravance, Inc. as Vibativ. Vancomycin has been a widely used and well known antibiotic for over 40 years and is sold in a relatively inexpensive generic IV form. Vancomycin, daptomycin, linezolid, telavancin, tigecycline, quinupristin/dalfopristin and ceftaroline are all approved treatments for serious gram-positive infections such as cSSSI or ABSSSI. Additionally, daptomycin is an approved treatment for bacteremia, linezolid is an approved treatment for pneumonia and vancomycin is an approved treatment for both bacteremia and pneumonia. If we are unable to obtain regulatory approval of tedizolid phosphate for some or all of the indications for which our competitors are approved, we may not be able to compete effectively with such antibiotics. In addition, if approved, tedizolid phosphate may face additional competition from antibiotics currently in clinical development. Other antibiotics currently in development include CEM-102, under development by Cempra Pharmaceuticals, Inc., dalbavancin, under development by Durata Therapeutics, Inc., delafloxacin and radezolid, both under development by Rib-X Pharmaceuticals, Inc., NXL-103, under development by AstraZeneca PLC, oritavancin, under development by The Medicines Company, PTK 0796, under development by Paratek Pharmaceuticals, Inc., BC-3781, under development by Nabrivia, PMX-30063, under development by Polymedix, GSK1322322, under development by GlaxoSmithKlein, AFN-1252, under development by Affinium Pharmaceuticals, Inc. and JNJ-Q2, under development by Furiex Pharmaceuticals, Inc., which, if approved, would compete in the antibiotic market and would target indications such as ABSSSI. In addition, tedizolid phosphate may face competition from drug candidates currently in clinical development and drug candidates that could receive regulatory approval before tedizolid phosphate in countries outside the United States and the European Union, or EU. If we are unable to demonstrate the advantages of tedizolid phosphate over competing drugs and drug candidates, we will not be able to successfully commercialize tedizolid phosphate and our results of operations will suffer.

Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make tedizolid phosphate or any other product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing antibiotics before we do.

Reimbursement may not be available for tedizolid phosphate or any other product candidates that we develop, which could make it difficult for us to sell our products profitably.

Market acceptance and sales of tedizolid phosphate or any other product candidates that we develop will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities, hospital formularies and third-party payers, such as private

health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that reimbursement will be available for tedizolid phosphate or any other product candidates that we develop. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. In addition, third-party payers may implement prior authorizations which may lead to a decrease in sales of our future products. If reimbursement is not available or is available only to limited levels or extensive prior authorizations are introduced, we may not be able to successfully commercialize tedizolid phosphate or any other product candidates that we develop.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation established Medicare Part D, which expanded Medicare coverage for outpatient prescription drug purchases by the elderly but provided authority for limiting the number of drugs that will be covered in any therapeutic class. The MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs.

In March 2010, the Patient Protection and Affordable Care Act, or PPACA, became law. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of PPACA of greatest importance to the pharmaceutical industry are the following:

- An annual, nondeductible fee on the prescription drug and biologics industry, apportioned among manufacturers according to their market share in certain government health care programs;
- An increase in the rebates a manufacturer must pay to state Medicaid programs on utilization of the manufacturer's products;
- A new program, funded primarily by manufacturers, to provide discounts on pharmacy prescription prices to Medicare Part D beneficiaries in the program's coverage gap;
- Expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- New requirements to report certain financial arrangements with physicians;
- A licensure framework for follow-on biologic products; and
- A new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical research.

We anticipate that this legislation will result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payers.

The availability of numerous generic antibiotics at lower prices than branded antibiotics, such as tedizolid phosphate if it were approved for commercial introduction, may also substantially reduce the likelihood of reimbursement for tedizolid phosphate. We expect to experience pricing pressures in connection with the sale of tedizolid phosphate and any other products that we develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

The commercial success of tedizolid phosphate and any other product candidates that we develop, if approved in the future, will depend upon attaining significant market acceptance of these products among physicians and payers.

We have never commercialized a product candidate for any indication. Even if tedizolid phosphate or any other product candidates that we develop are approved by the appropriate regulatory authorities for marketing and sale, physicians may not prescribe our approved products, which would prevent us from generating revenues or becoming profitable. Market acceptance of tedizolid phosphate and any other product candidates that we develop by physicians and payers will depend on a number of factors, many of which are beyond our control, including:

- The clinical indications for which the product is approved;
- Acceptance by physicians and payers of each product as a safe and effective treatment;
- The cost of treatment in relation to alternative treatments, including numerous generic drug products, such as vancomycin;
- The relative convenience, ease of administration and acceptance by physicians and payers of tedizolid phosphate in the treatment of ABSSSI;
- The availability and efficacy of competitive drugs;
- The extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- The extent to which bacteria develop resistance to any antibiotic product candidates that we develop, thereby limiting its efficacy in treating or managing infections;
- Whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular infections;
- The availability of adequate reimbursement by third parties, such as insurance companies and other healthcare payers, and/or by government healthcare programs, including Medicare and Medicaid;

- Limitations or warnings contained in a product's FDA-approved labeling;
- Prevalence and severity of adverse side effects; and
- The ability to develop convincing health economics and outcomes research

Even if the medical community accepts that tedizolid phosphate is safe and efficacious for its approved indications, physicians may not immediately be receptive to the use of tedizolid phosphate or may be slow to adopt it as an accepted treatment for ABSSSI. In addition, even though we believe tedizolid phosphate has significant advantages, we cannot assure you that any labeling approved by the FDA will contain claims that tedizolid phosphate is safer or more effective than linezolid, or that will permit us to promote tedizolid phosphate as being superior to competing products. Moreover, in the future, as has happened with other antibiotics, bacteria could over time develop resistance to tedizolid phosphate, particularly if it becomes widely used, which would render it less effective and therefore less appealing to physicians. If tedizolid phosphate is approved but does not achieve an adequate level of acceptance by physicians and payers, we may not generate sufficient or any revenues from this product candidate and we may not become profitable. In addition, our efforts to educate the medical community and third-party payers on the benefits of tedizolid phosphate may require significant resources and may never be successful.

We currently have limited marketing capabilities and no sales organization and have no experience in marketing drug products. If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our products after they are approved, we may not be able to generate product revenues.

We currently have limited marketing capabilities and do not have a sales organization or distribution capabilities. In order to commercialize any products, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. Outside of Korea and the Bayer Licensed Territory, we own exclusive rights to commercialize tedizolid phosphate worldwide, and we contemplate establishing our own sales force or seeking third-party partners to sell tedizolid phosphate in the United States and, in addition to our collaboration and license agreement with Bayer, will seek third-party partners outside the United States. We have partnered with Bayer in the Bayer Licensed Territory and will be reliant on them to develop and commercialize tedizolid phosphate in the Bayer Licensed Territory. The establishment and development of our own sales force to market any products we may develop will be expensive and time consuming and could delay any product launch, and we cannot be certain that we will be able to successfully develop this capability. We, Bayer for the Bayer Licensed Territory and any potential future third-party commercialization partners will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

In addition, we may not be able to enter into collaboration and license arrangements with third parties to sell tedizolid phosphate in Europe on favorable terms or at all. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenue would be limited as a significant portion of the market opportunity for tedizolid phosphate and any other product candidates we develop is likely to be in international markets. To the extent we rely on third parties to commercialize our approved products whether within or outside the United States, we will receive less revenues than if we commercialized these products ourselves. In international markets in particular, we would have little or no control over the sales efforts of any other third parties involved in our commercialization efforts. In the event we are unable to develop our own marketing and sales force or collaborate with a third-party marketing and sales organization, we would not be able to commercialize tedizolid phosphate or any other product candidates that we develop, which would negatively impact our ability to generate product revenues.

Even if the FDA approves tedizolid phosphate for treatment of ABSSSI, adverse effects discovered after approval could limit the commercial profile of any approved label.

If we obtain regulatory approval for tedizolid phosphate or any other product candidate that we develop, and we or others later discover, after approval and use in an increasing number of patients for longer periods of time, that our products could have adverse effect profiles that limit their usefulness or require their withdrawal (whether or not the therapies showed the adverse effect profile in Phase 1 through Phase 3 clinical trials), a number of potentially significant negative consequences could result, including:

- Regulatory authorities may withdraw their approval of the product;
- Regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- We may be required to change the way the product is administered, conduct additional clinical studies, implement a burdensome risk evaluation and mitigation strategy, or REMS, or restrict the distribution of the product;
- We could be sued and held liable for harm caused to patients; and
- Our reputation may suffer.

Any of these events could prevent us from maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

If we are not successful in attracting and retaining highly qualified personnel, including our current senior executive team, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends in large part upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our executive team. In order to

induce these and other valuable employees to remain with us, we have provided stock options that vest over time. The value to employees of stock options is significantly affected by movements in our stock price that we cannot control and may at any time be insufficient to counteract more lucrative offers from other companies.

Our scientific team has expertise in many different aspects of drug discovery and development. We conduct our operations at our facility in San Diego, California. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions and, as a result, competition for skilled personnel in our market is very intense and competition for experienced research scientists and development personnel may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

Despite our efforts to retain valuable employees, members of our management, scientific and medical teams may terminate their employment with us on short notice. While we have employment agreements with all of our employees, these employment arrangements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results or financial condition. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

Other biotechnology and pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can discover, develop and commercialize drug candidates will be limited.

We will need to grow our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.*

As of November 1, 2012, we employed 88 full-time employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize tedizolid phosphate and our other product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

If we fail to develop tedizolid phosphate for additional indications, our commercial opportunity will be limited.*

To date, we have focused primarily on the development of tedizolid phosphate for the treatment of ABSSSI. A key element of our strategy is to pursue clinical development of tedizolid phosphate for pneumonia and potentially for other indications, including bacteremia. Although we believe there is large commercial opportunity for the treatment of ABSSSI alone, our ability to generate and grow revenues will be highly dependent on our ability to successfully develop and commercialize tedizolid phosphate for the treatment of these additional indications. The development of tedizolid phosphate for these additional indications is prone to the risks of failure inherent in drug development and we cannot provide you any assurance that we will be able to successfully advance any of these programs through the development process. Even if we receive FDA approval to market tedizolid phosphate for the treatment of any of these additional indications, we cannot assure you that any such additional indications will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize tedizolid phosphate for these additional indications, our commercial opportunity will be limited and our business prospects will suffer.

Even if we obtain FDA approval of tedizolid phosphate or any other product candidate we develop, we or Bayer may never obtain approval or commercialize our products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we and Bayer in the Bayer Licensed Territory must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our or Bayer's failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we or Bayer fail to comply with regulatory requirements in our international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

If we fail to develop and commercialize product candidates other than tedizolid phosphate, we may not be able to grow our business or sustain profitability.*

A key element of our strategy is to develop and commercialize a portfolio of new product candidates in addition to tedizolid phosphate. As

a significant part of this strategy, we intend to develop and commercialize additional products and product candidates through our proprietary drug discovery platform. The success of this strategy depends upon our ability to leverage this platform to identify optimal bacterial targets and subsequently design small molecule inhibitors against these targets leading to the development of differentiated new antibiotics.

We cannot be certain that we will be successful in our efforts to identify and develop additional differentiated new antibiotics or that any of our product candidates we do identify will produce commercially viable drugs that safely and effectively treat infectious diseases or other diseases. To date, our proprietary discovery platform has yielded certain candidates that are advancing into IND enabling studies. While these candidates hold significant promise in treating serious infections, they might fail to advance to clinical development or might fail in clinical trials to show the desirable pharmacokinetics, safety and efficacy needed to advance to a product. In addition, research and discovery programs to identify new disease targets and product candidates require substantial technical, financial and human resources whether or not we ultimately identify any candidates. To date, our discovery programs have been largely funded by United States government grants and research contracts. If we are unable to maintain existing funding or secure additional funding for these programs and/or continue to devote the other technical and human resources to them, our ability to continue these programs will be adversely affected.

Any product candidate we do successfully identify may require substantial additional development efforts prior to commercial sale, including preclinical studies, extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are susceptible to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives.

If we are unable to develop suitable potential product candidates through internal research and discovery programs or otherwise by obtaining rights to novel therapeutics from third parties, our business and prospects will suffer.

A variety of risks associated with our international business relationships could materially adversely affect our business.

We have entered into a collaboration and license agreement with Bayer in the Bayer Licensed Territory and intend to enter into other agreements with third parties who will market tedizolid phosphate in Europe. Consequently, we expect that we will be subject to additional risks related to entering into international business relationships, including:

- Differing regulatory requirements for drug approvals in foreign countries;
- Potentially reduced protection for intellectual property rights;
- The potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- Unexpected changes in tariffs, trade barriers and regulatory requirements;
- Economic weakness, including inflation, or political instability in particular foreign economies and markets;
- Compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- Foreign taxes, including withholding of payroll taxes;
- Foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- Workforce uncertainty in countries where labor unrest is more common than in the United States;
- Production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- Business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

These and other risks may materially adversely affect our ability to attain or sustain profitable operations.

Risks Related to Our Industry

We are subject to extensive and costly government regulation.

Antibiotics, including those we are developing and plan to develop in the future, are subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the United States Department of Health and Human Services, the United States Department of Justice, state and local governments and their respective foreign equivalents. The FDA regulates the research, development, preclinical and clinical testing, manufacture, safety, effectiveness, record-keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import and export of biopharmaceutical products. If any products we or our partners develop are tested or marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not we have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding United States regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing and selling the products that we are developing.

New and future legislation, and/or regulations and policies adopted by the FDA or other regulatory health authorities, in addition to findings in ongoing and future clinical and nonclinical studies, may increase the time and cost required for us to conduct and complete

clinical trials for tedizolid phosphate or other product candidates that we develop.*

The FDA revised its existing guidance for industry entitled, “Uncomplicated and Complicated Skin and Skin Structure Infections—Developing Antimicrobial Drugs for Treatment” (Final July 1998) and issued “Guidance for Industry Acute Bacterial Skin and Skin Structure Infections: Developing Drugs for Treatment (Draft August 2010). It is not known when the FDA will issue its final guidance on ABSSSI. In addition in March 2010, the FDA released a draft guidance entitled “Guidance for Industry Non-Inferiority Clinical Trials.” This guidance document is relevant to our Phase 3 clinical program because our Phase 3 clinical trials use a non-inferiority trial design. It is not known when the FDA will issue a final guidance document or whether the final guidance will differ significantly from the draft guidance. In January 2012, the EMA issued its finalized revision to the “Guideline on the Evaluation of Medicinal Products Indicated for the Treatment of Bacterial Infections.” In July 2012, the EMA issued a draft addendum to the Note for Guidance on Evaluation of New Anti-bacterial Medicinal Product that addresses indication specific guidance. The timing for the issuance of the EMA finalized addendum, as well as its contents, is not known. In November 2010, the FDA issued draft guidance entitled “Guidance for Industry Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment.” It is not known when the FDA will issue final HAP guidance.

Along with the information in the draft guidance for ABSSSI, we have received input from the FDA regarding specific changes that are being contemplated. Based on this input, we know that the enrollment criteria for patients in our Phase 3 clinical trials for treatment of ABSSSI are different than those that were applicable under the July 1998 guidance regarding cSSSI. As a result, we need to enroll patients with a different proportion of infection types than we enrolled in our completed Phase 2 clinical trial for the treatment of cSSSI. In addition, the draft guidance recommends a change in the time at which the clinical cure is tested relative to the end of antibiotic therapy. As part of the SPA procedure, we have reached agreement with the FDA on the appropriate endpoints.

While we have received information from the FDA regarding certain aspects that have been incorporated into the draft guidance, we will not know the potential impact that any finalized guidance, should it be issued, may have on the design and conduct of our planned Phase 3 clinical trials and supportive studies or on the FDA’s approval of ABSSSI as the indication for which we are seeking approval, which could potentially significantly increase the time and cost required for us to conduct and complete these trials if size and scope were to be modified. Additionally, changes in regulatory requirements due to the adoption by FDA and/or foreign health authorities of new legislation, regulation, or policies may require us to amend clinical trial protocols or add new clinical trials to comply with these changes. Such amendments to existing protocols and/or clinical trial applications or the need for new ones, may impact the cost, timing and completion of the clinical trials.

Even if we obtain regulatory approval for tedizolid phosphate or any of our future product candidates, we will still face extensive regulatory requirements and our products may face future development and regulatory difficulties.

Even if regulatory approval in the United States is obtained, the FDA may still impose significant restrictions on a product’s indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the labeling ultimately approved for tedizolid phosphate, if any, may include restrictions on use. Tedizolid phosphate or any of our other product candidates will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is subject to obligations to monitor and report AEs and instances of the failure of a product to meet the specifications in the NDA. Application holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials. New legal requirements have also been enacted to require disclosure of clinical trial results on publicly available databases.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices regulations. If we or a regulatory agency discovers problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. The FDA and other regulatory authorities may also revisit the risk-benefit profile of an approved product if, for example, previously unknown problems with a product, such as AEs of unanticipated severity of frequency arise. In such circumstances, the FDA or other regulatory authorities may withdraw approval, require new warnings or other labeling changes to limit use of the drug, impose new study or monitoring requirements or require that we establish a REMS. Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws. Our relationships with healthcare providers will be subject to federal and state requirements prohibiting or requiring the disclosure of payments or items of value given to potential prescribers of our products. For example, as part of PPACA, pharmaceutical manufacturers must report certain gifts and payments to physicians beginning in 2013. These reports will then be placed on a public database. Failure to so report could subject companies to significant financial penalties.

The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veteran’s Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. If we or Bayer fail to comply with applicable regulatory requirements, a regulatory agency may:

- Issue warning letters or untitled letters asserting that we are in violation of the law;
- Seek an injunction or impose civil or criminal penalties or monetary fines;
- Suspend or withdraw regulatory approval;

- Suspend any ongoing clinical trials;

- Refuse to approve pending applications or supplements to applications filed by us;
- Suspend or impose restrictions on operations, including costly new manufacturing requirements;
- Seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall; or
- Refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenues.

Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our products.

The risk that we may be sued on product liability claims is inherent in the development of pharmaceutical products. Our products and the clinical trials using our product candidates may expose us to product liability claims and possible adverse publicity. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further development and commercialization of those products.

Although we maintain general liability and product liability insurance with limits of $2 million and $10 million, respectively, this insurance may not fully cover potential liabilities. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. In addition, inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the development and commercial production and sale of our products, which could adversely affect our business, operating results and financial condition.

If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials and viruses. In addition, our operations produce hazardous waste products. Federal, state and local laws and regulations in the United States govern the use, manufacture, storage, handling and disposal of hazardous materials. Although we believe that our procedures for use, handling, storing and disposing of these materials comply with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. We also cannot predict the impact on our business of new or amended environmental laws or regulations, or any changes in the way existing and future laws and regulations are interpreted or enforced. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. If we fail to comply with applicable requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs, or capital expenditures for control equipment or operational changes necessary to achieve or maintain compliance. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, operating results and financial condition.

Risks Related to our Intellectual Property

Our ability to pursue the development and commercialization of tedizolid phosphate depends upon the continuation of our license from Dong-A.

Our license agreement with Dong-A provides us with a worldwide exclusive license to develop and sell tedizolid phosphate outside of Korea. If we are unable to make the required milestone and royalty payments under the license agreement, if we do not continue to use commercially reasonable efforts to achieve certain development and commercialization milestones for tedizolid phosphate within the timeframes required by the license agreement or if we otherwise materially breach the license agreement, our rights to develop and commercialize tedizolid phosphate would terminate and revert to Dong-A. In addition, either we or Dong-A may terminate the license agreement upon an uncured material breach of the license agreement for 90 days. If our license agreement with Dong-A were terminated, we would lose our rights to develop and commercialize tedizolid phosphate, which would materially and adversely affect our business, results of operations and future prospects.

If our efforts to protect the proprietary nature of the intellectual property related to tedizolid phosphate and our other product candidates are not adequate, we may not be able to compete effectively in our market.*

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to tedizolid phosphate and our other product candidates. Any involuntary disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain and our commercial success will depend on our ability to obtain patents and maintain adequate protection for tedizolid phosphate and other product candidates in the United States and other countries. Through our license agreement with Dong-A, we currently license an issued United

States utility patent, a pending United States utility patent application and issued and pending foreign national and regional counterpart patent applications covering various aspects of tedizolid and tedizolid phosphate. In addition, we own pending United States utility patent applications and pending foreign national and regional counterpart patent applications directed to aspects of tedizolid phosphate discovered by our scientists. The patent applications that we licensed or have filed on our own may fail to result in issued patents in the United States or in foreign countries. Even if the patents do successfully issue, third parties may challenge the patents. Further, the future patents to which we have rights based on our

agreement with Dong-A, or that we file on our own, may be too narrow to prevent third parties from developing or designing around these patents. If the sufficiency of the breadth or strength of protection provided by the patent applications we licensed or own with respect to tedizolid phosphate or the patents we pursue related to any of our other product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, tedizolid phosphate and our other product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our drug candidates under patent protection would be reduced. In addition, we do not know whether:

- We or Dong-A were the first to make the inventions covered by each of our pending or issued patent applications or our licensed pending or issued patent applications;
- We or Dong-A were the first to file patent applications for these inventions;
- Others will independently develop similar or alternative technologies or duplicate any of our technologies;
- Any of our or Dong-A's pending patent applications will result in issued patents;
- Any of our or Dong-A's patents, once issued, will be valid or enforceable;
- Any patents issued to us or Dong-A will provide us with any competitive advantages, or will be challenged by third parties;
- We will develop additional proprietary technologies that are patentable;
- The patents of others will have an adverse effect on our business; or
- Our unissued patents in the Bayer Licensed Territory will ever issue, and if they do not issue, this could adversely affect our collaboration and license agreement with Bayer.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our drug discovery program that involve proprietary know-how, information and technology that is not covered by patents. Although we require all of our employees, consultants, advisors and third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law and includes a number of significant changes to U.S. patent law. These include changes in the way patent applications will be prosecuted and may also affect patent litigation. The U.S. Patent and Trademark Office is currently developing regulations and procedures to administer the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the cost of prosecuting our patent applications, our ability to obtain patents based on our patent applications and our ability to enforce or defend our issued patents. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or, if established, maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the United States Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm, Computer Patent Annuities, to pay these fees due to foreign patent agencies. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

We have not yet registered our trademarks in all of our potential markets, and failure to secure those registrations could adversely affect our business.

The TRIUS THERAPEUTICS mark has been registered in the United States, Canada, Australia, European Community, India, Japan, China, New Zealand and Singapore for use in connection with pharmaceutical research and development services and for anti-infective and antibacterial pharmaceutical preparations for the treatment of infections. We are not aware of any third party opposition or cancellation proceedings against the TRIUS THERAPEUTICS mark.

Third-party claims of intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents with claims to materials,

methods of manufacture or methods for treatment related to the use or manufacture of tedizolid phosphate and/or our other product candidates. Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. If any third-party patents were held by a court of competent jurisdiction to cover the tedizolid phosphate manufacturing process, any molecules formed during the tedizolid phosphate manufacturing process or the final tedizolid phosphate product for any use thereof, the holders of any such patents may be able to block our ability to commercialize tedizolid phosphate unless we obtained a license under the applicable patent or patents, or until such patents expire. We cannot predict whether we would be able to obtain a license on commercially reasonable terms, if at all. Any inability to obtain such a license under the applicable patents on commercially reasonable terms, or at all, may have a material adverse effect on our ability to commercialize tedizolid phosphate until such patents expire.

In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Furthermore, parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties. In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of tedizolid phosphate or any of our other product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would not be able to further develop and commercialize such product candidates, which could harm our business significantly.

We may be required to file lawsuits or take other actions to protect or enforce our patents or the patents of our licensors, which could be expensive and time consuming.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents, or those of Dong-A, do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents, or those of Dong-A, at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications, or those of Dong-A, at risk of not issuing.

Interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management. We may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Issued patents may be challenged during reexamination proceedings brought by a third party or the USPTO, or in foreign countries, during post-grant opposition proceedings or invalidation appeal proceedings. These proceedings may result in loss of patent claims, adverse changes to the scope of the claims and may result in substantial costs and distract our management.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, if securities analysts or investors perceive public announcements of the results of hearings, motions or other interim proceedings or developments to be negative, the price of our common stock could drop.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our United States Government Contracts and Grants

All of our immediately foreseeable future contract research revenues to support our ongoing preclinical programs are dependent upon our NIAID and LLNL contracts and if we do not receive all of the funds under these contracts or are unable to generate additional revenues from additional contracts, we may be forced to suspend or terminate one or more of our preclinical programs.*

Substantially all of our contract research revenues that support our preclinical programs have been derived from United States government grants and our government contracts. There can be no assurances that our contracts will continue or that we will be able to enter into new contracts with the United States government to support our preclinical programs. The process of obtaining government contracts is lengthy and uncertain and we will have to compete with other companies and institutions for each contract. Further, changes in government budgets and agendas may result in a decreased and de-prioritized emphasis on supporting the discovery and development of biodefense products in our preclinical programs. In such event, NIAID and LLNL may not be required to continue funding our existing contracts. In May 2012, DTRA notified us that, due to programmatic priorities toward later stage programs, it elected not to exercise its option to extend funding under the four and one-half-year federal contract with us for the development of novel antibiotics directed against gram-negative bacterial pathogens, and therefore, the contract was not extended beyond July 20, 2012. As a result, we discontinued our marine natural products discovery program,

which was solely funded by the DTRA contract.

Due to the decline of federal tax receipts and substantial increase in the federal deficit, the United States government may be forced or choose to reduce or delay spending in the biodefense field, which could decrease the likelihood of our receipt of future government contract revenues.

United States government agencies have special contracting requirements that give them the ability to unilaterally control our contracts.*

United States government contracts typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, which will subject us to additional risks. These risks include the ability of the United States government to unilaterally:

- Audit and object to our NIAID, DTRA or LLNL contract-related costs and fees, and require us to reimburse all such costs and fees;
- Suspend or prevent us for a set period of time from receiving new contracts or extending our existing contracts based on violations or suspected violations of laws or regulations;
- Cancel, terminate or suspend our contracts based on violations or suspected violations of laws or regulations;
- Terminate our contracts if in the government's best interest, including if funds become unavailable to the applicable governmental agency;
- Reduce the scope and value of our contracts; and
- Change certain terms and conditions in our contracts.

The United States government will be able to terminate each of its contracts with us, either for its best interests or if we default by failing to perform in accordance with or to achieve the milestones set forth in the contract schedules and terms. Termination-for-convenience provisions generally enable us to recover only our costs incurred or committed and settlement expenses on the work completed prior to termination. In May 2012, DTRA notified us that, due to programmatic priorities toward later stage programs, it elected not to exercise its option to extend funding under the four and one-half-year federal contract with us for the development of novel antibiotics directed against gram-negative bacterial pathogens, and as a result, the contract was not extended beyond July 20, 2012. Except for the amount of services received by the government, termination-for-default provisions do not permit these recoveries and would make us liable for excess costs incurred by the United States government in procuring undelivered items from another source.

The United States government's determination to award any contracts may be challenged by an interested party, such as another bidder, at the United States Government Accountability Office, or the GAO or in federal court. If such a challenge is successful, our NIAID or LLNL contracts or any future contract we may be awarded may be terminated.*

The laws and regulations governing the procurement of goods and services by the United States government provide procedures by which other bidders and interested parties may challenge the award of a government contract. If we are awarded a government contract, such challenges or protests could be filed even if there are not any valid legal grounds on which to base the protest. If any such protests are filed, the government agency may decide to suspend our performance under the contract while such protests are being considered by the GAO or the applicable federal court, thus potentially delaying delivery of payment. In addition, we could be forced to expend considerable funds to defend any potential award. If a protest is successful, the government may be ordered to terminate any one or more of our contracts and reselect bids. The government agencies with which we have contracts could even be directed to award a potential contract to one of the other bidders.

Our business is subject to audit by the United States government, including under our contracts with NIAID, DTRA and LLNL, and a negative audit could adversely affect our business.*

United States government agencies such as the Department of Health and Human Services, or DHHS, the Defense Contract Audit Agency, or the DCAA, routinely audit and investigate government contractors and recipients of Federal grants. These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards.

The DHHS and the DCAA also review the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be refunded. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including:

- Termination of contracts;
- Forfeiture of profits;
- Suspension of payments;
- Fines; and
- Suspension or prohibition from conducting business with the United States government.

In addition, we could suffer serious reputational harm if allegations of impropriety were made against us, which could cause our stock price to decrease.

Laws and regulations affecting government contracts make it more costly and difficult for us to successfully conduct our business.*

We must comply with numerous laws and regulations relating to the formation, administration and performance of government contracts, which can make it more difficult for us to retain our rights under our government contracts. These laws and regulations affect how we conduct business with government agencies. Among the most significant government contracting regulations that affect our business are:

- The Federal Acquisition Regulations, or FAR, and agency-specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts;
- The business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act and Foreign Corrupt Practices Act;
- Export and import control laws and regulations; and
- Laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

Foreign governments typically also have laws and regulations governing contracts with their respective agencies. These foreign laws and regulations affect how we and our customers conduct business and, in some instances, impose added costs on our business. Any changes in applicable laws and regulations could restrict our ability to maintain our existing government contracts and obtain new contracts, which could limit our ability to conduct our business and materially adversely affect our revenues and results of operations.

Agreements with government agencies may lead to claims against us under the Federal False Claims Act, and these claims could result in substantial fines and other penalties.*

The biopharmaceutical industry is, and in recent years has been, under heightened scrutiny as the subject of government investigations and enforcement actions. Our government contracts are subject to substantial financial penalties under the Federal Civil Monetary Penalties Act and the Federal Civil False Claims Act. Under the False Claims Act's "whistleblower" provisions, private enforcement of fraud claims against businesses on behalf of the United States government has increased due in part to amendments to the False Claims Act that encourage private individuals to sue on behalf of the government. These whistleblower suits, known as qui tam actions, may be filed by private individuals, including present and former employees. The False Claims Act statute provides for treble damages and up to $11,000 per false claim. If our operations are found to be in violation of any of these laws, or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, exclusions, curtailment, or restructuring of our operations could adversely affect our ability to operate our business and our financial results.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above your purchase price.*

We cannot assure you that an active trading market for our common stock will develop or persist, and, as of November 1, 2012 our executive officers, directors, 5% shareholders and their affiliates own approximately 46% of our common stock, which may further reduce trading activity in our common stock. You may not be able to sell your shares quickly or at the market price if trading in our common stock is not active.

The trading price of our common stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- Adverse results or delays in clinical trials;
- Any delay in filing our NDA for tedizolid phosphate and any adverse development or perceived adverse development with respect to the FDA's review of the NDA, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- Failure to successfully commercialize tedizolid phosphate, develop additional product candidates and commercialize additional product candidates;
- Changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- Unanticipated serious safety concerns related to the use of tedizolid phosphate or any of our other product candidates;
- A decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- Inability to obtain adequate product supply for tedizolid phosphate or any other approved drug product, or the inability to do so at acceptable prices;
- Adverse regulatory decisions;
- Introduction of new products, services or technologies offered by us or our competitors;

- Failure to meet or exceed revenue and financial projections we provide to the public;
- Actual or anticipated variations in quarterly operating results;
- Failure to meet or exceed the estimates and projections of the investment community;

- The perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- General market conditions and overall fluctuations in United States equity markets;
- Developments concerning our sources of manufacturing supply and our future international commercialization partners;
- Announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- Disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- Additions or departures of key scientific or management personnel;
- Issuances of debt or equity securities;
- Significant lawsuits, including patent or stockholder litigation;
- Changes in the market valuations of similar companies;
- Sales of our common stock by us or our stockholders in the future;
- Trading volume of our common stock; and
- Other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the Nasdaq Global Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.*

As of November 1, 2012, our executive officers, directors, 5% stockholders and their affiliates own approximately 46% of our outstanding voting stock. Therefore, these stockholders may have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Certain holders of shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2010 Equity Incentive Plan, or the 2010 Plan, and our 2010 Non-employee Directors' Stock Option Plan, or the 2010 Directors' Plan, our management is authorized to grant stock options to our employees, directors and consultants. The number of shares available for future grant under our 2010 Plan will automatically increase each year by an amount equal to the lesser of 800,000 shares or 3% of all shares of our capital stock outstanding as of January 1st of such year, subject to the ability of our board of directors to take action to reduce the size of such increase in any given year. The number of shares available for future grant under our 2010 Directors' Plan will automatically increase each year by an amount equal to the lesser of the aggregate number of shares of common stock subject to options granted during the immediately preceding calendar year or 150,000 shares, subject to the ability of our board of directors to take action to reduce the size of such increase in any given year.

Pursuant to our 2010 Employee Stock Purchase Plan, or the 2010 Purchase Plan, rights to purchase common stock are granted to our employees. The number of shares reserved for issuance under our 2010 Purchase Plan will automatically increase each year by an amount equal to the least of 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year or 250,000

shares, subject to the ability of our board of directors to take action to reduce the size of such increase in any given year.

Currently, we plan to register the increased number of shares available for issuance under our 2010 Plan, 2010 Directors' Plan and 2010 Purchase Plan each year. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change in its equity ownership over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We performed an analysis under Section 382 through December 31, 2011 and determined that we did not trigger an "ownership change" limitation. In January 2012, we raised an additional $48.4 million, net of offering costs in our public offering. We updated our Section 382 analysis after the January 2012 public offering and determined that an "ownership change" had occurred. However, the "ownership change" did not create any loss of net operating loss carryforwards. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our net operating loss carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management. These provisions include:

- Authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- Limiting the removal of directors by the stockholders;
- Creating a staggered board of directors;
- Prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- Eliminating the ability of stockholders to call a special meeting of stockholders;
- Permitting our board of directors to accelerate the vesting of outstanding option grants upon certain transactions that result in a change of control; and
- Establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Item 4. Mine Safety Disclosures

None

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Item 6. Exhibits

EXHIBIT INDEX

Exhibit No:	Description
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(1)	Amended and Restated Bylaws.
4.1(1)	Form of Common Stock Certificate.
4.2(1)	Warrant issued by Trius Therapeutics, Inc. on November 1, 2004 to Forsy the Biotechnology Group, Inc.
4.3(2)	Amended and Restated Investor Rights Agreement dated March 19, 2008, as amended, among Trius Therapeutics, Inc. and certain of its stockholders.
4.4(3)	Form of Warrant issued pursuant to the Securities Purchase Agreement dated May 24, 2011, among Trius Therapeutics, Inc. and the Purchasers listed therein.
4.5(3)	Form of Registration Rights Agreement dated May 24, 2011, among Trius Therapeutics, Inc. and the Purchasers listed therein.
10.1	Tenth Amendment Dated August 30, 2012 to Standard Industrial/Commercial Multi-Tenant Lease-Net dated September 7, 2004, as amended, between the Registrant and Nancy Ridge Technology Center, L.P.
10.2(4)	Common Stock Purchase Agreement between Trius Therapeutics, Inc. and Terrapin Opportunity, L.P. dated August 30, 2012.
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14 or 15d-14 of the Exchange Act.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14 or 15d-14 of the Exchange Act.
32.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
32.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Incorporated herein by reference to Trius Therapeutics, Inc.'s Registration Statement on Form S-1 (File No. 333-162945), as amended, filed with the Securities and Exchange Commission.

(2) Incorporated by reference to Trius Therapeutics, Inc.'s Registration Statement on Form S-1 (File No. 333-175050), filed with the Securities and Exchange Commission on June 21, 2011.

(3) Incorporated herein by reference to Trius Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-34828), filed with the Securities and Exchange Commission on May 25, 2011.

(4) Incorporated herein by reference to Trius Therapeutics, Inc.'s Current Report on Form 8-K (File No. 001-34828), filed with the Securities and Exchange Commission on August 31, 2012.

** Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T, these interactive data files are deemed not filed and otherwise are not subject to liability.

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SIGNATURES

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

Trius Therapeutics, Inc.

Date: November 7, 2012

By: /s/ Jeffrey Stein

Jeffrey Stein, Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 7, 2012

By: /s/ John P. Schmid

John P. Schmid
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 10.1

TENTH AMENDMENT DATED AUGUST 30, 2012

Nancy Ridge Technology Center, L.P., a California limited partnership ("Lessor"), and Trius Therapeutics, Inc., a Delaware corporation, ("Lessee"), hereby amend the Lease dated September 7, 2004 for Suites #101 thru #106 at 6310 Nancy Ridge Drive and Suite #104 at 6330 Nancy Ridge Drive, San Diego, CA 92121 ("Premises") as follows effective September 1, 2012:

1. **Lease Term:** The Lease Term is hereby extended. The Expiration Date shall be June 30, 2014.
2. **Premises & Lessee's Share:** The Premises has been expanded to include the downstairs of suite #104 at 6330 Nancy Ridge Drive, which is approximately 4,000 square feet. With this additional space, the total premises is approximately 39,404 square feet, and Lessee's Share is approximately twenty two point three percent (22.3%).
3. **Rent Credit:** Lessor will reimburse Lessee for the vivarium demolition costs through a rent credit pursuant to the 9 th Amendment dated March 29, 2012. The credit shall be applied to Base Rent for October 2012.
4. **Base Rent:** The Base rent is $58,673.80 per month. The Base Rent shall increase four percent (4%) on March 1, 2013, and every twelve (12) months thereafter.
5. **Option to Extend:** Lessee shall have the one time right to extend the Lease Term for one, two or three years (to June 30 of 2015, 2016 or 2017 – Lessee's choice). Lessee may exercise this option by delivering Notice to Lessor of the Lessee's exercise of said option on or before December 31, 2013. Said Notice shall specify whether the extension is for one, two or three years. This option shall expire if not exercised by Lessee on or before December 31, 2013. Lessee shall have no options to extend other than the one granted herein.
6. **Confidentiality:** The terms of the Lease are confidential. No party to the Lease, nor any broker, shall disclose any of the terms of the Lease to any other party.
7. **No Lessor Default:** Lessor is not currently in Default of any of the terms or conditions of the Lease.
8. **Authority to Execute:** Each person executing this Amendment represents and warrants to all parties that he or she is duly authorized to execute and deliver this Amendment on behalf of that party.

All other terms and conditions of the original Lease shall remain in full force and effect.

Lessor: Nancy Ridge Technology Center, L.P., a California Limited Partnership

By: **Nancy Ridge Technology Center, L.L.C., a California Limited Liability Company, its General Partner**

By: /s/ Chris Loughridge
Chris Loughridge, its Manager

Date: September 4, 2012

Lessee: Trius Therapeutics, Inc., a Delaware Corporation

By: /s/ John P. Schmid
John P. Schmid, CFO

Date: August 31, 2012

EXHIBIT 31.1

CERTIFICATION PURSUANT
TO RULE 13a-14(a) UNDER
THE SECURITIES EXCHANGE ACT OF 1934

I, Jeffrey Stein, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Trius Therapeutics, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2012

/s/ JEFFREY STEIN

Jeffrey Stein, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION PURSUANT
TO RULE 13a-14(a) UNDER
THE SECURITIES EXCHANGE ACT OF 1934

I, John P. Schmid, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Trius Therapeutics, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2012

/s/ JOHN P. SCHMID

John P. Schmid
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION 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 Trius Therapeutics, Inc. (the "Company") for the period ended September 30, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jeffrey Stein, Chief 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, to my knowledge that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ J EFFREY S TEIN

Jeffrey Stein, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

November 7, 2012

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

EXHIBIT 32.2

CERTIFICATION 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 Trius Therapeutics, Inc. (the "Company") for the period ended September 30, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John P. Schmid, Chief 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, to my knowledge that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ JOHN P. SCHMID

John P. Schmid
Chief Financial Officer
(Principal Financial Officer)

November 7, 2012

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.