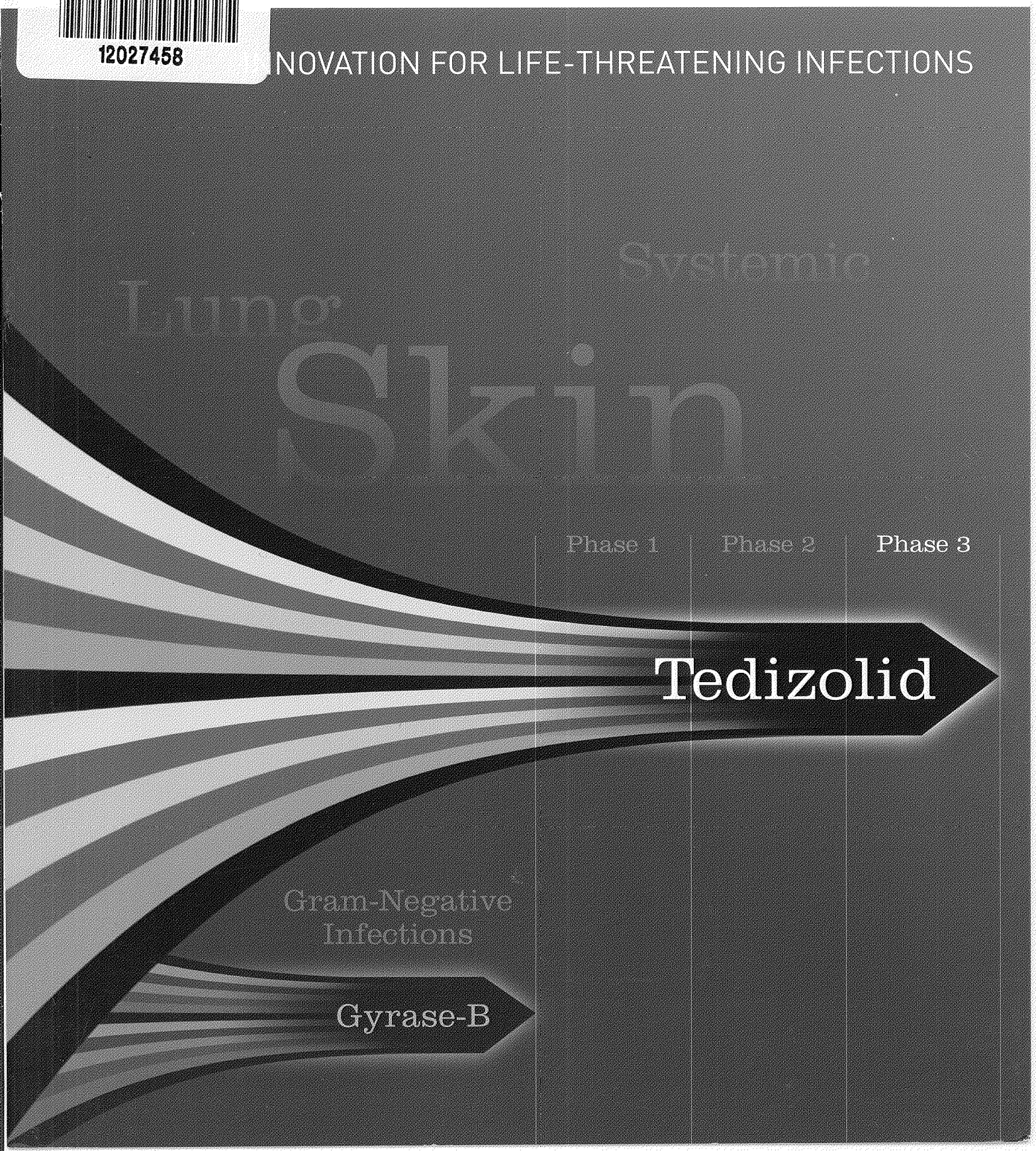
Trius Therapeutics

2011 Annual Report

INNOVATION FOR LIFE-THREATENING INFECTIONS



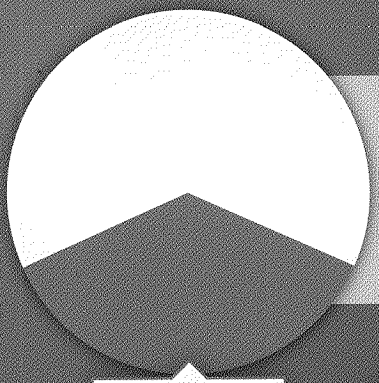
U.S. MARKET OPPORTUNITY FOR TEDIZOLID

Differentiated attributes present opportunities to compete with branded and generic drugs

$1.7 BILLION
U.S. Market in 2011
(18% CAGR FROM 2005-2011)

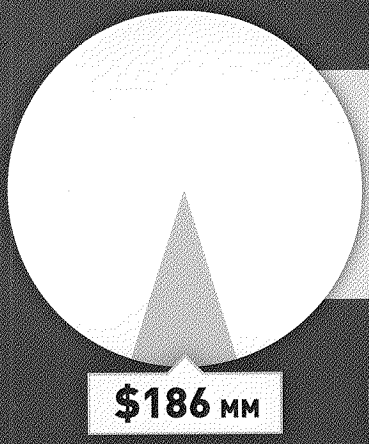
Competing with Branded Drugs

Market Opportunity	Competitive Weakness	**Tedizolid Opportunity**
Zyvox® (BRANDED)	39% of surveyed discontinuations due to tolerability	Fewer GI events (16% vs. 25%) and less myelosuppression (9% vs. 15%)
Cubicin® (BRANDED)	50% of surveyed discontinuations switched from intravenous Cubicin to an oral tablet alternative	Available in IV and oral forms

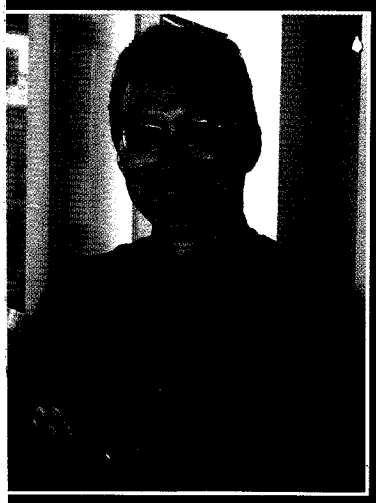


Competing with the Volume Leader

Vancomycin (GENERIC)	46% of surveyed discontinuations due to non-response	Shows activity against resistant strains, estimated >10%
	Limited use with renally impaired patients (~10-20% DOT)	Bactericidal, shorter course of therapy and easier to tolerate



Data Sources: Company Reports, IMS – National Sales Perspectives, AMR – Hospital Insight Series



Jeffrey Stein, Ph.D. *President & CEO*

Key 2011 Milestones

Reported positive results from first Phase 3 trial (112) of tedizolid

Initiated second Phase 3 trial (113) of IV/oral dosage of tedizolid

Established a strategic partnership with Bayer for Asia-Pacific and emerging markets

Completed $30MM financing

Released positive Phase 1 lung data

Dear Trius Shareholders,

2011 was an eventful year for Trius during which we were able to extend our exemplary record of solid execution against our objectives. Our focus has enabled us to advance tedizolid a critical step closer to the market as well as advance our externally funded Gyrase program toward clinical testing.

Positive Phase 3 Clinical Results for Tedizolid Program

In December of 2011, we reported positive results for our "112" Phase 3 trial of the oral dosage form of tedizolid for acute bacterial skin and skin structure infections (ABSSSI). The trial was successful by all measures, achieving all primary and secondary efficacy endpoints. Importantly, tedizolid patients demonstrated a statistically significant improvement in key safety and tolerability parameters versus the comparator linezolid (Zyvox®). This pivotal Phase 3 trial examined the efficacy and safety of a once daily 200 milligram dose of oral tedizolid phosphate over a 6-day course of therapy (followed by four days of placebo) versus a twice daily 600 milligram dose of oral linezolid over a 10-day course of therapy in 667 patients recruited across sites in North America, South America and Europe. The 112 trial was designed to satisfy both the FDA and EMA regulatory submission requirements and the results align with physician and payer preferences for fast acting drugs with improved tolerability and safety.

We believe that the results of the 112 trial have substantially de-risked the ongoing "113" Phase 3 trial testing the IV to oral transition dosing of tedizolid versus linezolid in ABSSSI. We initiated the 113 trial in September 2011 in U.S. trial sites and will enroll additional patients at centers in South America, Europe and Asia. As with the 112 trial, the 113 trial is being conducted under a Special Protocol Agreement (SPA) with the FDA. Enrollment is on schedule as of this writing and we expect to release top line data in early 2013.

In February, we announced the results of a Phase 1 clinical trial to evaluate the ability of a 200 mg once daily dose of tedizolid to penetrate into lung tissue for potential use to treat lung infections. This study demonstrated that tedizolid at the current therapeutic dose is able to achieve a target exposure of drug expected to effectively treat bacteria in the lungs.

Commercial Progress

In addition to the positive clinical results we reported for tedizolid in 2011, we made progress in preparing for tedizolid's commercial development. Most significantly, we formed a strategic collaboration with Bayer Pharma AG to develop and commercialize tedizolid in Asia-Pacific and emerging markets. Under the agreement, Trius received a $25 million upfront payment and is eligible to receive up to an additional $69 million upon the achievement of certain development, regulatory and commercial milestones. In addition, Bayer will support 25% of the future development costs of tedizolid required for global approval in ABSSSI and pneumonia. Bayer will pay Trius double-digit royalties on net sales of tedizolid in the licensed territory, which includes China, Japan and other countries in Asia, Africa, Latin America and the Middle East, excluding North and South Korea. We are pleased to have such a strong partner, with comprehensive development and commercial infrastructure in Asia, while retaining full development and commercialization rights outside of the licensed territory including the United States, Canada and the European Union.

To further our commercial strategy for tedizolid, we appointed Craig Thompson to the newly created role of Chief Commercial Officer, responsible for developing the positioning and planning for the launch of tedizolid. With more than 18 years of pharmaceutical marketing and sales experience, Craig was a key addition to our management team. His strong background in infectious disease and

successful experience in launching industry blockbusters is a valuable asset in advancing the commercial program and maximizing the market opportunity for tedizolid.

Market Opportunity for Tedizolid

The current market presents us with an opportunity to compete with generic vancomycin, which currently represents over 75% of the market volume, as well as with the branded leaders Zyvox and Cubicin, whose combined sales represent more than 80% of an approximately $1.7 billion market. Tedizolid has several important attributes that can allow us to address multiple segments of the current market for anti-infectives.

2011 was an eventful year for Trius during which we were able to extend our exemplary record of solid execution against our objectives. Our focus has enabled us to advance tedizolid a critical step closer to the market as well as advance our externally funded Gyrase program toward clinical testing.

If we look at the total potential addressable market for tedizolid, generic vancomycin is the volume leader, representing 75% of the days of therapy. We believe that tedizolid will have significant competitive advantages over vancomycin when it comes to efficacy and tolerability. Currently, resistance to vancomycin is estimated at approximately 10% and has shown a sharp increase in recent years, especially amongst the vancomycin-intermediate *Staphylococcus aureus*. This presents an opportunity for tedizolid, which has a low rate of resistance and a shorter course of therapy with an improved tolerability profile versus other agents. In addition, a recent survey of physicians indicated that lack of efficacy accounts for nearly half of vancomycin discontinuations, which illustrates the growing problem of vancomycin resistant strains. This efficacy issue is further exacerbated in the 25% of renally impaired patients treated with vancomycin where increasing vancomycin dosing can be problematic. Some experts believe this trend indicates a tipping point in vancomycin resistance, which we expect can be addressed by tedizolid.

As branded agents Zyvox and Cubicin have established strong market positions by differentiating against vancomycin, we believe they each have shortcomings that can be addressed by tedizolid. In the case of Zyvox, a recent survey of physicians showed that tolerability problems accounted for nearly 40% of all Zyvox discontinuations. The results of our Phase 3 clinical trial demonstrated that tedizolid had improved tolerability and safety compared to Zyvox. Specifically, tedizolid had a statistically lower rate of both gastrointestinal adverse events (16% vs. 25%) as well as myelosuppression signals (9% vs. 15%). When we look at the nearly $700M in Cubicin sales in 2011, we believe that tedizolid's availability in both IV and oral forms and penetration into lung tissues will facilitate transition into the outpatient setting as well as provide an opportunity to treat lung infections. Both of these provide strong competitive differentiation to Cubicin. In all, tedizolid boasts all of the key competitive attributes of the market leading antibacterial drugs: IV and oral availability, in-vivo bactericidal activity, activity in lung infections, once daily treatment and short course of therapy.

Gyrase-B Broad Spectrum Program

In addition to the opportunity in the current market, the need for more potent anti-infectives is only expected to increase in the future. This year we made important progress in the pre-clinical development of our Gyrase-B Program, which is fully funded through Phase 1 by a $28MM National Institute of Allergy and Infectious Diseases (NIAID) contract. We have demonstrated that our lead molecules have potent activity against a broad spectrum of gram-negative and gram-positive bacterial pathogens, are efficacious in multiple animal models of infection and have an excellent preclinical safety profile. Based on these encouraging results, we expect to complete pre-clinical development of a Gyrase-B development candidate in 2012 and file for an Investigational New Drug application (IND) in 2013.

In summary, 2011 was a pivotal year for Trius. We made significant progress in advancing the clinical development of tedizolid phosphate and we expect that our partnership with Bayer will accelerate the development of tedizolid in skin and lung infections globally. Looking forward, we are focused on key milestones including initiating our Phase 3 lung trial, pursuing a potential partnership for commercializing tedizolid in Europe, completing pre-clinical development of our Gyrase-B program and completing enrollment for our 113 Phase 3 trial.

Thank you for your ongoing support.

Jeffrey Stein, Ph.D.
President & Chief Executive Officer

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2011

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	**20-1320630**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
6310 Nancy Ridge Drive, Suite 101 San Diego, California 92121	**92121**
(Address of Principal Executive Offices)	**(Zip Code)**

(858) 452-0370
Registrant's telephone number, including area code

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Exchange on Which Registered**
Common Stock, par value $0.0001 per share	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 ☒

As of June 30, 2011, the aggregate market value of the voting stock held by non-affiliates of the registrant, computed by reference to the last sale price of such stock as of such date on the NASDAQ Stock Market LLC, was approximately $77,305,259. Excludes an aggregate of 18,764,914 shares of common stock held by officers and directors and by each person known by the registrant to own 5% or more of the outstanding common stock as of June 30, 2011. Exclusion of shares held by any of these persons should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

As of March 13, 2012, there were 38,562,612 shares of the registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Part III of this Annual Report on Form 10-K is incorporated by reference from the registrant's definitive proxy statement for the registrant's 2012 annual meeting of stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the close of the registrant's fiscal year ended December 31, 2011.

TRIUS THERAPEUTICS, INC.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, these forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as "believes," "expects," "hopes," "may," "will," "plan," "intends," "estimates," "could," "should," "would," "continue," "seeks," "pro forma," or "anticipates," or other similar words (including their use in the negative). Similarly, statements that describe our future plans, strategies, intentions, expectations, objectives, goals or prospects and other statements that are not historical facts are also forward-looking statements. These statements include but are not limited to statements under the captions "Business", "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as other sections in this Annual Report on Form 10-K. You should be aware that the occurrence of any of the events discussed under the heading "Item 1A. Risk Factors" and elsewhere in this report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock. The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this Annual Report on Form 10-K. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. Except as required by law, we assume no obligation to update our forward-looking statements, even if new information becomes available in the future.

PART I.

ITEM 1. *BUSINESS*

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of innovative antibiotics for life threatening infections. Our current development efforts are focused on developing tedizolid phosphate (formerly known as torezolid phosphate), an intravenous, or IV, and oral antibiotic, for the treatment of serious gram-positive bacterial infections, initially for acute bacterial skin and skin structure infections, or ABSSSI, and subsequently for other indications, including pneumonia. ABSSSI is a new classification for complicated skin and skin structure infections, or cSSSI. Tedizolid phosphate is an IV and orally administered second generation oxazolidinone.

In December 2011, we completed our first Phase 3 clinical trial 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 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, for tedizolid phosphate for the treatment of ABSSSI during the third quarter of 2013. We also completed a Phase 1 clinical trial during the first quarter of 2011, 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 pursue further development of tedizolid phosphate for the treatment of pneumonia 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 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 intend to continue to evaluate potential strategic alliances for tedizolid phosphate in Europe.

In May 2011, we raised a total of approximately $28.0 million in net proceeds from our private placement of 4,750,000 units at a purchase price of $6.35 per unit, with each unit consisting of one share of our common stock and a warrant to purchase an additional 0.35 shares of our common stock. Each warrant is exercisable in whole or in part for a period of five years from November 27, 2011 at a per share exercise price of $8.50, subject to certain adjustments.

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.

In addition, we are discovering antibiotics for broad spectrum infections using our proprietary discovery platform under three contracts: one funded by the National Institute of Allergy and Infectious Diseases, or NIAID, a part of the National Institutes of Health, or NIH; a second funded by the Defense Threat Reduction Agency, or DTRA, a part of the Department of Defense; and a third contract that we initiated in April 2011 with Lawrence Livermore National Laboratory, or LLNL, a part of the U.S. Department of Energy's National Nuclear Security Administration.

We were originally incorporated in California in June 2004 as RexC Pharmaceuticals, Inc. and changed our name to Rx^3 Pharmaceuticals, Inc. in September 2004. In February 2007, we changed our name to Trius Therapeutics, Inc. and reincorporated in Delaware in December 2007. Our principal offices are in San Diego, California. We maintain an internet site at *www.triusrx.com,* which includes links to reports we have filed with the Securities and Exchange Commission, or SEC. Any information that is included on or linked to our Internet site is not a part of this report or any registration statement that incorporates this report by reference. Our filings may also be read and copied at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-732-0330. The SEC also maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is *www.sec.gov*.

Our Product Candidates

We believe that our product candidates may offer advantages over existing antibiotics in terms of efficacy, safety, bacterial resistance and dosing convenience. We also believe that the markets for our product candidates present us with significant commercial opportunities. Our product candidates are in various stages of development and none have been approved for sale. Our ability or our licensees' ability to obtain regulatory approval of any of our product candidates requires us or our licensees to successfully complete the clinical development of each such product candidate and demonstrate through data submissions the safety and efficacy of the product candidate to the satisfaction of the Food and Drug Administration, or FDA, and comparable foreign regulatory authorities. Clinical trials involve a lengthy and expensive process with an uncertain outcome, and efficacy and safety data of earlier studies and trials conducted thus far may not be predictive of future trial results.

Our current product candidate portfolio consists of the following:

Product Candidate	Target Indications	Development Status
Tedizolid Phosphate	ABSSSI	Phase 3 oral clinical trial completed in December 2011 Phase 3 IV to oral clinical trial ongoing
	Pneumonia	Phase 1 clinical trial completed; Phase 3 HAP/VAP[1] clinical trial to commence in 2013
	Bacteremia	Completed studies support moving to Phase 3 study
GyrB/ParE	Broad spectrum	Preclinical IV, Phase 1 to commence in 2013
Marine Natural Products	Broad spectrum	Preclinical IV

[1] Hospital Acquired Pneumonia/Ventilator Acquired Pneumonia

Our Strategy

Our strategy is to discover and develop a pipeline of antibiotics focused on the treatment of life-threatening infections, consisting of tedizolid phosphate and additional compounds discovered internally using our proprietary discovery platform.

With respect to tedizolid phosphate, our strategy is to:

- Conduct two Phase 3 clinical trials for the treatment of ABSSSI, the first of which has been completed and the second of which is currently ongoing;
- Pursue further clinical development for the treatment of pneumonia;
- Pursue clinical development for the treatment of other indications;
- Obtain regulatory approval for the treatment of ABSSSI initially in the United States and subsequently in the European Union, or EU;
- Build a hospital-directed sales force and/or collaborate with third parties for commercialization in the United States; and
- Out-license rights to, or collaborate with, third parties, in Europe, as we have done with Bayer for development and commercialization rights in the Bayer Licensed Territory.

With respect to our preclinical programs and proprietary discovery platform, our strategy is to:

- Advance our preclinical programs into clinical development;
- Actively pursue additional government contract revenues to support the discovery and development of existing and additional compounds; and
- Continue to use our proprietary discovery platform to discover additional antibiotics that we may develop internally or with third parties.

To execute on our strategy, we have built a strong management team with significant development and regulatory experience. Our senior management team consists of eight individuals who collectively have been involved in the development and approval of a significant number of anti-infective drugs.

As of March 1, 2012, we had 73 employees, of which 28 hold Ph.D., M.D. or equivalent degrees. None of our employees are represented by a collective bargaining arrangement, and we believe our relationship with our employees is good. Recruiting and retaining qualified scientific personnel to perform research and development work in the future will be critical to our success. We may not be able to attract and retain personnel on acceptable terms given the competition among biotechnology, pharmaceutical and health care companies, universities and non-profit research institutions for experienced scientists. In addition, we rely on a number of consultants to assist us in formulating our research and development strategies.

Background on the Antibiotic Market

Bacterial infections are caused by pathogens present in the environment that enter the body and overwhelm the body's immune system. These bacteria establish themselves in various tissues and organs throughout the body and cause a number of serious and, in some cases, lethal infections, including infections of the skin, lung, blood, bone, heart and urinary tract.

Bacteria are differentiated into two broad categories based on the structure of the bacterial envelope. Gram-positive bacteria possess a single membrane and a thick cell wall and turn dark-blue or violet when subjected to a laboratory staining method known as Gram's stain. Gram-negative bacteria possess two membranes with a thin cell wall and lose the stain or are decolorized when subjected to Gram's staining. The most clinically relevant gram-positive bacteria include staphylococci, streptococci and enterococci. Common infections that are caused by gram-positive bacteria and result in hospitalization include infections of the skin, lung, blood and bone.

Antibacterial agents, also referred to as antibiotics, work by inhibiting a function essential to a bacterium's growth or survival, usually by binding to and thereby inhibiting one, or occasionally more than one, specific "target" in a bacterial cell. Antibiotics are classified by both the type of bacteria against which they are effective, such as gram-positive or gram-negative bacteria, as well as their basic molecular structure, which is known as their antibiotic "class." Antibiotics are typically differentiated based on several characteristics, the most important of which are:

- **Potency.** The potency of an antibiotic is generally expressed as the minimum inhibitory concentration, or MIC, measured in micrograms per milliliter, needed to arrest bacterial growth in vitro, which means that it occurs outside of a living organism under laboratory conditions. Potency against a panel of bacterial strains is expressed as MIC_{90}, which refers to the concentration needed to inhibit the growth of 90% of a panel of bacterial strains isolated from patients. A lower MIC_{90} indicates greater potency against a particular bacterium.
- **Dosing Schedule and Duration.** The number of times per day that an antibiotic is administered is referred to as its dosing schedule. This can be once daily, twice daily or more frequent. Once daily dosing and shorter duration of therapy have been demonstrated to correlate with higher patient compliance, an improved safety profile and decreased potential for generation of resistant organisms.
- **Cidality.** Antibiotics are classified by whether their inhibitory effect results in growth arrest, referred to as bacteriostatic, or the killing of the bacterial pathogen, referred to as bactericidal. Such activity is observed either in vitro, or in vivo, which means that it occurs within a living organism. In general, clinicians prefer to treat severe infections with antibiotics that have bactericidal activity.
- **Spectrum of Coverage.** Antibiotics that are active against both gram-positive and gram-negative bacteria are referred to as broad spectrum. Those that are active only against gram-positive or gram-negative bacteria are referred to as focused spectrum. Antibiotics that are active against a select subset of gram-positive or gram-negative bacteria are referred to as narrow spectrum.

- **Route of Administration.** Antibiotics are usually administered intravenously or orally. Most antibiotics for serious infections are available only as IV dosage forms and are typically administered by a healthcare professional.
- **Pharmacokinetics.** Antibiotics are evaluated based on the effect of the body on the drug, including the absorption, distribution, metabolism and excretion of the drug by the body, as reflected by measuring drug concentration over time. Less patient-to-patient variability in the concentration of the antibiotic in blood generally means that drug exposure, and subsequently, the drug's efficacy and safety is more predictable across a broad patient population.
- **Resistance.** The use of antibiotics can promote the development of bacterial strains with decreased susceptibility to the antibiotic. The frequency at which a resistance mutation appears, an indicator of the likelihood that resistance will develop, can be experimentally determined.
- **Safety and Tolerability.** The safety of an antibiotic is characterized by the type and number of adverse events, or AEs, reported when administered to a patient. Examples of AEs include nausea, vomiting, headache, dizziness or other expressions of discomfort. It is also assessed by its impact on biological compartments such as blood, kidney or liver, changes in cardiovascular or other physiological signals and effects on other vital organ and tissue functions typically expressed by abnormal clinical laboratory tests or parameters. The tolerability of an antibiotic generally refers to its effects on the route used to administer the drug into the body. For example, the gastrointestinal and the venous tolerability are a focus of attention for oral and intravenous drugs, respectively.

Generally, new antibiotics have offered improvements in one or more of the above characteristics over older members of the same class. In addition, new classes of antibiotics have been discovered that provide advantages over other, older classes. Over the last 40 years there have been only two new classes of antibiotics introduced to treat infections caused by gram-positive bacteria, including methicillin resistant *S. Aureus*, or MRSA. These new classes offered greater potency against MRSA and an improved safety profile over older alternatives. However, there is still a significant need for new antibiotics with improved potency, convenience of use and improved safety profiles, particularly those that also target resistant strains, including MRSA infections.

The Need for New Antibiotics for Drug-Resistant Gram-Positive Pathogens

There is a significant need for new antibiotics to treat serious gram-positive infections, due primarily to the growing incidence of drug resistance to currently marketed antibiotics. By far the most prevalent resistant gram-positive bacterial pathogen in the hospital and community today is MRSA. The market for antibiotics approved to treat MRSA is growing rapidly. According to IMS Health, the total United States sales of the five antibiotics approved to treat MRSA grew from $778 million in 2005 to $1.68 billion in 2011. We believe that this market will continue to grow rapidly due to several factors:

- **Increasing obsolescence of vancomycin.** The most widely prescribed antibiotic for treating gram-positive infections is vancomycin IV, which accounted for 82% of in-hospital days of therapy in the United States for gram-positive infections in 2010. It is administered twice daily as an IV infusion and for many years had been reserved for use only after treatment with other antibiotics has failed. However, the emergence of MRSA has led to an increase in use of vancomycin as the initial treatment assuming the presence of MRSA before it has been confirmed. This increasing usage, in turn, has contributed to the emergence of vancomycin-resistant bacteria such as vancomycin-resistant *Enterococcus* , or VRE, and vancomycin-intermediate *Staphylococcus aureus* , or VISA. The latter strain is of particular concern given the high rate of MRSA infections in the hospital and community. Based on the rapid rise of MRSA with reduced susceptibility to vancomycin, we believe that vancomycin may soon be rendered obsolete as a treatment for MRSA and that new, more effective antibiotics, are increasingly replacing vancomycin as the standard treatment for MRSA infections.
- **Demand for focused spectrum agents.** The use of broad spectrum antibiotics, such as cephalosporins and quinolones, which have both gram-positive and gram-negative activity, has led to a dramatic

increase in the prevalence of infectious diarrhea caused by highly virulent strains of *Clostridium difficile* . Further, the use of these agents is leading to increased prevalence of MRSA strains that are cross-resistant to these agents. Consequently, there is a significant and growing need for focused spectrum drugs with potent activity against MRSA.

- **Demand for both IV and orally available antibiotics.** The majority of recently introduced antibiotics designed to treat MRSA are available only in IV dosage form and must be administered by a healthcare professional. With the increased pressure to reduce the costs of healthcare, there is a significant need for antibiotics that are available in both IV and oral dosage forms so that patients can be transitioned to oral therapy and, therefore, discharged earlier from the hospital or treated on an outpatient basis.

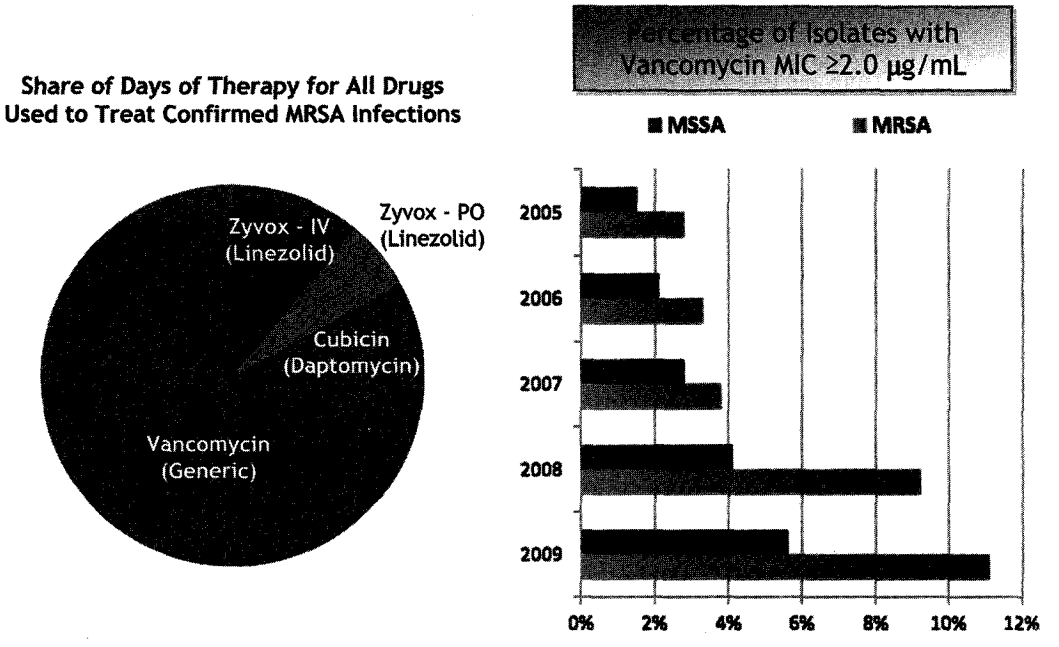
Despite the significant need for new antibiotics with the above attributes, over the last 40 years, only two new classes of focused spectrum antibiotics have been marketed for the treatment of infections caused by gram-positive bacteria: the oxazolidinones, introduced to the market in 2000, and the lipopeptides, introduced to the market in 2003. To date, only one antibiotic has been approved in each of these new classes: Zyvox (linezolid), an oxazolidinone; and Cubicin (daptomycin), a lipopeptide. Sales of these two antibiotics accounted for 80% of the 2011 revenues for antibiotics labeled for MRSA in the United States. We believe that both Zyvox and Cubicin have been commercially successful because of their activity against drug-resistant gram-positive bacteria, particularly MRSA, although resistance to these antibiotics has been increasing.

Cubicin is a lipopeptide antibiotic that can be dosed once daily by IV infusion. It is labeled for the treatment of cSSSI, bacteremia and right sided endocarditis involving gram-positive bacteria. However, Cubicin is ineffective in treating lung infections. Cubist Pharmaceuticals, Inc. reported net United States revenues of $699.0 million in 2011 related to Cubicin.

Zyvox is the only IV and oral antibiotic labeled for the treatment of gram-positive infections, including those caused by MRSA, and remains the market leading antibiotic for serious gram-positive infections based on worldwide sales of $1.3 billion in 2011, as reported by Pfizer. We believe Zyvox's sales advantage over Cubicin stems from its availability in both IV and oral dosage forms and activity against lung infections. Zyvox is labeled for the treatment of cSSSI and uncomplicated skin and skin structure infections, or uSSSI, CABP involving *Streptococcus pneumoniae*, HAP, VAP and VRE infections.

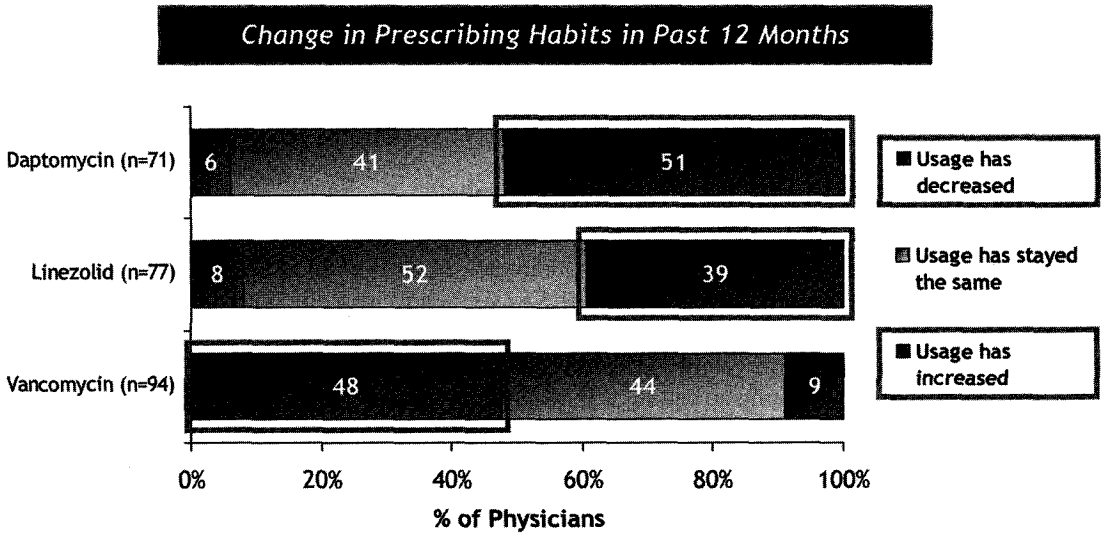
Because of the commercial success of Zyvox and the potential for an improved oxazolidinone, a number of companies, including Pfizer Inc., Merck & Co. Inc., Johnson & Johnson, AstraZeneca PLC, Kyorin Pharmaceutical Co. Ltd., Ranbaxy Laboratories Ltd. and Rib-X Pharmaceuticals Inc., have attempted to develop a new oxazolidinone antibiotic. To our knowledge, only we have reported Phase 3 data of a new oxazolidinone for the treatment of severe infections such as ABSSSI.

While Zyvox has been commercially successful, we believe that the market opportunity for tedizolid is broader than that defined by recent Zyvox sales. Generic vancomycin still comprises 75% of the days of therapy in the U.S. market and its efficacy has continued to erode as noted in the following table:



Source: Theravance Company Report, April 2010 & AMR (United States market).

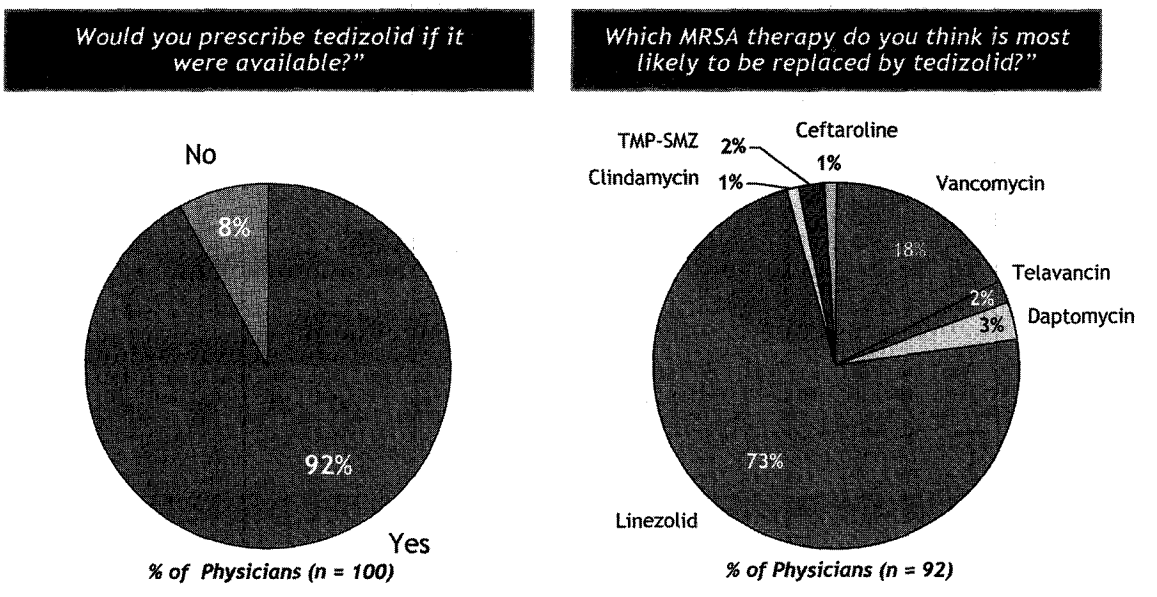
In a recent survey of U.S. physicians, nearly half have stated that they have decreased their prescriptions of vancomycin and a commensurate number have increased usage of branded agents, such as linezolid and daptomycin.



Note: n = the number of physicians who have used the drug and indicated treatment failure with the given drug in the past 12 months.

AMR - Hospital Insight Series, US Data, August 2011

We believe that tedizolid is well suited to capture some of this market share given its unique combination of once daily IV or oral dosing, rapid bactericidal activity and short course of therapy. This is supported by data from the same recent market survey in which 92% of surveyed physicians stated that they would prescribe tedizolid if it were available and that 27% of those prescriptions would replace those of drugs other than Zyvox.



Note: n = the number of physicians who stated they would prescribe tedizolid if it was available.

AMR - Hospital Insight Series, US Data, August 2011

Therefore, we believe there is a significant opportunity for new antibiotics available in both IV and oral dosage forms that offer potency, convenience and safety advantages over existing therapies for the treatment of serious gram-positive infections.

Tedizolid Phosphate

Tedizolid phosphate is a second generation oxazolidinone being developed for the treatment of serious gram-positive infections, including those caused by MRSA. We believe tedizolid phosphate is the second generation oxazolidinone furthest advanced in clinical development for the treatment of such infections. Tedizolid phosphate is a novel prodrug antibiotic that is cleaved in the blood stream to the active compound, tedizolid. We acquired exclusive rights to certain patent applications and other intellectual property related to tedizolid phosphate through a license agreement with Dong-A Pharmaceutical Co., Ltd. in January 2007. We have licensed or own United States utility patent applications, one of which has been issued and have issued and pending foreign national and regional counterpart applications, which if all are issued, may provide composition of matter patent protection for tedizolid phosphate that would expire between 2024 and 2030, absent any extension.

As a second generation oxazolidinone, tedizolid phosphate shares the positive attributes of linezolid, including the availability of IV and oral dosage forms, highly efficient oral absorption and tissue penetration and

distribution, and activity against MRSA. However, based on clinical and nonclinical data, we believe that tedizolid phosphate has significant potential advantages over linezolid, including the following:

- **Greater Potency.** In vitro tests on over 6,000 recent bacterial strains isolated from patients show that the potency of tedizolid is four to 16 times greater than linezolid against linezolid-susceptible strains and up to 16 times greater than linezolid against linezolid-resistant strains. Tedizolid has maintained this potency advantage in all animal models of infection tested to date, including models of skin and lung infections as well as sepsis and endocarditis.

- **Shorter Dosing Regimen and More Convenient, Once Daily Dosing.** Tedizolid phosphate can be administered once daily for six days for the treatment of ABSSSI as compared to twice daily for 10 to 14 days for linezolid. We believe this shorter and once daily dosing regimen will contribute to improved patient compliance and potentially decrease the risk of drug induced adverse events and limit the emergence of resistance. We believe that this may result in improved clinical outcomes and significant savings for hospitals and payor organizations.

- **Bactericidal Activity In Vivo.** Tedizolid, unlike linezolid, acts synergistically with the immune system to kill bacteria and eliminate the infection. Tedizolid penetrates in high concentration into macrophages and its antibacterial effects are amplified more than 200 times by circulating leucocytes, both key players in the innate immune system of humans. These features of tedizolid phosphate contribute to its in vivo bactericidal activity, or killing of pathogenic bacteria in the body, which is thought to yield a higher degree of efficacy and faster eradication of the pathogenic bacteria than is achieved with bacteriostatic antibiotics.

- **Activity Against Key Gram-Positive Drug-Resistant Strains and Select Gram-Negative and Atypical Bacteria.** Tedizolid phosphate is active against all clinically relevant gram-positive bacteria tested to date, including organisms resistant to linezolid and other antibiotics. Unlike linezolid, tedizolid phosphate is also active against strains of the gram-negative bacterium *Legionella* and the bacterium *Chlamydia*, and thus may have utility in treating lower respiratory tract infections involving these bacteria.

- **Low Intrinsic Frequency of Resistance.** The frequency at which MRSA evolved resistance to tedizolid phosphate was 16 times lower than the frequency at which it evolves resistance against linezolid. We believe that this low intrinsic frequency of resistance indicates that tedizolid phosphate may generate fewer resistant strains of bacteria compared to linezolid. We believe this low frequency of resistance may allow for wider use of tedizolid phosphate and limit the emergence of resistance, especially in community applications where the rapid spread of bacterial resistance is of significant concern. This should also result in the slower emergence of bacterial pathogens that are resistant to tedizolid.

- **Favorable and Predictable Pharmacokinetics.** Studies have shown little patient-to-patient variability in the concentration of tedizolid in blood, as compared to linezolid, which generally means that drug exposure is more predictable. As a result, we expect that tedizolid may have more predictable drug exposure which may lead to a more uniform efficacy and safety profile across different patients when compared to linezolid.

- **Fewer Drug-Drug Interactions.** Enzymes known as cytochrome P450's, or CYPs, are responsible for the metabolism of most drugs. As tedizolid does not affect this important pathway of drug metabolism and itself is not metabolized by CYPs, metabolic drug drug interactions with tedizolid are unlikely.

- **Improved Safety Profile for Long Term Dosing.** The results of our comparative 21-day Phase 1 clinical trial showed that a 200 mg daily dose of tedizolid phosphate had less impact on hematological parameters indicative of myelosuppression than the labeled dose of linezolid (600 mg twice daily). Based upon the results of this clinical trial, we believe that tedizolid phosphate may offer a safer alternative to linezolid for infections requiring longer term dosing such as bacteremia/endocarditis.

Despite its advantages, market acceptance and sales of tedizolid phosphate will depend on many factors, including successfully demonstrating the safety and efficacy of tedizolid phosphate in our Phase 3 clinical trials, competitiveness of the product labeling approved by the FDA, effectiveness of the sales and promotional efforts for the product, acceptance by physicians and payors of tedizolid phosphate as a safe and effective treatment, reimbursement status, its cost relative to competing antibiotics and the outcomes of the development and approval of competitive products. In particular, in the absence of a diagnosis of a gram-positive infection, clinicians may prefer to initially prescribe an antibiotic with a broader spectrum of coverage than tedizolid phosphate until the diagnosis of a gram-positive infection is confirmed. If approved, tedizolid phosphate will compete against a number of antibiotics that have been approved and have shown activity against serious gram-positive infections, including those caused by MRSA. These antibiotics include vancomycin, linezolid, daptomycin, tigecycline, telavancin and ceftaroline. We may also compete with antibiotics currently in, or which may soon enter, Phase 3 development or registration for ABSSSI (or cSSSI), such as CEM-102, dalbavancin, delafloxacin, NXL-103, oritavancin, PTK 0796, radezolid, BC-3781, a systemically delivered pleuromutilin from Nabrivia, Inc., and JNJ-Q2, under development by Furiex Pharmaceuticals, Inc. However, we believe that tedizolid phosphate will provide physicians with a safe antibiotic for the treatment of serious gram-positive infections that is more potent and more convenient than linezolid and other currently available alternatives. Further, we believe that use of tedizolid phosphate will result in earlier discharge from the hospital, lower incidence of resistance and a reduced need to switch to alternative antibiotics. All of these factors may contribute to reduced costs for treating serious gram-positive infections.

Overview of our Tedizolid Phosphate Clinical Program

We have completed Phase 1, Phase 2 and Phase 3 clinical trials of the oral dosage form of tedizolid phosphate and have completed a Phase 1 clinical trial for the IV dosage form of tedizolid phosphate. We believe our Phase 1 clinical trial for the IV dosage form of tedizolid phosphate indicated acceptable safety and tolerability and that no dose adjustment will be required between the IV and oral dosage forms of tedizolid phosphate.

We completed our first Phase 3 clinical trial of the oral dosage form of tedizolid phosphate for the treatment of ABSSSI, including MRSA, in December 2011. In this clinical trial, tedizolid phosphate met the primary objective of non-inferiority of the efficacy outcome of early clinical response versus the comparator linezolid (Zyvox) in patients with ABSSSI and also met all secondary efficacy outcomes in this first of two pivotal Phase 3 trials that were designed to support the filing of an NDA, with the FDA, as well as a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA. In this trial, we demonstrated that a 6-day course of once daily oral tedizolid is as efficacious as a 10-day course of twice daily oral linezolid while showing an improved tolerability profile. We also initiated our second Phase 3 clinical trial of tedizolid phosphate in ABSSSI for the IV to oral transition therapy in September 2011 and expect to report top-line data from this clinical trial in early 2013.

To date, 882 healthy volunteers and patients have received tedizolid phosphate.

Our Single and Multiple Ascending Dose Phase 1 Clinical Trial of the Oral Dosage Form of Tedizolid Phosphate

The objective of the single ascending dose, or SAD, portion of the Phase 1 clinical trial was to evaluate the safety and pharmacokinetics, or PK, of the oral dosage form of tedizolid phosphate in single doses between 200 and 1200 mg in healthy volunteers. Tedizolid phosphate was well tolerated in single doses up to the maximum 1200 mg tested. The results of the PK analysis showed a linear relationship between serum concentrations and dose and that all doses supported once daily administration of tedizolid phosphate.

The objective of the multiple ascending dose, or MAD, portion of the clinical trial was to compare the safety, tolerability and PK of tedizolid and linezolid administered for 21 consecutive days in healthy volunteers. Tedizolid phosphate was dosed at 200, 300 and 400 mg. Linezolid was dosed at its labeled dosage of 600 mg twice a day. All three doses of tedizolid phosphate, up to the maximum of the 400 mg dose tested, were generally

well-tolerated. Importantly, in the MAD portion of the Phase 1 clinical trial we found that tedizolid had less inter-subject variability than linezolid.

The results of both the SAD and MAD portions of our Phase 1 clinical trial demonstrate that tedizolid phosphate may have a safety, tolerability and PK advantage over linezolid. In addition, all three dose levels of tedizolid phosphate resulted in sufficient drug concentrations in the blood to support once daily dosing. This was consistent with the blood half-life of the 200 mg dose of tedizolid, which was approximately 11 hours.

Our Phase 1 Clinical Trial of the Oral Dosage Form of Tedizolid Phosphate to Evaluate Tedizolid for Potential Use to Treat Lung Infections

We completed a Phase 1 clinical trial, during the first quarter of 2011, which evaluated the ability of tedizolid phosphate to penetrate into the lung, for potential use in treating lung infections. The results showed that the same 200 mg, once daily dose of tedizolid that we are currently testing for skin infections, also distributed into the lung at concentrations well above that needed to treat infections caused by key gram positive pathogens. Based on these results we plan to pursue further development of tedizolid phosphate for treatment of pneumonia using the same once daily 200 mg dose. These results are consistent with those of prior animal studies that demonstrated considerable penetration of tedizolid into lung fluids and tissues which translated into high efficacy in lung infections due to *S. pneumoniae* (penicillin-susceptible and -resistant) and *S. aureus* (methicillin-susceptible and -resistant) pathogens.

During 2011, we completed a Phase 1 pharmacokinetic study in adolescent subjects (12 – 17 years old) showing that systemic exposure was comparable to that of adult subjects. As a result, the same dose of 200 mg once daily used for adults can also be used in adolescent patients 12 years old and older.

We also conducted a human absorption, distribution, metabolism and excretion, or ADME, study during 2011 that showed that there are no significant metabolites in the circulation other than the active moiety tedizolid. Renal elimination was found to be a minor pathway. As hepatic elimination was found to be the major pathway of elimination, pharmacokinetics of tedizolid were studied in subjects with moderate hepatic impairment. Results from this study indicate that dose adjustments would not be required for subjects with mild to moderate hepatic impairment. We expect to enroll additional subjects with severe hepatic impairment, a group that has not been studied with linezolid, in 2012 to better understand the potential impact of hepatic insufficiency on the PK of tedizolid.

Our Phase 2 Clinical Trial of the Oral Dosage Form of Tedizolid Phosphate

This multicenter, randomized, double-blind, noncomparative Phase 2 clinical trial evaluated the clinical and microbiological response, safety and PK of tedizolid phosphate in 188 adult patients diagnosed with severe cSSSI at eight sites in the United States. Subjects were enrolled with major abscesses, surgical or post-traumatic wounds, or deep cellulitis, and one systemic sign of infection unless the lesion was greater than or equal to five centimeters in diameter.

Patients were randomized to receive tedizolid phosphate at 200, 300 or 400 mg once daily for up to five to seven days. The primary endpoint was the clinical cure rate in the clinically evaluable, or CE, data set, which comprised patients that received the full course of treatment at test of cure (TOC, 7-14 days after end of therapy, or EOT) and fulfilled key inclusion/exclusion criteria, and the intent to treat, or ITT, data set, which comprised all patients who took at least one dose of tedizolid phosphate. Key secondary endpoints were the clinical cure rate in the microbiologically evaluable, or ME, data set, clinical relapse rates, and microbiological response rates.

Clinical cure rates for the CE, ME and ITT groups were consistently high across all dose groups, with the cure rate at 200 mg similar to the cure rates at the 300 mg and 400 mg doses. Within 48 hours from baseline, 91%, 89% and 89% of the patients randomized to receive 200, 300 and 400 mg doses of tedizolid phosphate, respectively, showed cessation of lesion spread as compared to baseline and none of the patients experienced a clinical relapse.

The MIC_{90} of tedizolid against MRSA isolates from our Phase 2 clinical trial patients was 0.25 micrograms per milliliter while the MIC_{90} of linezolid against these same isolates was 2 micrograms per milliliter.

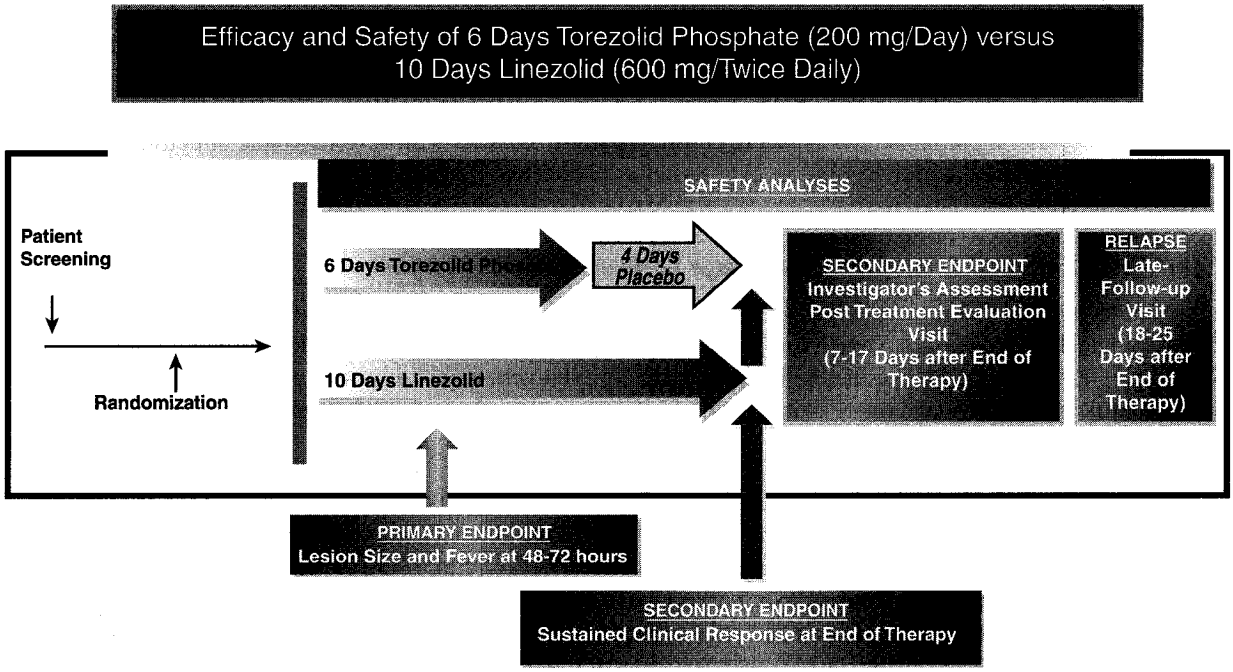
The oral dosage form of tedizolid phosphate appeared to be safe and well-tolerated at all doses evaluated in our Phase 2 clinical trial. Approximately 97% of the drug related AEs were rated "mild" or "moderate" and no patients discontinued the clinical trial due to an AE. The most common AEs included nausea, diarrhea, vomiting and headache and there was no clear dose dependency in the incidence of these AEs. Median platelet and red blood cell counts remained relatively stable and within the normal range during treatment, and there were no significant alterations in safety laboratory values.

Our Phase 3 ABSSSI Clinical Program for Tedizolid Phosphate

Our clinical program for tedizolid phosphate for ABSSSI consists of two Phase 3 clinical trials and a number of clinical safety and special population trials. Each Phase 3 clinical trial is a randomized, double-blind, multicenter clinical trial that tests a 200 mg dose of tedizolid phosphate administered once daily for six days versus a 600 mg dose of linezolid twice daily for 10 days. Each Phase 3 study contemplates enrolling approximately 658 patients from approximately 100 sites in North America, Latin America, Europe and other territories.

In accordance with the Special Protocol Assessment, or SPA, obtained for each of the Phase 3 ABSSSI studies, the second of which was obtained in the third quarter of 2011, our Phase 3 clinical trials are non-inferiority studies comparing short course of therapy with tedizolid (6 days) versus longer course of therapy with linezolid (10 days).

The following figure provides an overview of the design of our Phase 3 clinical trials of tedizolid phosphate.



In December 2011, we completed our first Phase 3 clinical trial of the oral dosage form of tedizolid phosphate for the treatment of ABSSSI, which was a randomized, double-blind, multicenter clinical trial with a 200 mg dose of tedizolid phosphate administered once daily for six days versus a 600 mg dose of linezolid (Zyvox) twice daily for 10 days. There were 667 subjects enrolled from sites in North America, Latin America and Europe.

The following table summarizes the top-line data from the 112 trial:

ITT Analysis Set		Tedizolid 6 days treatment	Linezolid 10 days treatment
Primary Endpoint	Cessation of spread and absence of fever at 48-72 hours	79.5%	79.4%
Additional Endpoint	Greater than or equal to 20% decrease from baseline in lesion area at 48-72 hours	78.0%	76.1%
Key Secondary Endpoints	Sustained clinical response at end of therapy (Day 10)	69.3%	71.9%
	Investigators assessment of clinical response at 7-14 days after end of therapy	85.5%	86.0%

In the ITT analysis set, tedizolid phosphate met the primary objective of non-inferiority of the efficacy outcome of early clinical response versus linezolid, with primary endpoint outcome rates of 79.5% and 79.4%, respectively. Additionally, favorable outcomes were found for all secondary efficacy endpoints.

Both tedizolid phosphate and linezolid were well-tolerated, with drug-related treatment emergent adverse events, or TEAEs, as noted below:

Adverse Event	Tedizolid (200 mg QD 6 days)	Linezolid (600 MG BID 10 Days)
Any Treatment Emergent Adverse Event (TEAE)	40.8%	43.3%
Any Drug Related TEAE	24.2%	31.0%
Gastrointestinal Disorders[1]	16.3%[2]	25.4%

1 Gastrointestinal AEs include: diarrhea, nausea, vomiting and dyspepsia
2 Statistically significant (p=0.004)

The chart above indicates that tedizolid had a numerically lower rate of drug-related TEAE's and a statistically significant lower number of gastrointestinal adverse events.

In addition, the 112 trial showed that tedizolid had a significantly lower impact on platelets than linezolid:

	Percent of Patients with Value below the Lower Limit of Normal (LLN)	
Hematology Parameter	Tedizolid (200mg QD 6 Days)	Linezolid (600mg BID 10 Days)
Platelets[1]	9.2%	14.9%
Platelets – Substantially Abnormal Value (<75% LLN)	2.3%	4.9%

1 Statistically significant (p=0.038).

In September 2011, we initiated our second Phase 3 clinical trial of tedizolid phosphate in ABSSSI for the IV to oral transition therapy with 200 mg of tedizolid phosphate administered once daily for six days versus a 600 mg dose of linezolid twice daily for 10 days, and we expect to report top-line data from this clinical trial in early 2013. We currently expect to submit an NDA for tedizolid phosphate for the treatment of ABSSSI during the third quarter of 2013.

In addition to our ongoing Phase 3 trial, we expect to complete in the next year certain clinical pharmacology Phase 1 studies that include the following: PK in elderly patients; hepatic impairment; renal impairment; cardiovascular safety; and vasoconstrictor and SSRI drug interaction and tyramine pressor studies.

Our Nonclinical Studies of Tedizolid Phosphate

Both tedizolid phosphate and tedizolid have been tested extensively in vitro and in vivo in nonclinical primary and safety pharmacology, toxicology and efficacy studies.

Overall results from multiple susceptibility testing studies against a variety of gram-positive aerobic and anaerobic bacteria demonstrate that tedizolid is four to 16 times more potent than linezolid against linezolid-susceptible strains and up to 16 times more potent against linezolid-resistant strains. In nonclinical studies, tedizolid phosphate has demonstrated efficacy in multiple animal models and was consistently more potent than linezolid, whether dosed by the oral or IV form. Typically, these studies also evaluate the effect of the body on the drug, including the absorption, distribution, metabolism and excretion of the drug by the body, as reflected by measuring drug concentration over time, referred to as pharmacokinetics, and the physiological effects that the drug has on the body and the duration of those effects, referred to as pharmacodynamics. In a rigorous pharmacokinetic/ pharmacodynamic, or PK/PD, mouse thigh infection model, tedizolid phosphate demonstrated in vivo bactericidal activity similar to that of daptomycin, while linezolid showed bacteriostatic activity. In this model, the in vivo decrease in colony forming units, or CFU, or numbers of viable *S. aureus* bacteria in mice dosed with tedizolid phosphate was five log 10 CFU while the number of viable bacteria in mice dosed with linezolid dropped less than three log 10 CFU. In general, greater than three log 10 CFU decrease in viable bacteria in such experiments is correlated with bactericidal activity. Moreover, unlike linezolid, tedizolid was bactericidal in vivo against both methicillin susceptible *S. aureus* , or MSSA, and community-associated MRSA, or CA-MRSA.

The in vitro potency advantage of tedizolid over linezolid against lung pathogens *S. pneumoniae* and *S. aureus* is also manifested in vivo in mouse pneumonia models of infection which are generally predictive of efficacy in humans.

Planned Nonclinical Studies

In parallel with our Phase 3 clinical development of tedizolid phosphate for the treatment of ABSSSI, we will continue to conduct nonclinical studies to further support the development of tedizolid phosphate for the treatment of additional clinical indications. These studies will include efficacy, safety and PK studies in support of indications requiring long-term dosing, such as bacteremia and endocarditis.

Our Research Platform

We have developed a proprietary platform called *FAST* which uses antisense technology to identify suitable bacterial drug targets and have built state-of-the-art capabilities in SBDD. We use these technologies to discover and develop novel antibacterial agents that act on targets essential for bacterial growth.

The *FAST* platform consists of a set of engineered bacterial strains containing antisense DNA fragments whose synthesis can be regulated to inhibit the production of a targeted protein. We have demonstrated that antibacterial compounds that inhibit the enzyme whose production is also inhibited by the *FAST* antisense strain, require a significantly lower concentration to inhibit bacterial growth of the *FAST* strain than the control strain.

We have developed *FAST* strains for a set of over 20 essential bacterial specific targets selected for the likelihood of discovering broad spectrum antibacterial agents. We have filed patent applications to protect our *FAST* technology, including the compounds that act on the targets we have identified.

Using SBDD, we obtain the structural information for the target enzymes of multiple bacterial pathogens to design compounds that bind specifically to the intended bacterial target. We also use this information to design compounds with improved drug properties such as solubility and serum binding.

GyrB/ParE Dual Target Preclinical Program

Our GyrB/ParE preclinical program is fully funded through Phase 1 clinical trials, subject to the achievement of program milestones, by our NIAID contract. The bacterial enzymes DNA gyrase, consisting of GyrA and GyrB, and Topoisomerase IV, consisting of ParC and ParE, are required for the replication of bacterial cells. GyrA and ParC are the targets of the fluoroquinolone class of antibacterial agents, such as ciprofloxacin. GyrB is the target of the natural product novobiocin. However, there are no antibacterial agents in clinical use that inhibit both GyrB and ParE.

In our research funded by NIAID, we are developing broad-spectrum agents that include those important gram-negative pathogens for biodefense. Antibiotics active against these biodefense organisms are often also active against clinically important gram-negative bacteria, such as *Pseudomonas aeruginosa, Acinetobacter baumannii, Klebsiella pneumoniae* and *Escherichia coli.* Consequently, compounds developed under our NIAID contract should also have significant utility in treating infections caused by these clinically important bacteria, such as respiratory tract, urinary tract and intra-abdominal infections. Because resistance to current drug classes (including carbapenems and fluoroquinolones) is growing rapidly among gram-negative bacteria, we believe treatment for these infections is a significant unmet medical need.

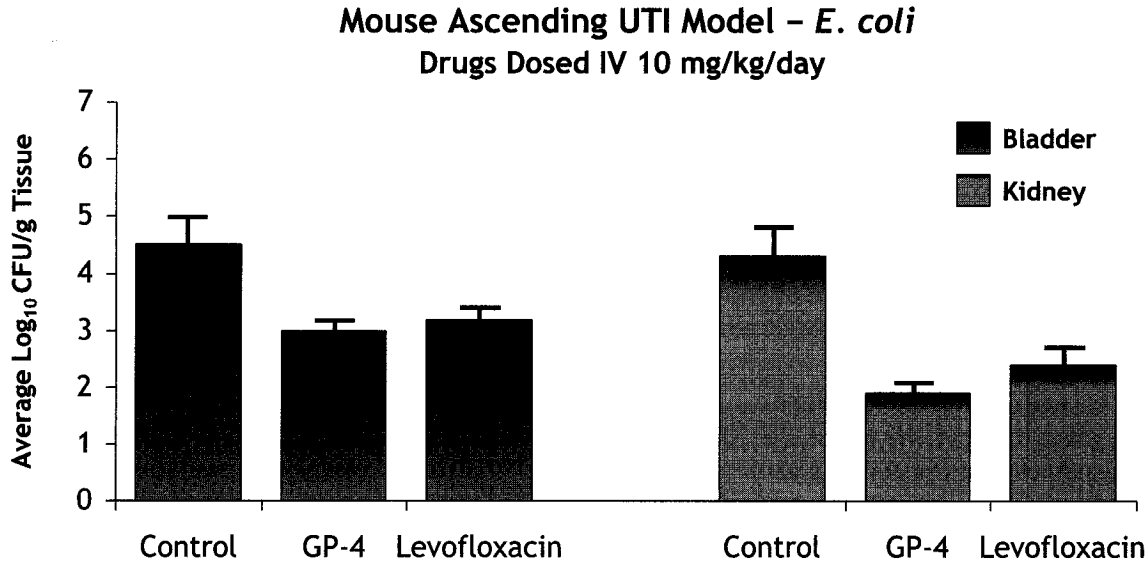
Because our lead compounds inhibit both GyrB and ParE, they are active against fluoroquinolone-resistant strains of bacteria. Key advantages of inhibiting both targets include a low rate of emergence of bacterial resistance to this antibacterial class and increased potency. The compounds that we have identified in our GyrB/ParE program have broad spectrum antibacterial activity. We have tested our lead compounds in antibacterial assays against broad panels of bacteria including representative panels of current clinical isolates. In general, the GyrB/ParE antibacterial agents have similar potency versus both wild type and resistant strains. As shown in the table below, the antibacterial potency for multiple compounds in this series is in the range (MIC < 4 mg/mL) considered clinically relevant and includes strains of *Pseudomonas aeruginosa, Acinetobacter baumannii* and, *Klebsiella pneumoniae* that are resistant to commonly used antibacterial classes, including the fluoroquinolines. We have also demonstrated that these compounds are efficacious in multiple animal models of gram-negative infections.

Antibacterial Activity of GyrB/ParE (GP) Compounds Versus Both Wild Type and Fluoroquinolone Resistant Bacterial Strains

	Antibacterial Potency MIC (mg/mL)				
Pathogen (resistance)	**GP-1**	**GP-2**	**GP-3**	**GP-4**	**Cipro**
S. aureus (wild type)	0.008	0.008	≤0.001	0.008	0.5
S. aureus (VISA)	0.015	0.015	0.008	0.015	>4
S. pneumoniae (PSSP)	≤0.001	≤0.001	≤0.001	≤0.001	1
S. pneumoniae (PRSP)	≤0.001	≤0.001	≤0.001	≤0.001	>4
E. coli (wild type)	0.25	0.25	0.13	0.13	0.015
E. coli (ESBL)	0.5	0.5	0.25	0.25	>128
K. pneumoniae (wild type)	0.25	0.25	0.5	0.5	0.03
K. pneumoniae (KPC-2)	2	2	2	1	>128
A. baumannii (wild type)	0.06	0.03	0.06	0.06	0.12
A. baumannii (MDR/ESBL)	0.12	0.06	0.03	0.12	64
P. aeruginosa (wild type)	4	2	1	1	0.12
P. aeruginosa (MDR)	4	2	1	0.5	64

Cipro = ciprofloxacin; Resistance types: VISA (vancomycin intermediate resistant *S. aureus*); PSSP (penicillin sensitive *Strep. pneumoniae*); PRSP (penicillin resistant *Strep. pneumoniae);* ESBL (extended spectrum beta lactamase); KPC-2 *(K. pneumoniae* carbapenemase); MDR (multiple-drug resistance).

The table below demonstrates that one of our lead compounds, GP-4, demonstrates superior efficacy to a commonly used drug levofloxacin in a mouse model of complicated urinary tract infection (cUTI).



We are currently evaluating our lead compounds in advanced preclinical studies including IND-enabling toxicity studies. We intend to submit an IND with the FDA and plan to conduct a Phase 1 clinical trial in 2013.

Marine Natural Products Preclinical Program

Our marine natural products preclinical program is fully funded by our DTRA contract through the research and preclinical development stages, subject to the achievement of certain milestones under our DTRA contract. Under this program, we intend to apply our proprietary *FAST* and SBDD technologies to screen chemical libraries created from marine micro-organisms. We are employing a panel of *FAST* assays which are selectively sensitized to inhibitors of unique bacterial targets. As a result, we believe the *FAST* approach will identify novel compounds active against resistant organisms and gram-negative antibacterial agents. In addition, we believe this program has the potential to provide compounds with strong potency and in vivo efficacy.

The goal of the program is to produce an IND candidate and complete all of the studies required to submit an IND with the FDA. A suitable candidate will have a broad spectrum of activity against both gram-negative and gram-positive bacterial pathogens, including multiple biodefense pathogens. We believe that any such candidate is likely to have broad commercial interest.

Commercial Agreements

Dong-A Pharmaceutical Co., Ltd. License Agreement

In January 2007, we entered into a license agreement with Dong-A Pharmaceutical Co., Ltd., or 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. To our knowledge, Dong-A has not conducted any development or commercialization activities with respect to tedizolid phosphate since January 2007. We have the right to grant sublicenses to third parties through multiple tiers of sublicense.

Upon entering into the license agreement, we paid a $500,000 upfront-fee and have made subsequent milestone payments of $3.7 million through December 31, 2011. In addition, we may be required to make up to an aggregate of $13.0 million of additional payments upon the achievement of specified development and regulatory approval milestones.

In addition, we are obligated to pay Dong-A mid-single digit tiered royalties on net sales of tedizolid phosphate. The license agreement will remain in effect until the later of 12 years after the date of the first commercial sale of tedizolid phosphate or the expiration of the last to expire of the licensed patents on a product-by-product and country-by-country basis, unless terminated earlier at our election or for material breach by either party. Dong-A has the right to terminate the license agreement on 90 days' written notice if we fail to make a payment when due or fail to use commercially reasonable efforts to develop and commercialize tedizolid phosphate. Upon expiration of the license agreement, our license will remain in effect and convert to a royalty-free, irrevocable and perpetual license. If we elect to terminate the license agreement due to Dong-A's material breach of the license agreement, our license will remain in effect subject to our compliance with certain provisions of the license agreement, including payment obligations.

NIAID Contract

In September 2008, we entered into a five-year contract with NIAID to provide services to NIAID relating to the development of a dual-target antibacterial agent as a therapeutic for the treatment of gram-negative biodefense pathogens. Under our NIAID contract, we may receive up to $27.7 million in support of our GyrB/ParE preclinical program. The scope of the services under the contract includes preclinical, nonclinical and clinical Investigational New Drug application, or IND, and NDA-enabling development activities. Pursuant to our NIAID contract, subject to our compliance with applicable regulations, we may elect to obtain ownership of each patentable invention that arises from the performance of the research and development funded by our NIAID contract, subject to certain United States government march-in rights with respect to such inventions. March-in rights allow the United States government to grant licenses to such inventions to others if: (1) we do not "achieve practical application" of a subject invention (i.e. commercialize the technology); (2) such action is necessary to alleviate health or safety needs that are not reasonably satisfied by us; (3) such action is necessary to meet requirements for public use specified by federal regulations and such requirements are not reasonably satisfied by us; or (4) such action is necessary because we and/or our sublicensees are manufacturing patented products outside of the United States. If the United States government exercised its march-in rights, we could be obligated to license intellectual property developed by us on terms unfavorable to us, and there can be no assurance that we would receive compensation from the United States government for the exercise of such rights. In addition, the contract may be terminated by NIAID 10 days after giving notice of a material default which remains uncured 10 days after written notice. NIAID may also terminate the contract if it is in the United States government's best interest. From contract inception through December 31, 2011, we have recognized $19.0 million in revenues related to the research performed under the NIAID contract.

Lawrence Livermore Cooperative Research and Development Agreement

In November 2008, we entered into a five-year cooperative research and development agreement, or CRADA, with Lawrence Livermore National Security LLC, or Lawrence Livermore. Under the CRADA, we are jointly researching and developing gram-negative biodefense pathogens with Lawrence Livermore. We plan to fund the cost of the research and development with Lawrence Livermore with the funds we receive under our NIAID contract. The total cost of the project to us under the CRADA is approximately $5.6 million (excluding in-kind distributions). Pursuant to the CRADA, we have the right to obtain an exclusive license to any invention developed by Lawrence Livermore under the CRADA if we agree to pay Lawrence Livermore reasonable compensation for such license. Subject to our compliance with applicable regulations, we may elect to obtain ownership of each patentable invention that arises from the performance of the research and development under this CRADA, subject to the United States government's certain march-in rights with respect to such inventions. March-in rights allow the United States government to grant licenses to such inventions to others if: (1) we do

not "achieve practical application" of a subject invention (i.e. commercialize the technology); (2) such action is necessary to alleviate health or safety needs that are not reasonably satisfied by us; (3) such action is necessary to meet requirements for public use specified by federal regulations and such requirements are not reasonably satisfied by us; or (4) such action is necessary because we and/or our sublicensees are manufacturing patented products outside of the United States. If the United States government exercised its march-in rights, we could be forced to license or sublicense intellectual property developed by us or that we license from Lawrence Livermore on terms unfavorable to us, and there can be no assurance that we would receive compensation from the United States government for the exercise of such rights. Either party may terminate the CRADA after giving 30 days' written notice to the other party. Lawrence Livermore may also terminate the CRADA if we fail to provide necessary funding. From contract inception through December 31, 2011, we have recognized $2.2 million in research and development expense related to the research performed by Lawrence Livermore under the CRADA.

DTRA

In April 2010, we entered into a four and one-half year contract with DTRA under which we may receive up to $29.5 million to support a preclinical program for the development of novel antibiotics directed against gram-negative and gram-positive bacterial pathogens in collaboration with UCSD. Pursuant to our DTRA contract, subject to our compliance with applicable regulations, we may elect to obtain ownership of each patentable invention that arises from the performance of the research and development funded by our DTRA contract, subject to certain United States government march-in rights with respect to such inventions. If the United States government exercised its march-in rights, we could be obligated to license intellectual property developed by us on terms unfavorable to us, and there can be no assurance that we would receive compensation from the United States government for the exercise of such rights. In addition, the contract may be terminated by DTRA 10 days after giving notice of a material default which remains uncured 10 days after written notice. DTRA may also terminate the contract if it is in the United States government's best interest. From contract inception through December 31, 2011, we have recognized $6.0 million in revenues related to the research performed under our DTRA contract.

UCSD Research Agreement

In May 2010, we entered into a four and one-half year research agreement with UCSD. Under the agreement, we are jointly researching antibacterial agents for combating gram-negative and gram-positive biodefense pathogens. We plan to fund the cost of the research with UCSD with the funds we receive under our DTRA contract. The estimated total cost of UCSD's efforts under the project is up to approximately $4.3 million. Pursuant to the agreement, we have the right to negotiate an exclusive license to any invention developed by UCSD. Subject to our compliance with applicable regulations, we may elect to obtain ownership of each patentable invention that arises from the performance of the research and development under this agreement, subject to the United States government's certain march-in rights with respect to such inventions. If the United States government exercised its march-in rights, we could be forced to license or sublicense intellectual property developed by us or that we license from UCSD on terms unfavorable to us, and there can be no assurance that we would receive compensation from the United States government for the exercise of such rights. We may terminate the research agreement after giving 30 days' written notice to UCSD and UCSD may terminate the research agreement after giving 90 days written notice to us. We may also terminate the agreement immediately upon written notice to UCSD if our DTRA contract is terminated. From contract inception through December 31, 2011, we have recognized $1.2 million in research and development expense related to the research performed by UCSD under the agreement.

Lawrence Livermore National Laboratory

In April 2011, we entered into a three year research contract with Lawrence Livermore National Laboratory, or LLNL, for the development of novel antibiotics directed against gram negative multi-drug resistant bacterial pathogens. We may receive up to $3.0 million over three years in support of its development efforts. LLNL can

terminate the contract upon delivering notice to us for default or convenience. Upon receipt of a notice of termination, we must discontinue contract activities and LLNL must pay us a final settlement based on eligible expenses incurred under the contract. As of December 31, 2011, we have not received a notice of termination relative to contract activities. From contract inception through December 31, 2011, we have recognized $0.7 million in revenues related to the research performed under the LLNL contract.

Collaboration and License Agreement with Bayer Pharma AG

In July 2011, we signed our collaboration and license agreement with Bayer to develop and commercialize tedizolid phosphate in the Bayer Licensed Territory. Under the collaboration and license agreement, we are responsible for all development and commercialization activities outside of the Bayer Licensed Territory. We retain full development and commercialization rights in the United States, Canada and the European Union. 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 costs of tedizolid phosphate required for global approval for the treatment of ABSSSI and pneumonia. In addition, Bayer agreed to be responsible for 100% of future development as well as the future development costs required for local approval 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. In September, 2011, we dosed our first patient in our second Phase 3 clinical trial, and in accordance with the collaboration and license agreement, this entitled us to a $2 million milestone payment from Bayer, which was received prior to the end of 2011. In January 2012, the joint steering committee for the license and collaboration agreement met and Bayer confirmed that they agreed that we had met the primary objective of non-inferiority of the efficacy outcome of early clinical response versus the comparator linezolid (Zyvox) in patients with ABSSSI in our first Phase 3 clinical trial, and in accordance with the license and collaboration agreement, we were then entitled to receive an additional $5 million milestone from Bayer. Bayer has the ability to terminate the agreement in its entirety by providing at least six months notice to us within the first two years of the agreement. After two years, Bayer must provide at least 90 days notice. In addition, Bayer has the right to terminate the agreement within 30 days of determining that either of our two ongoing Phase 3 clinical trials 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. From contract inception through December 31, 2011, we have recognized $25.7 million in license revenues and $3.2 million in contract research revenues related to the collaboration and license agreement with Bayer.

Commercialization—Marketing and Sales

Our overall goal is to establish tedizolid phosphate as a leading therapy for the treatment of serious gram-positive infections. Our initial focus is to develop tedizolid phosphate for the treatment of ABSSSI. Over time, through clinical trials, regulatory approvals and publications, we plan to expand the data establishing the utility of tedizolid phosphate for the treatment of a wide variety of serious gram-positive infections including pneumonia and bacteremia. This comprehensive strategy is intended to support product differentiation from both current and anticipated competitors and also to enable us to fully support broad and appropriate usage of tedizolid phosphate.

We currently intend to focus our initial commercial efforts on the United States market, which we believe represents the largest market opportunity for tedizolid phosphate. We currently have limited marketing, no sales nor distribution capabilities. Pending NDA approval, we plan to build a United States sales organization focused on the promotion of tedizolid phosphate to healthcare professionals and payors, primarily in hospital and other institutional settings. We also plan to evaluate potential partnerships to support our commercialization objectives.

In addition to the significant opportunity in the United States, we believe that Latin America, Europe and Asia represent opportunities for tedizolid phosphate. In July 2011, we licensed certain development and commercialization rights to Bayer in China, Japan and substantially all other countries in Asia, Africa, Latin

America and the Middle East, excluding North and South Korea, or the Bayer Licensed Territory. For this right, in addition to reimbursement for certain development efforts and payment of certain milestones, if tedizolid phosphate is approved for sale in these countries, then we will also receive royalties on net sales by Bayer in the Bayer Licensed Territory We continue to evaluate our commercialization strategy outside the United States but expect to outlicense rights to or collaborate with third parties for commercialization of tedizolid phosphate in Europe.

Intellectual Property

The proprietary nature of, and protection for, tedizolid phosphate and our preclinical programs, processes and know-how are important to our business. We seek patent protection in the United States and internationally for tedizolid phosphate, our preclinical programs and any other technology to which we have rights where available and when appropriate. Our policy is to pursue, maintain and defend patent rights, developed internally and licensed from third parties and to protect the technology, inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets that may be important to the development of our business. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our technology. For this and more comprehensive risks related to our intellectual property, please see "Risk Factors—Risks Related to Our Intellectual Property."

Our success will depend significantly on our ability to:

- Obtain and maintain patent and other proprietary protection for the technology, inventions and improvements we consider important to our business;
- Defend our patents;
- Preserve the confidentiality of our trade secrets; and
- Operate our business without infringing the patents and proprietary rights of third parties.

We have established and continue to build proprietary positions for tedizolid phosphate and our pipeline product candidates and technology in the United States and abroad. As of March 1, 2012, our patent portfolio included four families of patent applications related to tedizolid phosphate and two families of patent applications related to our *FAST* research platform.

For tedizolid phosphate, the first family of patent applications is exclusively licensed (except in South and North Korea) from Dong-A. This family is expected to provide basic composition of matter coverage and includes issued and pending United States utility patent applications, and issued and pending foreign national and regional counterpart patent applications. We own the remaining three families of applications related to aspects of tedizolid phosphate, which include issued and pending United States utility patent applications, and issued and pending foreign national and regional counterpart patent applications. The second family of applications is directed to a method of synthesis and related compositions of matter. The third family of applications is directed to aspects of crystalline forms of tedizolid phosphate and associated methods. The fourth family of applications is directed to aspects of tedizolid phosphate dimers and associated methods. If issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, we expect that these four families of patent applications would expire between 2024 and 2030, excluding any additional term for patent term adjustments or patent term extensions.

For our *FAST* research platform, we have one issued and one pending United States patent applications. If issued, these patent applications would both expire in 2026, excluding any additional term for patent term adjustments or patent term extensions.

Further, we seek trademark protection in the United States and internationally where available and when appropriate. We have filed for trademark protection in many countries for the TRIUS THERAPEUTICS mark, which we use in connection with our pharmaceutical research and development services as well as products. We currently have registered trademarks for Trius Therapeutics in Australia, China, the European Union, Japan, New Zealand, Singapore, and pending trademark applications for Trius Therapeutics in the United States, Canada, and India.

Competition

Our industry is highly competitive and subject to rapid and significant technological change. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. We believe that the key competitive factors that will affect the development and commercial success of tedizolid phosphate and the product candidates that we develop are efficacy, safety and tolerability profile, convenience in dosing, price and reimbursement.

We expect that, if approved, tedizolid phosphate would compete with a number of drugs that target serious gram-positive infections. Many of our potential competitors, including many of the organizations named below, have substantially greater financial, technical and human resources than we do and significantly more experience in the discovery, development and regulatory approvals of products, and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render tedizolid phosphate or any other product candidates that we develop obsolete or non-competitive before we can recover the expenses of developing and commercializing any product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market, as advanced technologies become available and as generic forms of currently branded drugs become available. Finally, the development of new treatment methods for the diseases we are targeting could render our drugs non-competitive or obsolete.

We anticipate that, if approved, tedizolid phosphate will compete with other antibiotics that demonstrate MRSA activity. These include vancomycin, a generic drug that is manufactured by a variety of companies, linezolid (marketed by Pfizer as Zyvox), daptomycin (marketed by Cubist Pharmaceuticals, Inc. as Cubicin), quinupristin/dalfopristin (marketed by King Pharmaceuticals, Inc., a subsidiary of Pfizer as Synercid), tigecycline (marketed by Wyeth, a subsidiary of Pfizer as Tygacil), ceftaroline (marketed by Forest Laboratories and AstraZeneca PLC as Teflaro), and ceftobiprole (under development by Basilea Pharmaceutica AG, telavancin (marketed as Vibativ by Theravance, Inc.). Further, we expect that product candidates currently in Phase 3 development, or that could enter Phase 3 development in the near future, may represent significant competition if approved. These include, but are not necessarily limited to PTK 0796 (under development by Paratek Pharmaceuticals, Inc.), NXL-103 (under development by AstraZeneca PLC), radezolid (under development by Rib-X Pharmaceuticals, Inc.), delafloxacin (under development by Rib-X Pharmaceuticals, Inc.), CEM-102 (under development by Cempra Pharmaceuticals, Inc.), oritavancin (under development by The Medicines Company), dalbavancin (under development by Durata Therapeutics, Inc.), BC-3781 (under development by Nabrivia), and JNJ-Q2 (under development by Furiex Pharmaceuticals, Inc.). Many of these companies may have significantly greater resources than we have. We believe that the key potential advantages of tedizolid phosphate over these competitive products, including activity against linezolid-resistant MRSA, should enable tedizolid phosphate to capture market share from these competitive products and, over time, garner a meaningful share of both the in- patient and out-patient MRSA market. Even with these advantages, we may not be able to make promotional claims that tedizolid phosphate is superior to these competing products.

Third-Party Reimbursement and Pricing

In the United States and elsewhere, sales of pharmaceutical products depend in significant part on product availability (formulary access) and reimbursement from payors, such as government and private insurance plans. To allow access to tedizolid phosphate, we will work with payors to demonstrate the value of tedizolid phosphate in improved, cost-effective patient care. We believe that the improved features and potential benefits of tedizolid phosphate will differentiate tedizolid phosphate from other competitive therapies and ultimately will lead to its widespread adoption by hospital formularies and reimbursement. We will be conducting pricing research to understand the pricing of tedizolid phosphate to ensure that it delivers the appropriate value to our customers.

In markets outside the United States, including the countries in the EU, pricing of pharmaceutical products is subject to governmental control. Evaluation criteria used by many EU government agencies for the purposes of pricing and reimbursement typically focus on a product's degree of innovation and its ability to meet a clinical need unfulfilled by currently available therapies. We believe that the clinical profile and patient friendly dosing of tedizolid phosphate will enable us to achieve an appropriate price and reimbursement for tedizolid phosphate in countries where pricing is set by a government agency, and to obtain reimbursement for tedizolid phosphate from the responsible agencies in each market. As in the United States, we will conduct EU pricing research to determine the appropriate pricing to provide appropriate value with other branded gram-positive antibiotics.

Manufacturing

We do not own or operate manufacturing facilities for the production of tedizolid phosphate or other product candidates that we develop, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, API and finished products for our preclinical research and clinical trials. We employ the services of Albany Molecular Research Incorporated, or AMRI, to produce tedizolid phosphate API and Patheon, Inc., or Patheon, to produce the solid oral and sterile IV tedizolid phosphate finished products. We do not have any current contractual arrangements for the manufacture of commercial supplies of tedizolid phosphate or any other product candidates that we develop. If tedizolid phosphate is approved for treatment of ABSSSI by the FDA, we intend to enter into agreements with third-party contract manufacturers for the commercial production of tedizolid phosphate. We currently employ internal resources and third-party consultants to manage our manufacturing contractors.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. Tedizolid phosphate and any other antibiotic product candidate that we develop must be approved by the FDA through the NDA process before they may be legally marketed in the United States.

United States Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, or FDCA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil

or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices or other applicable regulations;
- Submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- Performance of adequate and well-controlled human clinical trials according to the FDA's current good clinical practices, or cGCP, to establish the safety and efficacy of the proposed drug for its intended use;
- Submission to the FDA of an NDA for a new drug;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with the FDA's current good manufacturing practice, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and approvals are inherently uncertain.

Before testing any compounds with potential therapeutic value in humans, the drug candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance.

Each new clinical protocol must be submitted to the FDA for review, and to an Institutional Review Board, or IRB, for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2.* The drug is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected AEs or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Some studies also include a data safety monitoring board, which receives special access to unblinded data during the clinical trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds such as no demonstration of efficacy.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

United States Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, which was reauthorized under the Food and Drug Administration Amendments Act of 2007, or FDAAA, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be re-submitted with the additional information. The re-submitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it

determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. During the drug approval process, the FDA also will determine whether a risk evaluation and mitigation strategy, or REMS, is necessary to assure the safe use of the drug. If the FDA concludes an REMS is needed and notifies the drug sponsor of this decision, the sponsor of the application must submit a proposed REMS; the FDA will not approve a marketing application without an REMS, if required.

In addition, under the FDAAA, all drugs prior to approval are referred to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions, unless the Secretary of Health and Human Services provides in the action letter on the drug application a summary of the reasons why it was not referred. An advisory committee is a panel of experts who provide advice and recommendations when requested by the FDA on matters of importance that come before the agency. The FDA is not bound by the recommendation of an advisory committee but it generally follows such recommendations.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA in its present form. The complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug safety and effectiveness after NDA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of the use of our product candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications of other companies seeking to reference another company's NDA. The FDCA provides a five-year

period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study. The current pediatric exclusivity provision was reauthorized in September 2007 as part of the FDAAA.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. For a fast track product, the FDA may consider for review on a rolling basis sections of the NDA before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

A product may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drugs studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Fast track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Post-Approval Requirements

Any drug products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. For example, drugs may be promoted only for the approved indications and in accordance with the provisions of the approved labeling, and information regarding effectiveness must be fairly balanced by safety information. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

The FDA may withdraw a product approval if compliance with regulatory standards is not maintained or if problems (quality or safety) occur after the product reaches the market. Later discovery of previously unknown quality, safety, other problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, warning letters, holds on clinical trials, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or civil or criminal penalties.

In addition, from time to time, legislation is drafted, introduced and passed in the United States Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. Failure to comply with any requirements under the new law may result in significant penalties. In addition, FDA regulations and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

Additional Post-Approval Healthcare Compliance Laws

Our sales, promotion, medical education and other activities following product approval are subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to FDA, including potentially the Federal Trade Commission, the Department of Justice, the Centers for Medicare and Medicaid Services, other divisions of the Department of Health and Human Services, the Consumer Product Safety Commission and state and local governments. Our promotional and scientific/educational programs must comply with the anti-kickback provisions of the Social Security Act, the Foreign Corrupt Practices Act, the False Claims Act, the Veterans Health Care Act and similar state laws.

Our pricing and rebate programs must comply with pricing and reimbursement rules, including the Medicaid drug rebate requirements of the Omnibus Budget Reconciliation Act of 1990. Also, under the Veterans Health Care Act, we are required to offer certain drugs at a reduced price to a number of federal agencies including the Veterans Health Administration and the Department of Defense, the Public Health Service and certain private Public Health Service designated entities in order to participate in other federal funding programs including Medicare and Medicaid. In addition, recent legislative changes purport to require that discounted prices be offered for certain Department of Defense purchases for its TRICARE program via a rebate system. As with the Medicaid program described above, participation under the Veterans Health Administration requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations.

In addition, federal legislation now imposes additional requirements. For example, as part of the Patient Protection and Affordable Care Act, or PPACA, a federal physician payment disclosure provision based on the Physician Payments Sunshine Act was enacted, which requires pharmaceutical manufacturers to 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.

Depending on the circumstances, failure to meet these applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "qui tam" actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to sell any products outside of the United States. Whether or not we obtain FDA approval for a product, we, or our collaborative partners must obtain approval of a product by the comparable regulatory authorities of foreign countries before we, or our collaborative partners can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

EU member states require both regulatory clearance by the national competent authority and a favorable ethics committee opinion prior to the commencement of a clinical trial. Under the EU regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all EU member states. The centralized procedure is compulsory for medicines produced by certain biotechnological processes, products with a new active substance indicated for the treatment of certain diseases such as neurodegenerative disorder or diabetes and products designated as orphan medicinal products and optional for those products which are highly innovative or for which a centralized process is in the interest of patients. The decentralized procedure of approval provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state, known as the reference member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials (draft summary of product characteristics, draft labeling and package leaflet) to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points may eventually be referred to the European Commission, whose decision is binding on all member states.

Reimbursement

Sales of pharmaceutical products depend significantly on the availability of third-party reimbursement. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. We anticipate third-party payors will provide reimbursement for our products. However, these third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. The product candidates that we develop may not be considered cost-effective. It is time consuming and expensive for us to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

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 payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/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. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee.

The MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs.

The American Recovery and Reinvestment Act of 2009, or ARRA, allocated funding for the accelerated development and dissemination of research assessing the comparative effectiveness of health care treatments and strategies to treat diseases, disorders and other health conditions. The objectives of this Comparative Effectiveness Research, or CER, are to provide essential information to clinicians and patients with which to decide on the best treatment and enable the nation to improve the health of communities and the performance of the health system. It is unclear at this time how the outcome of this research may influence legislative or regulatory proposals that could have a significant effect on our profitability. We cannot anticipate the impact on the use of our drugs by healthcare practitioners or their placement on healthcare formularies or insurance reimbursement programs.

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 payors. In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition, and results of operations.

There is an additional body of United States law that governs a company's eligibility to participate in Medicare and Medicaid reimbursements and is designed to eliminate fraud and abuse. For example, a company may be debarred from participation if it is found to have violated federal anti-kickback laws, which could have a significant effect on a company's ability to operate its business.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of a company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products.

ITEM 1A. *RISK FACTORS*

You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report on Form 10-K and in our other public filings in evaluating our business. 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 December 31, 2011, we had an accumulated deficit of $95.4 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 three 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 payors;
- Pursuing clinical development of tedizolid phosphate for the treatment of other indications, including pneumonia and 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.

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 other indications, including pneumonia and bacteremia; and
- Continue our discovery and development programs to advance our preclinical product pipeline.

In August 2010, we completed our initial public offering, raising $45.1 million in net proceeds. In May 2011, we completed our 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. We expect that the net proceeds from our recent public offering, 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 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 $13.0 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 $69.1 million 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 9 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 announced the positive results on both the early endpoints used by the FDA and the post-treatment assessment used by the EMA in December 2011. 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 MAA 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 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 clinical safety, pharmacology and special population Phase 1 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, based on the review of our initial Phase 3 study safety data, require us to conduct additional clinical trials or enroll additional patients in our Phase 3 clinical program. 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

AAI Pharma Services, or AAI, 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, AAI 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, AAI, Patheon or any other third party.

With respect to the manufacturing for our commercial scale product, we intend to eventually 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, AAI, 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 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 dependence on 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 future development plans and Bayer may delay future clinical trials or stop a future 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, 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;
- 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 payors 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 payors, 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 payors 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 payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/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 payors.

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 payors.

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 payors 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 payors 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 payors 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 payors, 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 payors, 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 payors 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 March 1, 2012, we employed 73 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 other indications, including pneumonia and 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 with NIAID, DTRA and LLNL. 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 February 2010, the European Medicines Agency, or EMA, issued its draft revision to the "Guideline on the Evaluation of Medicinal Products Indicated for the Treatment of Bacterial Infections." As with the FDA, the timing for the issuance of the EMA finalized guideline document, 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 and provisional patent applications and Patent Cooperation Treaty 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 licensed pending 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.

The Leahy-Smith America Invents Act, or the Leahy-Smith Act, was recently 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 one year or 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, DTRA 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 NIAID, DTRA and LLNL contracts. There can be no assurances that these 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, DTRA and LLNL may not be required to continue funding our existing contracts.

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 NIAID, DTRA or LLNL contracts; and
- Change certain terms and conditions in our NIAID, DTRA or LLNL 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. 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, DTRA 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.

For example, under our DTRA contract, the DCAA may conduct a post award audit of our indirect cost rates, and review of our accounting and purchasing systems. If we receive negative findings from the DCAA, the contract may be terminated.

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 NIAID, DTRA and LLNL 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 NIAID, DTRA and LLNL 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 NIAID, DTRA and LLNL 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 March 1, 2012 our executive officers, directors, 5% shareholders and their affiliates own approximately 47% 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 March 1, 2012, our executive officers, directors, 5% stockholders and their affiliates own approximately 47% 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 1B. *UNRESOLVED STAFF COMMENTS*

None.

ITEM 2. *PROPERTIES*

We lease approximately 35,000 square feet of laboratory and office space in our headquarters in San Diego, California under a lease that expires in 2013. We currently do not plan to purchase or lease facilities for manufacturing, packaging or warehousing, as such services are provided to us by third-party contractors. We believe that our current facilities are adequate for our needs for the immediate future and that, should it be needed, suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms.

ITEM 3. *LEGAL PROCEEDINGS*

We are not currently a party to any material legal proceedings.

ITEM 4. *MINE SAFETY DISCLOSURES*

None.

PART II

ITEM 5. *MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES*

Our common stock has been listed on the NASDAQ Global Market under the symbol "TSRX" since it began trading on August 2, 2010. Prior to that time there was no public market for our common stock. Shares sold in our initial public offering on August 2, 2010 were priced at $5.00 per share. The following table sets forth, for the periods indicated, the high and low sale price of our common stock. These prices do not include retail markups, markdowns or commissions.

	High	Low
Year Ended December 31, 2011		
1st Quarter	$7.49	$3.70
2nd Quarter	8.85	5.00
3rd Quarter	9.00	5.82
4th Quarter	8.00	5.51
Year Ended December 31, 2010		
3rd Quarter (beginning August 2, 2010)	$5.47	$3.88
4th Quarter	4.26	2.93

Holders of Record

As of March 2, 2012, there were approximately 100 stockholders of record of our common stock, one of which is Cede & Co., a nominee for Depository Trust Company, or DTC. Shares of common stock that are held by financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are considered to be held of record by Cede & Co. as one stockholder.

Dividends

We have not paid any cash dividends on our common stock since inception and do not anticipate paying cash dividends in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

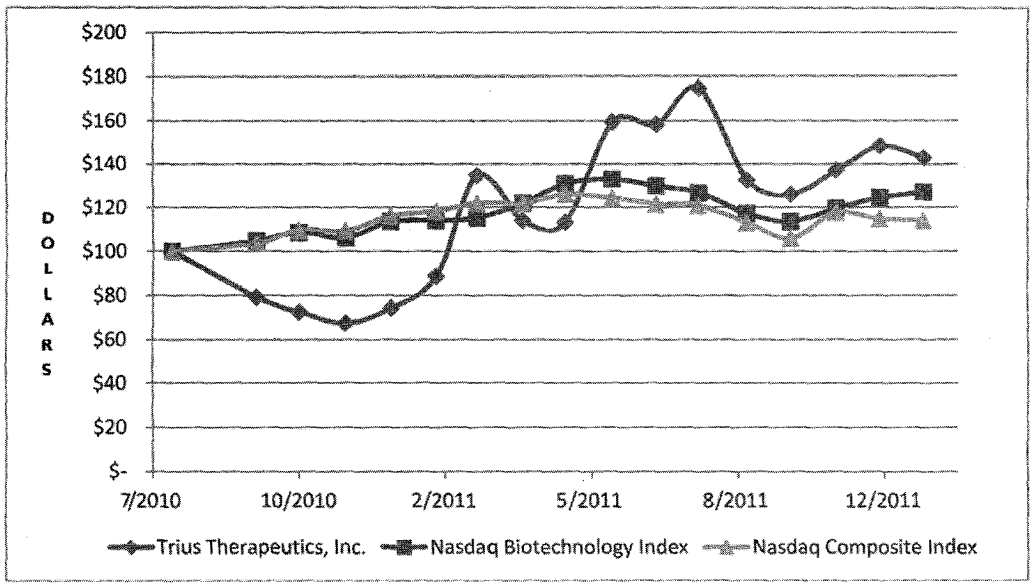
Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Repurchases of Equity Securities

There were no repurchases of equity securities during the fourth quarter of 2011.

Stock Performance Graph and Cumulative Total Return (1)

The graph below shows the cumulative total stockholder return assuming the investment of $100 on August 2, 2010, our IPO pricing date (and the reinvestment of dividends thereafter) through December 31, 2011 in each of (i) Trius Therapeutics, Inc.'s common stock, (ii) the Nasdaq Biotechnology Index and (iii) the Nasdaq Composite Index. The comparisons in the graph below are required by the Securities and Exchange Commission, are based upon historical data, and are not indicative of, or intended to forecast, future performance of our common stock.



(1) This section is not "soliciting material," is not deemed "filed" with the SEC, is not subject to the liabilities of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference in any of our filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

Use of Proceeds

The initial public offering of our common stock was effected through a Registration Statement on Form S-1 (File No. 333-162945) that was declared effective by the SEC on August 2, 2010, which registered an aggregate of 10,750,000 shares of our common stock, including 750,000 shares that the underwriters had the option to purchase to cover over-allotments. On August 6, 2010, 10,000,000 shares of common stock were sold on our behalf at an initial public offering price of $5.00 per share, for an aggregate gross offering price of $50,000,000 to us. The over-allotment option was not exercised.

We paid to the underwriters underwriting discounts and commissions totaling approximately $1.6 million in connection with the offering. In addition, we incurred additional costs of approximately $3.3 million in connection with the offering, which when added to the underwriting discounts and commissions paid by us, amounts to total fees and costs of approximately $4.9 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and commissions and offering costs, were approximately $45.1 million.

As of December 31, 2011, all $45.1 million in net proceeds from our IPO has been used in funding our clinical and nonclinical research and development costs for tedizolid phosphate for the treatment of ABSSSI and other indications and to fund working capital and other general corporate purposes.

ITEM 6. *SELECTED FINANCIAL DATA*

The following selected financial data have been derived from our audited financial statements and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K. The information set forth below is historical and is not necessarily indicative of our results of future operations.

	Year Ended December 31,				
	2011	2010	2009	2008	2007
	(In thousands, except per share data)				
Statement of Operations:					
Revenues:					
NIH grants	$ —	$ —	$ —	$ 429	$ 679
Contract research	12,086	8,032	4,980	658	141
Collaborations	3,217	—	36	243	345
License	25,708	—	—	—	—
Total revenues	41,011	8,032	5,016	1,330	1,165
Operating expenses:					
Research and development	49,503	23,320	23,049	20,086	8,517
General and administrative	11,339	5,406	4,134	2,290	1,546
Total operating expenses	60,842	28,726	27,183	22,376	10,063
Loss from operations	(19,831)	(20,694)	(22,167)	(21,046)	(8,898)
Other income (expense):					
Interest income	21	8	36	582	308
Interest expense	—	(3,889)	(284)	(76)	(170)
Fair value adjustment of stock warrant liability	1,558	467	(245)	(221)	18
Other income (expense)	2	245	(21)	(30)	(6)
Total other income (expense)	1,581	(3,169)	(514)	255	150
Net loss	(18,250)	(23,863)	(22,681)	(20,791)	(8,748)
Accretion of deferred financing costs on redeemable convertible preferred stock	—	(18)	(28)	(26)	(8)
Net loss attributable to common stockholders	$(18,250)	$(23,881)	$(22,709)	$(20,817)	$ (8,756)
Net loss per share, basic and diluted	$ (0.69)	$ (2.36)	$ (31.11)	$ (40.19)	$ (31.72)
Shares used in calculating net loss per share allocable to common stockholders, basic and diluted	26,517	10,099	730	518	276

Balance Sheet Data:

	As of December 31,				
	2011	2010	2009	2008	2007
			(In thousands)		
Cash, cash equivalents and short-term investments	$ 59,143	$ 45,338	$ 18,259	$ 21,661	$11,534
Working capital (deficit)	48,453	44,751	17,852	20,539	10,594
Total assets	68,125	49,500	21,378	23,865	13,161
Capital lease obligation, net of current portion	—	—	—	71	191
Stock warrant liability	7,124	—	661	415	203
Convertible notes payable	—	—	19,402	—	—
Convertible preferred stock	—	—	51,082	51,054	20,633
Accumulated deficit	(95,392)	(77,142)	(53,261)	(30,552)	(9,735)
Total stockholders' equity (deficit)	49,891	45,454	(51,497)	(29,946)	(9,629)

ITEM 7. *MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS*

You should read the following discussion and analysis in conjunction with "Item 8. Financial Statements and Supplementary Data" included below in this Annual Report on Form 10-K. Operating results are not necessarily indicative of results that may occur in future periods.

This discussion and analysis contains forward-looking statements that involve a number of risks, uncertainties and assumptions. Actual events or results may differ materially from our expectations. Important factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements include, but are not limited to, those set forth in "Item 1A. Risk Factors" in this Annual Report on Form 10-K. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us as of the time we file this Annual Report on Form 10-K and, except as required by law, we undertake no obligation to update publicly or revise 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, initially for acute bacterial skin and skin structure infections, or ABSSSI, and subsequently for other indications, including pneumonia. ABSSSI is a new classification for complicated skin and skin structure infections, or cSSSI. Tedizolid phosphate is an IV and orally administered second generation oxazolidinone.

In December 2011, we completed our first Phase 3 clinical trial 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 of the IV to oral transition therapy for the treatment of ABSSSI. 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, for tedizolid phosphate for the treatment of ABSSSI during the third quarter of 2013. We also completed a Phase 1 clinical trial, during the first quarter of 2011, 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 pursue further development of tedizolid phosphate for the treatment of pneumonia 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 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 intend to continue to evaluate potential strategic alliances for tedizolid phosphate in Europe.

In May 2011, we raised a total of approximately $28.0 million from our private placement of 4,750,000 units at a purchase price of $6.35 per unit, with each unit consisting of one share of our common stock and a warrant to purchase an additional 0.35 shares of our common stock. Each warrant is exercisable in whole or in part for a period of five years from November 27, 2011 at a per share exercise price of $8.50, subject to certain adjustments.

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

In addition, we are discovering antibiotics for broad spectrum infections using our proprietary discovery platform under three contracts: one funded by the National Institute of Allergy and Infectious Diseases, or NIAID, a part of the National Institutes of Health, or NIH, a second funded by the Defense Threat Reduction Agency, or DTRA, a part of the Department of Defense and a new third contract that we entered into in April 2011 with Lawrence Livermore National Laboratory, or LLNL, a part of the U.S. Department of Energy's National Nuclear Security Administration.

We acquired worldwide rights to tedizolid phosphate outside of South and North Korea, or Korea, from Dong-A Pharmaceutical Co., Ltd., or Dong-A, in January 2007. Since then we have progressed tedizolid phosphate from submitting an Investigational New Drug Application, or IND, through our first Phase 3 clinical trial, and we are currently conducting a second Phase 3 clinical trial. In addition, we have substantially lowered the manufacturing costs of tedizolid phosphate.

In September 2008, we entered into a five-year contract with NIAID under which we may receive up to $27.7 million to support our development of novel dual-target antibacterial agents as therapeutics for the treatment of gram-negative biodefense pathogens. The scope of the contract includes preclinical, nonclinical and clinical IND and NDA-enabling development activities. Pursuant to our NIAID contract, subject to our compliance with applicable regulations, we may elect to obtain ownership of each patentable invention that arises from the performance of the research and development funded by our NIAID contract, subject to the United States government's march-in rights with respect to such inventions. We have recognized $19.0 million in revenues through December 31, 2011 related to research performed under the NIAID contract.

In April 2010, we entered into a four and one-half year contract with DTRA under which we may receive up to $29.5 million to support a preclinical program to identify targets of antibacterial compounds from marine natural product libraries from The Regents of the University of California, or UCSD, and to apply our structure based drug design and development capabilities to optimize promising antibacterial compounds for activity against gram-negative bacteria, including multiple biodefense pathogens. Pursuant to the DTRA contract, subject to our compliance with applicable regulations, we may elect to obtain ownership of each patentable invention that arises from the performance of the research and development funded by our DTRA contract, subject to the United States government's march-in rights with respect to such inventions. We have recognized $6.0 million in revenues through December 31, 2011 related to research performed under the DTRA contract.

In April 2011, we entered into a three year research contract with Lawrence Livermore National Laboratory, or LLNL, for the development of novel antibiotics directed against gram negative multi-drug resistant bacterial pathogens. We may receive up to $3.0 million over three years in support of its development efforts. LLNL can terminate the contract upon delivering notice to us for default or convenience. Upon receipt of a notice of termination, we must discontinue contract activities and LLNL must pay the Company a final settlement based on eligible expenses incurred under the contract. As of December 31, 2011, we have not received a notice of termination relative to contract activities. From contract inception through December 31, 2011, we have recognized $0.7 million in revenues related to the research performed under the LLNL contract.

We were originally incorporated as RexC Pharmaceuticals, Inc. in California in June 2004 and changed our name to Rx^3 Pharmaceuticals, Inc. in September 2004. We subsequently changed our name to Trius

Therapeutics, Inc. in February 2007 and reincorporated in Delaware in December 2007. We have never been profitable and have incurred significant net losses since our inception. As of December 31, 2011, we had an accumulated deficit of $95.4 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 Obligations Related to the License of Tedizolid Phosphate

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. We have the right to grant sublicenses to third parties.

Upon entering into the license agreement, we paid a $500,000 upfront-fee and have made subsequent milestone payments of $3.7 million. In addition, we may be required to make up to an aggregate of $13.0 million in additional payments, upon the achievement of specified development and regulatory approval milestones. We are also obligated to pay Dong-A mid-single digit tiered royalties on net sales of tedizolid phosphate.

Financial Overview

Revenues

We have derived substantially all of our revenues from our Bayer Agreement and NIAID, DTRA and LLNL 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, DTRA and LLNL, as well as through our license and collaboration agreement with Bayer. We continue to pursue government contract funding for our non-clinical, preclinical and clinical programs. If our development efforts for any of our product candidates result in clinical success and regulatory approval or collaboration agreements with third parties, we may generate revenues from those product candidates.

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 preclinical and non-clinical 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 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):

	Year Ended December 31,		
	2011	2010	2009
Clinical and nonclinical research and development	$37,665	$15,787	$16,701
Preclinical research and development	11,838	7,533	6,348
	$49,503	$23,320	$23,049

At this time, due to the inherently unpredictable nature of preclinical, non-clinical 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 expenses, 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 short-term investments.

Interest Expense

There is no interest expense for the year ended December 31, 2011. Interest expense for the year ended December 31, 2010 consists primarily of a non-cash charge related to the conversion of the 2009 Notes at a 12.5% discount to the price of our common stock sold in our initial public offering, or IPO, non-cash interest related to the amortization of debt discount costs associated with the capital leases and non-cash interest expense associated with the increase in fair value of the preferred stock warrants issued in connection with obtaining our capital leases and cash interest accrued or paid on our capital lease and convertible notes payable balances.

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.

As of December 31, 2011, we had federal and state net operating loss carryforwards of approximately $18.9 million and $20.0 million, respectively. If not utilized, the net operating loss carryforwards will begin expiring in 2025 for federal purposes and 2015 for state purposes. Additionally, we had both federal and state research and development tax credit carryforwards of approximately $4.0 million and $2.0 million, respectively. The federal tax credits will begin expiring in 2027 unless previously utilized and the state tax credits carryforward indefinitely. 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 have recently completed an updated Section 382/383 study to ascertain whether our initial public offering, our most recent private placement and other transactions that have occurred over the past three years, may have triggered an "ownership change" limitation. Based upon this study, we have determined that these recent events did not trigger an "ownership change" limitation, therefore these recent transactions did not impact our carryforwards. In each period since our inception, we have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the 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 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 management 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 revenues under our federal contracts, preclinical, nonclinical and clinical development costs and drug manufacturing costs (research and development expense), and share-based compensation. 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.

While our significant accounting policies are more fully described in Note 1 to our financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements.

Revenue Recognition

Our revenues currently consist of federal contract revenues and license and collaboration revenues from third parties and historically have consisted of federal contract and grant revenues and fees for research services from license or collaboration agreements. We recognize 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.

For arrangements that include multiple deliverables, we determine the deliverables and then identify separate units of accounting. The expected non-contingent arrangement consideration is then allocated to the separate units of accounting based on their relative fair values. Applicable revenue recognition criteria are considered separately for each unit of accounting. Upfront fees are allocated to the license and recorded immediately as license revenue as long as the payment is less than the value ascribed to the license. Any upfront payments in excess of the value ascribed to the license, are deferred and recognized as either license revenues or collaboration revenues, in proportion to the original percentages of estimated selling prices. For ongoing development and regulatory efforts, we record revenues as the development and regulatory efforts that are subject to reimbursement are incurred, throughout the expected development and regulatory period. Amounts received in advance of services performed are recorded as deferred revenue until earned.

We have made an election to utilize the milestone method for recognizing milestone payments into revenue, when the milestone is deemed substantive. 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.

These milestones will be recorded as revenue, when achieved and will be recorded as license fees and collaboration revenues, in accordance with the initial ratios of the selling prices for the units of accounting.

For contract payments achieved during the period where we have material ongoing performance obligations, and the contract payment is deemed not to be substantive, we do not treat these payments as milestones for accounting purposes, and use the cumulative catch up approach for recording non-substantive contract payments. We update the remaining expected arrangement consideration by adding to it the amount to be received for achieving the payment. This payment amount is prorated, with a portion being applied to the allocated arrangement consideration for the license and a portion applied to the allocated arrangement consideration for the development services based upon the initial proration of the deemed selling prices for the license and development services at the inception of the agreement. We then calculate the amount of cumulative revenue recognizable for both the license and development services upon achievement of the event resulting in the payment. The amount recognizable as revenue for the development services is equal to the percentage calculated by dividing the cumulative costs completed as of the time of earning the payment divided by the total expected costs to be incurred by us during the development period and then multiplying this percentage by the new updated arrangement consideration for the development services. From this amount, we subtract the previous cumulative amount recognized for development service revenues to calculate the amount of development service revenues to record for the period. The revenue to be recorded is the lower of this amount or the actual amount of development service billings for the period. If the calculated amount is lower than the actual billings, then the difference will be recorded as deferred revenue until such time as the efforts are greater than or equal to the billings. The amount recognizable for the license is generally equal to the difference between the new allocated arrangement consideration for the license and the prior allocated arrangement consideration for the license, given that the earnings process for delivery of the license is typically complete.

For contract payments which are not deemed to be substantive milestones in accordance with U.S. generally accepted accounting principles, or GAAP, that are expected to be achieved after the completion of any material performance obligations required by us, since there are no material further performance obligations, the earnings process is deemed complete when the contract payment is earned and the entire amount of the contract payment is recorded as License revenues and Collaboration revenues, in accordance with the initial ratios of the selling prices for the units of accounting.

Research and Development

Research and development expenses are comprised primarily of CROs and clinical trial sites; employee and consultant-related expenses, which include salaries, benefits and share-based compensation for research and development personnel; external research and development expenses incurred pursuant to agreements with third-party manufacturing organizations; license fees paid to third parties for use of their intellectual property; facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and depreciation of leasehold improvements and equipment; payments to consultants; and third-party supplier expenses including laboratory and other supplies. Third-party research and development expenses are recorded when the contracted work has been performed or the milestone payment has been earned.

We estimate preclinical study and clinical trial expenses based on the services received pursuant to contracts with research institutions and CROs that conduct and manage preclinical studies and clinical trials on our behalf. We accrue service fees based on work performed, which relies on estimates of total costs incurred based on milestones achieved, patient enrollment and other events. The majority of our service providers invoice us in arrears, and to the extent that amounts invoiced differ from our estimates of expenses incurred, we accrue for additional costs. The financial terms of these agreements vary from contract to contract and may result in uneven expenses and payment flows. Preclinical study and clinical trial expenses include:

- Fees paid to CROs, consultants and laboratories in connection with preclinical studies;
- Fees paid to CROs, clinical trial sites, investigators and consultants in connection with clinical trials; and

- Fees paid to contract manufacturers and service providers in connection with the production, testing and packaging of active pharmaceutical ingredients and drug materials for preclinical studies and clinical trials.

Payments under some of these agreements depend on factors such as the milestones accomplished, including enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones. To date, we have not experienced any events requiring us to make material adjustments to our accruals for service fees. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates which could materially affect our results of operations. Adjustments to our accruals are recorded as changes in estimates become evident. Furthermore, based on amounts invoiced to us by our service providers, we may also record payments made to those providers as prepaid expenses that will be recognized as expense in future periods as services are rendered.

Share-based Compensation

We account for share compensation by measuring and recognizing compensation expense for all share-based payments made to employees and directors based on estimated grant date fair values. We allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period. We estimate the fair value of our 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 the expected stock price volatility, the calculation of expected term and the fair value of the underlying common stock on the date of grant, among other inputs. Our results of operations for fiscal 2011 and 2010 were impacted by the recognition of non-cash expense related to the fair value of our share-based compensation awards. Share-based compensation expense recognized under Accounting Standards Codification 718 "Compensation—Stock Compensation", or ASC 718 for the years ended December 31, 2011, 2010 and 2009 was $2.7 million, $1.1 million and $1.1 million, respectively.

We estimate forfeitures at the time of grant and revise, if necessary, in subsequent periods if actual forfeitures differ from estimates. We estimate forfeitures based on our historical experience.

Results of Operations

Comparison of the Years Ended December 31, 2011 and 2010

Revenues

The following table summarizes our revenues for the years ended December 31, 2011 and 2010 (in thousands, except percentages):

	Year Ended December 31,		$	%
	2011	2010	Change	Change
Contract research	$12,086	$8,032	$ 4,054	50%
License	25,708	—	25,708	100%
Collaborations	3,217	—	3,217	100%
Total	$41,011	$8,032	$32,979	411%

Contract research revenues increased for the year ended December 31, 2011 as compared to the year ended December 31, 2010 primarily due to additional research performed under our DTRA and NIAID contracts as well as the commencement of research under our LLNL contract which was entered into in April 2011.

License and collaboration revenues for the year ended December 31, 2011 relate to commencement of activities under our collaboration and license agreement with Bayer that we entered into in July 2011. We

recorded $25.7 million as License revenues during the year ended December 31, 2011. 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 at the inception of the agreement.

In September 2011, we dosed our first patient in our second global Phase 3 study of tedizolid phosphate for the treatment of ABSSSI. This event triggered a $2.0 million payment to us under the Agreement. We reallocated the new expected arrangement consideration and added $0.8 million to the license and $1.2 million to the Global Development Plan Services. The $0.8 million was recorded as license revenue, in the third quarter, as there were no ongoing services to be provided for the license.

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 December 31, 2011, we provided certain Global Development Plan Services to Bayer. Under the agreement, we are entitled to invoice Bayer for certain of these services. In addition, at December 31, 2011, we calculated our updated percentage complete estimate by taking our total actual costs for Global Development Plan Services, since inception of the agreement, and dividing it by our updated best estimate of the expected total costs to be incurred for providing the Global Development Plan Services for the remainder of the collaboration. This updated percentage completion amount was then multiplied by the updated expected arrangement consideration amount to determine the maximum amount of revenue that we could record as revenue for the year. This amount was compared to the total amount billed and billable to Bayer for these services throughout the year, and the lesser of these two amounts was recorded as total Collaborations revenue related to the Global Development Plan Services. For the year ended December 31, 2011, the Company recorded $3.2 million in Collaborations revenues.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2011 and 2010 (in thousands, except percentages):

	Year Ended December 31,		$	%
	2011	2010	Change	Change
Research and development expenses	$49,503	$23,320	$26,183	112%

During the year ended December 31, 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. During the year ended December 31, 2010, our research and development costs related primarily to preparation for the initiation of our first Phase 3 clinical trial for which the first patient was dosed in August 2010 and research under our NIAID, and DTRA contracts. Clinical trial expenses increased by $16.6 million during the year ended December 31, 2011 primarily due to additional development activities performed on our first Phase 3 trial of tedizolid phosphate which commenced in August 2010 and initiation of our second Phase 3 clinical trial of tedizolid phosphate for which the first patient was dosed in September 2011. In conjunction with the initiation of our second Phase 3 clinical trial, we began to manufacture drug product to support our registration activities. We incurred approximately $3.0 million in manufacturing costs for this purpose during the year ended December 31, 2011. In addition, our nonclinical research expenses increased by $3.1 million during the year ended December 31, 2011 when compared to the same period in 2010 primarily due to additional work performed under our DTRA contract which commenced in April 2010.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2011 and 2010 (in thousands, except percentages):

	Year Ended December 31,		$	%
	2011	2010	Change	Change
General and administrative expenses	$11,339	$5,406	$5,933	110%

The increase in general and administrative expenses was due primarily to an increase of $1.2 million of costs related to partnering activities due to the negotiation of the collaboration and license agreement with Bayer, an increase of $968,000 of personnel costs due to additional headcount, $784,000 in additional share-based compensation, an increase of $741,000 due to commercial planning activities, $534,000 of costs related to operating as a publicly traded company in 2011, $440,000 of additional intellectual property costs, and $225,000 in additional employee relocation costs.

Other Income (Expense)

The following table summarizes our other income (expense) for the year ended December 31, 2011 and 2010 (in thousands, except percentages):

	Year Ended December 31,		$	%
	2011	2010	Change	Change
Interest income	$ 21	$ 8	$ 13	163%
Interest expense	—	(3,889)	(3,889)	(100)%
Other income	3	245	(242)	(99)%
Other expense	(1)	—	(1)	100%
Fair value adjustment of stock warrant liability	1,558	467	1,091	234%
Total Other Income (Expense)	$1,581	$(3,169)	$ 4,750	(150)%

There was no interest expense recognized during the year ended December 31, 2011 because we had no debt outstanding during the period. The interest expense recognized during the year ended December 31, 2010 related to notes payable that were converted to common stock upon the closing of our IPO in August 2010. The conversion of the notes payable resulted in a $2.9 million non-cash conversion charge which was recognized as a component of interest expense.

Other income for the year ended December 31, 2011 was $1.6 million and resulted from the remeasurement of the estimated fair value of the common stock warrant liability. This liability was recorded upon the issuance of warrants in connection with our private placement in May 2011 and is remeasured at each reporting date with changes in estimated fair value recorded as other income or expense. During the year ended December 31, 2010, we recognized $467,000 of other income related to the remeasurement of the estimated fair value of preferred stock warrants that were outstanding prior to our IPO in August 2010. Upon our IPO, the preferred stock warrants converted to common stock warrants and the estimated fair value of the warrants was reclassified to additional paid-in capital.

Comparison of the Years Ended December 31, 2010 and 2009

Revenues

The following table summarizes our revenues for the years ended December 31, 2010 and 2009 (in thousands, except percentages):

	Year Ended December 31,		$	%
	2010	2009	Change	Change
Contract research	$8,032	$4,980	$3,052	61%
Collaborations	—	36	(36)	(100)%
Total	$8,032	$5,016	$3,016	60%

Total revenues increased for the year ended December 31, 2010 as compared to the prior year primarily due to commencement of work performed under our DTRA contract which was entered into in April 2010.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2010 and 2009 (in thousands, except percentages):

	Year Ended December 31,		$	%
	2010	2009	Change	Change
Research and development expenses	$23,320	$23,049	$271	1%

During the year ended December 31, 2010, our research and development costs were primarily related to preparation for and initiation of our Phase 3 clinical trial of tedizolid phosphate for which the first patient was dosed in August 2010 as well as work performed under our NIAID and DTRA contracts. Costs related to these activities resulted in increases in clinical trial expenses of approximately $1.5 million and salaries and related of $1.3 million in 2010 versus 2009. In addition, due to increased work performed under the NIAID contract in 2010 versus 2009, and the addition of the DTRA contract during 2010, lab supplies expense increased by $1.2 million, subcontractor fees increased by $1.0 million and other direct costs increased by $0.5 million. Indirect research and development costs also increased by $0.2 million during 2010 versus 2009 due to these increased efforts. These increases were partially offset by a decrease of approximately $3.0 million in manufacturing costs in 2010 versus 2009 to produce clinical drug product for our Phase 3 trial which were incurred during the year ended December 31, 2009, as well as a decrease in license fees expense of $2.5 million in 2010 versus 2009, related to a $2.5 million milestone payment to Dong-A for completion of Phase 2 clinical trials made during 2009.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2010 and 2009 (in thousands, except percentages):

	Year Ended December 31,		$	%
	2010	2009	Change	Change
General and administrative expenses	$5,406	$4,134	$1,272	31%

The increase of $1.3 million in general and administrative expenses for the year ended December 31, 2010 as compared to the prior year was due primarily to our operating as a publicly-traded company in 2010. This

increase consisted of additional accounting and audit fees of $300,000, additional salaries and recruiting fees of $300,000, board of director fees of $200,000 not paid in previous years, bonus payments of $400,000 not paid in 2009, additional directors' and officers' insurance expenses of $100,000 and additional costs related to patent protection of $100,000.

Other Income (Expense)

The following table summarizes our other income (expense) for the year ended December 31, 2010 and 2009 (in thousands, except percentages):

	Year Ended December 31,		$	%
	2010	2009	Change	Change
Interest income	$ 8	$ 36	$ (28)	(78)%
Interest expense	(3,889)	(284)	(3,605)	1269%
Other income	245	—	245	100%
Other expense	—	(21)	21	(100)%
Fair value adjustment of stock warrant liability	467	(245)	712	(291)%
Total Other Income (Expense)	$(3,169)	$(514)	$(2,655)	517%

The decrease in interest income for the year ended December 31, 2010 resulted from lower prevailing interest rates. The increase in interest expense for the year ended December 31, 2010 as compared to the prior year was primarily attributable to the non-cash charge of $2.9 million that we recognized when the convertible notes payable that were issued in November 2009 and related accrued interest were converted to common stock upon the closing of our IPO in August 2010.

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, collaboration fees under our partnership with Bayer, contract research funding under our NIAID, DTRA and LLNL contracts, license and research grants. As of December 31, 2011, we had cash and cash equivalents and short-term investments of approximately $59.1 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 December 31, 2011, our funds are held in cash, money market funds and United States Treasury securities.

	For the Year Ended December 31,		
	2011	2010	2009
	(In thousands)		
Cash Flows from Continuing Operations:			
Net cash used in operating activities	$(13,242)	$(18,717)	$(20,672)
Net cash (used in) provided by investing activities	(18,539)	(31,550)	6,781
Net cash provided by financing activities	28,647	46,523	17,639
Net increase (decrease) in cash and cash equivalents	$ (3,134)	$ (3,744)	$ 3,748

Net cash used in operating activities during 2011 was $13.2 million compared to $18.7 million in 2010. This decrease was due to a lower operating loss in 2011 which primarily resulted from the recognition of an upfront payment from Bayer of $25 million, a $2.0 million milestone earned under our Bayer collaboration and increases in revenues recognized for services performed on our NIAID, DTRA and LLNL contracts. The decrease in net cash used in operating activities during 2011 was also due to increases in accounts payable and accrued expenses at December 31, 2011 related to our Phase 3 clinical program. Net cash used in operating activities during 2010 was $18.7 million compared to $20.7 million in 2009. This decrease was primarily due to increases in accounts payable and accrued expenses at December 31, 2010 related to the first Phase 3 trial of tedizolid phosphate which was initiated in August 2010.

Net cash used in investing activities was $18.5 million and $31.6 million during 2011 and 2010, respectively, compared to net cash provided by investing activities of $6.8 million during 2009. Purchases of short-term investments for the years ended December 31, 2011, 2010 and 2009 were $64.6 million, $31.0 million and $3.6 million, respectively. These cash outflows were offset by cash inflows from sales and maturities of investments for the years ended December 31, 2011, 2010 and 2009 of $47.0 million, $0.0 million and $10.5 million, respectively. We expect similar fluctuations to continue in future periods. Capital equipment purchases for 2011, 2010 and 2009 were $0.8 million, $0.6 million and $0.2 million, respectively.

Net cash provided by financing activities was $28.6 million, $46.5 million and $17.6 million during 2011, 2010 and 2009, respectively. During 2011, we sold 4,750,000 shares of common stock for cash proceeds of $28.0 million, net of underwriting discounts and offering costs. During 2010, we sold 10,000,000 shares of common stock for cash proceeds of $45.1 million, net of underwriting discounts and offering costs. Net cash provided by financing activities in 2009 was primarily a result of the sale of convertible notes payable for net proceeds of $19.2 million, offset by costs incurred to prepare for our IPO of $1.4 million. The amount and frequency of stock-related transactions are dependent upon the market performance of our common stock.

Operating Capital Requirements

We anticipate that we will continue to incur net losses for the next several years as we incur expenses for our clinical and nonclinical studies for 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, DTRA or LLNL contracts is discontinued. In November 2009, we sold $19.2 million in aggregate principal amount of secured convertible promissory notes, or the 2009 Notes, in a private placement to certain of our existing investors and other parties with whom we have substantive, preexisting relationships. The 2009 Notes were secured by a first priority security interest in all of our assets. The 2009 Notes accrued interest at a rate of 8% per annum and converted into our common stock upon completion of our IPO at a 12.5% discount to the IPO price on August 6, 2010.

On August 6, 2010, we completed our IPO in which we sold 10,000,000 shares of our common stock, at a price of $5.00 per share. After deducting underwriting discounts and commissions of $1.6 million and offering expenses of $3.3 million, we raised a total of $45.1 million in net proceeds. Costs directly associated with our IPO were capitalized and recorded as deferred IPO costs prior to the closing of the IPO. These costs have been recorded as a reduction of the proceeds received in arriving at the amount to be recorded in additional paid-in capital.

On May 31, 2011, we closed our private placement transaction 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 our 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.

Including the funds received in January 2012 from our public offering, 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 trials 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 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 clinical trials of tedizolid phosphate, including expenses to support the 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 establish and maintain 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 by period at December 31, 2011:

	Payment by Period				
	Total	Less Than 1 Year	1 - 3 Years	3-5 Years	More Than 5 Years
			(In thousands)		
Operating leases	$989	$652	$337	$—	$—

Under our license agreement with Dong-A, we may be required to make up to an aggregate of $13.0 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 standards-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 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 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. Early adoption is permitted, but full retrospective application is required under the accounting standard. We do not expect the amendment to GAAP to have a material impact on our results of operations, cash flows or financial position.

In December 2011, the FASB issued ASU 2011-12, Deferral of the Effective Date for Amendments to Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update 2011-05. This ASU defers certain provisions of ASU 2011-05, which required entities to present reclassification adjustments out of accumulated other comprehensive income by component in the statement in which net income is presented and the statement in which comprehensive income is presented for both interim and annual periods. This requirement is indefinitely deferred by this ASU and will be further deliberated by the FASB at a future date. The new ASU is effective for public entities as of the beginning of a fiscal year that begins after December 15, 2011 and interim and annual periods thereafter, the same as that for the

unaffected provisions of ASU 2011-05. We do not expect the amendments in this ASU to have a material impact on our results of operations, cash flows or financial position.

ITEM 7A. *QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK*

Cash Equivalents and Investments

Our cash equivalents and short-term investments are classified as available-for-sale and consisted of money market funds and debt instruments of agencies of the U.S. government at December 31, 2011. 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 8. *FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA*

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Trius Therapeutics, Inc.

We have audited the accompanying balance sheets of Trius Therapeutics, Inc. as of December 31, 2011 and 2010, and the related statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Trius Therapeutics, Inc. at December 31, 2011 and 2010, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the financial statements, Trius Therapeutics, Inc. changed its method of accounting for revenue recognition effective January 1, 2011.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Trius Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 14, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
March 14, 2012

Trius Therapeutics, Inc.

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

	December 31, 2011	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 11,381	$ 14,515
Short-term investments, available-for-sale	47,762	30,823
Accounts receivable	4,272	1,832
Prepaid expenses and other current assets	3,272	1,389
Total current assets	66,687	48,559
Property and equipment, net	1,037	701
Restricted cash	150	0
Other assets	251	240
Total assets	$ 68,125	$ 49,500
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,774	$ 2,147
Accrued liabilities	6,959	1,661
Common stock warrant liability	7,124	—
Current portion of deferred revenue	377	—
Total current liabilities	18,234	3,808
Deferred revenue	—	238
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2011 and December 31, 2010; no shares issued and outstanding at December 31, 2011 and December 31, 2010	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized at December 31, 2011 and December 31, 2010; 28,663,548 and 23,648,646 shares issued and outstanding at December 31, 2011 and December 31, 2010, respectively	4	3
Additional paid-in capital	145,272	122,593
Accumulated other comprehensive income	7	—
Accumulated deficit	(95,392)	(77,142)
Total stockholders' equity	49,891	45,454
Total liabilities and stockholders' equity	$ 68,125	$ 49,500

See accompanying notes.

Trius Therapeutics, Inc.

Statements of Operations
(In thousands except per share data)

	Year Ended December 31,		
	2011	**2010**	**2009**
Revenues:			
Contract research	$ 12,086	$ 8,032	$ 4,980
Collaborations	3,217	—	36
License	25,708	—	—
Total revenues	41,011	8,032	5,016
Operating expenses:			
Research and development	49,503	23,320	23,049
General and administrative	11,339	5,406	4,134
Total operating expenses	60,842	28,726	27,183
Loss from operations	(19,831)	(20,694)	(22,167)
Other income (expense):			
Interest income	21	8	36
Interest expense	—	(3,889)	(284)
Fair value adjustment of stock warrant liability	1,558	467	(245)
Other income (expense)	2	245	(21)
Total other income (expense)	1,581	(3,169)	(514)
Net loss	(18,250)	(23,863)	(22,681)
Accretion of deferred financing costs on redeemable convertible preferred stock	—	(18)	(28)
Net loss attributable to common stockholders	$(18,250)	$(23,881)	$(22,709)
Net loss per share, basic and diluted	$ (0.69)	$ (2.36)	$ (31.11)
Weighted-average shares outstanding, basic and diluted	26,517	10,099	730

See accompanying notes.

Trius Therapeutics, Inc.

Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands except share and per share data)

	Series A-1 Convertible Preferred Stock		Series A-2 Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2008	1,454,545	$ 729	36,363,641	$ 19,917	30,500,000	$ 30,408	949,502	$ 1	$ 593	$ 12	$(30,552)	$(29,946)
Components of comprehensive loss:												
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	(12)	—	(12)
Net loss	—	—	—	—	—	—	—	—	—	—	(22,681)	(22,681)
Comprehensive loss												(22,693)
Issuance of common stock upon exercise of options	—	—	—	—	—	—	18,728	—	23	—	—	23
Early exercise of common stock subject to repurchase	—	—	—	—	—	—	—	—	(3)	—	—	(3)
Vesting of early-exercised stock options	—	—	—	—	—	—	—	—	51	—	—	51
Share-based compensation	—	—	—	—	—	—	—	—	1,099	—	—	1,099
Accretion of deferred financing costs on redeemable convertible preferred stock	—	—	—	13	—	15	—	—	—	—	(28)	(28)
Balance at December 31, 2009	1,454,545	$ 729	36,363,641	$ 19,930	30,500,000	$ 30,423	968,230	$ 1	$ 1,763	$—	$(53,261)	$(51,497)
Net loss and comprehensive loss	—	—	—	—	—	—	—	—	—	—	(23,863)	(23,864)
Issuance of common stock, net of offering costs	—	—	—	—	—	—	10,000,000	1	45,056	—	—	45,057
Issuance of common stock upon exercise of options	—	—	—	—	—	—	60,858	—	60	—	—	60
Issuance of stock under employee stock purchase plan							34,165	—	98	—	—	98
Vesting of early-exercised stock options	—	—	—	—	—	—	—	—	52	—	—	52
Repurchase of unvested common stock	—	—	—	—	—	—	(1,793)	—	(1)	—	—	(1)
Share-based compensation	—	—	—	—	—	—	—	—	1,056	—	—	1,056
Accretion of deferred financing costs on redeemable convertible preferred stock	—	—	—	8	—	9	—	—	—	—	(18)	(17)
Conversion of notes payable to common stock upon initial public offering	—	—	—	—	—	—	4,643,227	—	23,216	—	—	23,216
Conversion of preferred stock to common stock upon initial public offering	(1,454,545)	(729)	(36,363,641)	(19,938)	(30,500,000)	(30,432)	7,943,959	1	51,099	—	—	51,100
Conversion of preferred stock warrants to common stock warrants	—	—	—	—	—	—	—	—	194	—	—	194

See accompanying notes.

Trius Therapeutics, Inc.

Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)—(Continued)
(In thousands except share and per share data)

	Series A-1 Convertible Preferred Stock		Series A-2 Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2010	—	$—	—	$—	—	$—	23,648,646	$ 3	$122,593	$—	$(77,142)	$ 45,454
Components of comprehensive loss:												
Unrealized gain on marketable securities	—	—	—	—	—	—	—	—	—	7	—	7
Net loss	—	—	—	—	—	—	—	—	—	—	(18,250)	(18,250)
Comprehensive loss												(18,243)
Issuance of common stock, net of offering costs	—	—	—	—	—	—	4,750,000	1	28,013	—	—	28,014
Common stock warrants issued in connection with private placement of common stock recorded as a liability	—	—	—	—	—	—	—	—	(8,682)	—	—	(8,682)
Issuance of common stock upon exercise of options	—	—	—	—	—	—	70,180	—	83	—	—	83
Issuance of common stock upon exercise of warrants	—	—	—	—	—	—	21,560	—	—	—	—	—
Issuance of stock under employee stock purchase plan	—	—	—	—	—	—	173,162	—	551	—	—	551
Vesting of early-exercised stock options	—	—	—	—	—	—	—	—	29	—	—	29
Share-based compensation	—	—	—	—	—	—	—	—	2,685	—	—	2,685
Balance at December 31, 2011	—	—	—	—	—	—	28,663,548	4	145,272	7	95,392	49,891

See accompanying notes.

Trius Therapeutics, Inc.

Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2011	2010	2009
Operating activities			
Net loss	$(18,250)	$(23,863)	$(22,681)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	497	386	694
Share-based compensation	2,685	1,056	1,099
(Gain) loss on fair value adjustment of stock warrant liability	(1,558)	(467)	245
Amortization of debt issuance costs	—	—	11
Amortization of investment premiums	625	136	197
Loss on disposal of equipment	—	—	9
Interest accrual on convertible notes payable	—	912	238
Non-cash charge on conversion of convertible notes payable	—	2,902	—
Deferred revenue	139	72	128
Changes in operating assets and liabilities:			
Accounts receivable	(2,440)	(1,144)	(31)
Prepaid expenses and other current assets	(1,883)	(921)	24
Accounts payable	1,627	1,538	198
Accrued liabilities	5,327	827	(733)
Other assets	(11)	(151)	(70)
Net cash used in operating activities	(13,242)	(18,717)	(20,672)
Investing activities			
Purchases of short-term investments	(64,589)	(30,957)	(3,559)
Sales and maturities of short-term investments	47,033	—	10,500
Change in restricted cash	(150)	—	—
Purchases of property and equipment	(833)	(593)	(160)
Net cash (used in) provided by investing activities	(18,539)	(31,550)	6,781
Financing activities			
Proceeds from issuance of common stock and warrants, net of underwriting discounts	28,013	48,350	—
Public offering costs	—	(1,915)	(1,378)
Proceeds from exercise of stock options and stock issuances under employee stock purchase plans	634	159	23
Proceeds from debt financing	—	—	19,163
Payments on capital lease obligation	—	(70)	(169)
Repurchase of common stock	—	(1)	—
Net cash provided by financing activities	28,647	46,523	17,639
Net increase (decrease) in cash and cash equivalents	(3,134)	(3,744)	3,748
Cash and cash equivalents at beginning of period	14,515	18,259	14,511
Cash and cash equivalents at end of period	$ 11,381	$ 14,515	$ 18,259
Supplemental cash flow information			
Cash paid for interest	$ —	$ 2	$ 18
Non-cash Investing and Financing Activities			
Conversion of convertible notes payable and accrued interest thereon into common stock	$ —	$ 20,314	—
Conversion of convertible preferred stock and convertible redeemable preferred stock into common stock	$ —	$ 51,100	—
Reclassification of warrant liability to additional paid-in capital	$ —	$ 194	—
Deferred Initial Public Offering costs incurred in 2009 and reclassified to equity	$ —	$ 1,378	—

See accompanying notes.

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 as RexC Pharmaceuticals, Inc. and changed its name to Rx^3 Pharmaceuticals, Inc. in September 2004. In February 2007, the Company changed its name to Trius Therapeutics, Inc. and reincorporated in Delaware in December 2007.

Initial Public Offering

On August 6, 2010, the Company completed its Initial Public Offering, or IPO, of common stock pursuant to a Registration Statement that was declared effective on August 2, 2010. In the IPO, the Company sold 10,000,000 shares of its common stock, at a price of $5.00 per share. As a result of the IPO, the Company raised a total of $45.1 million in net proceeds after deducting underwriting discounts and commissions of $1.6 million and offering expenses of $3.3 million.

Upon the closing of the IPO, 1,454,545 shares of the Company's convertible preferred stock and 66,863,641 shares of the Company's redeemable convertible preferred stock automatically converted into a total of 7,943,959 shares of the Company's common stock. Also upon the closing of the IPO, $19.2 million of secured convertible notes, including accrued interest thereon, converted into 4,643,227 shares of the Company's common stock, a non-cash charge of $2.9 million related to such conversion was recorded, and the preferred stock warrant liability was reclassified to additional paid-in capital upon the conversion of warrants to purchase preferred stock into warrants to purchase common stock.

Private Placement

On May 31, 2011, the Company closed a private placement, or 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. As a result of the Private Placement, the Company 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.

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.

Reclassifications

Certain reclassifications have been made to previously reported amounts to conform to current presentations. The adjustment of the fair value of the Company's warrant liability during the years ended December 31, 2010 and 2009 has been reclassified from other income (expense) in the Statements of Operations to a separate line item to be consistent with financial statement presentation at December 31, 2011.

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.

Short-term 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 in this category 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 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. Accounts receivable at December 31, 2010 represent amounts due from NIAID and DTRA. 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. Expenses directly associated with the Company's contracts that have been accrued at the end of the reporting period are not billed to customers and collaborators until third party invoices have been received or until internal costs have been paid.

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 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 December 31, 2011.

Restricted Cash

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

Preferred Stock Warrant Liability and Common Stock Warrants

Warrants to purchase the Company's convertible preferred stock were classified as liabilities and, through the date of the IPO, were recorded at estimated fair value with changes in market value recorded separately within other income (expense). Upon the closing of the IPO 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 fair value of the preferred stock warrants was estimated on the date of the IPO and recorded to additional paid-in capital upon conversion to common stock warrants. The Company reassessed the accounting treatment for the warrants as of the IPO date and deemed that accounting for the warrants within additional paid-in capital was appropriate.

The Company evaluated the accounting treatment for the warrants to purchase the Company's common stock that were issued in connection with the Private Placement and determined that liability classification was appropriate. The warrants are classified as a liability and are marked to estimated fair value at each reporting date with changes in estimated fair value recorded separately within other income (expense).

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 changed its revenue recognition methodology for agreements entered into with multiple elements to adopt the provisions of Accounting Standards Update 2009-13 which codified modifications to Accounting Standards Codification 605-25 *Revenue Recognition—Multiple Element Arrangements* ("ASC 605-25"). 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 adoption of this revenue recognition methodology did not have a material impact on historical periods and is expected to have a material impact on future periods.

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, license fees paid to third parties for use of their intellectual property, share-based compensation, costs to third-party contractors to perform research, conduct clinical trials and develop drug materials, research supplies, associated overhead expenses and facilities costs. 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 and is reported in the statements of stockholders' equity (deficit).

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 December 31, 2011 and 2010. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense.

Net Loss per Common Share

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

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

	Year Ended December 31,		
	2011	2010	2009
Historical net loss per share			
Numerator			
Net loss attributable to common stockholders	$(18,250)	$(23,881)	$(22,709)
Denominator			
Weighted-average common shares outstanding	26,536	10,186	953
Less: Weighted-average shares subject to repurchase	(19)	(87)	(223)
Denominator for basic and diluted net loss per share	26,517	10,099	730
Basic and diluted net loss per share	$ (0.69)	$ (2.36)	$ (31.11)

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

	December 31,		
	2011	2010	2009
Preferred stock	—	—	7,943,959
Common stock warrants	1,678,884	66,075	—
Preferred stock warrants	—	—	66,075
Common stock subject to repurchase	3,341	47,851	136,577
Common stock options	2,550,589	1,992,078	974,175
	4,232,814	2,106,004	9,120,786

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.

Impact of Recently Issued Accounting Standards

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. Early adoption is permitted, but full retrospective application is required under the accounting standard. The Company does not expect the amendment to U.S. GAAP to have a material impact on its results of operations, cash flows, and financial position.

In December 2011, the FASB issued ASU 2011-12, Deferral of the Effective Date for Amendments to Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update 2011-05. This ASU defers certain provisions of ASU 2011-05, which required entities to present reclassification adjustments out of accumulated other comprehensive income by component in the statement in which net income is presented and the statement in which comprehensive income is presented for both interim and annual periods. This requirement is indefinitely deferred by this ASU and will be further deliberated by the FASB at a future date. The new ASU is effective for public entities as of the beginning of a fiscal year that begins after December 15, 2011 and interim and annual periods thereafter, the same as that for the unaffected provisions of ASU 2011-05. The Company does not expect the amendments in this ASU to have a material impact on its results of operations, cash flows, and financial position.

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. As consideration for the license, the Company paid an up-front non-refundable, non-creditable payment of $500,000 in February 2007. The Company also paid $700,000 in December 2007, $500,000 in September 2008 and $2.5 million in November 2009 related to milestones under the license agreement. The Company recorded the payments as research and development expense. The agreement requires future payments of up to an aggregate of $13.0 million between completion of Phase 2 and registration of the product in various regions. 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 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 $7.1 million, $6.3 million, and $5.0 million for the years ended December 31, 2011, 2010, and 2009, 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 December 31, 2011, 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 December 31, 2011 and 2010 were $644,000 and $398,000, respectively. Unbilled receivables were $994,000 and $931,000 at December 31, 2011 and 2010, respectively.

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. This is a cost-plus-fixed-fee contract with total payments of up to $29.5 million. The Company recognizes revenue under this contract as the services are performed. The Company recorded revenues under this contract of $4.3 million and $1.7 million for the years ended December 31, 2011 and 2010. DTRA 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 DTRA must pay the Company a final settlement based on eligible expenses incurred under the contract. As of December 31, 2011, 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. There were no billed receivables due under the Company's contract with DTRA at December 31, 2011 and 2010. Unbilled receivables were $795,000 and $503,000 at December 31, 2011 and 2010, respectively.

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 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 $0.7 million for the year ended December 31, 2011. 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 December 31, 2011, 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 December 31, 2011 were $81,000. Unbilled receivables were $154,000 at December 31, 2011.

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 and regulatory milestones 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 $28.9 million for the year ended December 31, 2011.

Note 3. Investments in Marketable Securities

Investments classified as available-for-sale at December 31, 2011 and 2010 consist of the following (in thousands):

	December 31, 2011	December 31, 2010
U.S. Treasury securities	$47,762	$30,823
Total available-for-sale investments	$47,762	$30,823

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
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
December 31, 2010				
U.S. Treasury securities with unrealized gains	$18,351	$ 2	$—	$18,353
U.S. Treasury securities with unrealized losses	12,472	—	(2)	12,470
Total available-for-sale securities	$30,823	$ 2	$ (2)	$30,823

(1) Unrealized gains and losses on available-for-sale securities are included as a component of other comprehensive loss. The eighteen securities in unrealized loss positions have been in a continuous unrealized loss position for 12 months or longer. 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 amortized cost and estimated fair value of debt securities classified as available-for-sale by contractual maturity at December 31, 2011 and December 31, 2010 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
December 31, 2011				
U.S. Treasury securities	$47,755	$47,762	$—	$—
Total available-for-sale securities	$47,755	$47,762	$—	$—
December 31, 2010				
U.S. Treasury securities	$30,823	$30,823	$—	$—
Total available-for-sale securities	$30,823	$30,823	$—	$—

The proceeds from sales of available-for-sale securities during the year ended December 31, 2011 were $3.3 million and resulted in realized gains of less than $1,000. There were no sales of available-for-sale securities during the years ended December 31, 2010 or 2009.

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 December 31, 2011 and 2010 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
December 31, 2011				
Assets:				
Money Market funds, included in cash equivalents	$ 4,587	$4,587	$ —	$ —
U.S. Treasury securities, included in cash equivalents[1][2]	850	—	850	—
U.S. Treasury securities, available-for-sale[2]	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
December 31, 2010				
Assets:				
Money Market funds, included in cash equivalents	$ 4,039	$4,039	$ —	$ —
U.S. Treasury securities, included in cash equivalents[1][2]	9,500	—	9,500	—
U.S. Treasury securities, available-for-sale[2]	30,823	—	30,823	—
Total	$44,362	$4,039	$40,323	$ —

(1) U.S. Treasury securities were classified as cash equivalents because the securities were scheduled to mature less than 90 days from the purchase dates.

(2) During 2011, the Company changed how it categorizes amounts within the fair value hierarchy and thus, the amounts now reported as Level 2 fair value instruments at December 31, 2010 were previously shown as Level 1 and have been reclassified.

The fair value of preferred stock and common stock warrant liabilities was determined based on "Level 3" inputs and utilizing the Black-Scholes option pricing model. The following table presents activity for the preferred stock and common stock warrant liabilities measured at fair value using significant unobservable Level 3 inputs during the years ended December 31, 2011 and 2010.

	Fair Value Measurements at Reporting Date Using Significant Unobservable Inputs (Level 3) Liability-classified Common Stock Warrants	Fair Value Measurements at Reporting Date Using Significant Unobservable Inputs (Level 3) Liability-classified Preferred Stock Warrants
	(In thousands)	(In thousands)
Fair value at December 31, 2009	$ —	$ 661
Changes in fair value recognized in earnings	—	(467)
Estimated fair value at August 6, 2010 recorded to additional paid-in capital	—	(194)
Fair value at December 31, 2010	—	—
Estimated fair value at May 31, 2011	8,682	—
Changes in fair value recognized in earnings	(1,558)	—
Fair value at December 31, 2011	$ 7,124	$ —

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 were to decrease by 10%, the liability would have decreased approximately $0.8 million. If the volatility rate were to increase by 10%, the liability would have increased approximately $0.7 million. These changes would have been recognized in the related component of other income (expense) in the Statement of Operations.

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. Prior to conversion to common stock warrants, the changes in the fair value of the preferred stock warrants were recognized as a separate component within other income (expense) in the Statement of Operations.

Note 5. Property and Equipment

Property and equipment at December 31, 2011 and 2010 consisted of the following (in thousands):

	2011	2010
Laboratory equipment	$ 1,784	$ 1,431
Furniture and fixtures	92	92
Office and computer equipment	415	392
Software	245	120
Leasehold improvements	744	457
	3,280	2,492
Less accumulated depreciation and amortization	(2,243)	(1,791)
Property and equipment, net	$ 1,037	$ 701

For the years ended December 31, 2011, 2010 and 2009, depreciation and amortization expense was $497,000, $386,000, and $694,000, respectively.

Note 6. Accrued Liabilities

Accrued liabilities at December 31, 2011 and 2010 consisted of the following (in thousands):

	2011	2010
Accrued payroll and employee-related costs	$2,177	$ 469
Accrued research and development costs	4,350	883
Other accrued liabilities	432	309
Total	$6,959	$1,661

Note 7. Preferred and Common Stock Warrants

Equity-classified warrants

During 2004, 2005 and 2006, in conjunction with its financing arrangements, the Company issued warrants to purchase 140,909, 40,909 and 40,090, respectively, of shares of Series A-1 convertible preferred stock at $0.55 per share and in 2007, issued warrants to purchase an aggregate of 346,363 shares of Series A-2 redeemable convertible preferred stock at $0.55 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 IPO 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. The fair value of the preferred stock warrants increased by approximately $246,000 during the twelve months ended December 31, 2009 and decreased by approximately $467,000 prior to their reclassification to additional paid-in capital on August 6, 2010.

Liability-classified warrants

In connection with the Private Placement that closed on May 31, 2011, the Company issued warrants to purchase 1,662,500 shares of common stock at $8.50 per share. These warrants became exercisable on November 27, 2011 and expire five years thereafter. 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 as other income (expense) in the Statement of Operations. The fair value of the warrants decreased by approximately $1.6 million after initial recognition on May 31, 2011 due primarily to a decline in the Company's stock price from the time the warrants were issued. The warrants have been recorded at an estimated fair value of $7.1 million at December 31, 2011.

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

During the year ended December 31, 2011, 49,691 equity-classified warrants were net exercised resulting in the issuance of 21,560 shares of common stock. No warrants were exercised during the year ended December 31, 2010. At December 31, 2011, there are 1,678,884 common stock warrants outstanding all of which are

exercisable. The common stock warrants outstanding will expire between three years and five years from December 31, 2011 and have a weighted average exercise price of $8.46. At December 31, 2010, there were 66,075 common stock warrants outstanding and exercisable with a weighted average exercise price of $4.73.

The fair values of the liability-classified common stock warrants and preferred stock warrants were estimated using the Black-Scholes option pricing model based on the following assumptions:

	Common Stock Warrants	Preferred Stock Warrants		
	December 31, 2011	August 6, 2010	December 31, 2009	December 31, 2008
Expected volatility	80%	70%	70%	66%
Expected term (in years)	4.9	1.4-6.9	2.0-8.0	3.0-9.0
Risk-free interest rate	0.83%	0.25%-2.21%	2.54%	2.25%
Expected dividend yield	0%	0%	0%	0%

Note 8. Convertible Notes Payable

In November 2009, the Company sold $19.2 million in aggregate principal amount of secured convertible promissory notes, or the 2009 Notes, in a private placement to certain existing investors and other parties with whom it had substantive, pre-existing relationships. The 2009 Notes were secured by a first priority security interest in all of the Company's assets and were convertible into equity upon the occurrence of certain events. The 2009 Notes accrued interest at a rate of 8% per annum and had a maturity date of the earlier of (1) January 31, 2011 or (2) the sale of the company, or all or substantially all of its assets. The 2009 Notes, including interest thereon, were automatically converted into 4,643,227 shares of common stock upon the closing of the IPO on August 6, 2010 (representing a conversion at a 12.5% discount to the IPO price). The Company recorded a beneficial conversion charge of $2.9 million related to the conversion of the 2009 Notes at a discount to the IPO price. There was $912,000 and $238,000 of interest expense incurred related to the 2009 Notes for the years ended December 31, 2010 and 2009, respectively. There was no interest expense related to the 2009 Notes for the year ended December 31, 2011 due to the conversion of the 2009 Notes to common stock upon the Company's IPO in August 2010.

Note 9. Common Stock Reserved for Issuance

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

	December 31, 2011	December 31, 2010
Common stock warrants	1,678,884	66,075
Shares available for purchase under the 2010 Employee Stock Purchase Plan	529,159	465,835
Common stock options outstanding	2,550,589	1,992,078
Common stock options available for future grant	1,770,844	1,666,076
Total common shares reserved for issuance	6,529,476	4,190,064

Note 10. Share-based Compensation

During 2006, the Company adopted an equity compensation plan, the 2006 Equity Incentive Plan, or the 2006 Plan, for eligible employees, officers, directors, advisors and consultants. The 2006 Plan provided for the grant of up to 1,588,495 incentive and nonstatutory stock options. The terms of the stock option agreements, including vesting requirements, were determined by the Board of Directors, subject to the provisions of the 2006 Plan. Options granted by the Company under the 2006 Plan generally vest over four years and are exercisable after they have been granted and up to ten years from the date of grant. The exercise price of the incentive stock options must equal at least the fair market value of the stock on the date of grant. If an optionholder exercises an

option prior to the vesting of such option, the Company has the right, in the event of termination of services, to repurchase unvested shares issued under the 2006 Plan at the original issue price. In connection with the IPO, the 2010 Equity Incentive Plan, or the 2010 Plan, the 2010 Non-Employee Directors' Stock Option Plan, or the 2010 Directors' Plan, and the 2010 Employee Stock Purchase Plan, or the 2010 Purchase Plan, became effective immediately upon the signing of the underwriting agreement for the IPO.

2010 Plan. The 2010 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance-based stock awards, and other forms of equity compensation, or collectively, stock awards. In addition, the 2010 Plan provides for the grant of performance cash awards. The exercise price for an incentive or a nonstatutory stock option cannot be less than 100% of the fair market value of the Company's common stock on the date of grant. Options granted will generally vest over a four-year period and the term can be up to ten years. The aggregate number of shares of common stock that may be issued initially pursuant to stock awards under the 2010 Plan is 2,400,000 shares, plus the shares that remained available for future issuance under the 2006 Plan as of the effective date of the 2010 Plan. In addition, the number of shares of common stock reserved for issuance will automatically increase (i) on January 1 of each calendar year, from January 1, 2011 through January 1, 2020, by the least of (a) 3% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, (b) 800,000 shares, or (c) a number determined by the Company's board of directors that is less than (a) or (b) and (ii) from time to time by shares that are issuable pursuant to options granted under the 2006 Plan that were outstanding as of the effective date of the 2010 Plan that are forfeited or expire after the effective date of the 2010 Plan. On January 1, 2011, an increase of 709,459 shares to the 2010 Plan share reserve was authorized by the Company's board of directors. As of December 31, 2011, there were 1,584,844 shares available for future grants under the 2010 Plan.

2010 Directors' Plan. The 2010 Directors' Plan provides for the automatic grant of nonstatutory stock options to purchase shares of the Company's common stock to the Company's non-employee directors and will terminate at the discretion of the Company's board of directors. The exercise price of the options granted under the 2010 Directors' Plan will be equal to 100% of the fair market value of the Company's common stock on the date of grant with initial grants vesting in equal monthly installments over three years after the date of grant and annual grants vesting in equal monthly installments over 12 months after the date of grant. The term of these stock options can be up to ten years. An aggregate of 300,000 shares of the Company's common stock was initially reserved for issuance under the 2010 Directors' Plan. This amount will be increased annually on January 1, from 2011 until 2020, by the lesser of the aggregate number of shares of the Company's common stock subject to options granted as initial grants and annual grants under the 2010 Directors' Plan during the immediately preceding year or 150,000 shares. However, the Company's board of directors will have the authority to designate a lesser number of shares by which the authorized number of shares of the Company's common stock will be increased. On January 1, 2011, an increase of 24,000 shares to the 2010 Directors' Plan share reserve was authorized by the Company's board of directors. As of December 31, 2011, there were 186,000 shares available for future grants under the 2010 Directors' Plan.

2010 Purchase Plan. The 2010 Purchase Plan authorizes the issuance of shares of the Company's common stock pursuant to purchase rights granted to the Company's employees. An aggregate of 500,000 shares of the Company's common stock was initially reserved for issuance under the 2010 Purchase Plan and was increased by 236,486 on January 1, 2011. The number of shares of the Company's common stock reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2011 through January 1, 2020, by the least of (a) 1% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, (b) 250,000 shares or (c) a number determined by the Company's board of directors that is less than (a) or (b). The 2010 Purchase Plan is implemented through a series of offerings of purchase rights to eligible employees. Under the 2010 Purchase Plan, the Company may specify offerings with a duration of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of the Company's common stock will be purchased for employees participating in the offering. An offering may be terminated under certain circumstances. Generally, all regular

employees, including executive officers, employed by the Company may participate in the 2010 Purchase Plan and may contribute up to 15% of their earnings, subject to certain limitations, for the purchase of the Company's common stock under the 2010 Purchase Plan. Unless otherwise determined by the Company's board of directors, common stock will be purchased for accounts of employees participating in the 2010 Purchase Plan at a price per share equal to the lower of (a) 85% of the fair market value of a share of the Company's common stock on the first date of an offering or (b) 85% of the fair market value of a share of the Company's common stock on the date of purchase. As of December 31, 2011, there were 529,159 shares available for future sale under the 2010 Purchase Plan.

The Company accounts for cash received in consideration for the early-exercise of unvested stock options as a current liability, included as a component of accrued liabilities in the Company's Balance Sheets. As of December 31, 2011 and 2010, there were 3,341 and 47,851 unvested shares of the Company's common stock outstanding, respectively, for which related liabilities of $4,000 and $32,000, respectively were recorded.

The following table summarizes stock option activity:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Options outstanding at December 31, 2008	767,721	$1.03		
Granted	260,602	$2.32		
Exercised	(18,728)	$1.23		$ 113
Canceled	(35,417)	$1.29		
Options outstanding at December 31, 2009	974,178	$1.36	8.36	$6,048
Granted	1,084,122	$3.61		
Exercised	(60,858)	$0.99		$ 174
Canceled	(5,364)	$1.24		
Options outstanding at December 31, 2010	1,992,078	$2.60	8.69	$2,412
Granted	641,000	$6.58		
Exercised	(70,180)	$1.19		$ 374
Canceled	(12,309)	$3.72		
Options outstanding at December 31, 2011	2,550,589	$3.63	8.15	$9,247
Options vested or expected to vest at December 31, 2011	2,543,539	$3.63	8.12	$9,232
Options exercisable at December 31, 2011	1,315,031	$2.47	7.36	$6,223

At December 31, 2011 and December 31, 2010, there was approximately $3.8 million and $3.2 million, respectively, of total unrecognized compensation costs related to outstanding options granted which is expected to be recognized over a weighted average period of 2.79 and 2.84 years, respectively.

The Company received cash from the exercise of stock options of $83,000, $60,000 and $23,000 during the years ended December 31, 2011, 2010 and 2009, 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 over the vesting period of the applicable option on a straight-line basis. The estimated per share-weighted average fair value of stock options granted to employees during the years ended December 31, 2011, 2010 and 2009 was $4.26, $2.29, and $5.76, respectively.

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 years ended December 31, 2011, 2010 and 2009 was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31,		
	2011	2010	2009
Expected volatility	75%	70%	67%
Expected term (in years)	5.27-6.08	5.77-6.25	4.96-6.10
Risk-free interest rate	1.02%-2.71%	1.41%-1.70%	1.70%-2.79%
Expected dividend yield	0%	0%	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.

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. The Company granted 5,000 and 1,500 stock options to non-employees during the years ended December 31, 2011 and 2010.

In connection with non-employee options, the Company recognized expense of less than $1,000, $22,000, and $120,000 during the years ended December 31, 2011, 2010, and 2009 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 Purchase Plan and has been reported in the Company's statements of operations as follows (in thousands):

	Year Ended December 31,		
	2011	2010	2009
Research and development	$1,283	$ 437	$ 461
General and administrative	1,402	619	638
Total	$2,685	$1,056	$1,099

Since the Company had a net operating loss carryforward as of December 31, 2011, 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 years ended December 31, 2011, 2010 and 2009 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 11. 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 phospate in 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 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 has evaluated the two material non-contingent deliverables under the 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 ("License") to develop and commercialize tedizolid in the Bayer Licensed Territory; and
- Certain Global Development Plan Services ("Global Development Plan Services") which will be conducted by the Company through an expected date of 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 added to the value of the Global Development Plan Services. If the allocated amount to the License had been less than the upfront payment, then that difference would not be recorded immediately but would be deferred until the future periods over which the Global Development Plan Services were 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 services, which would have been recorded over the period of performance of such services.

The Company recorded $25.7 million as License revenues during the year ended December 31, 2011. At contract inception, it was determined that approximately $24.9 million of the expected arrangement consideration was allocable to the License. Since the delivery of the License occurred upon the execution of the Bayer Agreement and there was no general right of return, approximately $24.9 million of the $25.0 million upfront payment was allocated to the License and was recorded as License revenues at the inception of the agreement Bayer agreement.

In September 2011, the Company dosed its first patient in its second global Phase 3 study of tedizolid phosphate for the treatment of ABSSSI. This event triggered a $2.0 million payment to the Company under the Bayer Agreement. The Company reallocated the new expected arrangement consideration and added $0.8 million to the License and $1.2 million to the Global Development Plan Services. In the third quarter of 2011, $0.8 million was recognized as License revenues and $1.2 million was recognized as Collaboration revenues.

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 December 31, 2011, the Company provided certain Global Development Plan Services to Bayer. Under the agreement, the Company is entitled to bill Bayer for certain costs associated with the performance of these services. At December 31, 2011, the Company calculated its percentage of completion estimate by taking its total actual costs for Global Development Plan Services from 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 collaboration. This updated percentage of completion was then multiplied by the updated expected arrangement consideration 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 year ended December 31, 2011, the Company recognized $3.0 million in Collaboration revenues related to Global Development Plan Services.

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

	Year Ended December 31,	
	2011	2010
License	$25,708	$—
Collaborations	3,217	—
Total	$28,925	$—

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 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 year ended December 31, 2011 consisted of $26,000 in contract research and $220,000 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 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 Agreement. After two years, Bayer must provide at least 90 days notice. In addition, Bayer has the right to terminate the Agreement within 30 days of determining that either of the Company's two ongoing Phase 3 clinical trials 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 12. Income Taxes

The Company adopted the accounting guidance related to accounting for uncertainty in income taxes on January 1, 2008, which prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. Upon implementation of the new guidance, the Company had no unrecognized tax benefits. As of December 31, 2011 and 2010, there are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the Company's effective tax rate.

Significant components of the Company's deferred tax assets are shown below (in thousands). A valuation allowance has been established to offset the deferred tax assets as realization of such assets has not met the more-likely-than-not threshold.

	Year Ended December 31,	
	2011	2010
Deferred Tax Assets:		
Net operating loss carryforwards	$ 7,480	$ 5,089
Research tax credits	4,497	2,935
Capitalized research costs	26,157	21,741
Other, net	942	462
Total Deferred Tax Assets	39,076	30,227
Deferred Tax Liabilities	—	—
Net deferred tax assets	39,076	30,227
Valuation allowance	(39,076)	(30,227)
Net Deferred Tax Assets	$ —	$ —

The Company had no accrual for interest or penalties on the Company's balance sheets at December 31, 2011 or December 31, 2010, and has not recognized interest and/or penalties in the Statements of Operations for the years ended December 31, 2011, 2010 or 2009.

At December 31, 2011, the Company has federal net operating loss carryforwards of approximately $18.9 million, of which $749,000 are subject to limitation under Section 382 of the Internal Revenue Code of 1986, as amended, or the IRC, and will expire unused and the remaining federal net operating losses will begin to expire in 2025 unless previously utilized. The Company has California net operating loss carryforwards of approximately $20.0 million, of which $785,000 are subject to limitation under IRC Section 382 and will expire unused and the remaining California net operating losses will begin to expire in 2015 unless previously utilized. Included in these amounts are federal and California net operating losses of approximately $47,000 attributable to stock option deductions of which the tax benefit will be credited to equity when realized. The Company also has federal research tax credit carryforwards of approximately $4.0 million, of which $34,000 are subject to IRC Section 382 and will expire unused and the remaining federal research tax credit carryforwards will begin to expire in 2027. The Company also has California research tax credit carryforwards of approximately $2.0 million, which do not expire. Additional limitations may arise if the Company experiences an ownership change in subsequent years.

A reconciliation of the Federal statutory tax rate of 34% to the Company's effective income tax rate follows:

	2011	2010	2009
Statutory tax rate	34.0%	34.0%	34.0%
State taxes, net of Federal benefits	9.9	7.1	5.6
Permanent differences	(0.4)	(10.0)	(1.6)
Credits	5.0	10.4	0.0
Change in valuation allowance	(48.5)	(41.5)	(38.0)
Effective tax rate	0.0%	0.0%	0.0%

The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty of the Company's ability to generate sufficient taxable income to realize the deferred tax assets. The Company's valuation allowance increased approximately $8.8 million, $10.0 million and $8.6 million in 2011, 2010 and 2009, respectively, primarily due to net operating losses incurred during these periods. Management periodically evaluates the recoverability of the deferred tax assets. At such time as it is determined that it is more likely than not that deferred tax assets are realizable, the valuation allowance will be reduced.

The following table summarizes the activity related to the Company's gross unrecognized tax benefits at the beginning and end of the years ended December 31, 2011, 2010 and 2009 (in thousands):

	December 31,		
	2011	2010	2009
Gross unrecognized tax benefits at the beginning of the year	$570	$—	$—
Increases related to current year tax positions	334	570	—
Decreases related to prior year tax positions	—	—	—
Expiration of unrecognized tax benefits	—	—	—
Gross unrecognized tax benefits at the end of the year	$904	$570	$—

Due to the valuation allowance, none of the unrecognized tax benefits as of December 31, 2011, if recognized, would reduce the Company's annual effective tax rate. The Company does not expect its unrecognized tax benefits to change significantly over the next 12 months.

Note 13. Commitments

In June 2011, the Company amended its facility lease to expand its premises and extend the term of the lease to June 30, 2013. The Company accounts for this lease as an operating lease. In addition to the minimum lease payments, the Company is required to pay a pro-rata share of certain building expenses. The Company's amended lease includes options to extend the term for up to 12 additional months beyond the current termination date and contains a 4% annual escalation provision. Rent expense for the years ended December 31, 2011, 2010 and 2009 was $607,000, $451,000 and $418,000, respectively. As of December 31, 2011, the total future minimum payments under the Company's operating leases were as follows (in thousands):

2012	$652
2013	337
Thereafter	—
Total	$989

Note 14. Subsequent Events

The Company earned a $5.0 million milestone under its collaboration and license agreement with Bayer in January 2012. The milestone payment was earned as a result of the achievement of all efficacy and safety objectives in the Company's first Phase 3 clinical trial of tedizolid phosphate.

In January 2012, the Company completed a public offering of common stock in which it sold 9,890,000 million shares of its common stock at an offering price of $5.25 per share. The Company 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.

Note 15. Selected Quarterly Financial Data (Unaudited)

The following is a summary of the quarterly results of operations of the Company for the years ended December 31, 2011 and 2010 (unaudited, in thousands, except for loss per share data):

	Quarter Ended				Year Ended
	Mar 31	Jun 30	Sep 30	Dec 31	December 31
2011					
Revenues	$ 2,715	$ 2,859	$30,436	$ 5,001	$ 41,011
Operating expenses	12,784	12,854	18,634	16,570	60,842
Net income (loss) attributable to common stockholders	(10,062)	(9,988)	14,311	(12,511)	(18,250)
Net income (loss) per share:					
Basic	$ (0.43)	$ (0.40)	$ 0.50	$ (0.44)	$ (0.69)
Diluted	$ (0.43)	$ (0.40)	$ 0.49	$ (0.44)	$ (0.69)
Shares used in the calculation of net income (loss) per share:					
Basic	23,613	25,255	28,527	28,597	26,517
Diluted	23,613	25,255	29,477	28,597	26,517
2010					
Revenues	$ 1,486	$ 2,084	$ 1,940	$ 2,522	$ 8,032
Operating expenses	5,362	4,505	7,335	11,524	28,726
Net loss attributable to common stockholders	(4,283)	(2,348)	(8,500)	(8,750)	(23,881)
Net loss per share:					
Basic and diluted	$ (5.08)	$ (2.69)	$ (0.57)	$ (0.37)	$ (2.36)
Shares used in the calculation of net loss per share					
Basic and diluted	843	872	14,834	23,544	10,099

ITEM 9. *CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE*

None.

ITEM 9A. *CONTROLS AND PROCEDURES*

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) of the Securities Exchange Act of 1934, as amended, or 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 Annual Report on Form 10-K 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) 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

As of December 31, 2011, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Based on this assessment, our management concluded that, as of December 31, 2011, our internal control over financial reporting was effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2011 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Trius Therapeutics, Inc.

We have audited Trius Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Trius Therapeutics, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Trius Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the COSO criteria.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the accompanying balance sheets of Trius Therapeutics, Inc. as of December 31, 2011 and 2010, and the related statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2011 of Trius Therapeutics, Inc. and our report dated March 14, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
March 14, 2012

ITEM 9B. *OTHER INFORMATION*

2012 Executive Officer Base Salary and Stock Option Grants

On March 8, 2012, our Board of Directors, based on the recommendation of our Compensation Committee, approved increases in base salary and the grant of additional stock options for our executive officers. The increases in base salary are effective as of March 1, 2012. The following table sets forth 2012 base salaries and the number of shares underlying the stock option grants for our executive officers:

Name	Title	2012 Base Salary	Stock Options
Jeffrey Stein, Ph.D.	Chief Executive Officer	$ 431,000	250,000
Philippe Prokocimer, Ph.D.	Chief Medical Officer	$ 350,000	90,000
Ken Bartizal, Ph.D.	Chief Development Officer	$ 305,000	75,000
John P. Schmid	Chief Financial Officer	$ 305,000	85,000
John Finn, Ph.D.	Chief Scientific Officer	$ 305,000	95,000
Craig Thompson	Chief Commercial Officer	$ 305,000	90,000

The stock options described above (i) were granted effective as of March 8, 2012 pursuant to our 2010 Equity Incentive Plan, (ii) terminate ten years after March 8, 2012 or earlier in the event the option holder's service to us is terminated and (iii) have an exercise price per share equal to $4.80, the closing price of our common stock as reported on the Nasdaq Stock Market on March 8, 2012. Subject to the option holder's continued service to us, the shares of common stock subject to such stock options vest in equal monthly installments over the four years following the date of grant.

2011 Incentive Cash Bonus Payments

On March 8, 2012, our Board of Directors, based on the recommendation of our Compensation Committee, also approved 2011 incentive cash bonus payments based on an assessment of both corporate and individual performance during 2011. The 2011 cash bonuses approved for each of our executive officers were as follows:

Name	2011 Cash Bonus
Jeffrey Stein, Ph.D.	$175,275
Philippe Prokocimer, Ph.D.	$ 79,406
Ken Bartizal, Ph.D.	$ 69,781
John P. Schmid	$ 79,406
John Finn, Ph.D.	$ 64,125
Craig Thompson	$ 83,738

2012 Executive Bonus Plan

On March 8, 2012, our Board of Directors, based on the recommendation of our Compensation Committee, also approved our 2012 Executive Bonus Plan, or 2012 Bonus Plan. Under the 2012 Bonus Plan, our executives are provided with the opportunity to earn bonus payments conditioned upon the achievement of specified corporate and individual goals. Under the 2012 Bonus Plan, each individual is assigned a target bonus opportunity, calculated as a percentage of that individual's 2012 base salary, based on the person's role and title in the company. In addition, the payout for all of our officers is calculated based on our achievement of corporate and individual goals during 2012, with each officer being assigned a corporate and individual goal weighting.

Under the 2012 Bonus Plan, the target bonus opportunity as a percentage of 2012 base salary and corporate and individual goal weighting for each of our executive officers is as follows:

Name	Title	Target Bonus	Corporate	Individual
Jeffrey Stein, Ph.D.	Chief Executive Officer	65%	100%	0%
Philippe Prokocimer, Ph.D.	Chief Medical Officer	40%	75%	25%
Ken Bartizal, Ph.D.	Chief Development Officer	40%	75%	25%
John P. Schmid	Chief Financial Officer	40%	75%	25%
John Finn, Ph.D.	Chief Scientific Officer	40%	75%	25%
Craig Thompson	Chief Commercial Officer	40%	75%	25%

On March 8, 2012 our Board of Directors, based on the recommendation of our Compensation Committee, established corporate goals for 2012. For 2012, our corporate goals are a combination of clinical development goals, strategic goals and financial goals.

PART III

Certain information required by Part III of this Annual Report on Form 10-K is omitted from this report because the registrant will file a definitive Proxy Statement within 120 days after the end of its fiscal year pursuant to Regulation 14A for its 2011 Annual Meeting of Stockholders to be held within 180 days of December 31, 2011, referred to as the Proxy Statement, and the information included therein is incorporated herein by reference.

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

The information required by this item is incorporated by reference to the Proxy Statement under the sections entitled "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance."

ITEM 11. *EXECUTIVE COMPENSATION*

The information required by this item is incorporated herein by reference to the information from the Proxy Statement under the sections entitled "Executive Compensation," "Compensation Committee Report" and "Compensation Committee Interlocks and Insider Participation."

ITEM 12. *SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS*

The information required by this item is incorporated herein by reference to the information from the Proxy Statement under the sections entitled "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans."

ITEM 13. *CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE*

The information required by this item is incorporated herein by reference to the information from the Proxy Statement under the sections entitled "Election of Directors" and "Certain Relationships and Related Transactions."

ITEM 14. *PRINCIPAL ACCOUNTANT FEES AND SERVICES*

The information required by this item is incorporated herein by reference to the information from the Proxy Statement under the section entitled "Principal Accountant Fees and Services."

PART IV

ITEM 15. *EXHIBITS AND FINANCIAL STATEMENT SCHEDULES*

(a) Documents filed as part of this report.

1. List of Financial Statements. The following are included in Item 8 of this report:

Report of Independent Registered Public Accounting Firm

Balance Sheets as of December 31, 2011 and 2010

Statements of Operations for the years ended December 31, 2011, 2010 and 2009

Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit) for the years ended December 31, 2011, 2010 and 2009

Statements of Cash Flows for the years ended December 31, 2011, 2010 and 2009

Notes to the Financial Statements (includes unaudited Selected Quarterly Financial Data)

2. List of all Financial Statement schedules. All schedules are omitted because they are not applicable or the required information is shown in the Financial Statements or notes thereto.

3. List of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) Exhibits. The following exhibits are filed as part of, or incorporated by reference into, this report:

Exhibit	Description of Document
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 Registrant on November 1, 2004 to Forsythe Biotechnology Group, Inc.
4.3(2)	Form of Warrant issued pursuant to the Securities Purchase Agreement dated May 24, 2011, among Trius Therapeutics, Inc. and the Purchasers listed therein.
4.4(1)	Amended and Restated Investor Rights Agreement dated March 19, 2008 among the Registrant and certain of its stockholders.
4.5(2)	Form of Registration Rights Agreement dated May 24, 2011, among Trius Therapeutics, Inc. and the Purchasers listed therein.
10.1+(1)	Form of Indemnity Agreement by and between Registrant and its directors and executive officers.
10.2+(1)	Amended and Restated 2006 Equity Incentive Plan and Form of Stock Option Agreement there under.
10.3+(1)	2010 Equity Incentive Plan and Form of Stock Option Agreement there under.
10.4+(3)	Amended and Restated 2010 Non-Employee Directors' Stock Option Plan and Form of Stock Option Agreement there under.
10.5+(1)	2010 Employee Stock Purchase Plan and Form of Offering Document there under.
10.6+(1)	Employment Agreement dated February 1, 2007 between the Registrant and Jeffrey Stein, Ph.D.
10.7+	Offer of Employment dated January 10, 2011 from the Registrant to John Craig Thompson.
10.8+(1)	Amended and Restated Offer of Employment dated February 28, 2007 from the Registrant to John Finn, Ph.D.
10.9+(1)	Offer of Employment dated June 15, 2007 from the Registrant to Philippe G. Prokocimer, M.D.
10.10+(1)	Amended and Restated Offer of Employment dated February 28, 2007 from the Registrant to John P. Schmid.
10.11+(3)	Trius Therapeutics, Inc. Severance Benefit Plan.
10.12+(1)	Form of Employee Proprietary Information and Inventions Agreement.
10.13(1)	Standard Industrial/Commercial Multi-Tenant Lease—Net dated September 7, 2004 between the Registrant and Nancy Ridge Technology Center, L.P., as amended on August 1, 2006, March 14, 2007, September 24, 2007, July 15, 2008 and March 11, 2010.
10.14(4)	Sixth Amendment Dated September 29, 2010 to Standard Industrial/Commercial Multi-Tenant Lease-Net dated September 7, 2004, as amended, between the Registrant and Nancy Ridge Technology Center, L.P.

Exhibit	Description of Document
10.15(5)	Seventh Amendment Dated March 19, 2011 to Standard Industrial/Commercial Multi-Tenant Lease-Net dated September 7, 2004, as amended, between the Registrant and Nancy Ridge Technology Center, L.P.
10.16(6)	Eighth Amendment Dated June 15, 2011 to Standard Industrial/Commercial Multi-Tenant Lease-Net dated September 7, 2004, as amended, between the Registrant and Nancy Ridge Technology Center, L.P.
10.17*(1)	License Agreement dated January 31, 2007, by and between the Registrant and Dong-A Pharmaceutical Co., Ltd.
10.18*(3)	Collaboration and License Agreement dated July 26, 2011, by and between the Registrant and Bayer Pharma AG.
10.19*(1)	Contract Award issued by the National Institutes of Health, DHHS, NIAID, DEA and OA, dated September 1, 2008, relating to the development of novel agents for gram-negative biodefense pathogens.
10.20*(1)	Stevenson-Wydler (15 USC 3710) Cooperative Research and Development Agreement dated March 17, 2009, by and between the Registrant and Lawrence Livermore National Security LLC.
10.21*(1)	Contract Award issued by the Defense Threat Reduction Agency/BE-BC, dated April 21, 2010, relating to Broad Spectrum Antibacterial Therapeutics from Marine Natural products.
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23.1	Consent of Independent Registered Public Accounting Firm.
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.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Database.

+ Indicates management contract or compensatory plan.

* Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

(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 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.

(3) Incorporated herein by reference to Trius Therapeutics, Inc.'s Quarterly Report on Form 10-Q (File No. 001-34828) for the quarter ended September 30, 2011, filed with the Securities and Exchange Commission on November 10, 2011.
(4) Incorporated herein by reference to Trius Therapeutics, Inc.'s Quarterly Report on Form 10-Q (File No. 001-34828) for the quarter ended September 30, 2010, filed with the Securities and Exchange Commission on November 12, 2010.
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(6) Incorporated herein by reference to Trius Therapeutics, Inc.'s Quarterly Report on Form 10-Q (File No. 001-34828) for the quarter ended June 30, 2011, filed with the Securities and Exchange Commission on August 15, 2011.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Trius Therapeutics, Inc.

By: /s/ JEFFREY STEIN

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

Dated: March 14, 2012

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jeffrey Stein, Ph.D. and John P. Schmid, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Jeffrey Stein Jeffrey Stein, Ph.D.	President, CEO and Director *(Principal Executive Officer)*	March 14, 2012
/s/ John Schmid John Schmid	Chief Financial Officer *(Principal Financial Officer)*	March 14, 2012
/s/ Michael Morneau Michael Morneau	Vice President Finance and Chief Accounting Officer *(Principal Accounting Officer)*	March 14, 2012
/s/ David S. Kabakoff David S. Kabakoff, Ph.D.	Chairman of the Board of Directors	March 14, 2012
/s/ Brian G. Atwood Brian G. Atwood	Director	March 14, 2012
/s/ Karin Eastham Karin Eastham	Director	March 14, 2012
/s/ Nina Kjellson Nina Kjellson	Director	March 14, 2012

Signature	Title	Date
/s/ Brendan O'Leary Brendan O'Leary	Director	March 14, 2012
/s/ Michael Powell Michael Powell, Ph.D.	Director	March 14, 2012
/s/ Theodore R. Schroeder Theodore R. Schroeder	Director	March 14, 2012
/s/ Risa Stack Risa Stack, Ph.D.	Director	March 14, 2012
/s/ Paul Truex Paul Truex	Director	March 14, 2012

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MANAGEMENT

Jeffrey Stein, Ph.D.
President & Chief Executive Officer

John P. Schmid
Chief Financial Officer

John Finn, Ph.D.
Chief Scientific Officer

Philippe Prokocimer, M.D.
Chief Medical Officer

Kenneth Bartizal, Ph.D.
Chief Development Officer

Craig Thompson
Chief Commercial Officer

Karen Joy Shaw, Ph.D.,
Senior Vice President of Biology

Karen E. Potts, Ph.D.
Senior Vice President of Regulatory Affairs

Neil Abdollahian
Vice President of Corporate Development

BOARD OF DIRECTORS

Jeffrey Stein, Ph.D.
President & Chief Executive Officer, Trius Therapeutics

David S. Kabakoff, Ph.D.
Chairman of the Board, Trius Therapeutics
Director, InterMune, Amplimmune, Intellikine, and Allylix

Brian G. Atwood
Managing Director, Versant Ventures

Karin Eastham
Director, Trius Therapeutics, Amylin Pharmaceuticals, Geron, and Illumina

Nina Kjellson
Managing Director, InterWest Partners

Brendan O'Leary, Ph.D.
General Partner, Prism VentureWorks

Michael Powell, Ph.D.
General Partner, Sofinnova Ventures

Theodore Schroeder
President & Chief Executive Officer, Cadence Pharmaceuticals

Risa Stack, Ph.D.
Partner, Kleiner Perkins Caufield & Byers

Paul Truex
President & Chief Executive Officer, Anthera Pharmaceuticals

TRANSFER AGENT

Computershare
480 Washington Boulevard
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OUTSIDE LEGAL COUNSEL

Cooley LLP
San Diego, CA 92121

COMMON STOCK SYMBOL

NASDAQ: TSRX

CORPORATE

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Web www.triusrx.com

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