Ampio Pharmaceuticals, Inc.
Form S-1
November 12, 2010
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**As filed with the Securities and Exchange Commission on November 12, 2010.**

**Registration No. 333- .**

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM S-1

# REGISTRATION STATEMENT

***UNDER***

***THE SECURITIES ACT OF 1933***

# AMPIO PHARMACEUTICALS, INC.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **2834** | **26-0179592** |
|---|---|---|
| **(State or other jurisdiction of** | **(Primary Standard Industrial** | **(I.R.S. Employer** |

| incorporation or organization) | Classification Code Number) | Identification No.) |
|---|---|---|

**5445 DTC Parkway, P4**

**Greenwood Village, Colorado 80111**

**(303) 418-1000**

**(Address, including zip code, and telephone number, including area code, of the registrant s principal executive offices)**

**Donald B. Wingerter, Jr.**

**Chief Executive Officer**

**Ampio Pharmaceuticals, Inc.**

**5445 DTC Parkway, P4**

**Greenwood Village, Colorado 80111**

**(303) 418-1000**

**(Name, address, including zip code, and telephone number, including area code, of agent for service)**

***Copies to:***

**Robert W. Walter, Esq.**

**Richardson & Patel, LLP**

**10900 Wilshire Boulevard, Suite 500**

**Los Angeles, California 90024**

**(310) 208-1182**

**(310) 208-1154 Facsimile**

**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ¨

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

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

| | |
|---|---|
| Large accelerated filer ¨ | Accelerated filer ¨ |
| Non-accelerated filer ¨ (Do not check if a smaller reporting company) | Smaller reporting company þ |

**CALCULATION OF REGISTRATION FEE**

| Title of Each Class of Securities to be Registered | Amount to be Registered | Proposed Maximum Offering Price per Unit | Proposed Maximum Aggregate Offering Price | Amount of Registration Fee |
|---|---|---|---|---|
| Common Stock, par value $0.0001 per share | 8,500,000(1) | N/A | $17,085,000(2) | $1,219 |

(1) Represents the fixed number of shares of the Registrant s Common Stock to be issued in connection with the merger described herein.
(2) Estimated solely for purposes of calculating the registration fee required by Section 6(b) of the Securities Act and calculated pursuant to Rules 457(f)(1) and 457(c) under the Securities Act, based upon the last reported sale price of Ampio Pharmaceuticals, Inc. Common Stock on November 9, 2010.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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**EXPLANATORY NOTE**

This Registration Statement contains two prospectuses (the Prospectuses ), as set forth below.

*Offering Prospectus*. A prospectus to be used for the offering by Ampio Pharmaceuticals, Inc. ( Ampio ) of a fixed 8,500,000 shares of Ampio s common stock, as further described in the prospectus.

*Resale Prospectus*. A prospectus to be used for the resale by the selling stockholders set forth therein of an aggregate of 8,500,000 shares of Ampio s common stock issuable upon closing of the acquisition of DMI BioSciences, Inc. (the Resale Prospectus ).

The Resale Prospectus is substantively identical to the Offering Prospectus, except with respect to the following principal points:

the Prospectuses contain different outside and inside front covers and back covers;

the Resale Prospectus includes a section entitled Determination of Offering Price ;

the section entitled Description of Securities is omitted from the Resale Prospectus;

a Selling Stockholder section is included in the Resale Prospectus; and

any references in the Offering Prospectus to the Resale Prospectus will be deleted from the Offering Prospectus.

Ampio has included in this Registration Statement a set of alternate pages after the back cover page of the Offering Prospectus (the Alternate Pages ) to reflect the foregoing differences in the Resale Prospectus as compared to the Offering Prospectus. The Offering Prospectus will exclude the Alternate Pages and will be used for the public offering by the Registrant of its common stock. The Resale Prospectus will be substantively identical to the Offering Prospectus except for the addition or substitution of the Alternate Pages and will be used for the resale offering by the selling stockholders.

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**The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**SUBJECT TO COMPLETION, DATED NOVEMBER 12, 2010**

**PRELIMINARY PROSPECTUS**

# 8,500,000 Shares

# Common Stock

Ampio Pharmaceuticals, Inc. is offering 8,500,000 shares of our common stock in conjunction with our acquisition of DMI BioSciences, Inc., or BioSciences. The common stock will be issued to the BioSciences shareholders on the date of this prospectus. The BioSciences shareholders approved the merger of BioSciences into a subsidiary of Ampio on September 14, 2010, and a majority of our shareholders executed a consent to approve the acquisition of BioSciences in November 2010. This prospectus also provides notice to Ampio shareholders of the action taken by consent of a majority of the Ampio shareholders in November 2010. After the consent was executed, we and BioSciences executed all documents necessary to close the merger and placed these documents into escrow. The only condition for release of the closing documents from escrow is the effectiveness of the registration statement of which this prospectus is a part.

BioSciences was organized in 1990 and currently has 191 shareholders. In conjunction with the planned merger, BioSciences circulated purchaser questionnaires to its shareholders, a majority of which were returned to BioSciences in October and early November 2010. To date, 64 BioSciences shareholders have identified themselves as non-accredited investors, 49 BioSciences shareholders have not returned their purchaser questionnaires, and 78 BioSciences shareholders have identified themselves as accredited investors. Due to the actual and potential number of non-accredited investors in BioSciences, we do not believe we can rely on an exemption from the registration requirements of the federal securities laws. Accordingly, we are registering the 8,500,000 shares of common stock we will issue to the BioSciences shareholders. We have contemporaneously filed a resale prospectus usable by the BioSciences shareholders to effect sales of our common stock to be issued to such shareholders on effectiveness of the merger.

We will not receive any cash proceeds from this offering or from sales of our common stock effected by the BioSciences shareholders. Our common stock is quoted on the OTC Bulletin Board under the symbol AMPE. On November 11, 2010, the last reported sale price of our common stock on the OTC Bulletin Board was $2.20 per share.

**An investment in our common stock involves significant risks. See Risk Factors beginning on page 14 to read about factors you should consider.**

**Neither the Securities and Exchange Commission nor any state securities regulator has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

**The date of this prospectus is , 2010.**

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**You should rely only on the information contained in this document. We have not authorized anyone to provide you with additional or different information from that contained in this prospectus. If anyone provides you with additional, different or inconsistent information, you should not rely on it. This prospectus does not constitute an offer to sell, or a solicitation of an offer to buy, any securities in any jurisdiction to or from any person to whom it is unlawful to make any such offer or solicitation. The information in this document may only be accurate on the date of this document, regardless of its time of delivery. Our business, financial condition, results of operations or cash flows may have changed since such date.**

The registration statement containing this prospectus, including the exhibits to the registration statement, provides additional information about us and the shares of our common stock covered by this prospectus. The registration statement, including the exhibits, can be read on the SEC website or at the SEC offices mentioned under the heading Where You Can Find More Information.

Ampio s common stock is registered under Section 15(d) of the Securities Exchange Act of 1934, or the Exchange Act. As such, we are obligated to file quarterly reports, annual reports and reports of current events with the SEC. We are not required to file proxy statements or information statements with the SEC, and our executive officers, directors and control persons are not required to file reports of beneficial ownership of our common stock with the SEC. At such time as our common stock is registered under Section 12 of the Exchange Act, we and our executive officers, directors and control persons will become subject to these additional filing requirements.

This prospectus includes trademarks, such as Optina, Ampion, Vasaloc and Zertane, which are protected under applicable intellectual property laws and are our property or the property of our subsidiaries. This prospectus also contains trademarks, service marks, copyrights and trade names of other companies which are the property of their respective owners. Solely for convenience, our trademarks and tradenames referred to in this prospectus may appear without the ® or symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames.

For investors outside the United States, we have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. You are required to inform yourselves

about and to observe any restrictions.

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## PROSPECTUS SUMMARY

*The following summary highlights selected information from this prospectus and does not contain all of the information that you should consider before investing in our common stock. This prospectus contains information regarding our business and detailed financial information. You should carefully read this entire prospectus, including the historical financial statements and related notes.*

### About Ampio Pharmaceuticals

We are a development stage pharmaceutical company engaged in the discovery and development of innovative, proprietary pharmaceutical and diagnostic products to identify and treat inflammatory conditions, including metabolic disorders and diabetic complications. We have a disciplined strategy and productive innovation platform that generates compounds and diagnostics with large potential value while minimizing development risk, cost, and time. Our discovery process occurs in a true clinical environment that carries low overhead costs. Each drug candidate undergoes a sophisticated business filter to identify products that can be clinically and cost-effectively developed to generate substantial value and returns while minimizing risk. Our strategy focuses on generating human safety and efficacy data in order to position our product candidates for value-creating licensing agreements with strategic partners, and is not focused on conducting FDA-directed clinical trials.

Ampio Pharmaceuticals has several unique characteristics distinguished from similar stage companies:

- a range of substantive products that are the result of our innovation process, have strong patent or patent pending positions, multi-billion dollar markets, and shorter regulatory paths than new molecular entities, or NMEs;
- a licensing-focused strategy based on conducting safety and efficacy trials geared towards understanding a drug s potential for addressing multiple clinical indications, not by first pursuing FDA-centric clinical trials;
- an innovative and proprietary drug discovery process that rapidly identifies candidates for large unmet clinical needs at considerably lower cost than NME product candidates;
- access to clinical and scientific resources as a result of a contractual agreement and long-term relationship with Trauma Research LLC, or TRLLC, a related party controlled by our chief scientific officer; and
- a sophisticated business filter, clinical review and intellectual property evaluation that select clinically and commercially valuable products coupled with a rapid development timeframe to reach significant value creation.

### Our Drug Discovery Platform

*Clinical Discovery Process*

Our disciplined innovative drug discovery process begins with input from clinicians in the field, not research in the lab, and is guided primarily by patent strength, solving an unmet need, and identifying repositioned product candidates previously approved for other indications by the FDA or biologics. This process is built on clinical observations and patient data gathered under appropriate IRB supervision from clinicians who collaborate closely with Ampio scientists and TRLLC clinicians. As a result of these unique collaborative agreements and historic relationships, we obtain access to research and clinical resources at substantially lower cost than industry norms. As a result, our platform has generated lead product candidates, Optina , Vasaloc , Ampion , and Zertane to address large unmet clinical needs.

*Collaborations and Resources*

Our chief scientific officer, Dr. David Bar-Or, collaborates with a team of biochemists, epidemiologists, molecular biologists, immunologist, computational biologists and nursing staff, and also oversees TRLLC, which provides accreditation services for two of the three Level I trauma centers in the State of Colorado. Over 120,000 emergency room consultations take place annually at these hospital facilities. Under a sponsored research agreement, Ampio funds a variety of targeted research projects conducted by TRLLC, allowing us to further the short term clinical aims of TRLLC and to obtain intellectual property rights to any resulting product candidates. This also provides us access to clinical observations, biology and scientific information we apply to product discovery and development. In collaboration with other professional colleagues who provide advisory input such as vascular

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surgeons, orthopedic surgeons, neurologists, nephrologists and ER specialists, Dr. Bar-Or uses a multi-disciplinary approach to evaluate clinical interaction that direct further research. The clinical team has access to a large patient database and blood samples for testing or validating drug candidates. With over a decade of scientific research supporting many of our developments, we have built an extensive patent portfolio with over 50 granted patents and a number of license arrangements.

*Business Filter and Product Evaluation*

We focus our development work on advancing product candidates that we believe offer significant therapeutic advantages over currently available treatments and which represent large potential markets. We look to advance product candidates that address multiple clinical indications, have proven safety profiles, and which can timely demonstrate clinical efficacy. We intend to continue to maintain a diversified product candidate pipeline to mitigate risks associated with pharmaceutical development and increase the likelihood of commercial success. During the development process, we review pertinent scientific literature and conduct searches of patent records in order to make a preliminary determination of patentability. As many of our product candidates are repositioned drugs, the nature and extent of potentially available patent protection is central to our development decisions.

Once identified, candidates are filtered and screened for:

- indirect evidence of efficacy based on review of related publications;
- market size, market acceptance and likely penetration;
- patentability and other modes for protecting exclusivity; and
- competitive products and manufacturing issues.

**Cost Effective Clinical Strategy**

In order to control development costs and expedite the commencement of clinical trials, we intend to conduct clinical trials at sites located in Canada, the European Union member states, Australia, India and perhaps countries in the Far East. We plan also to outsource manufacturing, and to out-license to collaborators the rights to sell and market, any product candidates that receive regulatory approval within or outside the U.S. We may also opportunistically enter into agreements with collaborators prior to licensing that may be country, region or application specific and that may lead to sublicenses. Although outsourcing may reduce income derived from any sales of approved products, our business model is premised on carefully controlling fixed overhead and development costs, creating a catalyst to value by identifying patent-protectable product candidates with significant commercial potential and clinical efficacy, and to support the licensee in advancing those product candidates through any additional required clinical trials and the regulatory approval process in order to position an approved product for global market entry.

**Product Pipeline**

Our disciplined innovation process is built on Dr. Bar-Or s research on inflammation and its role in trauma, which is an ideal platform to study inflammation. Dr. Bar-Or has completed several ground-breaking studies on the role of transition metals in inflammation and ischemia and the composition of commercially available human serum albumin products and the effect of variations in composition on trauma patient outcomes. We believe his studies are valuable because of their originality and application to patient care, and because the results are obtained from well-preserved and characterized human biosamples without the confounding influence of interspecies differences. In this context, Dr. Bar-Or s approach plays a key role in bridging the gulf between basic molecular-cellular research and human clinical research.

Three of our most advanced product candidates are repositioned drugs (Optina, Vasaloc, and Zertane)for which we have secured or are seeking U.S. and international patent protection covering their unique composition or application. Strategically, repositioned drugs reduce the risk of product failure due to adverse toxicology, lead to more modest investments during development, and may achieve more rapid marketing approval. Ampion is a biologic and being developed as a NME for inflammatory diseases. Because Ampion is naturally produced in the body to fight inflammation, we believe it has a favorable safety, efficacy, and risk profile. We have also developed an Oxidation Reduction Potential

(ORP) diagnostic device which is now being prototyped for use in emergency rooms to assess stroke and chest pain stratification of patients.

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We intend to demonstrate statistical proof of human efficacy of our product candidates for specific indications:

**Optina and Vasaloc**, repurposed danazol with patents in process for complications of diabetes;

**Ampion**, an innovative biological agent with composition of matter patent coverage and efficacy in treating inflammatory disorders, including osteoarthritis, rheumatoid disease and related disorders;

**Zertane**, repurposed analgesic tramadol with extensive patent coverage for premature ejaculation and potential combination therapies with erectile dysfunction; and

**Oxidation Reduction Potential (ORP) Diagnostic Device**, a diagnostic machine that measures the net oxidants and antioxidants in human blood to determine oxidative stress in the body to assess cardiovascular events and other inflammatory conditions.

*Optina for Diabetic Macular Edema and Wet AMD*

Optina is an orally-administered repositioned compound based on a low-dose formulation of approved drug danazol. Developed initially to treat endometriosis, danazol was first approved by the FDA in the early 1970 s and is a derivative of the synthetic steroid ethisterone. Dr. David Bar-Or, our chief scientific officer, has determined that danazol in low doses has the capability to control the permeability of tissues, thus reducing vascular leakage. Vascular permeability is a key endothelial mechanism by which inflammatory cytokines and angiogenic factors affect target cells and organs to mediate the inflammatory response or cell growth. During the disease state, there is an increase in vascular permeability factors leading to vasodilation, edema formation, and disruption of intercellular membrane structure.

Optina is designed to treat diabetic macular edema, or DME, and neovascular age-related macular degeneration, or wet AMD. If untreated, diabetic macular edema leads to moderate vision loss for one out of four diabetics over a period of three years and can lead to blindness over a period of seven years. We contracted with a Canadian hospital to conduct Phase II clinical trials of Optina for $0.97 million and expect patient enrollment to begin in November 2010. We believe this study will be completed in the second quarter of 2011. We intend to partner or entertain licensing opportunities once we have realized significant value for Optina s application based on reported human safety and efficacy data. According to BCC Research, the market for DME and AMD in 2009 was over$2.4 billion in the U.S.

Approximately 14% of people with diabetes have DME. According to the American Academy of Ophthalmology, the prevalence of DME increases to 29% for people with diabetes who use insulin for more than 20 years. Existing therapies for DME and wet AMD include focal and grid laser therapy, which is the current standard of care, as well as photodynamic therapy, surgery, and intravitreal treatment for AMD using Lucentis. Lucentis is costly compared to alternative injection therapies. Avastin is currently approved only for cancer treatment, but it is being used off-label by ophthalmologists to treat DME and wet AMD. There are currently no oral medications available for treatment of DME and wet AMD. We believe Optina has the potential to effectively treat DME and wet AMD without costly laser therapy and without requiring ongoing injections of pharmaceuticals in the eye.

*Vasaloc for Diabetic Nephropathy*

Vasaloc, like Optina, is also based on low-dose danazol. Vasaloc is an orally-administered compound designed to treat diabetic nephropathy. Untreated diabetic nephropathy leads to kidney damage or renal failure. Approximately 20-30% of the estimated 20.8 million diabetics in the U.S. have diabetic nephropathy, according to the Cleveland Clinic. We expect to contract for Phase II clinical trials of Vasaloc to commence in the first quarter of 2011, and believe the trial will be completed by the first quarter of 2012. Our estimated cost for the trial is under $1.2 million.

Diabetes has become the most common single cause of end-stage renal disease in the U.S. and Europe. Standard modalities for the treatment of diabetic nephropathy include controlling blood glucose levels by using a variety of hormone therapies such as insulin, by stimulating the release of insulin using sulfonylureas, or through use of insulin derivatives. As high blood pressure is known to increase the rate of decline in renal function, diabetics are generally advised to control blood pressure using one or a combination of angiotensin-converting enzyme (ACE) inhibitors, Angiotensin II receptor blockers (ARBs), calcium channel blockers, diuretics, or beta-blockers. When renal failure occurs, dialysis is

often required and a kidney transplant may become the only viable treatment option. We believe Vasaloc offers an effective means to treat diabetic nephropathy by reducing vascular permeability of nephrons and glomerulus, thereby stabilizing kidney function and reducing complications from kidney damage.

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*Ampion for Inflammation*

Ampion is a non-steroidal biologic, aspartyl-alanyl diketopiperazine, referred to as DA-DKP. This compound is comprised of two amino acids derived from human blood, and is designed to treat chronic inflammatory and autoimmune diseases. Because it is a naturally occurring human molecule, DA-DKP is present in the body. Like danazol, Ampion has significant effects on vascular permeability when concentrated for clinical efficacy. Dr. Bar-Or has published a number of studies and articles on the anti-inflammatory immune response of DA-DKP. We intend to conduct pilot clinical studies on the effect of DA-DKP in patients suffering from multiple sclerosis, an autoimmune disease caused by nerve damage attributable to inflammation. There is currently no cure for MS and it is unknown what triggers the body s inflammatory response. We plan to conduct four proof of concept studies of Ampion in India or Australia commencing in the second or third quarter of 2011, and expect these studies will take approximately 24 months to complete. Our estimated cost for each trial is under $0.5 million. We intend to partner or entertain licensing opportunities once we have realized significant value for Ampion through obtaining human efficacy data.

*Zertane for Premature Ejaculation*

Zertane is a new use for tramadol hydrocloride, which was approved for marketing as a noncontrolled analgesic in 1995. Based on the results of two clinical trials we conducted, we believe it can be an effective oral medication to treat premature ejaculation, or PE, in men. Premature ejaculation is the most common form of male sexual dysfunction and has a major impact on the quality of life for many men and their partners. The market opportunity is large, with an estimated 30% of males suffering from premature ejaculation (four times the number with erectile dysfunction). According to Australia s Keogh Institute of Medical Research, PE is the most common sexual complaint in males. At present no drug has been approved by the FDA for the treatment of premature ejaculation. Priligy, an orally-administered anti-depressant in the SSRI class, has been approved for the treatment of PE in two European countries, where it is marketed by Janssen-Cilag, a unit of Johnson & Johnson. National approvals and licenses in five other European countries are expected to shortly follow. Behavioral therapy is the current standard of care for treatment of PE.

We granted an option to license Zertane to a large pharmaceutical company in 2007, and the option was exercised in January 2009. The licensee commenced two large Phase III clinical trials in Europe which were discontinued when the licensee terminated the license agreement in the second quarter of 2010, which we understand to have occurred due to a change in the licensee s strategic direction. At that time, Ampio regained all rights to develop, license and seek regulatory approval to market Zertane worldwide. Ampio is entitled to obtain the clinical trial data from the pharmaceutical company and its CRO. We expect to complete our preliminary review of this data in December 2010. We have applied for patent protection for a combination of Zertane and an erectile dysfunction, or ED, medicine to offer male patients a single oral medication that will treat both PE and ED. A combination drug would address the significant co-morbid ED and PE population. We currently intend to partner or seek licensing opportunities for this Zertane drug combination.

*Oxidation-Reduction Potential (ORP) Diagnostic for Oxidative Stress*

We have also developed an Oxidation-Reduction Potential, or ORP, diagnostic machine that will measure the oxidants and antioxidants in human blood. Designed for use at a patient s bedside or at home, the ORP device is currently being prototyped and the first three prototypes are expected to be available for testing by November 2010. We developed a disposable electrode for use in the ORP device and have calibrated the device to measure oxidants and antioxidants while taking into account various factors that may affect oxidative stress. Oxidative stress is often a marker for inflammation, which in turn indicates the presence of disease-related processes or developing conditions. We believe that identifying patients who are experiencing oxidative stress prior to hospital discharge can serve as a predictor of readmission rates, and as a means for patients to self-detect early indicators of health-related issues.

*Preclinical Candidate Pipeline*

Ampio s development process has produced numerous product candidates with various levels of patent protection in process, and for which we have obtained *in vitro* and clinical data. These earlier stage products may be candidates for a number of potential licensees, including pharmaceutical and biotechnology companies with substantial manufacturing facilities, established sales organizations, and significant marketing resources. Dr. Bar-Or has synthesized and obtained patents for nine compounds known as methylphenidates for anti-angiogenesis and anti-metastasis applications. These compounds are derivatives of Ritalin, but are considered NMEs. We expect to seek a special protocol assessment from the FDA under which one or more of our methylphenidate compounds can be

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administered under a compassionate need exception to patients suffering from advanced liver, ovarian, brain or other cancers. Methylphenidates may also have applications for macular degeneration and to Alzheimer s or other neurodegenerative disorders, as methylphenidates have strong anti-inflammatory properties. Similarly, we have conducted early research into how Copper chelating peptides, also considered an NME, may be used to treat Acute Coronary Syndrome and strokes. Because of the nature and extent of clinical trials needed to obtain regulatory approval for NMEs, we plan to out-license these compounds to collaborators after we have obtained early clinical data, in the case of methylphenidates, and after toxicology studies are completed, in the case of copper chelating peptides. Our product candidate portfolio includes a number of additional compounds we are now studying, including compounds to treat gingivitis and periodontitis, to assist in the diagnosis and monitoring of skin disorders, and to use in testing for blood-borne infectious agents.

**Common Stock Offered**

| | |
|---|---|
| Common Stock to be issued to Biosciences shareholders: | 8,500,000 shares |
| Shares of Common Stock outstanding after BioSciences acquisition: | 22,107,036 |
| Use of proceeds: | We will not receive any proceeds from the sale of the Merger Stock by the BioSciences shareholders. |

The number of shares of our common stock to be outstanding after closing of the BioSciences acquisition (i) gives effect to the donation to capital of 3,500,000 shares of Ampio common stock by BioSciences immediately before the closing of the merger, and (ii) excludes 2,900,000 shares of common stock issuable on exercise of outstanding options issued pursuant to our stock incentive plan.

**Risk Factors**

Our business is subject to a number of risks of which you should be aware. These risks are described in more detail in the Risk Factors section of this prospectus immediately following this prospectus summary. These risks include the following:

- Clinical trials have not yet been completed for Optina, Vasaloc, or Ampion, and the results of those clinical trials may yield unfavorable results that cause us to discontinue efforts to develop these product candidates;
- We may not secure regulatory approval to market any of our product candidates in the U.S. or other countries;
- If we do not secure collaborators with manufacturing, marketing and sales capabilities, we may not be successful in commercializing any of our product candidates that receive regulatory approvals;
- We have incurred significant operating losses since inception and we expect those losses to continue for at least several years;
- Even if a product candidate is approved and reaches the market, the product may not achieve physician and patient acceptance, or may not obtain adequate reimbursement from third party payors;and
- We face significant competition from companies much larger than us, and our product candidates will compete with other treatments and medicines that may be more effective, or safer, than our product candidates.

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**Corporate Information and History**

Our executive offices are located at 5445 DTC Parkway, P4 , Greenwood Village, Colorado 80111, and our telephone number is (303) 418-1000. Additional information about us is available on our website at www.ampiopharma.com. The information contained on or that may be obtained from our website is not, and shall not be deemed to be, a part of this prospectus. Our common stock is currently traded on the OTC Bulletin Board under the symbol AMPE.

Life Sciences was formed in December 2008 and commenced operations when it acquired certain assets of BioSciences in April 2009. In March 2010, Life Sciences merged with a subsidiary of Chay Enterprises, Inc., a Colorado corporation. Immediately after the merger, Chay Enterprises changed its name to Ampio Pharmaceuticals, Inc., and reincorporated in Delaware. We sometimes refer in this prospectus to Life Sciences as we or us when referring to our operations prior to the Chay merger.

**Market and Industry Data**

We obtained statistical data, market and product data, and forecasts used throughout this prospectus from market research, publicly available information and industry publications. While we believe that the statistical data, industry data and forecasts and market research are reliable, we have not independently verified the data, and we do not make any representation as to the accuracy of the information.

Estimates of historical growth rates in diabetes and other diseases are not necessarily indicative of future growth rates. When referring to clinical indications, observations, and treatment modalities, we relied on clinical data evaluated by, and publications authored or co-authored by, Dr. Bar-Or, our chief scientific officer, and published information from medical journals and other sources concerning clinical trials conducted by others and regulatory approvals obtained for other pharmaceutical products. With respect to diabetes-related conditions, we relied in part also on the Proceedings of the American Academy of Ophthalmology Preferred Practice Patterns: Diabetic Retinopathy, 2008 and *Clinical Effect of Danazol in Patients with IgA Nephropathy,* Tomino, *et al*, Japan J. Med.; 26(2): 162-166. In estimating the market size for Ampion, we referred in part to information published by Datamonitor, *Stakeholder Insight: Osteoarthritis,* DMHC1907, December 2003.

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**Summary Selected Unaudited Pro Forma Consolidated Combined Financial Information**

The following tables set forth selected unaudited pro forma consolidated combined financial data for us and BioSciences at and for each of the years in the two-year period ended December 31, 2009 and for the six month periods ended June 30, 2010 and 2009. You should read the summary selected unaudited pro forma consolidated combined financial information presented below in conjunction with the Management s Discussion and Analysis of Financial Condition and Results of Operations section, our audited financial statements and those of BioSciences for the two-year periods ended December 31, 2009, and our unaudited financial statements and those of BioSciences for the six months ended June 30, 2010 and 2009, and the related notes contained in this prospectus.

In April 2009, Life Sciences commenced operations when it purchased assets, principally intellectual property, from BioSciences. In March 2010, Life Sciences merged with a subsidiary of Chay Enterprises, a Colorado corporation. Immediately following the merger, Chay Enterprises reincorporated in Delaware and changed its name to Ampio Pharmaceuticals, Inc. For accounting and financial reporting purposes, Life Sciences was considered the acquirer and the merger was treated as a reverse acquisition. All financial information presented in this prospectus for periods prior to the Chay merger reflects only that of Life Sciences or the assets purchased from BioSciences, and does not reflect the pre-merger Chay assets, liabilities, or operating results. In addition, all share, per share and related Life Sciences information has been adjusted to take into account the Chay merger. In November 2010 we closed the acquisition of BioSciences in escrow. The only condition to be satisfied for the closing of escrow is the registration of the 8,500,000 shares of our common stock to be issued to the BioSciences shareholders. BioSciences is simultaneously donating back to our capital an aggregate of 3,500,000 shares of our common stock issued to BioSciences in April 2009. Accordingly, we will be issuing a net of 5,000,000 additional shares of our common stock to acquire BioSciences.

The selected unaudited pro forma financial data set forth below gives retroactive effect, to the beginning of the periods presented, of the acquisition of BioSciences. We have presented the pro forma consolidated combined financial information below to provide you a better picture of what our business would have looked like had we owned BioSciences since October 1, 1, 2007. As Life Sciences was organized on December 18, 2008 and had no material operations in 2008, the pro forma statement of operations data for the years ended December 31, 2008 and September 30, 2008 consist primarily of financial information pertaining to BioSciences. BioSciences fiscal year ends on September 30 and Ampio s fiscal ends on December 31, so the pro forma information presented below for 2009 and 2008 represents 12-month periods for BioSciences and Ampio ending September 30 and December 31, respectively. We have also eliminated inter-company transactions from the information below. The summary selected pro forma consolidated combined financial data at and for the six month periods ended June 30, 2010 and 2009 have been derived from our and BioSciences unaudited interim consolidated financial statements, and represent six months of BioSciences operations. These unaudited interim pro forma consolidated financial statements include all adjustments (consisting only of normal recurring adjustments) that we consider necessary for a fair presentation of our financial condition and results of operations as of the dates and for the periods indicated.

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| | Pro Forma Consolidated Six Months Ended June 30, | | Ampio Pharmaceuticals, Inc. Six Months Ended June 30, | | Ampio Pharmaceuticals, Inc. Year Ended December 31, | | DMI BioSciences, Inc. Six Months Ended June 30, | | DMI BioSciences, Inc. Year Ended September 30, | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 2010 (unaudited) | 2009 (unaudited) | 2010 (unaudited) | 2009 (unaudited) | 2009 | 2008 | 2010 (unaudited) | 2009 (unaudited) | 2009 | 2008 |
| Revenues | | | | | | | | | | |
| License fees | $ 404,410 | $ 404,410 | $ | $ | $ | $ | $ 404,410 | $ 404,410 | $ 875,000 | $ 500,000 |
| Royalty fees | | 33,750 | | | | | | 33,750 | 58,750 | 75,000 |
| Milestone payments | | | | | | | | | 1,500,475 | |
| Other revenue | | 111,943 | | | | | | 111,943 | 111,943 | 36,865 |
| Total revenue | 404,410 | 550,103 | | | | | 404,410 | 550,103 | 2,546,168 | 611,865 |
| Expenses | | | | | | | | | | |
| Research and development | 637,419 | 1,044,985 | 589,999 | 258,725 | 1,070,370 | | 47,420 | 786,260 | 1,095,221 | 153,397 |
| General and administrative | 2,046,209 | 1,573,627 | 2,032,560 | 148,934 | 442,215 | 1,080 | 13,649 | 6,808,382 | 7,013,867 | 1,041,569 |
| Total expenses | 2,683,628 | 2,618,612 | 2,622,559 | 407,659 | 1,512,585 | 1,080 | 61,069 | 7,594,642 | 8,109,088 | 1,194,966 |
| Loss from operations | (2,279,218) | (2,068,509) | (2,622,559) | (407,659) | (1,512,585) | (1,080) | 343,341 | (7,044,539) | (5,562,920) | (583,101) |
| Other income (expense), net | (1,489) | (11,734) | (5,603) | 252 | (323) | | (18,136) | (28,039) | (55,952) | (572,084) |
| Net (loss) | $ (2,280,707) | $ (2,080,243) | $ (2,628,162) | $ (407,407) | $ (1,512,908) | $ (1,080) | $ 325,205 | $ (7,072,578) | $ (5,618,872) | $ (1,155,185) |
| Basic and diluted net loss per common share | $ (0.11) | $ (0.20) | $ (0.17) | $ (0.07) | $ (0.17) | $ (0.00) | | | | |
| Weighted average number of common shares outstanding | 20,456,332 | 10,575,856 | 15,456,332 | 5,575,856 | 8,787,650 | 1,080,000 | | | | |

(1) Please see the notes to our financial statements appearing elsewhere in this prospectus for an explanation of the method used to calculate basic and diluted net loss per share of common stock, the pro forma basic and diluted net loss per share of common stock, and the pro forma number of shares used in the computation of the pro forma per share amounts.

The following table presents balance sheet data as of June 30, 2010 and on a pro forma basis after giving effect to the acquisition of Biosciences.

| | Proforma Consolidated June 30, 2010 (unaudited) | Proforma Consolidated December 31, 2009 (unaudited) | Ampio Pharmaceuticals, Inc. June 30, 2010 (unaudited) | Ampio Pharmaceuticals, Inc. December 31, 2009 | DMI BioSciences, Inc. June 30, 2010 (unaudited) | DMI BioSciences, Inc. September 30, 2009 |
|---|---|---|---|---|---|---|
| **Balance sheet data:** | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Cash, cash equivalents and investments | $ 648,428 | $ 1,774,187 | $ 131,035 | $ 71,983 | $ 517,393 | $ 1,702,204 |
| Working capital (deficit) | 117,637 | 102,661 | (668,386) | (267,970) | (703,933) | (1,086,973) |
| Total assets | 12,592,785 | 14,028,480 | 295,219 | 86,280 | 888,996 | 1,702,204 |
| Total liabilities | 758,748 | 1,794,725 | 961,182 | 354,250 | 2,022,929 | 3,335,340 |
| Total stockholders equity (deficit) | 11,834,037 | 14,028,480 | (665,963) | 86,280 | (1,133,933) | 1,702,204 |

(1) The pro forma balance sheet data in the table above reflects the acquisition of BioSciences as if such acquisition had occurred on June 30, 2010, and reflects also (i) the elimination of inter-company debt, (ii) the cancellation of accrued compensation payable by BioSciences to its management team immediately prior to the acquisition, (iii) the cancellation and forgiveness of accrued interest on notes payable by BioSciences to a third party, and (iv) the conversion of the principal amount of such notes payable into Ampio common stock pursuant to a conversion agreement between BioSciences and the noteholder.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Forward-looking statements are those that predict or describe future events or trends and that do not relate solely to historical matters. You can generally identify forward-looking statements as statements containing the words believe, expect, may, will, anticipate, intend, estim project, plan, assume or other similar expressions, although not all forward-looking statements contain these identifying words. All statements contained in this prospectus regarding our future strategy, plans and expectations regarding clinical trials, future regulatory approvals, our plans for the commercialization of our products, future operations, projected financial position, potential future revenues, projected costs, future prospects, and results that might be obtained by pursuing management s current plans and objectives are forward-looking statements. Forward-looking statements include, but are not necessarily limited to, those relating to:

- the results and timing of our clinical trials, particularly the results of our Optina, Vasaloc and Ampion trials;
- the regulatory review process and any regulatory approvals that are issued or denied by the FDA, the EMEA, or other regulatory agencies;
- our need to secure collaborators to license, manufacture, market and sell any products for which we receive regulatory approval in the future;
- the results of our internal research and development efforts;
- the commercial success and market acceptance of any of our product candidates that are approved for marketing in the United States or other countries;
- the safety and efficacy of medicines or treatments introduced by competitors that are targeted to indications which our product candidates have been developed to treat;
- acceptance and approval of regulatory filings;
- our need for, and ability to raise, additional capital;
- our collaborators compliance or non-compliance with their obligations under our agreements with them, or decisions by our collaborators to discontinue clinical trials and return product candidates to us; and
- our plans to develop other product candidates.

You should not place undue reliance on our forward-looking statements because the matters they describe are subject to known and unknown risks, uncertainties and other unpredictable factors, many of which are beyond our control. Our forward-looking statements are based on the information currently available to us and speak only as of the date on the cover of this prospectus. New risks and uncertainties arise from time to time, and it is impossible for us to predict these matters or how they may affect us. Over time, our actual results, performance or achievements will likely differ from the anticipated results, performance or achievements that are expressed or implied by our forward-looking statements, and

such differences might be significant and materially adverse to our investors. We have no duty to, and do not intend to, update or revise the forward-looking statements in this prospectus after the date of this prospectus except to the extent required by the federal securities laws. Forward-looking statements may be contained in this prospectus. You should consider all risks and uncertainties disclosed in our filings with the Securities and Exchange Commission, or the SEC, described below under the heading Where You Can Find More Information, all of which are accessible on the SEC s website at www.sec.gov.

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## QUESTIONS AND ANSWERS

*The following are some questions that you, as a shareholder of BioSciences, may have regarding the merger and the answers to those questions. Ampio urges you to read carefully the remainder of this prospectus because the information in this section does not provide all the information that might be important to you with respect to the merger and the related matters*

Unless otherwise indicated or unless the context requires otherwise, all references in this prospectus to Ampio Pharmaceuticals, Inc. Ampio, the Company, we, us, our, or similar references, mean Ampio Pharmaceuticals, Inc. and its subsidiaries on a consolidated basis; references to BioSciences in this prospectus mean DMI BioSciences, Inc.; references to Life Sciences in this prospectus mean DMI Life Sciences, Inc., which is our predecessor for accounting purposes and now a wholly-owned subsidiary of ours; references to Merger Sub refer to Ampio Acquisition, Inc., a Colorado corporation and a direct wholly owned subsidiary of Ampio; references to Merger Agreement refer to the Agreement and Plan of Merger, dated as of September 3, 2010 and approved by our stockholders on or about November 9, 2010, among Ampio, BioSciences, Merger Sub, and the control shareholders of BioSciences, a copy of which is filed as an exhibit to the registration statement that includes this prospectus; references to Merger Stock refer to the 8,500,000 shares of our common stock to be issued to the BioSciences shareholders; and certain references to the combined company, as the context requires, refer to Ampio and its subsidiaries following completion of the merger.

**Q: Why am I receiving this prospectus?**

A: Ampio and BioSciences have agreed that Ampio will acquire BioSciences pursuant to the terms of the Merger Agreement described in this prospectus. A copy of the Merger Agreement has been previously circulated to the BioSciences shareholders and is on file with the SEC. In order to consummate the merger, we are required to first register the Merger Stock. In order to do so, we have filed a registration statement, of which this prospectus is a part, with the SEC. When the registration statement is declared effective, the merger closing documents that Ampio and BioSciences have already executed and placed in escrow will be released to each party. The only condition for termination of the escrow is the effectiveness of the registration statement, as the BioSciences shareholders have already approved the merger and a majority of the Ampio shareholders have executed a consent approving the Merger.

**Q: What will I receive in the merger?**

A: When the Merger Stock is registered, BioSciences shareholders will receive, for each share of BioSciences stock outstanding immediately prior to the effective time of the merger, 0.84789 shares of Ampio common stock. BioSciences shareholders will not receive any fractional shares in the merger. Instead, Ampio will round-up any fractional shares to the nearest whole share. Ampio shareholders will not receive any merger consideration and will continue to hold the Ampio shares owned by them.

**Q: What is the value of the merger consideration?**

A: Because Ampio will issue a fixed number of shares of Merger Stock in exchange for each share of BioSciences common stock, the value of the merger consideration that BioSciences stockholders will receive will depend on the price per share of Ampio common stock at the time the merger is completed. That price may be less or more than the market price of the Ampio common stock at the time of the BioSciences shareholder meeting.

**Q: When was the BioSciences special meeting held and what was the result?**

A: The BioSciences shareholders meeting was held on September 14, 2010. BioSciences had 17,975,587 shares of common stock outstanding on the record date and at the time of the meeting, and shareholders holding 14,319,203 shares were in attendance in person or by proxy at the meeting. Shareholders holding 14,293,368

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BioSciences shares of common stock voted in favor of the merger, shareholders holding 25,935 shares abstained, and no shareholders voted against the merger. The shareholders voting in favor of the merger represented 79.5% of the total outstanding BioSciences shares of common stock, more than the 66.6% threshold required for approval. In addition, the merger was approved by non-management shareholders holding 99.5% of the non-management shares. This percentage exceeded the requirement in the Merger Agreement that the merger be approved by at least 75% of the shares held by non-management BioSciences shareholders.

**Q: How and when was the merger approved by the Ampio stockholders?**

A: On November 9, 2010, we received signed consents from two of our shareholders who, combined with the shareholder consents we had already received, were sufficient to evidence Ampio shareholder approval of the merger. As of that date, consents in favor of the merger were signed by Ampio shareholders holding 14,374,066 shares of Ampio common stock, representing 84.2% of the 17,060,036 shares of Ampio common stock outstanding .

**Q: What are the material U.S. federal income tax consequences of the merger to U.S. holders of BioSciences common stock?**

A: Ampio and BioSciences structured the merger with the intent that it qualify as a reorganization under Section 368 of the Internal Revenue Code of 1986, as amended (the Code ). Assuming the merger qualifies as such a reorganization, BioSciences stockholders will not recognize any gain as a result of the merger. See the section entitled Material U.S. Federal Income Tax Consequences of the Merger beginning on page 72.

**Q: What are the material U.S. federal income tax consequences of the merger to Ampio shareholders?**

A: Ampio shareholders will not recognize any gain or loss as a result of the merger, regardless of whether the merger qualifies as a reorganization under Section 368 of the Code.

**Q: When do you expect the merger to be completed?**

A: The merger will be completed when the SEC declares the registration statement effective. That declaration will depend on the time required for SEC review of this prospectus and the accompanying documents, the nature and extent of SEC comments, and the time we require to respond to the SEC s comments or information requests.

**Q: What do you mean when you say that the merger has closed in escrow?**

A: Ampio and BioSciences have executed all of the documents required to close the merger, including all certificates, instructions and opinions that are required to be delivered at closing by either party or their affiliates, and deposited all of those documents with the Hon. James Kimmel. Judge Kimmel is a member of the board of directors of BioSciences, and agreed to serve as escrow agent and hold all the closing documents pending the satisfaction of the sole condition to closing.

**Q: What is the sole condition to the release of the closing documents from escrow?**

A: The sole condition is the registration of the Merger Stock.

**Q: What will happen if the Merger Stock is not registered for any reason?**

A: If the Merger Stock is not registered, meaning that the registration statement is not declared effective by the SEC, by June 15, 2011, then Ampio and BioSciences have agreed to restructure the merger as an asset sale. In that event, we will issue the Merger Stock to BioSciences, and BioSciences will be excused from its obligation under the Merger Agreement to donate to our capital, at no cost to us, the 3,500,000 Ampio shares of common stock now owned by BioSciences. In this event, BioSciences will own 8,500,000 shares of our common stock, as opposed to the BioSciences shareholders owning collectively 5,000,000 shares of our common stock, which will be the result if the Merger Stock is registered before June 15, 2011.

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**Q: Were the BioSciences shareholders entitled to appraisal or dissenters rights under Colorado law and, if so, did any of the BioSciences shareholders exercise appraisal or dissenters rights?**

A: The BioSciences shareholders were entitled to dissenters rights under Colorado law. None of the BioSciences shareholders elected to exercise such rights.

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## RISK FACTORS

*An investment in our common stock involves a high degree of risk. You should consider carefully the following risks and other information contained in this prospectus. If any of the events contemplated by the following discussion of risks should occur, our business, results of operations and financial condition could suffer significantly. As a result, the market price of our common stock could decline, and you may lose all or part of your investment. In addition, the risks described below are not the only ones facing our company. Additional risks and uncertainties of which we are unaware or currently deem immaterial may also become important factors that may harm our business.*

### Risks Related to Our Business

***We expect our net losses to continue for at least several years and are unable to predict the extent of future losses or when we will become profitable, if ever.***

We have experienced significant net losses since our inception. As of June 30, 2010, we had an accumulated deficit of approximately $4.4 million and a stockholders deficit of $665,963. Had we closed the acquisition of BioSciences prior to June 30, 2010, our accumulated deficit would have been approximately $ 22.5 million, and our stockholders deficit would have been approximately $1.8 million. We expect our annual net losses to continue over the next several years as we advance our development programs and incur significant clinical development costs.

We have not received, and do not expect to receive for several years, any revenues from the commercialization of our product candidates. BioSciences received revenues in 2009 and 2010 from an exclusive, worldwide license of Zertane that was terminated by the licensee in 2010. We anticipate that licensing and collaboration arrangements, which provide us with potential milestone payments and royalties, will be our primary source of revenues for the next several years. We cannot be certain that additional licensing or collaboration arrangements will be concluded, or that the terms of those arrangements will result in us receiving material revenues. To obtain revenues from our product candidates, we must succeed, either alone or with others, in developing, obtaining regulatory approval for, and manufacturing and marketing drugs with significant market potential. We may never succeed in these activities, and may never generate revenues that are significant enough to achieve profitability.

***If we do not secure collaborations with strategic partners to test, commercialize and manufacture product candidates, we will not be able to successfully develop products and generate meaningful revenues.***

A key aspect of our strategy is to selectively enter into collaborations with third parties to conduct clinical testing, commercialize and manufacture product candidates. We have no collaboration agreements currently in effect. Collaboration agreements typically call for milestone payments that depend on successful demonstration of efficacy and safety, obtaining regulatory approvals, and clinical trial results. Collaboration revenues such as those generated by BioSciences are not guaranteed, even when efficacy and safety are demonstrated. The current economic environment may result in potential collaborators electing to reduce their external spending, which may prevent us from developing our product candidates.

Even if we succeed in securing collaborators, they may fail to develop or effectively commercialize products using our product candidates or technologies because they:

- do not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as budget limitations, lack of human resources, or a change in strategic focus;
- believe our intellectual property or the product candidate may infringe on the intellectual property rights of others;
- dispute their responsibility to conduct development and commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenues;

decide to pursue a competitive product developed outside of the collaboration;

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- cannot obtain, or believe they cannot obtain, the necessary regulatory approvals;
- delay the development or commercialization of our product candidates in favor of developing or commercializing another party s product candidate; or
- decide to terminate or not to renew the collaboration for these or other reasons.

For example, the collaborator that licensed Zertane conducted clinical trials which we believe demonstrated efficacy in treating PE, but the collaborator undertook a merger that we believe altered its strategic focus. The merger also created a potential conflict with a principal customer of the acquired company, which sells a product to treat PE in certain European markets.

As BioSciences experienced in this instance, collaboration agreements are generally terminable without cause on short notice. Once a collaboration agreement is signed, it may not lead to commercialization of a product candidate. We also face competition in seeking out new collaborators. If we are unable to secure new collaborations that achieve the collaborator s objectives and meet our expectations, we may be unable to advance our product candidates and may not generate meaningful revenues.

***Optina, Vasaloc and Ampion will soon undergo clinical trials that are time-consuming and expensive, the outcomes of which are unpredictable, and for which there is a high risk of failure.***

Preclinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to delays. It may take several years to complete the preclinical testing and clinical development necessary to commercialize a drug, and delays or failure can occur at any stage. Interim results of clinical trials do not necessarily predict final results, and success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials.

Our product development programs are at various stages of development. We recently signed a contract with St. Michael s Hospital, Toronto, Canada, under which St. Michael s will conduct a Phase II trial for our product candidate Optina for the treatment of diabetic macular edema, an early stage of diabetic retinopathy. We intend also to commence a Phase II clinical trial for Vasaloc, our product candidate to treat diabetic nephropathy, by the first quarter of 2011. We are currently preparing to seek approval for a Phase II double-blind, placebo-controlled clinical trial of our product candidate Ampion for the treatment of chronic inflammatory and autoimmune disease. An unfavorable outcome in one or more trials for Optina, Vasaloc, or Ampion would be a major set-back for the development programs for these product candidates and for our company. Due to our limited financial resources, an unfavorable outcome in one or more of these trials may require us to delay, reduce the scope of, or eliminate one of these product development programs, which could have a material adverse effect on our company and the value of our common stock. We anticipate that clinical trials of Optina and Vasaloc will take at least six to nine months to complete, and clinical trials of Ampion will take between 18 to 24 months to complete.

We are currently in development and testing of various compounds for use in repurposed applications including various derivatives of Methylphenidates, a diketopiperazineune, or DA-DKP, and several types of metal-binding compounds. We are also now prototyping the ORP device to measure oxidation and antioxidation levels in the blood.

In connection with clinical testing and trials, we face risks that:

- a product candidate is ineffective, inferior to existing approved medicines, unacceptably toxic, or has unacceptable side effects;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;

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- the results may not confirm the positive results of earlier testing or trials; and

- the results may not meet the level of statistical significance required by the U.S. Food and Drug Administration, or FDA, or other regulatory agencies.

The results of preclinical studies do not necessarily predict clinical success, and larger and later-stage clinical studies may not produce the same results as earlier-stage clinical studies. Frequently, product candidates developed by pharmaceutical companies have shown promising results in early preclinical or clinical studies, but have subsequently suffered significant setbacks or failed in later clinical studies. In addition, clinical studies of potential products often reveal that it is not possible or practical to continue development efforts for these product candidates.

If we do not successfully complete preclinical and clinical development, we will be unable to market and sell products derived from our product candidates and generate revenues. Even if we do successfully complete clinical trials, those results are not necessarily predictive of results of additional trials that may be needed before anew drug application, or NDA, may be submitted to the FDA. Although there are a large number of drugs in development in the U.S. and other countries, only a small percentage result in the submission of an NDA to the FDA, even fewer are approved for commercialization, and only a small number achieve widespread physician and consumer acceptance following regulatory approval. If our clinical studies are substantially delayed or fail to prove the safety and effectiveness of our product candidates in development, we may not receive regulatory approval of any of these product candidates and our business and financial condition will be materially harmed.

***Delays, suspensions and terminations in our clinical trials could result in increased costs to us and delay our ability to generate revenues.***

Human clinical trials are very expensive, time-consuming, and difficult to design, implement and complete. We expect clinical trials of our product candidates will take from six to 24 months to complete, but the completion of trials for our product candidates may be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;

- reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;

- manufacturing sufficient quantities of a product candidate;

- obtaining approval of an Investigational New Drug Application, or IND, from the FDA;

- obtaining institutional review board approval to conduct a clinical trial at a prospective clinical trial site;

- determining dosing and making related adjustments; and

- patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

The commencement and completion of clinical studies for our product candidates may be delayed, suspended or terminated due to a number of factors, including:

lack of effectiveness of product candidates during clinical studies;

adverse events, safety issues or side effects relating to the product candidates or their formulation;

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- inability to raise additional capital in sufficient amounts to continue clinical trials or development programs, which are very expensive;
- the need to sequence clinical studies as opposed to conducting them concomitantly in order to conserve resources;
- our inability to enter into collaborations relating to the development and commercialization of our product candidates;
- failure by us or our collaborators to conduct clinical trials in accordance with regulatory requirements;
- our inability or the inability of our collaborators to manufacture or obtain from third parties materials sufficient for use in preclinical and clinical studies;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines, including mandated changes in the scope or design of our clinical trials or requests for supplemental information with respect to our clinical trial results;
- failure of our collaborators to advance our product candidates through clinical development;
- delays in patient enrollment, variability in the number and types of patients available for clinical studies, and lower-than anticipated retention rates for patients in clinical trials;
- difficulty in patient monitoring and data collection due to failure of patients to maintain contact after treatment;
- a regional disturbance where we or our collaborative partners are enrolling patients in our clinical trials, such as a pandemic, terrorist activities or war, or a natural disaster; and
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

Many of these factors may also ultimately lead to denial of regulatory approval of a current or potential product candidate. If we experience delays, suspensions or terminations in a clinical trial, the commercial prospects for the related product candidate will be harmed, and our ability to generate product revenues will be delayed.

***If our product candidates are not approved by the FDA, we will be unable to commercialize them in the United States.***

The FDA must approve any new medicine before it can be marketed and sold in the United States. We must provide the FDA with data from preclinical and clinical studies that demonstrate that our product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. We will not obtain this approval for a product candidate unless and until the FDA approves a NDA. The processes by which regulatory approvals are obtained from the FDA to market and sell a new product are complex, require a number of years and involve the expenditure of substantial resources. We cannot assure you that any of our product candidates will receive FDA approval in the future, and the time for receipt of any such approval is currently incapable of estimation.

***We intend to seek FDA approval for most of our product candidates using an expedited process established by the FDA, but we may be asked to submit additional information to support a proposed change of a previously approved drug, which may substantially increase our clinical trial costs, postpone any FDA product approvals, and delay our receipt of any product revenues.***

NDAs we submit to the FDA for Optina, Vasaloc, and Zertane will be made under §505(b)(2) of the Food, Drug and Cosmetic Act, as amended, or the FDCA. NDAs submitted under this section are eligible

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to receive FDA new drug approval by relying in part on the FDA s findings for a previously approved drug. The FDA s 1999 guidance on §505(b)(2) applications states that new indications for a previously approved drug, a new combination product, a modified active ingredient, or changes in dosage form, strength, formulation, and route of administration of a previously approved product are encompassed within the §505(b)(2) NDA process. Relying on §505(b)(2) is advantageous because this section of the FDCA does not require us (i) to perform the full range of safety and efficacy trials that is otherwise required to secure approval of a new drug, and (ii) obtain a right of reference from the applicant that obtained approval of the previously approved drug. However, a §505(b)(2) application must support the proposed change of the previously approved drug by including necessary and adequate information, as determined by the FDA, and the FDA may still require us to perform a full range of safety and efficacy trials.

If one of our product candidates achieves clinical trial objectives, we must prepare and submit to the FDA a comprehensive §505(b)(2) application. Review of our application may lead the FDA to request more information or require us to perform additional clinical trials, thus adding to our product development costs and delaying any marketing approval from the FDA. We have no control over the FDA s review time for any future NDA we submit, which may vary significantly based on the disease to be treated, availability of alternate treatments, severity of the disease, and the risk/benefit profile of our proposed product. Even if one of our products receives FDA marketing approval, we could be required to conduct post-marketing Phase IV studies and surveillance to monitor for adverse effects. If we experience delays in NDA application processing, requests for additional information or further clinical trials, or are required to conduct post-marketing studies or surveillance, our product development costs could increase substantially, and our ability to generate revenues from a product candidate could be postponed, perhaps indefinitely. The resulting negative impact on our operating results and financial condition may cause the value of our common stock to decline, and you may lose all or a part of your investment.

***The approval process outside the United States varies among countries and may limit our ability to develop, manufacture and sell our products internationally.***

We may conduct clinical trials for, and seek regulatory approval to market, our product candidates in countries other than the United States. For example, the clinical trials for Optina will be conducted in Canada, the Zertane clinical trials were conducted in Europe, and we plan to conduct the clinical trials of Ampion in Australia and India. Depending on the results of clinical trials and the process to obtain regulatory approvals in other countries, we may decide to first seek regulatory approvals of a product candidate in countries other than the U.S., or we may simultaneously seek regulatory approvals in the U.S. and other countries. If we or any collaborators we secure seek marketing approvals for a product candidate outside the U.S., we will be subject to the regulatory requirements of health authorities in each country in which we seek approvals. With respect to marketing authorizations in Europe, we will be required to submit a European marketing authorization application, or MAA, to the European Medicines Agency, or EMEA, which conducts a validation and scientific approval process in evaluating a product for safety and efficacy. The approval procedure varies among regions and countries and can involve additional testing, and the time required to obtain approvals may differ from that required to obtain FDA approval. Obtaining regulatory approvals from health authorities in countries outside the U.S. is likely to subject us to all of the risks associated with obtaining FDA approval described above. In addition, marketing approval by the FDA does not ensure approval by the health authorities of any other country, and approval by foreign health authorities does not ensure marketing approval by the FDA.

***Even if one of our product candidates receives regulatory approval, commercialization of the product may be adversely affected by regulatory actions and oversight.***

Even if we receive regulatory approval for a product candidate, this approval may carry conditions that limit the market for the product or put our product at a competitive disadvantage relative to alternative therapies. For instance, a regulatory approval may limit the indicated uses for which we can market a product or the patient population that may utilize our product, or may be required to carry a warning on its packaging. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings. These restrictions could make it more difficult to market any product candidate effectively. Once a product candidate is approved, we remain subject to continuing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including

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regulatory oversight of promotion and marketing. In addition, the labeling, packaging, adverse event reporting, advertising, promotion and recordkeeping for an approved product remain subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with an approved product in the U.S. or overseas or at any contract manufacturers facilities, a regulatory agency may impose restrictions on the product, any contract manufacturers or on us, including requiring us to reformulate the product, conduct additional clinical studies, change the labeling of the product, withdraw the product from the market or require a contract manufacturer to implement changes to its facilities. In addition, we may experience a significant drop in the sales and royalties related to the product, our reputation in the marketplace may suffer, and we could face lawsuits.

We are also subject to regulation by regional, national, state and local agencies, including the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those other countries in which any of our product candidates are approved for commercialization. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including preclinical and clinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information, and promotion. If we or any third parties that provide these services for us are unable to comply, we may be subject to regulatory or civil actions or penalties that could significantly and adversely affect our business. Any failure to maintain regulatory approval will limit our ability to commercialize our product candidates, which would materially and adversely affect our business and financial condition.

***If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed and our business will be harmed and our stock price may decline.***

We sometimes estimate for planning purposes the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies, clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval, or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators, and our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA and other regulatory agencies and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of compounds used in the manufacture of our product candidates;
- the efforts of our collaborators with respect to the commercialization of our products; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

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If we fail to achieve our announced milestones in the timeframes we announce and expect, our business and results of operations may be harmed and the price of our stock may decline.

***Our success is dependent in large part upon the continued services of our Chief Scientific Officer.***

Our success is dependent in large part upon the continued services of our Chief Scientific Officer, Dr. David Bar-Or. We have an employment agreement with Dr. Bar-Or and a research agreement with Trauma Research, LLC, an entity owned by Dr. Bar-Or that conducts research and development activities on our behalf. These agreements are terminable on short notice for cause by us or Dr. Bar-Or and may also be terminated without cause under certain circumstances. We do not maintain key-man life insurance on Dr. Bar-Or, although we may elect to obtain such coverage in the future. If we lost the services of Dr. Bar-Or for any reason, our clinical testing and other product development activities may experience significant delays, and our ability to develop and commercialize new product candidates may be diminished.

***If we do not obtain the capital necessary to fund our operations, we will be unable to successfully develop, obtain regulatory approval of, and commercialize pharmaceutical products.***

The development of pharmaceutical products is capital-intensive. At June 30, 2010, we had cash of approximately $131,000, and BioSciences had cash of approximately $517,000. In order to continue funding our operations, we obtained bridge financing in August 2010 totaling $430,000 from two of our directors and an affiliate of one of those directors. We are currently seeking to raise additional capital to fund our operations. Our capital requirements will depend on, and could increase significantly as a result of, many factors including:

- progress in, and the costs of, our preclinical studies and clinical trials and other research and development programs;
- the scope, prioritization and number of our research and development programs;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we obtain;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory clearances to market our product candidates.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through private or public sales of our securities, debt financings, or by licensing one or more of our product candidates. Dislocations in the financial markets have generally made equity and debt financing more difficult to obtain, and may have a material adverse effect on our ability to meet our fundraising needs. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. Additional funding, if obtained, may significantly dilute existing stockholders if that financing is obtained through issuing equity or instruments convertible into equity.

***We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing product candidates.***

Although we design and manage our current preclinical studies, we do not have the in-house capability to conduct clinical trials for our product candidates. We rely, and will rely in the future, on medical

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institutions, clinical investigators, contract research organizations, contract laboratories, and collaborators to perform data collection and analysis and other aspects of our clinical trials. For example, we contracted with St. Michael s Hospital, Toronto, Canada, to perform clinical trials for Optina, and the collaborator contracted by BioSciences performed clinical trials for Zertane. We rely primarily on Trauma Research, LLC, a related party, to conduct preclinical studies and provide assessments of clinical observations.

Our preclinical activities or clinical trials conducted in reliance on third parties may be delayed, suspended, or terminated if:

- the third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines;
- we replace a third party; or
- the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory requirements, or for other reasons.

Third party performance failures may increase our development costs, delay our ability to obtain regulatory approval, and delay or prevent the commercialization of our product candidates. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without incurring delays or additional costs.

***Even if collaborators with which we contract in the future successfully complete clinical trials of our product candidates, those candidates may not be commercialized successfully for other reasons.***

Even if we contract with collaborators that successfully complete clinical trials for one or more of our product candidates, those candidates may not be commercialized for other reasons, including:

- failure to receive regulatory clearances required to market them as drugs;
- being subject to proprietary rights held by others;
- being difficult or expensive to manufacture on a commercial scale;
- having adverse side effects that make their use less desirable; or
- failing to compete effectively with products or treatments commercialized by competitors.

***Relying on third-party manufacturers may result in delays in our clinical trials and product introductions.***

We have no manufacturing facilities and have no experience in the manufacturing of drugs or in designing drug-manufacturing processes. If any of our product candidates are approved by the FDA or other regulatory agencies for sale, we will need to contract with a third party to manufacture it in commercial quantities. While we believe there are a number of alternative sources available to manufacture our product candidates if and when regulatory approvals are received, we may not be able to secure manufacturing arrangements on a timely basis when required, or at a reasonable cost. We cannot estimate any delay in manufacturing or unanticipated manufacturing costs with certainty but, if either occurs, our commercialization efforts may be impeded or our costs may increase.

Once regulatory approval is obtained, a marketed product and its manufacturer are subject to continual review. The discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer or manufacturing facility, including

withdrawal of the product from the market. Any manufacturers with which we contract are required to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs. A failure of any of our contract manufacturers to establish and follow cGMPs and to document their adherence to such practices, may lead to significant delays in the launch of products based on our product candidates into the market. Failure by

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our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, revocation or suspension of marketing approval for any products granted pre-market approvals, seizures or recalls of products, operating restrictions, and criminal prosecutions.

***We intend to enter into agreements with third parties to sell and market any products we develop and for which we obtain regulatory approvals, which may affect the sales of our products and our ability to generate revenues.***

We do not maintain an organization for the sale, marketing and distribution of pharmaceutical products and intend to contract with, or license, third parties to market any products we develop that receive regulatory approvals. Outsourcing sales and marketing in this manner may subject us to a variety of risks, including:

- our inability to exercise control over sales and marketing activities and personnel;
- failure or inability of contracted sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;
- disputes with third parties concerning sales and marketing expenses, calculation of royalties, and sales and marketing strategies; and
- unforeseen costs and expenses associated with sales and marketing.

If we are unable to partner with a third party that has adequate sales, marketing, and distribution capabilities, we will have difficulty commercializing our product candidates, which would adversely affect our business, financial condition, and ability to generate product revenues.

***We face substantial competition from companies with considerably more resources and experience than we have, which may result in others discovering, developing, receiving approval for, or commercializing products before or more successfully than we do.***

Our ability to succeed in the future depends on our ability to discover, develop and commercialize pharmaceutical products that offer superior efficacy, convenience, tolerability, and safety when compared to existing treatment methodologies. We intend to do so by identifying product candidates that address new indications using previously approved drugs, use new combinations of previously approved drugs, or are based on a modified active ingredient which previously received regulatory approval. Because our strategy is to develop new product candidates primarily for treatment of diseases that affect large patient populations, those candidates are likely to compete with a number of existing medicines or treatments, and a large number of product candidates that are being developed by others.

Many of our potential competitors have substantially greater financial, technical, personnel and marketing resources than we have. In addition, many of these competitors have significantly greater resources devoted to product development and preclinical research. Our ability to compete successfully will depend largely on our ability to:

- discover and develop product candidates that are superior to other products in the market;
- attract and retain qualified personnel;
- obtain patent and/or other proprietary protection for our product candidates;

obtain required regulatory approvals; and

obtain collaboration arrangements to commercialize our product candidates.

Established pharmaceutical companies devote significant financial resources to discovering, developing or licensing novel compounds that could make our product candidates obsolete. Accordingly, our competitors may obtain patent protection, receive FDA approval, and commercialize medicines before we do. Other companies are engaged in the discovery of compounds that may compete with the product candidates we are developing.

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Any new product that competes with a currently-approved treatment or medicine must demonstrate compelling advantages in efficacy, convenience, tolerability and/or safety in order to address price competition and be commercially successful. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

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

The risk that we may be sued on product liability claims is inherent in the development and commercialization of pharmaceutical products. Side effects of, or manufacturing defects in, products that we develop which are commercialized by any collaborators could result in the deterioration of a patient s condition, injury or even death. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits increases. Claims may be brought by individuals seeking relief for themselves or by individuals or groups seeking to represent a class. 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 commercialization of the affected products.

Although we maintain general liability and product liability insurance, this insurance may not fully cover potential liabilities. 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 commercial production and sale of any of our product candidates that receive regulatory approval, which could adversely affect our business. Product liability claims could also harm our reputation, which may adversely affect our collaborators ability to commercialize our products successfully.

***If any of our product candidates are commercialized, this does not assure acceptance by physicians, patients, third party payors, or the medical community in general.***

The commercial success of any of our product candidates that secure regulatory approval will depend upon acceptance by physicians, patients, third party payors and the medical community in general. We cannot be sure that any of our product candidates, if and when approved for marketing, will be accepted by these parties. Even if the medical community accepts a product as safe and efficacious for its indicated use, physicians may choose to restrict the use of the product if we or any collaborator are unable to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, our product is preferable to any existing medicines or treatments. We cannot predict the degree of market acceptance of any product candidate that receives marketing approval, which will depend on a number of factors, including, but not limited to:

- the demonstration of the clinical efficacy and safety of the product;
- the approved labeling for the product and any required warnings;
- the advantages and disadvantages of the product compared to alternative treatments;
- our and our collaborator s ability to educate the medical community about the safety and effectiveness of the product;
- the reimbursement policies of government and third party payors pertaining to the product; and
- the market price of our product relative to competing treatments.

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***Government restrictions on pricing and reimbursement, as well as other healthcare payor cost-containment initiatives, may negatively impact our ability to generate revenues if we obtain regulatory approval to market a product.***

The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect one or more of the following:

- our or our collaborators ability to set a price we believe is fair for our products, if approved;
- our ability to generate revenues and achieve profitability; and
- the availability of capital.

The 2010 enactments of the Patient Protection and Affordable Care Act, or PPACA, and the Health Care and Education Reconciliation Act are expected to significantly impact the provision of, and payment for, health care in the United States. Various provisions of these laws take effect over the next four years, and are designed to expand Medicaid eligibility, subsidize insurance premiums, provide incentives for businesses to provide health care benefits, prohibit denials of coverage due to pre-existing conditions, establish health insurance exchanges, and provide additional support for medical research. Additional legislative proposals to reform healthcare and government insurance programs, along with the trend toward managed healthcare in the United States, could influence the purchase of medicines and reduce demand and prices for our products, if approved. This could harm our or our collaborators ability to market any products and generate revenues. Cost containment measures that health care payors and providers are instituting and the effect of further health care reform could significantly reduce potential revenues from the sale of any of our product candidates approved in the future. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures at the federal and state level, as well as internationally, will continue and may increase, which may make it difficult for us to sell our potential products that may be approved in the future at a price acceptable to us or any of our future collaborators.

***If Trauma Research uses hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages or fines.***

The research and development activities conducted on our behalf by Trauma Research, LLC, a related party controlled by Dr. Bar-Or, involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials. In addition, Trauma Research s operations produce hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. If Trauma Research experiences a release of hazardous substances, it is possible that this release could cause personal injury or death, and require decontamination of facilities. Trauma Research has advised us that it believes it is in compliance with laws applicable to the handling of hazardous substances, but such compliance does not assure that a release of hazardous substances will not occur, or assure that such compliance will be maintained in the future. In the event of an accident involving research being conducted on our behalf, Trauma Research could be held liable for damages or face substantial penalties for which we could also be responsible. We do not have any insurance for liabilities arising from the procurement, handling, or discharge of hazardous materials. 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.

***Business interruptions could limit our ability to operate our business.***

Our operations are vulnerable to damage or interruption from computer viruses, human error, natural disasters, telecommunications failures, intentional acts of misappropriation, and similar events. We have not established a formal disaster recovery plan, and our back-up operations and our business interruption insurance may not be adequate to compensate us for losses that occur. A significant business interruption could result in losses or damages incurred by us and require us to curtail our operations.

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**Risks Related to Our Intellectual Property**

***Our ability to compete may decline if we do not adequately protect our proprietary rights.***

Our commercial success depends on obtaining and maintaining proprietary rights to our product candidates and compounds and their uses, as well as successfully defending these rights against third-party challenges. We will only be able to protect our product candidates, proprietary compounds, and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them. As of September 30, 2010, we and BioSciences collectively owned or were the exclusive licensee under 10 issued United States patents, 20 U.S. pending patent applications, 14 issued international patents, and 69 pending international patent applications.

Our ability to obtain patent protection for our product candidates and compounds is uncertain due to a number of factors, including:

- we may not have been the first to make the inventions covered by our pending patent applications or issued patents;
- we may not have been the first to file patent applications for our product candidates or the compounds we develop or for their uses;
- others may independently develop identical, similar or alternative products or compounds;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our pending patent applications may not result in issued patents;
- we may not seek or obtain patent protection in countries that may eventually provide us a significant business opportunity;
- any patents issued to us may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be successfully challenged by third parties;
- our proprietary compounds may not be patentable;
- others may design around our patent claims to produce competitive products which fall outside of the scope of our patents; or
- others may identify prior art which could invalidate our patents.

Even if we have or obtain patents covering our product candidates or compounds, we may still be barred from making, using and selling our product candidates or technologies because of the patent rights of others. Others have or may have filed, and in the future may file, patent applications covering compounds or products that are similar or identical to ours. There are many issued U.S. and foreign patents relating to chemical compounds and therapeutic products, and some of these relate to compounds we intend to commercialize. Numerous U.S. and foreign issued patents and pending patent applications owned by others exist in the area of metabolic disorders, cancer, inflammatory responses. and the other fields in which we are developing products. These could materially affect our ability to develop our product candidates or sell our products if approved. Because patent applications can take many years to issue, there may be currently pending applications unknown to us that may later result in issued patents that our product candidates or compounds may infringe. These patent applications may have priority over patent

applications filed by us.

We periodically conduct searches to identify patents or patent applications that may prevent us from obtaining patent protection for our compounds or that could limit the rights we have claimed in our patents and patent applications. Disputes may arise regarding the source or ownership of our inventions. It is difficult to determine if and how such disputes would be resolved. Others may challenge the validity of our

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patents. If our patents are found to be invalid, we will lose the ability to exclude others from making, using or selling the compounds or products addressed in those patents. In addition, compounds or products we may license may become important to some aspects of our business. We generally will not control the patent prosecution, maintenance or enforcement of licensed compounds or products.

***Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.***

Because we operate in the highly technical field of drug discovery and development of therapies that can address metabolic disorders, cancer, inflammation and other conditions, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party s relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. The failure to obtain or maintain trade secret protection could adversely affect our competitive position. We have entered into non-compete agreements with certain of our employees, but the enforceability of those agreements is not assured.

***A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.***

There is significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. In particular, there are many patents relating to repositioned drugs and chemical compounds used to treat metabolic disorders, cancer and inflammation. Some of these may encompass repositioned drugs or compounds that we utilize in our product candidates. If our development activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented repositioned drugs or compounds. We may need to resort to litigation to enforce a patent issued to us, to protect our trade secrets, or to determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel or consultants formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

- payment of damages, potentially treble damages, if we are found to have willfully infringed a party s patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or
- we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms, if at all.

As a result, we could be prevented from commercializing current or future product candidates.

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***Pharmaceutical patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.***

The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. For example, some of our patents and patent applications cover methods of use of repositioned drugs, while other patents and patent applications cover composition of a particular compound. The interpretation and breadth of claims allowed in some patents covering pharmaceutical compounds may be uncertain and difficult to determine, and are often affected materially by the facts and circumstances that pertain to the patented compound and the related patent claims. The standards of the United States Patent and Trademark Office, or USPTO, are sometimes uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, and U.S. patents may be subject to reexamination proceedings in the USPTO. Foreign patents may be subject also to opposition or comparable proceedings in the corresponding foreign patent office, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, reexamination and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the United States and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us or may limit the number of patents or claims we can obtain. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, some countries do not grant patent claims directed to methods of treating humans and, in these countries, patent protection may not be available at all to protect our product candidates. In addition, U.S. patent laws may change which could prevent or limit us from filing patent applications or patent claims to protect our products and/or compounds.

If we fail to obtain and maintain patent protection and trade secret protection of our product candidates, proprietary compounds and their uses, we could lose our competitive advantage and competition we face would increase, reducing any potential revenues and adversely affecting our ability to attain or maintain profitability.

**General Company-Related Risks**

***The price of our stock has been extremely volatile and may continue to be so.***

The price of our common stock has been extremely volatile and may continue to be so. The stock market in general and the market for pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies, to a greater extent during the last few years. The following factors, in addition to the other risk factors described in this section, may also have a significant impact on the market price of our securities:

- any actual or perceived adverse developments in our clinical trials for Optina, Vasaloc or Ampion;
- any actual or perceived adverse developments with respect to the effort to re-license Zertane, or a licensee s termination of a license, such as BioSciences experienced with Zertane earlier in 2010;
- any actual or perceived difficulties or delays in obtaining regulatory approval of any of our product candidates in the United States or other countries once clinical trials are completed;
- any finding that our product candidates are not safe or effective, or any inability to demonstrate clinical effectiveness in our product candidates when compared to existing treatments;

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any actual or perceived adverse developments in repurposed drug technologies, including any change in FDA policy or guidance on approval of repurposed drug technologies for new indications;

any announcements of developments with, or comments by, the FDA, the EMEA, or other regulatory authorities with respect to product candidates we have under development;

any announcements concerning our retention or loss of key employees, especially Dr. Bar-Or;

any announcements concerning the addition of a new chief executive officer, a new chief financial officer or new board members;

our success or inability to obtain collaborators to conduct clinical trials, commercialize a product candidate for which regulatory approval is obtained, or market and sell an approved product candidate;

any actual or perceived adverse developments with respect to our relationship with TRLLC;

announcements of patent issuances or denials, product innovations, or new commercial products by our competitors that will compete with any of our product candidates;

publicity regarding actual or potential study results or the outcome of regulatory reviews relating to products under development by us, our collaborator, or our competitors;

economic and other external factors beyond our control; and

sales of stock by us or by our stockholders.

***There is, at present, only a limited market for our common stock, and there is no assurance that an active trading market for our common stock will develop.***

Although our securities are currently quoted on the OTC Bulletin Board, our common stock has been thinly traded. To the extent that is true, an investor may not be able to liquidate his or her investment without a significant decrease in price, or at all.

***Unless our common stock is listed on a national securities exchange, the application of the penny stock rules to transactions in our common stock could limit the trading and liquidity of our common stock, adversely affect the market price of our common stock, and impose additional costs on transactions involving our common stock.***

Trades of our common stock are currently subject to Rule 15g-9 promulgated by the SEC under the Securities and Exchange Act of 1934, as amended, or the Exchange Act, which imposes certain requirements on broker-dealers who sell securities subject to the rule to persons other than established customers and accredited investors. For transactions covered by the rule, broker-dealers must make a special suitability determination for purchasers of the securities and receive the purchaser s written agreement to the transaction prior to sale. The SEC also has other rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks generally are equity securities with a price of less than $5.00 (other than securities listed on a national securities exchange, provided that current price and volume information with respect to transactions in those securities are provided by the exchange or system). The penny stock rules require a broker-dealer, prior to a

transaction in a penny stock not otherwise exempt from the penny stock rules, to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer s account. The bid and offer quotations, and the broker-dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer s confirmation. These disclosure requirements have the effect of reducing the level of trading activity for our securities. As a result of the foregoing, investors may find it difficult to sell their securities.

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***Concentration of our ownership will limit your ability to influence corporate matters.***

As of November 10, 2010, our directors, executive officers and their affiliates beneficially owned approximately 39.5% of our outstanding common stock. These stockholders may control effectively the outcome of actions taken by us that require stockholder approval.

***Anti-takeover provisions in our charter and bylaws and in Delaware law could prevent or delay a change in control of our company.***

Provisions of our certificate of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions include:

- requiring supermajority stockholder voting to effect certain amendments to our certificate of incorporation and bylaws;
- restricting the ability of stockholders to call special meetings of stockholders;
- prohibiting stockholder action by written consent except in certain circumstances; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

***Increased costs associated with corporate governance compliance may significantly impact our results of operations.***

Changing laws, regulations and standards relating to corporate governance, public disclosure and compliance practices, including the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the Sarbanes-Oxley Act of 2002, and new SEC regulations, are creating uncertainty for companies such as ours in understanding and complying with these laws and regulations. As a result of this uncertainty and other factors, devoting the necessary resources to comply with evolving corporate governance and public disclosure standards has resulted in and may in the future result in increased general and administrative expenses and a diversion of management time and attention to compliance activities. We also expect these developments to increase our legal compliance and financial reporting costs. In addition, these developments may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. Moreover, we may be unable to comply with these new laws and regulations on a timely basis.

These developments could make it more difficult for us to retain qualified members of our board of directors, or qualified executive officers. We are presently evaluating and monitoring regulatory developments and cannot estimate the timing or magnitude of additional costs we may incur as a result. To the extent these costs are significant, our general and administrative expenses are likely to increase.

***If we sell shares of our common stock or securities convertible into our common stock in future financings, the ownership interest of existing shareholders will be diluted and, as a result, our stock price may go down.***

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our existing shareholders will experience immediate dilution upon the purchase of any shares of our common stock sold at a discount. For example, in August 2010, two of our directors and an affiliate of one director purchased convertible debentures in the amount of $430,000. In addition, as other capital raising opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of additional debt securities,

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preferred stock or common stock. If we issue common stock or securities convertible into common stock, our shareholders will experience dilution and this dilution will be greater if we find it necessary to sell securities at a discount to prevailing market prices.

***If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired and investors views of us could be harmed.***

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to assess the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Even though our independent auditor is exempted by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 from having to currently opine on the effectiveness of our internal controls, our management team is still required to conduct an annual assessment of the effectiveness of our internal controls. If we are unable to comply with the requirements of Section 404 in a timely manner, or if we identify material weaknesses in our internal control over financial reporting, the market price of our shares of common stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require us to expend additional financial and management resources.

***If securities analysts do not publish research or reports about our business or if they downgrade our stock after instituting coverage, the price of our stock could decline.***

The research and reports that industry or financial analysts publish about us or our business may vary widely and may not predict accurate results, but will likely have an effect on the trading price of our common stock. If an industry analyst decides not to cover our company, or if an industry analyst institutes coverage and later decides to cease covering our company, we could lose visibility in the market, which in turn could cause our stock price to decline. If an industry analyst who covers our stock decides to downgrade our stock, our stock price would likely decline rapidly in response.

***We have no plans to pay dividends on our common stock, so you will not receive funds without selling your common stock.***

We have no plans to pay dividends on our common stock. We generally intend to invest our future earnings, if any, to fund our growth. Any payment of future dividends will be at the discretion of our Board of Directors and will depend on, among other things, our earnings, financial condition, capital requirements, level of indebtedness, statutory and contractual restrictions applying to the payment of dividends and other considerations that our Board of Directors deems relevant. Any future credit facilities or preferred stock financing we obtain may further limit our ability to pay dividends on our common stock. Accordingly, you may have to sell some or all of your common stock in order to generate cash flow from your investment. You may not receive a gain on your investment when you sell your common stock and you may lose the entire amount of the investment.

***A large number of shares may be sold in the market following the merger which may depress the market price of our common stock.***

A large number of shares may be sold in the market following the effectiveness of the registration statement which includes this prospectus, which may depress the market price of our common stock. If there are more shares of common stock offered for sale than buyers are willing to purchase, then the market price of our common stock may decline to a price at which buyers are willing to purchase shares.

Upon completion of the merger, we will have 22,107,036 shares of our common stock outstanding. Of these shares, the 8,500,000 shares issuable to the BioSciences shareholders are being registered on the registration statement that includes this prospectus. BioSciences shareholders receiving a total of 6,807,695 shares of our common stock in the BioSciences acquisition have executed lock-up agreements under which they have agreed not to sell, pledge or hypothecate the Ampio common stock to be received by them until May 31, 2011. We intend to condition the distribution of certificates representing free-trading shares of our common stock to the BioSciences shareholders on receipt of signed lock-up agreements from all of such persons.

Of the remaining 13,607,036 shares, 300,000 shares are free-trading and 13,307,036 shares are restricted securities as defined under Rule 144 under the Securities Act. We cannot predict the likelihood or timing of any future sales of our common stock previously issued to our stockholders. Any sales by these stockholders could depress the market price of our common stock.

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## USE OF PROCEEDS

We will not receive any proceeds from sales of the Merger Stock.

## CAPITALIZATION

The following table sets forth our actual cash and cash equivalents and capitalization, each as of June 30, 2010. The pro forma column represents our cash and cash equivalents and capitalization after giving effect to the BioSciences acquisition as if that acquisition was completed on June 30, 2010. You should read this table together with the Management s Discussion and Analysis of Financial Condition and Results of Operations section of this prospectus, our financial statements and the related notes included in this prospectus, and the pro forma financial statements and notes thereto.

| | As of June 30, 2010 | |
|---|---|---|
| | Actual | Pro Forma(1) |
| | (Dollars in thousands, except per share data) | |
| Cash and cash equivalents | $ 131 | $ 648 |
| Total liabilities | $ 961 | $ 759 |
| **Total stockholders equity** | | |
| Preferred stock, no shares authorized $0.0001 par value per share; no shares issued and outstanding | $ | $ |
| Common stock, authorized 100,000,000 shares, $0.0001 par value; issued and outstanding 17,107,036, actual; issued and outstanding 22,107,036, pro forma; issued and outstanding 22,107,036 shares, as adjusted | 2 | 2 |
| Additional paid in capital | 4,665 | 17,164 |
| Issuances for promotion and stockholder advances | (939) | (939) |
| Deficit accumulated in the development stage | (4,393) | (4,393) |
| Total stockholders equity (deficit) | $ (665) | $ 11,834 |
| Total capitalization (deficit) | $ (534) | $ 12,593 |

(1) Gives effect to the acquisition of BioSciences, including (i) cancellation of accrued management compensation and accrued interest totaling $1.5 million as of June 30, 2010, (ii) conversion of a $430,000 note payable and $450,000 in accrued interest payable from BioSciences to an unrelated third party into common stock, (iii) cancellation of intercompany debt owned by Ampio to BioSciences of $300,000 as of June 30, 2010, and (iv) allocation of the $12.5 million purchase price.

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## PRICE RANGE OF COMMON STOCK

There is no established public trading market for our common stock. However, our common stock is quoted on the Over-the-Counter Bulletin Board under the symbol AMPE. The following table sets forth the high and low bid information for our common stock for the period from January 1, 2008 through September 30, 2010. The Over-the-Counter Bulletin Board quotations reflect inter-dealer prices, are without retail markup, markdowns or commissions, and may not represent actual transactions.

| | Common Stock | |
|---|---|---|
| | **High** | **Low** |
| First quarter 2008 | $ | $ |
| Second quarter 2008 | $ | $ |
| Third quarter 2008 | $ 1.75 | $ 1.50 |
| Fourth quarter 2008 | $ 1.50 | $ 1.50 |
| First quarter 2009 | $ 1.50 | $ 1.50 |
| Second quarter 2009 | $ 1.50 | $ 1.50 |
| Third quarter 2009 | $ 1.50 | $ 1.50 |
| Fourth quarter 2009 | $ 1.50 | $ 1.50 |
| First quarter 2010 | $ 1.50 | $ 1.50 |
| Second quarter 2010 | $ 4.50 | |