

Ampio Pharmaceuticals, Inc.  
Form S-1  
November 12, 2010  
Table of Contents

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  
(State or other jurisdiction of

2834  
(Primary Standard Industrial

26-0179592  
(I.R.S. Employer

Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

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.

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

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. "

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

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

### 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.**

**Table of Contents**

**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.

**Table of Contents**

**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.**

**Table of Contents****TABLE OF CONTENTS**

	<b>Page</b>
<u>Prospectus Summary</u>	2
<u>Special Note Regarding Forward-Looking Statements</u>	10
<u>Risk Factors</u>	14
<u>Use of Proceeds</u>	31
<u>Dividend Policy</u>	32
<u>Summary Selected Unaudited Pro Forma Consolidated Combined Financial Information</u>	33
<u>Capitalization</u>	35
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	36
<u>Business</u>	45
<u>Management</u>	60
<u>Related Party Transactions</u>	68
<u>Principal Stockholders</u>	70
<u>Description of Capital Stock</u>	71
<u>Shares Eligible For Future Sale</u>	75
<u>Material U.S. Federal Tax Considerations For Non-U.S. Holders of Our Common Stock</u>	77
<u>Legal Matters</u>	81
<u>Experts</u>	81
<u>Where You Can Find More Information</u>	81
<u>Index to Consolidated Financial Statements</u>	F-1

**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.

## **Table of Contents**

### **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*

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

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

## **Table of Contents**

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

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

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

---

**Table of Contents**

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

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

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.

---

## **Table of Contents**

### *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 hydrochloride, 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





**Table of Contents**

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.



**Table of Contents**

**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](http://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.

**Table of Contents**

**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.

**Table of Contents**

	Pro Forma Consolidated		Ampio Pharmaceuticals, Inc.				DMI BioSciences, Inc.			
	Six Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,		Six Months Ended June 30,		Year Ended September 30,	
	2010	2009	2010	2009	2009	2008	2010	2009	2009	2008
	(unaudited)	(unaudited)	(unaudited)	(unaudited)			(unaudited)	(unaudited)		
<b>Revenues</b>										
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
<b>Expenses</b>										
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)
<b>Basic and diluted net loss per common share</b>										
	\$ (0.11)	\$ (0.20)	\$ (0.17)	\$ (0.07)	\$ (0.17)	\$ (0.00)				
<b>Weighted average number of common shares outstanding</b>										
	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.

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

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

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.

**Table of Contents**

**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, estimate, 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



## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

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](http://www.sec.gov).

**Table of Contents**

**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?**

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

- 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

**Table of Contents**

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.

**Table of Contents**

**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.

---

**Table of Contents**

**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;



---

**Table of Contents**

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 diketopiperazineone, 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;

## **Table of Contents**

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 a new 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:

Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

lack of effectiveness of product candidates during clinical studies;

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

**Table of Contents**

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.

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

*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.*

NDAAs 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. NDAAs submitted under this section are eligible

---

**Table of Contents**

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

---

**Table of Contents**

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.





## **Table of Contents**

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

## **Table of Contents**

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

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

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

**Table of Contents**

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;

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

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.

**Table of Contents**

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.

---

**Table of Contents**

***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.



## **Table of Contents**

### **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

---

**Table of Contents**

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.

---

## **Table of Contents**

*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;



**Table of Contents**

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 15c-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

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

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.

## **Table of Contents**

### ***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,



## **Table of Contents**

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.

**Table of Contents****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
<b>Total stockholders' equity</b>		
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)
<b>Total stockholders' equity (deficit)</b>	<b>\$ (665)</b>	<b>\$ 11,834</b>
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.

**Table of Contents****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	\$ 0.75
Third quarter 2010	\$ 3.50	\$ 1.00

As of November 10, 2010, there were of record approximately 250 holders of our common stock. This number is expected to increase on closing of the BioSciences acquisition by 191 additional holders.

**DIVIDEND POLICY**

We have never paid cash dividends and intend to employ all available funds in the development of our business. We have no plans to pay cash dividends in the near future. If we issue in the future any preferred stock or obtain financing from a bank, the terms of those financings may contain restrictions on our ability to pay dividends for so long as the preferred stock or bank financing is outstanding.

**Table of Contents****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 October 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.

	<b>Pro Forma Six Months Ended June 30,</b>		<b>Pro Forma Years Ended December 31 or September 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2009</b>	<b>2008</b>
<b>Statement of Operations Data:</b>				
Revenue				
License fees	\$ 404,410	\$ 404,410	\$ 875,000	\$ 500,000
Royalty fees		33,750	58,750	75,000
Milestone payments			1,500,475	
Other revenue		111,943	111,943	36,865
<b>Total revenue</b>	<b>404,410</b>	<b>550,103</b>	<b>2,546,168</b>	<b>611,865</b>
Expenses				
Research and development	637,419	1,044,985	2,165,591	153,397
General and administrative	2,046,209	1,573,627	2,072,393	1,042,649
Amortization	333,333	333,333	666,667	666,667
<b>Total expenses</b>	<b>3,016,961</b>	<b>2,951,945</b>	<b>4,904,651</b>	<b>1,862,713</b>

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

Loss from operations	(2,612,551)	(2,401,842)	(2,358,483)	(1,250,848)
Other income (expense), net	(1,489)	(11,734)	(55,601)	(526,310)
<b>Net loss</b>	<b>\$ (2,614,040)</b>	<b>\$ (2,413,576)</b>	<b>\$ (2,414,084)</b>	<b>\$ (1,777,158)</b>
Pro forma basic and diluted net loss per share of common stock	(0.13)	(0.23)	(0.11)	(0.29)
<b>Pro forma weighted average number of shares of common stock outstanding(1)</b>	<b>20,456,332</b>	<b>10,575,856</b>	<b>22,061,752</b>	<b>6,080,000</b>

- (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.

**Table of Contents**

The following table presents balance sheet data as of June 30, 2010 on an actual basis, on a pro forma basis after giving effect to the acquisition of Biosciences, and on a pro forma as adjusted basis to reflect our sale of 6,000,000 shares of common stock in this offering at an assumed offering price of \$2.80 per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses.

	As of June 30, 2010	
	Actual	Pro forma <sup>(1)</sup> (unaudited)
<b>Balance sheet data:</b>		
Cash, cash equivalents and investments	\$ 131,035	\$ 648,428
Working capital (deficit)	(668,386)	117,637
Total assets	295,219	12,592,785
Total stockholders' equity (deficit)	(665,963)	11,834,037

- (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.

**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.

**Table of Contents****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. The as adjusted column takes into account the BioSciences acquisition and gives effect to the issuance of the common stock offered hereby and the use of proceeds as described in the section entitled Use of Proceeds.

The pro forma as adjusted information set forth below is illustrative only and our capitalization following the closing of this offering will be adjusted based on the actual public offering price and other terms of this offering. 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 (Dollars in thousands, except per share data)	Pro Forma(1)
Cash and cash equivalents	\$ 131	\$ 648
Total liabilities(3)	\$ 961	\$ 759
<b>Total stockholders' equity</b>		
Preferred stock, authorized 2,000,000 shares, \$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 28,107,036 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 that totaled \$1.40 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 \$10.1 million purchase price to patents and \$4.1 million to goodwill.

---

**Table of Contents**

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

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the Risk Factors section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

**Overview**

We are a development stage company engaged in developing innovative, proprietary pharmaceutical drugs and diagnostic products to identify, treat and prevent a broad range of human diseases including metabolic disorders, cancer, and acute and chronic inflammation diseases. We intend to develop proprietary pharmaceutical drugs and diagnostic products which capitalize on our intellectual property that includes assigned patents, pending patent applications, and trade secrets and know-how, some of which may be the subject of future patent applications. Our intellectual property is strategically focused on three primary areas: new uses for FDA-approved drugs, referred to as repositioned drugs, new molecular entities, or NMEs, and rapid point-of-care tests for diagnosis, monitoring and screening.

Our predecessor, DMI Life Sciences, Inc., or Life Sciences, was incorporated in Delaware in December 2008 and did not conduct any business activity until April 16, 2009, at which time Life Sciences purchased certain assigned intellectual property (including 107 patents and pending patent applications), business products and tangible property from BioSciences. Life Sciences issued 3,500,000 shares of its common stock to BioSciences, and assumed certain liabilities, as consideration for the assets purchased from BioSciences. The assets we acquired from BioSciences had a carrying value of zero, as BioSciences had expensed all of the research and development costs it incurred with respect to the intellectual property we purchased. At the time of the asset purchase, Life Sciences and BioSciences agreed to a non-compete prohibiting both companies from competing with one another anywhere in the world for a period of three years, and also agreed that Life Sciences would receive 10% of royalty license revenues received by BioSciences from a drug developed by BioSciences (and as to which BioSciences retained ownership) to treat premature ejaculation, which we refer to as the PE drug.

In March 2010, Life Sciences was merged with a subsidiary of Chay Enterprises, Inc., a public company then traded on the OTC Bulletin Board. Chay Enterprises had minimal operations prior to the time of this merger, and like similar entities was referred to as a public shell. As a result of this merger, our stockholders became the controlling shareholders of Chay Enterprises and the former sole officer and director of Chay Enterprises appointed a majority of our current management team to their present positions. We were reincorporated in Delaware at that time as Ampio Pharmaceuticals, Inc. and commenced trading on the OTC Bulletin Board as Ampio Pharmaceuticals, Inc. in late March 2010 following approval from FINRA and the assignment of a new trading symbol.

In April 2010, we announced the execution of a letter of intent to acquire BioSciences. The purpose of this transaction was to unify our management team and ownership, as our chief financial officer and a number of our non-executive officers were then serving also as officers and employees of BioSciences. For example, Dr. Bar-Or was a member of the board of directors of BioSciences until April 2010 and formerly served as an executive officer of BioSciences, and he was also the largest shareholder of BioSciences until immediately prior to the closing of the BioSciences acquisition. At that time, Dr. Bar-Or and the other executive officers of BioSciences agreed to donate back to the capital of BioSciences all of the common stock owned by them in BioSciences. This donation to capital had the effect of increasing substantially the ownership percentage of the non-management shareholders of BioSciences, many of whom had been BioSciences shareholders for a number of years.

In addition, when our predecessor purchased intellectual property from BioSciences in April 2009, a transaction discussed further below, BioSciences received 3,500,000 shares of our common stock that represented approximately 20% of our outstanding shares. Because of this common ownership and the



## **Table of Contents**

common management described above, we concluded that an acquisition of BioSciences would remove the potential for conflicts of interest between us and BioSciences, and would provide us also with the opportunity to seek a new licensing partner for Zertane. That drug was returned to BioSciences in April 2010 by a major pharmaceutical company that had previously licensed the PE drug. In November 2010, we closed the acquisition of BioSciences into escrow. The only condition remaining to be satisfied in order to close the escrow is the registration of the 8,500,000 shares of our common stock to be issued to the BioSciences shareholders in exchange for all of the outstanding shares of BioSciences. Those shares are being registered on the registration statement of which this prospectus is a part.

## **Known Trends or Future Events**

We have not generated any revenues since our inception in December 2008. The assets we purchased from BioSciences in April 2009 did generate minimal revenues prior to their acquisition. Since purchasing those assets from BioSciences in April 2009, which included patents, pending patent applications, proprietary know-how and minimal fixed assets, we have engaged in organizational activities; conducted a private placement pursuant to which we raised \$1,457,387 in additional capital; added to our management team; completed the merger with Chay Enterprises; signed the letter of intent to acquire BioSciences; and closed the acquisition of BioSciences. As reflected in the BioSciences historical financial information included in this prospectus, BioSciences generated approximately \$3.8 million in revenues in fiscal 2008, fiscal 2009, and the nine months ended June 30, 2010 from the license of the PE drug to a large pharmaceutical concern. That license was terminated by the pharmaceutical company in April 2010, at which time BioSciences reacquired all rights to the PE drug.

Unless we secure a collaborator for one or more of our product candidates and generate license revenues, we will need additional capital in order to continue to implement our business strategy. We cannot assure you that we will secure such financing or that it will be adequate to execute our business strategy. Even if we obtain this financing, it may be costly and may require us to agree to covenants or other provisions that will favor new investors over our existing shareholders. Due to the time required to conduct clinical trials and obtain regulatory approval for any of our product candidates, we anticipate it will be some time before we generate substantial revenues, if ever. We expect to generate operating losses for the foreseeable future, but intend to limit the extent of these losses by entering into co-development or collaboration agreements with one or more strategic partners. We do not currently have any such agreements in effect.

Since our inception, we have incurred significant net losses and we expect to continue to experience significant losses as we invest in product candidate development, clinical trials, regulatory compliance, and building our portfolio of proprietary intellectual property. As of June 30, 2010, we had a deficit accumulated during the development stage of \$4.4 million. We incurred pro forma combined net losses with BioSciences of \$2.4 million and \$2.6 million in 2009 and the six months ended June 30, 2010, respectively.

## **Significant Accounting Policies and Estimates**

Our financial statements have been prepared in accordance with accounting policies generally accepted in the United States of America. The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, management evaluates its estimates and judgments, including those related to revenue recognition, recoverability of long-lived assets, and contingencies and litigation. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The methods, estimates, and judgments used by us in applying these most critical accounting policies have a significant impact on the results we report in our financial statements.

## **Table of Contents**

### *Cash and Cash Equivalents*

We consider all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents consist primarily of money market investments. We maintain balances from time to time in excess of the federally insured limits.

### *Patents*

Costs of establishing patents consisting of legal fees paid to third parties and related costs are currently expensed as incurred. We will continue this practice unless we can demonstrate that such costs add economic value to our business, in which case we will capitalize such costs as part of intangible assets. The primary consideration in making this determination is whether or not we can demonstrate that such costs have, in fact, increased the economic value of our intellectual property. Legal and related costs which do not meet the above criteria will be expensed as incurred.

### *Stock-Based Compensation*

We account for share-based payments by recognizing compensation expense based upon the estimated fair value of the awards on the date of grant. We determine the estimated grant fair value using the Black-Scholes option pricing model and recognize compensation costs ratably over the vesting period using the straight-line method. Common stock issued in exchange for services is recorded at the fair value of the common stock at the date at which we become obligated to issue the shares. The value of the shares is expensed over the service period.

### *Income Taxes*

Ampio uses the liability method of accounting for income taxes. Under this method, Ampio recognizes deferred assets and liabilities based on the differences between the tax basis of assets and liabilities and their reported amounts in the financial statements that will result in taxable or deductible amounts in future years. Ampio establishes a valuation allowance for all deferred tax assets for which there is uncertainty regarding realization.

### *Research and Development*

Research and development costs are expensed as incurred. These costs consist primarily of expenses for personnel engaged in the design and development of product candidates; the scientific research necessary to produce commercially viable applications of our proprietary drugs or compounds; early stage clinical testing of product candidates or compounds; expenditures for design and engineering of the ORP product; and development equipment and supplies, facilities costs and other related overhead. Through our relationship with TRLLC, a related party, the bulk of these costs are incurred by TRLLC and reimbursed by us to TRLLC.

### *General and Administrative Expenses*

General and administrative expenses consist primarily of personnel-related expense related to our executive, operations, human resource, and information technology functions, as well as fees for professional services and facility costs. Professional services consist principally of external legal, accounting and other consulting services. We expect general and administrative expenses to increase as we incur additional costs related to conducting clinical trials, continuing development of product candidates and, if clinical trials are successful, applying for regulatory approvals and commercializing our product candidates. As we are a publicly traded company, we also expect the costs associated with our public status will increase, including legal fees, accounting fees and costs of compliance with securities laws and other regulations. In addition, we expect to incur additional costs as we hire personnel and enhance our infrastructure to support the anticipated growth of our business.

## **Results of Operations Six Months Ended June 30, 2010 and 2009**

### *Revenue*

We are a development stage enterprise and have not generated material revenue in our operating history.



**Table of Contents***Expenses**Research and Development*

Research and development costs were \$776,000 and \$259,000 in the six months ended June 30, 2010 and 2009, respectively. Research and development costs consist of the research and development of patents and intellectual property as well as drug development and clinical trials. The increase in expenses in 2010 relates to the increase in business activity as we did not begin incurring operating expenses until April 2009. We have not capitalized any of our research and development costs.

*General and Administrative*

General and administrative costs are summarized as follows:

	<b>Six Months ended June 30,</b>	
	<b>2010</b>	<b>2009</b>
Stock-based compensation	\$ 1,014,000	\$
Professional fees	354,000	12,000
Labor	322,000	119,000
Occupancy, travel and other	157,000	18,000
	<b>\$ 1,847,000</b>	<b>\$ 149,000</b>

Stock-based compensation consists of the fair value of shares issued to outside consultants for services provided. Professional fees consist primarily of legal, audit and accounting costs related to the Chay Enterprises merger and public company compliance costs. Labor consists of compensation costs attributable to our administrative employees. The increase in expenses in 2010 relates to the increase in business activity as we did not begin incurring operating expenses until April 2009.

*Net Cash Used in Operating Activities*

During the six months ended June 30, 2010, our operating activities used \$1,250,000 of cash. The use of cash reflected a \$2,628,000 net loss, a non-cash charge of \$1,014,000 for stock based compensation, an increase in accounts payables of \$278,000 relating to professional fees incurred in conjunction with the Chay Enterprises merger and other expenses, an increase in accrued salaries of \$123,000 resulting from deferral of salaries by our management team, and changes in other assets and current liabilities which provided net cash of \$36,000.

*Net Cash from Financing Activities*

Net cash provided by our financing activities was \$1,312,000 for the six months ended June 30, 2010. During this period, we received \$200,000 in loans from shareholders and \$1,367,000 from the sale and subscription of common stock. Immediately prior to the Chay Enterprises merger, we made advances of \$150,000 to stockholders. Pursuant to the terms of the Chay Enterprises merger agreement, we were also required to place \$125,000 in restricted cash into an escrow account, \$20,000 of which was released in June 2010 and \$75,000 was released in July 2010. The remaining escrowed funds are to be released to us on closing of a Qualified Financing (as defined) during the escrow period, or will be released to the principal stockholders of Chay if we do not obtain such financing during the escrow period, subject to adjustment for any sales of our common stock made by the Chay principal stockholders.

---

**Table of Contents**

**Results of Operations Year Ended December 31, 2009**

*Year Ended December 31, 2009*

*Revenue*

We are a development stage enterprise and have not yet generated revenues.

*Expenses*

*Research and Development*

We are a development stage enterprise developing innovative, proprietary pharmaceutical drugs and diagnostic products to identify, treat and prevent a broad range of human diseases. Research and development costs for the year ended December 31, 2009 represents a full year's worth of costs related to the research and development of patents and intellectual property. We did not capitalize any of our research and development costs during the year ended December 31, 2009.

*General and Administrative*

General and administrative costs for the year ended December 31, 2009 represents a full year's worth of costs for our development stage enterprise.

*Net Cash Used in Operating Activities*

During the twelve months ended December 31, 2009, our operating activities used \$1,372,000 of cash. This reflected a \$1,512,000 net loss, an increase in accounts payables of \$80,000, accrued salaries of \$73,000 and accrued interest payable of \$1,000, offset with increases in prepaid expenses of \$7,000 and a related party receivable of \$7,000. All of these changes relate to the assumption of assets and liabilities in the asset purchase transaction with BioSciences.

*Net Cash from Financing Activities*

Net cash provided by our financing activities was \$1,444,000 for the twelve months ended December 31, 2009. During this period, we received \$200,000 in proceeds from a related note payable and proceeds from the sale of common and preferred stock of \$1,292,000, offset by payment of assumed liabilities of \$48,000.

**Results of Operations Year Ended September 30, 2008 and Period From October 1, 2008 through April 15, 2009 of the BioSciences Assets Sold**

Our predecessor Life Sciences was formed in December 2008 and had no activity prior to the acquisition of assets from BioSciences. Life Sciences entered into an asset purchase agreement during 2009 with BioSciences, under which Life Sciences acquired office and lab equipment, cell lines and intellectual property including patents and license agreements and assumed liabilities. This transaction was accounted for as a reverse merger and the assets acquired and liabilities assumed were recorded at predecessor cost. The assets had \$0 carrying value on the predecessor financial statements and liabilities totaled \$252,015. The carve out financial statements of the predecessor have been included in this prospectus in order to provide for two years of operations of the assets acquired. The assets acquired represented a discrete activity within BioSciences and management of BioSciences was able to provide a reasonable allocation of the activities within BioSciences related to the assets acquired. The acquisition occurred on April 16, 2009, therefore the carve out financial information includes the periods prior to the acquisition for its most recent fiscal year end, September 30, 2008, and the period from October 1, 2008 through April 15, 2009. The financial statements of BioSciences assets sold represent the activities of all assets transferred to Life Sciences for the period ended April 15, 2009 and the year ended September 30, 2008. These financial statements include all costs of doing business related to the assets acquired and liabilities assumed, including the development and research of proprietary pharmaceutical drugs and diagnostic products that inured to the benefit of Life Sciences, regardless of whether the research was successful or not. The activities of BioSciences performed by TRLLC under a research agreement with BioSciences that related to the BioSciences assets sold have also been included in the financial statements for the BioSciences assets sold.



## Table of Contents

### Liquidity and Capital Resources

We had unrestricted cash of \$131,000 at June 30, 2010, and an additional \$75,000 was released from restricted cash subsequent to June 30, 2010. We raised approximately \$1,500,000 in a private placement of common stock conducted from November 2009 to March 2010. As of June 30, 2010 we had \$400,000 in notes payable to stockholders, which mature on the earlier of a minimum financing of \$5,000,000 or September 2, 2010. Of these notes payable, \$300,000 was owed to BioSciences and was cancelled upon consummation of the BioSciences acquisition. During August 2010, two of our directors and an affiliate of one of those directors loaned an additional \$430,000 to us. The loans mature at the earlier of a minimum financing of \$10,000,000 or January 31, 2011. Additional loans from our stockholders may be a source of short-term liquidity. However, there is currently no formal commitment from our stockholders to provide additional short-term financing.

### Off Balance Sheet Arrangements

We do not have off-balance sheet arrangements, financings, or other relationships with unconsolidated entities or other persons, also known as variable interest entities.

### Contractual Obligations

As condition of the merger with Chay Enterprises, or Chay, we and certain of our shareholders, referred to as the guarantors, and the principal shareholders of Chay entered into a securities put and guarantee agreement. The agreement provides that if we are not successful in obtaining a minimum of \$5.0 million in financing within 150 days after the closing of the merger, the principal shareholders of Chay will have the right to put back to us all of the Chay common stock then owned by the Chay principal shareholders for a put price of \$250,000, subject to adjustment. Under the agreement, the guarantors agreed to jointly guarantee the payment of the put price by us if the put right becomes exercisable in accordance with its terms. In addition, we placed into escrow a cash deposit of \$125,000 that will be paid to the Chay principal shareholders in the event the put right becomes exercisable by its terms. The Chay principal shareholders have since released \$95,000 of the funds in escrow. If any amounts are paid to the Chay principal shareholders in accordance with the escrow agreement, such payment will reduce the amount the guarantors would be required to pay on exercise of the put right.

The following table summarizes contractual obligations and borrowings as of December 31, 2009 and the timing and effect that such commitments are expected to have on our liquidity and capital requirements in future periods. We expect to fund other commitments primarily with operating cash flows generated in the normal course of business.

#### Contractual Obligations

	Total	Due in Less than 1 Year	Due 1 3 Years	Due 3 5 Years	More than 5 years
Sponsored Research Agreement with Related Party <sup>(1)</sup>	\$ 1,285,467	\$ 350,582	\$ 701,164	\$ 233,721	
Related Party Debt Obligations <sup>(2)</sup>	200,000	200,000			
	\$ 1,485,467	\$ 550,582	\$ 701,164	\$ 233,721	\$

- (1) Represents amounts due under our sponsored research agreement with Trauma Research LLC, or TRLLC. This commitment may increase if our board of directors requests TRLLC to perform additional research and development activities. Such a request is expected to be made only in conjunction with our receipt of additional financing. This agreement may be terminated without cause by either party with 180 days written notice.
- (2) For more information on our debt obligations, see Related Party Transactions.

---

**Table of Contents**

**Quantitative and Qualitative Disclosures About Market Risk**

Our business is not currently subject to material market risk related to financial instruments, equity or commodities. Our outstanding indebtedness is limited currently to fixed rate instruments.

**Recently Issued Accounting Pronouncements**

In June 2009, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards ( SFAS ) No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles – a replacement of FASB Statement No. 162* ( SFAS 168 ). The FASB Accounting Standards Codification ( Codification or ASC ) became the source of authoritative GAAP recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. On the effective date of SFAS 168, the Codification superseded all then-existing non-SEC accounting and reporting standards. All other non-grandfathered non-SEC accounting literature not included in the Codification became non-authoritative.

Following SFAS 168, the FASB will no longer issue new standards in the form of Statements, FASB Staff Positions, or Emerging Issues Task Force Abstracts; instead, it will issue Accounting Standards Updates (ASUs). The FASB will not consider ASCs as authoritative in their own right; rather, these updates will serve only to update the Codification, provide background information about the guidance, and provide the bases for conclusions on the change(s) in the Codification. SFAS No. 168 is incorporated in ASC Topic 105, *Generally Accepted Accounting Principles*. The Company adopted SFAS No. 168 for the quarter ended September 30, 2009, and we will provide reference to both the Codification topic reference and the previously authoritative references related to Codification topics and subtopics, as appropriate.

In May 2009, the FASB issued ASC Topic 855, *Subsequent Events (ASC 855)* (formerly SFAS No. 165, *Subsequent Events*) which establishes general standards for the evaluation, recognition and disclosure of events and transactions that occur after the balance sheet date. Although there is new terminology, the standard is based on the same principles as those that currently exist in auditing standards. The standard, which includes a new required disclosure of the date through which management has evaluated subsequent events, is effective for interim and annual periods ending after June 15, 2009. The adoption of ASC 855 had no effect on our financial statements.

Effective October 1, 2008, the Company adopted certain aspects of ASC Topic 825, *Financial Instruments* (formerly SFAS 159, *The Fair Value Option for Financial Assets & Financial Liabilities* including an amendment of SFAS No. 115. ). The accounting guidance created a fair value option under which an entity may irrevocably elect fair value as the initial and subsequent measurement attribute for certain financial assets and liabilities on a contract by contract basis, with changes in fair values recognized in earnings as these changes occur. The adoption of ASC Topic 825 had no significant impact on our financial condition or results of operations.

In December 2007, the FASB issued ASC Topic 805, *Business Combinations (ASC 805)* (formerly SFAS 141R, *Business Combinations*), which establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in an acquiree and the goodwill acquired. ASC 805 will apply prospectively to business combinations with an acquisition date on or after November 1, 2009. The adoption of ASC Topic 805 did not have a material impact on our financial condition or results of operations. We will apply ASC 805-10 to any business combination subsequent to its adoption.

*New accounting pronouncements to be adopted*

In June 2009, the FASB issued SFAS No. 167, *Amendments to FASB Interpretation No. 46(R)*, (codified by ASU No. 2009-17 issued in December 2009). The standard amends FIN No. 46(R) to require a



---

**Table of Contents**

company to analyze whether its interest in a variable interest entity ( VIE ) gives it a controlling financial interest. A company must assess whether it has an implicit financial responsibility to ensure that the VIE operates as designed when determining whether it has the power to direct the activities of the VIE that significantly impact its economic performance. Ongoing reassessments of whether a company is the primary beneficiary are also required by the standard. SFAS No. 167 amends the criteria to qualify as a primary beneficiary as well as how to determine the existence of a VIE. The standard also eliminates certain exceptions that were available under FIN No. 46(R). This statement will be effective as of the beginning of each reporting entity's first annual reporting period that begins after November 15, 2009 (i.e. our fiscal year ending March 31, 2011). Earlier application is prohibited. Comparative disclosures will be required for periods after the effective date. It is expected that the adoption of this statement will have no material effect on our consolidated financial statements.

In October 2009, the FASB issued ASU No. 2009-15 *Accounting for Own-Share Lending Arrangements in Contemplation of Convertible Debt Issuance or Other Financing*. ASU 2009-15 amends ASC 470-20, *Debt with Conversion and Other Options*, to provide accounting and reporting guidance for own-share lending arrangements issued in contemplation of convertible debt issuance. ASU 2009-15 is effective for fiscal year beginning on or after December 15, 2009 with retrospective application required.

In January 2010, the FASB issued the following ASUs that may become applicable to us:

ASU No. 2010-02 *Consolidation (Topic 810): Accounting and Reporting for Decreases in Ownership of a Subsidiary*. This update amends Subtopic 810-10 and related guidance to clarify that the scope of the decrease in ownership provisions of the Subtopic and related guidance applies to (i) a subsidiary or group of assets that is a business or nonprofit activity; (ii) a subsidiary that is a business or nonprofit activity that is transferred to an equity method investee or joint venture; and (iii) an exchange of a group of assets that constitutes a business or nonprofit activity for a noncontrolling interest in an entity, but does not apply to: (i) sales of substantial real estate; and (ii) conveyances of oil and gas mineral rights. The amendments in this update are effective beginning the period that an entity adopts FAS 160 (now included in Subtopic 810-10).

ASU No. 2010-05 *Compensation - Stock Compensation (Topic 718): Escrowed Share Arrangements and the Presumption of Compensation*. This update simply codifies EITF Topic D-110, *Escrowed Share Arrangements and the Presumption of Compensation* issued on June 18, 2009. In EITF Topic No. D-110, SEC staff clarified that entities should consider the substance of the transaction in evaluating whether the presumption of compensation may be overcome, including whether the transaction was entered into for a reason unrelated to employment, such as to facilitate a financing transaction. In that situation, the staff generally believes that the escrowed shares should be reflected as a discount in the allocation of proceeds.

ASU No. 2010-06 *Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements*. This update amends Subtopic 820-10 that requires new disclosures about transfers in and out of Levels 1 and 2 and activity in Level 3 fair value measurements. This update also amends Subtopic 820-10 to clarify certain existing disclosures. The new disclosures and clarifications of existing disclosures are effective for interim and annual reporting periods beginning after December 15, 2009, except for the disclosures about purchases, sales, issuances, and settlements in the roll forward of activity in Level 3 fair value measurements, which are effective for fiscal year beginning after December 15, 2010.

In April 2010, the FASB issued an accounting standards update which provides guidance on the criteria to be followed in recognizing revenue under the milestone method. The milestone method of recognition allows a vendor who is involved with the provision of deliverables to recognize the full amount of a milestone payment upon achievement, if, at the inception of the revenue arrangement, the milestone is determined to be substantive as defined in the standard. The guidance is effective on a prospective basis for milestones achieved in fiscal years and interim periods within those fiscal years, beginning on or after June 15, 2010. The adoption of this guidance is not expected to have a material impact on our financial statements.

**Table of Contents**

On July 21, 2010, the FASB issued ASU 2010-20 Receivables (Topic 310) Disclosures about the Credit Quality of Financial Receivables and the Allowance for Credit Losses. ASU 2010-20 requires disclosure of additional information to assist financial statement users to understand more clearly an entity's credit risk exposures to finance receivables and the related allowance for credit losses. ASU 2010-20 is effective for all public companies for interim and annual reporting periods ending on or after December 15, 2010, with specific items, such as the allowance rollforward and modification disclosures, effective for periods beginning after December 15, 2010. We do not expect the adoption of this new guidance to have an impact on our financial position, cash flows or results of operations.

We expect that the adoption of the above updates will not have any significant impact on our financial position and results of operations.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on our consolidated financial statements upon adoption.

**Impact of Inflation**

In general, we believe that, over time, we are able to increase prices to counteract the majority of the inflationary effects of increasing costs.

## **Table of Contents**

### **BUSINESS**

#### **Overview and Background**

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, metabolic disorders, and cancer. Our predecessor, Life Sciences, was formed by Michael Macaluso, our chairman of the board, and incorporated in Delaware in December 2008. Life Sciences did not conduct any business activity until April 16, 2009, at which time Life Sciences purchased certain assigned intellectual property including 107 patents and patent applications, business products and tangible property from BioSciences. Life Sciences issued 3,500,000 shares of our common stock to BioSciences, and assumed certain liabilities, as consideration for the assets purchased from BioSciences. At the time of the asset purchase, Life Sciences and BioSciences agreed to a non-compete prohibiting both companies from competing with one another anywhere in the world for a period of three years, and also agreed that we would receive a 10% royalty on license revenues received by BioSciences from the PE drug.

Immediately prior to the merger of Life Sciences with a subsidiary of Chay, the outstanding Series A preferred stock of Life Sciences was converted into Life Sciences common stock, in accordance with Life Sciences amended and restated certificate of incorporation. That document called for the automatic conversion of the Series A preferred stock into common stock immediately prior to the merger of Life Sciences with a publicly traded company in which the holders of the voting securities of the publicly-traded company before the merger hold less than 25% of the total voting power of Life Sciences' voting securities after the merger. As our common stockholders before the Chay merger held less than 6% of the total outstanding shares after the merger, the Life Sciences' Series A preferred stock was then converted automatically into Life Sciences' common stock.

In April 2010, we announced the execution of a letter of intent to acquire BioSciences. The purpose of this transaction was to unify our management team and ownership, as our chief financial officer and a number of our non-executive officers were then serving also as officers and employees of BioSciences. At that time, Dr. Bar-Or and the other executive officers of BioSciences agreed to donate back to the capital of BioSciences all of the common stock owned by them in BioSciences. This donation to capital had the effect of increasing substantially the ownership percentage of the non-management shareholders of BioSciences, many of whom had been BioSciences shareholders for a number of years.

In addition, when Life Sciences purchased intellectual property from BioSciences in April 2009, BioSciences received 3,500,000 shares of our common stock that represented approximately 20% of our outstanding shares. Because of this common ownership and the common management described above, we concluded that an acquisition of BioSciences would remove the potential for conflicts of interest between us and BioSciences, and would provide us also with the opportunity to seek a new licensing partner for the PE drug. That drug was returned to BioSciences in April 2010 by a major pharmaceutical company that had previously licensed Zertane. In November 2010, we closed the acquisition of BioSciences into escrow. The only condition remaining to be satisfied in order to close the escrow is the registration of the 8,500,000 shares of our common stock to be issued to the BioSciences' shareholders in exchange for all of the outstanding shares of BioSciences. Those shares are being registered on the registration statement of which this prospectus is a part.

#### **Business Model**

Our principal focus is developing pharmaceutical products that can achieve more rapid marketing approvals through identifying new applications, indications, dosing, and chemical combinations for compounds previously approved as safe and effective by the FDA or EMEA. Known as drug repositioning, this strategy reduces the risk of product failure due to adverse toxicology, leads to more modest investments during development, and may achieve more rapid marketing approval. Three of our most advanced product candidates are repositioned drugs for which we have secured or are securing U.S. and international patent protection covering their unique composition or application.

---

## Table of Contents

We intend to develop proprietary pharmaceutical drugs and diagnostic products which capitalize on our intellectual property that includes owned and assigned patents, filed patent applications, exclusive licenses, and trade secrets and know-how, some of which may be the subject of future patent applications. Our intellectual property is strategically focused on three primary areas: new uses for repositioned drugs, new molecular entities, or NMEs, and rapid point-of-care tests for diagnosis, monitoring and screening.

### *Repositioned Drugs*

Drug repositioning is the use of approved drugs to treat new diseases, sometimes referred to as new indications. Drug repositioning, sometimes called drug repurposing, drug re-profiling, or therapeutic switching, is the discovery of new uses for FDA-approved drugs and making them available to new patient populations after completion of human clinical trials. In contrast to the development of New Molecular Entities ( NMEs ) we believe that repositioned drugs can significantly accelerate development, improve success rates and lower development costs. This belief is based on the fact that repositioned drugs have already passed a significant number of toxicity and other tests reflecting previously collected pharmacokinetic, toxicology and safety data; the drug s safety is known with respect to existing indications, and the risk of failure for reasons of adverse toxicology are reduced. By contrast, developing a NME can be significantly more costly than developing a repositioned drug, as pharmacokinetic, toxicology and safety data must first be collected in animal studies for a NME unless a compassionate need or other exception can be obtained.

Repositioning is becoming a primary strategy for many research-based pharmaceutical companies. Examples of some well-known repositioned drugs include Pfizer s Viagra® (sildenafil) in erectile dysfunction; CollaGenex Periostat® in periodontitis; and Oracea® in rosacea (both of which are new uses of the antibiotic doxycycline). Other companies that are engaged in repositioned initiatives include Horizon Therapeutics, which is developing a single-pill combination of ibuprofen and pepcid to reduce gastrointestinal complications that occur when patients take high doses of non-steroidal anti-inflammatory drugs; Orexigen, which is a repositioned two fixed-dose combination product for the treatment of obesity; and Somaxon, which is repositioning the antidepressant doxepin for use in insomnia.

### *Optina: Repositioned Drug to Treat Diabetic Retinopathy, DME, and Wet AMD*

Our leading drug candidate, Optina, is low-dose Danazol, which was first approved by the FDA in the early 1970 s and is a derivative of the synthetic steroid ethisterone. Dr. Bar-Or has determined that Danazol in low doses has the capability to control the permeability of blood vessels, thus reducing vascular leakage. Optina is an orally-administered compound designed to treat diabetic retinopathy, diabetic macular edema, or DME, and neovascular age-related macular degeneration, or wet AMD.

Although the mechanism of action of Optina is not fully understood, we have shown that Optina has multi-targeted, disease-modifying activity that inhibits inflammation, cell proliferation, neovascularization, fibrosis and scarring. We have demonstrated that Optina reaches the target blood vessels and tissue of the eye.

The market size for diabetic retinopathy, DME and wet AMD is difficult to measure but the demographics suggest a very large potential market exists. The American Diabetes Association reports that 20.8 million people in the U.S. have diabetes and another 54 million are pre-diabetic with 20% of type-2 diabetic patients having retinopathy when diagnosed. According to the World Health Organization, approximately 5 million individuals have diabetic retinopathy, accounting for 5 percent of world blindness. Over 360 million people worldwide are projected to have diabetes and its complications by 2030 with almost all patients with type-1 diabetes and more than 60% of patients with type-2 diabetes developing retinopathy. The International Diabetes Federation estimates that 285 million people around the world have diabetes and 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. By 2030, the incidence of diabetes is expected to rise to 438 million worldwide, and the incidence of diabetes-related conditions like DME, diabetic retinopathy, and diabetic nephropathy are also expected to continue to increase proportionately. We believe that an effective oral drug treatment of diabetic retinopathy, DME and wet AMD is a significant unmet medical need.

---

**Table of Contents**

If untreated, DME leads to moderate vision loss for one out of four people with diabetes over a period of three years and can lead to blindness over a period of seven years. Existing therapies for diabetic retinopathy, 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, or IVT, using Lucentis, Avastin, or Macugen. Lucentis is costly compared to alternative injection therapies, while Avastin is currently approved only for cancer treatment and is being used off-label by ophthalmologists to treat DME and wet AMD. Macugen recently completed a Phase III trial in which subjects were given injections in the eye as often as every six weeks in both the first and second year of the trial, which resulted in patients gaining 5.2 letters of vision compared to 1.2 letters for patients receiving a sham injection. 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. For these reasons, we believe Optina represents a significant Phase II stage clinical opportunity.

Having developed over four decades of experience in human use worldwide, we believe Optina has demonstrated an acceptable safety profile that supports treatment of human neovascular and inflammatory ocular diseases. We anticipate that Optina can be offered to patients in a variety of formulations, including oral tablets, extended release implants, local injections and topically as eye drops. These formulations can increase bioavailability to the eye, may increase patient compliance and could provide additional barriers to competition.

We have filed method of use, composition and devices for Optina in a variety of ocular and other indications in the U.S. and internationally.

We believe Optina will be eligible for regulatory approval in the U.S. as a §505(b)(2) New Drug Application submission and in the EU under its hybrid abridged procedure. Optina is potentially suitable for Fast Track designation and, if received, FDA 505(b)(2) regulatory approval can provide three years of market exclusivity in the U.S.

We have entered into a contract with St. Michael's Hospital in Toronto, Canada, and currently expect patient enrollment to begin in November 2010 for a human clinical trial tentatively titled, "A Randomized, Double-blind, Placebo-Controlled, Parallel Treatment Group, Dose-Ranging, Efficacy and Safety Study of Oral [Optina] Capsules in Subjects with Diabetic Macular Edema." We intend to prepare for a second clinical trial while examining formulation and manufacturing issues. On completion of the dose-ranging, efficacy and safety study, we will be positioned for a larger, pivotal FDA clinical trial to confirm safety and effectiveness. Based on our perception of the high unmet need for a drug such as Optina, the lack of pharmaceutical competition, and the history of the active pharmaceutical ingredient in Optina, we believe that Optina could potentially be available for marketing in approximately three years in the U.S., and could potentially be available for marketing in two years in some international markets.

*Vasaloc: Repositioned Drug to Treat Diabetic Nephropathy*

Untreated diabetic nephropathy leads to kidney damage or renal failure. Diabetes has become the most common single cause of end-stage renal disease, or ESRD, in the U.S. and Europe. While the exact cause of diabetic nephropathy is unknown, it is believed that excessive blood sugar damages nephrons. Once these structures are damaged, they begin to leak and protein (albumin) begins to pass into the urine. 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.

Vasaloc is an orally-administered compound based on low-dose Danazol that is designed to treat diabetic nephropathy. We believe Vasaloc offers an effective means to treat diabetic nephropathy by reducing glucose-induced damage to the small vessels of the kidney, thereby stabilizing kidney function and reducing complications from kidney damage. We expect to contract for Phase II clinical trials of Vasaloc to begin in the first quarter of 2011, and expect the trial will be complete by the first quarter of 2012.

## Table of Contents

### *Ampion: Repositioned Biologic to Treat Inflammatory Conditions and Autoimmune Diseases*

Ampion is a non-steroidal biologic, aspartyl-alanyldiketopiperazine, referred to as DA-DKP. This compound is comprised of two amino acids derived from human albumin, 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 and can be detected in plasma. Ampion has significant effects on inflammation and other physiological and metabolic parameters. 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 studies of Ampion in Australia and India commencing in the second or third quarter of 2011, and expect these studies will take approximately 24 months to complete. The trials in Australia will explore the efficacy of human albumin-derived Ampion in the treatment of two unrelated conditions. The Ampion-injection-into-knee (AIK) trial will be designed to assess the efficacy of Ampion in the reduction of pain and inflammation of osteoarthritis of the knee. The Wound Exudate Attenuation and Prevention (WEAP) trial will assess the efficacy of albumin-derived Ampion in the reduction of fluid loss across wounds. We expect the AIK trial to provide clinical data that will assist us in designing testing regimens for other inflammatory-related diseases such as Rheumatoid and autoimmune diseases, lupus, and multiple sclerosis, while the WEAP trial will provide us a model for evaluating early inflammatory changes related to fluid management.

The Indian trials are expected to assess the use of several Ampion formulations based on a synthetic version of the Ampion molecule we are producing under U.S. cGMP and API control. While the naturally-occurring molecule has been given to millions of patients in the form of approved human albumin, a number of countries have social or religious objections to the use of human blood products. In these countries, health authorities promote the use of substitutes, which we believe offers a market opportunity for the synthetic version of Ampion. The Indian trials will assess the use of synthetic Ampion oral therapy for the treatment of systemic inflammation from Rheumatoid disease, and for parameters associated with Metabolic syndrome, a group of factors that increase the risk of coronary artery disease, stroke and type 2 diabetes.

### *Zertane: Repositioned Drug to Treat PE*

Zertane is a patented, repurposed oral drug formulated using Tramadol, which was approved for marketing as a noncontrolled analgesic in 1995. Though the mechanism of action is unknown, Zertane has been shown to be an effective oral medication to treat premature ejaculation, or PE, in men. According to Australia's Keogh Institute of Medical Research, PE is the most common sexual complaint in males. Behavioral therapy is the current standard of care for treatment of PE. Premature ejaculation, usually defined as ejaculation in 1 to 2 minutes, is a common male sexual dysfunction that can have a major impact on the quality of life for many men and their sexual partners. Randomized, controlled Phase II clinical trials in Europe demonstrated the safety and efficacy of Zertane for treating premature ejaculation.

The first oral medication to treat PE, Dapoxetine, was the subject of five Phase III clinical trials which were reported upon in 2006 by the medical journal *The Lancet*. The studies demonstrated clinical efficacy in patient and partner satisfaction and an overall improvement in the PE condition. Although the FDA declined in 2005 to approve Dapoxetine for treatment of PE, both Finland and Sweden approved Dapoxetine in February 2009 for on-demand treatment of PE in men aged 18 to 64.

BioSciences granted an option to license Zertane to a large pharmaceutical firm in 2007, and the option was exercised in January 2009. The pharmaceutical firm then conducted two large Phase III clinical trials in multiple countries and clinical sites in Europe. The clinical trials were terminated in the second quarter of 2010 before full enrollment was completed, because the pharmaceutical firm changed its

## **Table of Contents**

strategic focus in conjunction with a merger. At that time, BioSciences regained all rights to develop, license and seek regulatory approval to market Zertane worldwide. BioSciences is entitled to obtain copies of the clinical trial data from the pharmaceutical firm but has not yet received all of the data. Once the data is received and analyzed, we will determine how the results of the trials may affect future licensing opportunities and whether dosing or other adjustments must be made in any future trials. In addition to the U.S. and international patents we have already obtained on Zertane, 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.

Based on our initial review of the Zertane Phase III trials, we believe Zertane is positioned on an attractive path forward. Safety and efficacy data for Zertane are currently being analyzed by the contract research organization that conducted these preliminary Phase III trials. Early safety reports reveal that over 440 subjects in these trials had no treatment-related serious adverse events. Added to the previous Phase II clinical trials, over 540 subjects have now been treated for premature ejaculation with no treatment-related serious adverse events. This safety data is important for final regulatory approval. The efficacy analysis of over 400 total subjects in these trials provides the best efficacy-to-standard deviation ratio for potentially saving development time by accurately calculating the minimum required sample size and ideal dosage formulation in a pivotal Phase III trial.

A clear clinical development and regulatory path for Zertane in the European Union has been established with the approval of another drug (dapoxetine) for premature ejaculation. Zertane will be submitted under §505(b)(2) for FDA approval in the U.S. The §505(b)(2) process provides for three years market exclusivity in U.S. In addition to the U.S. and international patents we have already obtained on Zertane, we have applied for patent protection for a combination of Zertane and an erectile dysfunction medicine to offer male patients a single oral medication that will treat both premature ejaculation and erectile dysfunction.

In addition to clinical trials, development includes use of a non-commercially available doses and novel delivery technology (e.g. a fast-dissolving tablet) to differentiate Zertane from other generic products and to facilitate discreet usage. Ampio believes Zertane represents an exclusive dosage and formulation opportunity with significant potential in a sexual dysfunction market that is presently underserved.

### *New Molecular Entities, or NMEs*

It has been widely reported that the average cost of developing a NME from discovery to launch is more than \$800 million. However, this cost reflects failed research efforts, the estimated value of alternative investments, and is based also on the experience of a sample of large pharmaceutical firms. Our development strategy for NMEs is to obtain laboratory and animal study evidence that a drug is safe and effective enough for human testing through rapid, low-cost preclinical proof-of-concept, or POC. Preclinical POC involves collecting pharmacokinetic, toxicology and safety data in a cost-effective and timely manner.

We believe that drugs derived from naturally-occurring peptides or that are analogues of previously approved drugs may have a higher chance of success in development. We have two classes of NMEs that have shown biological activity in the laboratory, including drug candidates that have been successfully tested for efficacy in animal models.

The first class of NMEs we are testing are nine compounds which are derivatives of Methylphenidate, which is a drug approved for treatment of attention-deficit hyperactivity disorder, Postural Orthostatic Tachycardia Syndrome, and narcolepsy, most commonly known under the trade name Ritalin. Dr. Bar-Or has synthesized and obtained patents for these nine compounds, which have demonstrated anti-angiogenesis and anti-metastasis properties. We expect to seek a special protocol assessment from the FDA under which one or more of our Methylphenidate compounds can be 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.

## Table of Contents

We have also conducted early research into how Copper chelating peptides, also considered an NME, can be used to treat Acute Coronary Syndrome, or ACS, 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 d-DAHK. d-DAHK, Asp-Ala-His-Lys-NH<sub>2</sub>, is a small, synthetic mimic of the high affinity metal binding site of the N-terminus of human serum albumin. Dr. Bar-Or has demonstrated that by sequestering copper, d-DAHK inhibits the formation of pro-angiogenic cytokines and chemokines, reduces ROS formation, and inhibits the earliest stages of inflammation initiated by ischemia-reperfusion events. Preclinical *in vitro* and whole animal *in vivo* myocardial infarction and stroke model studies have demonstrated that d-DAHK provides significant preservation of cardiac and cerebral function. d-DAHK can be delivered intravenously for ACS, low cardiac output syndrome, or stroke.

ACS includes acute myocardial infarction and unstable angina pectoris, and is the leading single cause of death in the U.S. According to the American Heart Association and the American College of Cardiology, more than 1.6 million cases of ACS occur each year in the U.S., with more than 500,000 associated annual deaths. d-DAHK is uniquely positioned to help preserve myocardial contractility during ACS, and also to prevent in-stent restenosis after angioplasty/stent procedures, especially now that drug-eluting stents are considered to be a less attractive treatment option. d-DAHK crosses the blood-brain barrier and can also help preserve cognitive function after open-heart bypass or valve replacement surgeries as well as during acute strokes.

Emerging evidence indicates that inflammatory responses during ACS are responsible for significant myocardial tissue damage and loss of cardiac function. Accordingly, reducing inflammation is an emerging target for cardiovascular disease. A number of studies have shown that inflammation of blood vessels is one of the major factors that increases the incidence of heart disease, including atherosclerosis (clogging of the arteries), stroke and myocardial infarction or heart attack. Studies have associated obesity and other components of metabolic syndrome and cardiovascular risk factors with low-grade inflammation.

d-DAHK is non-toxic in early preclinical safety studies at approximately 100 times an anticipated human dose. We anticipate currently that this class of compounds will have acceptable human safety profiles. D-DAHK is soluble, stable, easily manufactured, can be administered orally, and is protected by a variety of U.S. and international patent filings. We expect an investigational new drug application can be submitted to the Food and Drug Administration ( FDA ) in 12 to 18 months with access to additional financial resources. We are beginning to explore research and development opportunities with pharmaceutical companies interested in the treatment of ACS, low cardiac output syndrome, or stroke using d-DAHK.

### *In Vitro Diagnostics*

Diagnostics serve a key role in the health value chain by influencing the quality of patient care, health outcomes and downstream resource requirements. From consumer-friendly at-home pregnancy and glucose monitoring tests to more complex automated laboratory-based systems, these tests are often first-line health decision tools. While diagnostics comprise less than 5% of hospital costs and about 1.6% of all Medicare costs, their findings are commonly believed to influence as much as 60-70% of health care decision-making. The value of diagnostics accrues not only to clinicians and patients, but to health care managers, third-party payors and quality assurance organizations that use diagnostic performance to measure and improve health care quality.

Oxidation-reduction potential is a tightly controlled measurement, much like the vital signs routinely measured in medical practice—temperature, heart rate, respiratory rate, blood pressure and oxygen saturation of blood. Abnormal changes in oxidation-reduction potential are closely associated with poor outcomes in critically ill patients, including heart attack and pneumonia. Rapid results are essential for optimal treatment adjustments in critical care areas such as emergency and intensive care departments. Oxidation-reduction potential results may also help determine which patients are at high risk of early readmission at hospital discharge, especially patients with heart attack, heart failure, stroke, and pneumonia.



## **Table of Contents**

Numerous scientific studies confirm the clinical value of measuring oxidative stress. Recently, a large assortment of blood and cell tests have been used in research studies to measure separate biomarkers of oxidative stress, such as lipid peroxidation, protein oxidation and total antioxidants, but currently several of these separate biomarker test results are needed to start to assess total oxidative stress. We believe no practical or efficient method currently exists for measuring these oxidative stress biomarkers in a clinical setting. Oxidative stress is often a marker for inflammation, which in turn indicates the presence of disease-related processes or developing conditions.

We have developed a handheld Oxidation-Reduction Potential, or ORP, diagnostic device for use at home or in healthcare facilities that will measure the oxidants and antioxidants in human blood. The ORP device provides the first integrated measure of total oxidative stress status for clinical practice. This device is being developed as a battery-powered unit using a drop of whole blood exposed to disposable electrode strips to provide a rapid test result that will measure the oxidants and antioxidants in human blood. Four clinical trials are currently being conducted in two hospitals and include a stroke study, a PET/CT/ORP study in chest pain patients, evaluation of lactate and ORP by paramedical personnel and ORP in critically ill older traumatized patients. Results of these trials which are anticipated to be completed within the next six months will determine the clinical utility of Ampio's point of care ORP device.

The ORP device is currently being prototyped and the first prototypes are expected to be available for testing by November 2010. Dr. Bar-Or developed the disposable electrode for use in the ORP device and has calibrated the device to measure oxidants and antioxidants while taking into account various factors that may affect oxidative stress.

We have several other research initiatives underway at this time. However, these initiatives are early-stage and are not yet capable of being assessed for commercialization.

## **Business Strategy**

Our disciplined innovation process is built on clinical observations and patient data gathered under appropriate IRB supervision from clinicians who collaborate with Dr. Bar-Or. Dr. Bar-or is in charge of the research departments at two of the three Level I trauma centers in the State of Colorado, at which over 120,000 emergency room consultations take place annually. Dr. Bar-Or's clinical team includes biochemists, epidemiologists, molecular biologists, computational biologists and nursing staff. In collaboration with other professional colleagues who provide advisory input, such as vascular surgeons, orthopedic surgeons, neurologists, nephrologists and ER specialists, Dr. Bar-or uses a multidisciplinary approach to evaluate clinical interactions that direct further research.

Once product candidates are identified and clinical efficacy for one or more indications is initially determined, 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 also 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 discovery 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. Although we are in early clinical testing of two NMEs, we primarily target development of repositioned drugs because these drugs are based on compounds or medicines already approved by the FDA and/or the EMEA. We believe our repositioned drug product candidates may receive faster regulatory approvals than NMEs, thus extending the period during which these product candidates will enjoy patent protection for commercialization.

In order to control development costs and expedite the commencement of clinical trials, we intend to outsource clinical trials to hospitals 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

## **Table of Contents**

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 advance those product candidates through clinical trials and the regulatory approval process in order to position an approved product for global market introduction by a licensee.

We believe there are a number of potential licensees for any products that receive regulatory approval, including pharmaceutical and biotechnology companies with substantial manufacturing facilities, established sales organizations, and significant marketing resources. Even if a product candidate receives regulatory approval and is successfully commercialized, we have no plans to change our business model and substantially increase our retained development activities, engage in manufacturing, or develop a sales and marketing organization. We intend to maximize shareholder value by strategically identifying, developing and advancing patent-protectable product candidates to the point that a compelling rationale exists for a collaborator to license any product receiving regulatory approval. If any of our product candidates are licensed to a collaborator, we may marginally increase our operating budget to conduct additional research, but we will intentionally continue to outsource clinical trials, manufacturing, and marketing to collaborators in order to meet our business objectives.

## **Regulation**

The preclinical and clinical development, testing, manufacture, safety, efficacy, labeling, storage, distribution, promotion, sale and export, reporting, and record-keeping of our product candidates are subject to extensive regulation. The FDA and corresponding state agencies are primarily responsible for such regulation in the United States, and similar regulatory agencies in foreign countries are responsible for regulation of our product candidates outside the United States. We must provide the FDA and foreign regulatory authorities, if applicable, with clinical data that appropriately demonstrate each product candidate's safety and efficacy in humans the product candidate can be approved for the targeted indications. We are unable to predict whether regulatory approval will be obtained for any product candidate we are developing or plan to develop. The regulatory review and approval process can take many years, is dependent upon the type, complexity, and novelty of the product, requires the expenditure of substantial resources, involves post-marketing surveillance, and may involve ongoing reporting or monitoring.

We may encounter delays or product candidate rejections based on new governmental regulations, future legislative or administrative actions, or changes in FDA policy or interpretation during the period of product development. Even if we obtain required regulatory approvals, such approvals may later be withdrawn. Delays or failures in obtaining regulatory approvals may:

adversely affect the commercialization of any product candidates we develop; and

diminish any competitive advantages that such product candidates may have or attain.

Furthermore, if we fail to comply with applicable FDA and other regulatory requirements at any stage during the regulatory process, we may encounter or be subject to:

delays in clinical trials or commercialization;

refusal by the FDA to review pending applications or supplements to approved applications;

product recalls or seizures;

suspension of manufacturing;

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

withdrawals of previously approved marketing applications; and

fines, civil penalties, and criminal prosecutions.

The ability to market a product outside of the United States is contingent upon receiving a marketing authorization from appropriate regulatory authorities. Foreign regulatory approval processes typically

## **Table of Contents**

involve risks similar to those associated with obtaining FDA approval and may include additional risks. In addition, the requirements governing conduct of clinical trials and marketing authorizations, and the time required to obtain requisite approvals, may vary widely from country to country and differ from that required for FDA approval. We cannot assure you any of our product candidates will prove to be safe or effective, will receive regulatory approvals, or will be successfully commercialized.

Even if a product candidate receives regulatory approval, the approval is typically limited to specific clinical indications. Further, even after regulatory approval is obtained, subsequent discovery of previously unknown problems with a product may result in restrictions on its use or even complete withdrawal of the product from the market. Any FDA-approved products manufactured or distributed by us or on our behalf are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse events or experiences. Drug manufacturers and their subcontractors are required also to register their establishments with the FDA and state agencies, and are subject to periodic inspections by the FDA and state agencies for compliance with current Good Manufacturing Processes, or cGMP. The cGMP impose rigorous procedural and documentation requirements upon us and any manufacturers engaged by us. We cannot be certain that DMI or its present or future contract manufacturers or suppliers will be able to comply with cGMP regulations and other FDA regulatory requirements. Failure to comply with these requirements may result in, among other things, total or partial suspension of production activities, failure of the FDA to grant approval for marketing, and withdrawal, suspension, or revocation of marketing approvals.

If the FDA approves one or more of our product candidates, we and our contract manufacturers must provide certain updated safety and efficacy information to the FDA and other regulatory agencies. Product changes, as well as certain changes in the manufacturing process or facilities where the manufacturing occurs (or other post-approval changes) may necessitate additional FDA review and approval. The labeling, advertising, promotion, marketing and distribution of a drug product also must be in compliance with FDA and Federal Trade Commission, or FTC, requirements which include, among others, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA and FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing us to correct deviations from regulatory standards and enforcement actions that can include seizures, fines, injunctions and criminal prosecution.

The FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our product candidates. Moreover, increased attention to the containment of health care costs in the United States and in foreign markets could result in new government regulations that could cause an increase in our compliance, manufacturing, or other operating expenses, or decrease our gross margins on any product candidates we commercialize.

### *Regulatory Approval Process for NMEs*

FDA regulations require us to undertake a long and rigorous process before any of our NME product candidates may be marketed or sold in the United States. This regulatory process typically includes the following steps:

the performance of satisfactory preclinical laboratory and animal studies under the FDA's Good Laboratory Practices regulation;

the development and demonstration of manufacturing processes which conform to FDA-mandated cGMP;

the submission and acceptance of an Investigational New Drug ( IND ) application which must become effective before human clinical trials may begin in the United States;

obtaining the approval of Institutional Review Boards ( IRBs ), at each site where we plan to conduct a clinical trial to protect the welfare and rights of human subjects in clinical trials;

the successful completion of a series of adequate and well-controlled human clinical trials to establish the safety, purity, potency and efficacy of any product candidate for its intended use; and



---

## **Table of Contents**

the submission to, and review and approval by the FDA of a New Drug Application ( NDA ) before any commercial sale or shipment of a product.

This process requires a substantial amount of time and financial resources which we currently do not possess. Even if we obtain financing that can be directed to the NME product candidate approval process, there is not assurance this process will result in the granting of an approval for any of our product candidates on a timely basis, if at all.

### *Preclinical Testing*

Preclinical tests generally include laboratory evaluation of a product candidate, its chemistry, formulation, stability and toxicity, as well as certain animal studies to assess its potential safety and efficacy. Results of these preclinical tests, together with manufacturing information, analytical data and the clinical trial protocol, must be submitted to the FDA as part of an IND, which must become effective before human clinical trials can begin. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the intended conduct of the trials and imposes what is referred to as a clinical hold. Preclinical studies generally take several years to complete, and there is no guarantee that an IND based on those studies will become effective, allowing clinical testing to begin. In addition to FDA review of an IND, each medical site that desires to participate in a proposed clinical trial must have the protocol reviewed and approved by an independent IRB. The IRB considers, among other things, ethical factors, and the selection and safety of human subjects. Clinical trials must be conducted in accordance with the FDA's Good Clinical Practices requirements.

### *Clinical Trials*

Human clinical trials are typically conducted in three sequential phases:

- Phase 1. In Phase 1 clinical trials, a product candidate is typically introduced either into healthy human subjects or patients with the medical condition for which the new drug is intended to be used. The main purpose of the trial is to assess a product candidate's safety and the ability of the human body to tolerate the product candidate. Phase 1 clinical trials generally include less than 50 subjects or patients.
- Phase 2. During this phase, a product candidate is studied in an exploratory trial or trials in a limited number of patients with the disease or medical condition for which it is intended to be used in order to: (i) further identify any possible adverse side effects and safety risks, (ii) assess the preliminary or potential efficacy of the product candidate for specific target diseases or medical conditions, and (iii) assess dosage tolerance and determine the optimal dose for Phase 3 trial.
- Phase 3. If and when one or more Phase 2 trials demonstrate that a specific dose or range of doses of a product candidate is likely to be effective and has an acceptable safety profile, one or more Phase 3 trials are generally undertaken to demonstrate clinical efficacy and to further test for safety in an expanded patient population with the goal of evaluating the overall risk-benefit relationship of the product candidate. Phase 3 trials will generally be designed to reach a specific goal or endpoint, the achievement of which is intended to demonstrate the candidate product's clinical efficacy. The successful demonstration of clinical efficacy and safety in one or more Phase 3 trials is typically a prerequisite to the filing of a NDA for a product candidate.

We cannot be certain that we will successfully complete the Phase 1, Phase 2, or Phase 3 testing of our product candidates within any specific time period, if at all. Furthermore, The FDA or an IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

## **Table of Contents**

### *Post-Approval Regulation*

Even if a product candidate receives regulatory approval, the approval is typically limited to specific clinical indications. Further, even after regulatory approval is obtained, subsequent discovery of previously unknown problems with a product may result in restrictions on its use or even complete withdrawal of the product from the market. Any FDA-approved products manufactured or distributed by us are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse events or experiences. Further, drug manufacturers and their subcontractors are required to register their establishments with the FDA and state agencies, and are subject to periodic inspections by the FDA and state agencies for compliance with cGMP, which impose rigorous procedural and documentation requirements upon us and our contract manufacturers. We cannot be certain that we or our present or future contract manufacturers or suppliers will be able to comply with cGMP regulations and other FDA regulatory requirements. Failure to comply with these requirements may result in, among other things, total or partial suspension of production activities, failure of the FDA to grant approval for marketing, and withdrawal, suspension, or revocation of marketing approvals.

If the FDA approves one or more of our product candidates, we and our contract manufacturers must provide certain updated safety and efficacy information. Product changes, as well as certain changes in the manufacturing process or facilities where the manufacturing occurs or other post-approval changes may necessitate additional FDA review and approval. The labeling, advertising, promotion, marketing and distribution of a drug or biologic product also must be in compliance with FDA and Federal Trade Commission ( *FTC* ) requirements which include, among others, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA and *FTC* have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing us to correct deviations from regulatory standards and enforcement actions that can include seizures, fines, injunctions and criminal prosecution.

The FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our product candidates. Moreover, increased attention to the containment of health care costs in the United States and in foreign markets could result in new government regulations that could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

### *Fast Track Status and Orphan Drug*

The FDA has developed *Fast Track* policies, which provide the potential for expedited review of a NDA. However, there is no assurance that the FDA will, in fact, accelerate the review process for a *Fast Track* product candidate if we submit a product for that review. *Fast Track* status is provided only for those new and novel therapies that are intended to treat persons with life-threatening and severely debilitating diseases where there is a defined unmet medical need, especially where no satisfactory alternative therapy exists or the new therapy is significantly superior to alternative therapies. During the development of product candidates that qualify for this status, the FDA may expedite consultations and reviews of these experimental therapies. An accelerated approval process is potentially available to product candidates that qualify for this status and the FDA may expedite consultations and review of these experimental therapies. Further, an accelerated approval process is potentially available for product candidates that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses.

The FDA can base approval of a marketing application for a *Fast Track* product on an effect on a clinical endpoint, or on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may condition the approval of an application for certain *Fast Track* products to additional post-approval studies to validate the surrogate endpoint or confirm the effect on the clinical endpoint. *Fast Track* status also provides the potential for a product candidate to have a *Priority Review*. A *Priority Review* allows for portions of the NDA to be submitted to the FDA for review prior to the completion of the entire application, which could result in a reduction in the length of time it would otherwise take the FDA to complete its review of the NDA. *Fast Track* status may be revoked by the FDA at any time if the clinical results of a trial fail to continue to support the assertion that the respective product candidate has the potential to address and unmet medical need.

---

**Table of Contents**

The FDA may grant Orphan Drug status to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. If and when the FDA grants Orphan Drug status, the generic name and trade name of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Aside from guidance concerning the non-clinical laboratory studies and clinical investigations necessary for approval of the NDA, Orphan Drug status does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The FDA may grant Orphan Drug status to multiple competing product candidates targeting the same indications. A product that has been designated as an Orphan Drug that subsequently receives the first FDA approval is entitled to Orphan Drug exclusivity. This exclusivity means the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years from the date of the initial FDA approval. Orphan Drug approval may also provide certain tax benefits to the company that receives the first FDA approval. Finally, the FDA may fund the development of orphan products through its grants program for clinical studies.

*Foreign Regulatory Approval*

Outside of the United States, our ability to market DMI's product candidates will be contingent also upon our receiving marketing authorizations from the appropriate foreign regulatory authorities, whether or not FDA approval has been obtained. The foreign regulatory approval process in most industrialized countries generally encompasses risks similar to those we will encounter in the FDA approval process. The requirements governing conduct of clinical trials and marketing authorizations, and the time required to obtain requisite approvals, may vary widely from country to country and differ from that required for FDA approval.

*Europe*

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. The mutual recognition process results in separate national marketing authorizations in the reference member state and each concerned member state. We will seek to choose the appropriate route of European regulatory filing in an attempt to accomplish the most rapid regulatory approvals for our product candidates when ready for review. However, the chosen regulatory strategy may not secure regulatory approvals or approvals of the chosen product indications. In addition, these approvals, if obtained, may take longer than anticipated. We can provide no assurance that any of our product candidates will prove to be safe or effective, will receive required regulatory approvals, or will be successfully commercialized.

**Intellectual Property**

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. We also maintain trade secrets and proprietary know-how that we seek to protect through confidentiality and nondisclosure agreements. We expect to seek United States and foreign patent protection for drug and diagnostic products we discover, as well as therapeutic and diagnostic products and processes. We expect also to seek patent protection or rely upon trade secret rights to protect certain other technologies which may be used to discover and characterize drugs and diagnostic products and processes, and which may be used to develop novel therapeutic and diagnostic products and processes. These agreements may not provide meaningful protection or adequate remedies in the event of unauthorized use or disclosure of confidential and proprietary information. If we do not adequately protect our trade secrets and proprietary know-how, our competitive position and business prospects could be materially harmed.



## **Table of Contents**

The patent positions of companies such as ours involve complex legal and factual questions and, therefore, their enforceability cannot be predicted with any certainty. Our issued and licensed patents, and those that may be issued to us in the future, may be challenged, invalidated or circumvented, and the rights granted under the patents or licenses may not provide us with meaningful protection or competitive advantages. Our competitors may independently develop similar technologies or duplicate any technology developed by us, which could offset any advantages we might otherwise realize from our intellectual property. Furthermore, even if our product candidates receive regulatory approval, the time required for development, testing, and regulatory review could mean that protection afforded us by our patents may only remain in effect for a short period after commercialization. The expiration of patents or license rights we hold could adversely affect our ability to successfully commercialize our pharmaceutical drugs or diagnostics, thus harming our operating results and financial position.

We will be able to protect our proprietary intellectual property rights from unauthorized use by third parties only to the extent that such rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. If we must litigate to protect our intellectual property from infringement, we may incur substantial costs and our officers may be forced to devote significant time to litigation-related matters. The laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States.

Our pending patent applications, or those we may file or license from third parties in the future, may not result in patents being issued. Until a patent is issued, the claims covered by the patent may be narrowed or removed entirely, thus depriving us of adequate protection. As a result, we may face unanticipated competition, or conclude that without patent rights the risk of bringing product candidates to market exceeds the returns we are likely to obtain. We are generally aware of the scientific research being conducted in the areas in which we focus our research and development efforts, but patent applications filed by others are maintained in secrecy for at least 18 months and, in some cases in the United States, until the patent is issued. The publication of discoveries in scientific literature often occurs substantially later than the date on which the underlying discoveries were made. As a result, it is possible that patent applications for products similar to our drug or diagnostic candidates may have already been filed by others without our knowledge.

The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights, and it is possible that our development of product candidates could be challenged by other pharmaceutical or biotechnology companies. If we become involved in litigation concerning the enforceability, scope and validity of the proprietary rights of others, we may incur significant litigation or licensing expenses, be prevented from further developing or commercializing a product candidate, be required to seek licenses that may not be available from third parties on commercially acceptable terms, if at all, or subject us to compensatory or punitive damage awards. Any of these consequences could materially harm our business.

### **Competition**

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change as researchers learn more about diseases and develop new technologies and treatments. Significant competitive factors in our industry include product efficacy and safety; quality and breadth of an organization's technology; skill of an organization's employees and its ability to recruit and retain key employees; timing and scope of regulatory approvals; government reimbursement rates for, and the average selling price of, products; the availability of raw materials and qualified manufacturing capacity; manufacturing costs; intellectual property and patent rights and their protection; and sales and marketing capabilities.

There are many companies that are researching and developing ophthalmology products, and the competition among developed ophthalmology products is intense. Even if we develop a product candidate that receives regulatory approvals, it is likely that other companies in the ophthalmology industry could develop, purchase or license products that may address the same clinical indications. We cannot assure you that any ophthalmology product we succeed in developing will be clinically superior or scientifically preferable to products developed or introduced by our competitors.

## **Table of Contents**

Many of our actual and potential competitors have substantially longer operating histories and possess greater name recognition, product portfolios and significantly greater financial, research, and marketing resources than us. Among our smaller competitors, many of these companies have established co-development and collaboration relationships with larger pharmaceutical and biotechnology firms, which may make it more difficult for us to attract a strategic partner. Our current and potential competitors include major multinational pharmaceutical companies, biotechnology firms, universities and research institutions. Some of these companies and institutions, either alone or together with their collaborators, have substantially greater financial resources and larger research and development staffs than do we. In addition, many of these competitors, either alone or together with their collaborators, have significantly greater experience than us in discovering, developing, manufacturing, and marketing pharmaceutical products and diagnostics. If one of our competitors realizes a significant advance in pharmaceutical drugs or diagnostics that address one or more of the diseases targeted by our product candidates, our products or diagnostics could be rendered uncompetitive or obsolete.

Our competitors may also succeed in obtaining FDA or other regulatory approvals for their product candidates more rapidly than we are able to do, which could place us at a significant competitive disadvantage or deny us marketing exclusivity rights. Market acceptance of our product or diagnostic candidates will depend on a number of factors, including:

potential advantages over existing or alternative therapies or tests;

the actual or perceived safety of similar classes of products;

the effectiveness of sales, marketing, and distribution capabilities; and

the scope of any approval provided by the FDA or foreign regulatory authorities.

Although we believe our product candidates possess attractive attributes, we cannot assure you that our product candidates will achieve regulatory or market acceptance, or that we will be able to compete effectively in the pharmaceutical drug or diagnostic markets. If our product candidates fail to gain regulatory approvals and acceptance in their intended markets, we may not generate meaningful revenues or achieve profitability.

### **Research and Development**

Our strategy is to minimize fixed overhead by outsourcing much of our research and development activities. Through a sponsored research agreement, our discovery activities are conducted by Trauma Research LLC, or TRLLC, a limited liability company owned by Dr. David Bar-Or. Under the research agreement, TRLLC conducts drug and biomarker discovery and development programs at its research facilities, and we provide funding and some scientific personnel. Intellectual property from discovery programs conducted by TRLLC belongs to us, and we are solely responsible for protecting that intellectual property. While we have the right to generally request development work under the research agreement, TRLLC directs such work and is responsible for how the work is performed.

### **Compliance with Environmental Laws**

We believe we are in compliance with current material environmental protection requirements that apply to us or our business. Costs attributable to environmental compliance are not currently material.

### **Product Liability and Insurance**

The development, manufacture and sale of pharmaceutical products involve inherent risks of adverse side effects or reactions that can cause bodily injury or even death. Product candidates we succeed in commercializing could adversely affect consumers even after obtaining regulatory approval and, if so, we could be required to withdraw a product from the market or be subject to administrative or other proceedings. As we are not now manufacturing, marketing or distributing pharmaceutical products or diagnostics, we have elected not to obtain product liability

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

insurance at the current time. We expect to obtain clinical trial liability coverage for human clinical trials, and appropriate product liability insurance coverage for products we manufacture and sell for human consumption. The amount, nature and pricing of such insurance coverage will likely vary due to a number of factors such as the product candidate's clinical

## **Table of Contents**

profile, efficacy and safety record, and other characteristics. We may not be able to obtain sufficient insurance coverage to address our exposure to product recall or liability actions, or the cost of that coverage may be such that we will be limited in the types or amount of coverage we can obtain. Any uninsured loss we suffer could materially and adversely affect our business and financial position.

### **Facilities**

We maintain our headquarters in leased space in Greenwood Village, Colorado., for a monthly rental of \$2,400. The lease expires in April 2010. We anticipate that the lease can be renewed for an additional term of 12 months on terms similar to those now in effect.

### **Legal Proceedings**

We are currently not a party to any material legal or administrative proceedings and are not aware of any pending or threatened legal or administrative proceedings in which we will become involved. In 2005 and 2006, Isolagen, Inc. and certain of its current and former officers and directors were named as defendants in various class action suits that were later consolidated into a multi-district class action. The suit included purported claims for misrepresentations or omissions of material fact, violations of the registration provisions of the Securities Act of 1933, and violations of the Securities Exchange Act. Michael Macaluso, one of our directors, served as president and/or chief executive officer of Isolagen until September 2004, and as a director until May 2005, and was named as one of the defendants in this action. In September 2008, the suit was settled and a stipulation for dismissal was filed. Mr. Macaluso was not required to make any contribution to the settlement and obtained a full release as a condition of settlement.

### **Employees**

As of September 30, 2010, we had six full-time employees and utilized the services of a number of consultants on a part-time basis. Overall, we have not experienced any work stoppage and do not anticipate any work stoppage in the foreseeable future. Management believes that relations with our employees are good.

### **Corporate Information**

Our principal executive offices are located at 5445 DTC Parkway, P4, Greenwood Village, Colorado 80111 USA, and our phone number is (303) 418-1000.

**Table of Contents****MANAGEMENT****Executive Officers and Directors**

The following table sets forth the names, ages and positions of our executive officers and directors as of November 10, 2010.

<b>Name</b>	<b>Age</b>	<b>Position</b>
Michael Macaluso <sup>(1)(2)</sup>	58	Chairman of the Board
Donald B. Wingerter, Jr.	60	Chief Executive Officer and Director
David Bar-Or, M.D.	61	Chief Scientific Officer and Director
Bruce G. Miller	65	Chief Financial Officer
Dr. Vaughan Clift	49	Chief Regulatory Affairs Officer
Philip H. Coelho <sup>(1)(2)(3)</sup>	66	Director
Richard B. Giles <sup>(1)(2)(3)</sup>	60	Director

- (1) Member of our audit committee  
(2) Member of our compensation committee  
(3) Member of our corporate governance and nominating committee

*Michael Macaluso* founded Life Sciences and has been a member of the board of directors of Life Sciences, our predecessor, since its inception. Mr. Macaluso has also been a member of our board of directors since the merger with Chay Enterprises. Mr. Macaluso was appointed president of Isolagen, Inc. (AMEX: ILE) and served in that position from June 2001 to August 2001, when he was appointed chief executive officer. In June 2003, Mr. Macaluso was re-appointed as president of Isolagen and served as both chief executive officer and president until September 2004. Mr. Macaluso also served on the board of directors of Isolagen from June 2001 until April 2005. For information concerning Isolagen litigation in which Mr. Macaluso was named as a co-defendant with a number of other current and former officers and directors of Isolagen, see Legal Proceedings under Business above. From October 1998 until June 2001, Mr. Macaluso was the owner of Page International Communications, a manufacturing business. Mr. Macaluso was a founder and principal of International Printing and Publishing, a position Mr. Macaluso held from 1989 until 1997, when he sold that business to a private equity firm.

*Donald B. Wingerter, Jr.* has served as our Chief Executive Officer since December 2009 and a member of our board since March 2010. From 2006 until 2009, Mr. Wingerter has served as a member of the board of directors of several private companies in which he holds personal investments. From June 2002 until 2006, Mr. Wingerter served as chief executive officer of Sound Surgical Technologies, Inc., a specialty medical device company that developed and marketed proprietary ultrasonic-based products to break up and remove fat deposits from the human body. Mr. Wingerter was engaged in managing his personal investments from 2001 until June 2002. From 1995 to 2001, Mr. Wingerter was chairman of the board and chief executive officer of ClearVision Laser Centers, a company he founded in 1995 that operated centers providing laser vision correction services to consumers. ClearVision had operations in 14 states consisting of 10 centers utilizing fixed excimer lasers and 42 centers serviced by mobile lasers. In 2001, ClearVision was acquired by affiliates of two private equity firms. Before founding ClearVision, Mr. Wingerter served as chief executive officer and president, respectively, of Western Imaging Technologies and Accel Holdings, medical imaging companies that sold and leased magnetic resonance

## **Table of Contents**

imaging (MRI), positron emission tomography (PET), and computer tomography (CT) imaging equipment. He also spent 11 years in various sales positions with General Electric Medical Systems, the last of which was National Sales Manager for Digital Products. Mr. Wingerter holds a B.S. degree in biology from Lafayette College and a M.S. degree in physiology from Rutgers University.

*David Bar-Or, M.D.*, has served as a director and our chief scientific officer since the Chay Enterprises merger. Dr. Bar-Or also served as our chairman of the board from the closing of that merger until May 2010. From April 2009 until the closing of the Chay Enterprises merger, he served as chairman of the board and chief scientific officer of Life Sciences. Dr. Bar-Or is currently the director of Trauma Research at Swedish Medical Center, Englewood, Colorado, and St. Anthony's Hospital, Denver, Colorado. Dr. Bar-Or is principally responsible for the patented and proprietary technologies acquired by us from BioSciences in April 2009, having been issued over 50 patents and having filed or co-filed almost 120 patent applications. Dr. Bar-Or has authored or co-authored over 80 peer-reviewed journal articles and is the recipient of the Gustav Levi Award from the Hadassah/Mount Sinai Hospital, New York, New York, the Kornfield Award for an outstanding MD Thesis, the Outstanding Resident Research Award from the Denver General Hospital, and the Outstanding Clinician Award for the Denver General Medical Emergency Resident Program. Dr. Bar-Or received his medical degree from The Hebrew University, Hadassah Medical School, Jerusalem, Israel, and undertook post-graduate work at Denver Health Medical Center, specializing in emergency medicine, a discipline in which he is board certified.

*Bruce G. Miller* has served as our chief financial officer since April 2010 and has served as our chief operating officer from December 2009 until the present. He also served as the chief executive officer of Life Sciences from April 2009 until December 2009, and as a member of the board of directors from April 2009 until the Chay Enterprises merger. Thereafter, he served as a member of our board of directors until August 2010. Mr. Miller was the chief executive officer of BioSciences until we acquired BioSciences in September 2010. Mr. Miller joined BioSciences as an officer in 1992 and was named chief executive officer in 1992. Mr. Miller was instrumental in BioSciences securing a license agreement for the PE drug, which generated significant revenues for BioSciences. Prior to joining BioSciences, Mr. Miller was a practicing attorney for over 24 years with experience in diverse aspects of business law ranging from start-ups to acquisitions. While practicing law, he was a shareholder for six years in the Denver office of Popham, Haik, Schonbrich & Kaufman. Mr. Miller holds a J.D. degree from the University of Denver and a B.A. degree from Duke University.

*Philip H. Coelho* is currently the CEO and President of Synergenesis, Inc., a firm inventing and commercializing products that harness stem and progenitor cells derived from the patient's own body to treat human disease. Prior to founding Synergenesis in October 2009, Mr. Coelho was the President and CEO of PHC Medical, Inc, a consulting firm, from August 2008 through October 2009. From August 2007 through May 2008, Mr. Coelho served as the Chief Technology Architect of ThermoGenesis Corp. From 1989 through July 30, 2007, he was Chairman and Chief Executive Officer of ThermoGenesis Corp. Mr. Coelho served as Vice President of Research & Development of ThermoGenesis from 1986 through 1989. Mr. Coelho has been in the senior management of high technology consumer electronic or medical device companies for over 30 years. He was President of Castleton Inc. from 1982 to 1986, and President of ESS Inc. from 1971 to 1982. Mr. Coelho currently also serves as a member of the Board of Directors of two Nasdaq-listed companies, Catalyst Pharmaceuticals Partners, Inc. (since October 2002), and Medware Information Systems, Inc. (from December 2001 until July 2006, and commencing again in May 2008). Mr. Coelho received a B.S. degree in thermodynamic and mechanical engineering from the University of California, Davis and has been awarded more than 30 U.S. patents in the areas of cell cryopreservation, cryogenic robotics, cell selection, blood protein harvesting and surgical homeostasis.

*Richard B. Giles* currently serves as the Chief Financial Officer of Ludvik Electric Co., an electrical contractor headquartered in Lakewood, Colorado, a position he has held since 1985. Ludvik Electric is a private electrical contractor with 2009 revenues of over \$100 million that has completed electrical contracting projects throughout the Western United States, Hawaii, and South Africa. As CFO and Treasurer of Ludvik Electric, Mr. Giles oversees accounting, risk management, financial planning and analysis, financial reporting, regulatory compliance, and tax-related accounting functions. He serves also as the trustee of Ludvik Electric Co.'s 401(k) plan. Prior to joining Ludvik Electric, Mr. Giles was for three years an audit partner with Higgins Meritt & Company, then a Denver, Colorado CPA firm, and during the

---

**Table of Contents**

preceding nine years he was an audit manager and a member of the audit staff of Price Waterhouse, one of the legacy firms which now comprises PricewaterhouseCoopers. While with Price Waterhouse, Mr. Giles participated in a number of public company audits, including one for a leading computer manufacturer. Mr. Giles received a B.S. degree in accounting from the University of Northern Colorado and is a Certified Public Accountant. He is also a member of the American Institute of Certified Public Accountants and the Construction Financial Management Association.

*Family Relationships*

There are no family relationships between any of our directors or executive officers. Raphael Bar-Or, a non-executive officer, is the son of David Bar-Or, our chief scientific officer and a director.

*Employment Agreements*

Life Sciences previously entered into employment agreements with Dr. Bar-Or, Bruce G. Miller, and four non-executive officers, Dr. Vaughan Clift, Dr. James Winkler, Raphael Bar-Or, and Ms. Wannell Crook. In August and September 2010, we entered into a new employment agreement with Dr. Bar-Or, our chief scientific officer, and an employment agreement with Donald B. Wingerter, Jr., our chief executive officer. The new employment agreement with Dr. Bar-Or supersedes the prior agreement with Life Sciences. The terms of the employment agreements with Dr. Bar-Or and Mr. Wingerter are otherwise substantially identical, except as noted below. Each agreement has an initial term ending July 31, 2013. The agreements provide for annual salaries of \$145,000 for Mr. Wingerter and \$227,500 for Dr. Bar-Or, which will automatically increase to annual salaries of \$275,000 and \$300,000, respectively, following our receipt of financing in the amount of \$10 million or more. The Compensation Committee established the current salary levels to reflect our presently limited financial resources.

Each officer is entitled to receive an annual bonus each year that will be determined by the Compensation Committee of the board of directors based on individual achievement and company performance objectives established by the Compensation Committee. Included in those objectives, as applicable for the responsible officer, are (i) obtaining a successful phase 2 clinical trial for a drug to treat diabetic retinopathy, (ii) preparation and compliance with a fiscal budget, (iii) the launch of a second clinical trial for an additional product approved by the Board of Directors, and (iv) the sale of intellectual property not selected for clinical trials by the Company at prices, and times, approved by the Board of Directors. The targeted amount of the annual bonus shall be 50% of the base salary paid to each Officer, although the actual bonus may be higher or lower.

The employment agreements provide for an immediate grant of stock options to Mr. Wingerter and Drs. Bar-Or in the amount of 675,000 and 700,000 options, respectively. Each option is exercisable for a period of ten years at an exercise price per share equal to the quoted closing price of our common stock on August 11, 2010, the day immediately prior to the execution of the employment agreement. The options vest as follows: (i) one-third upon execution of the agreement, (ii) one-third on August 12, 2011, and (iii) one-third on August 12, 2012. The vesting of all options set forth above shall accelerate upon a change in control as defined in each agreement.

If the officer's employment is terminated at our election at any time, for reasons other than death, disability, cause (as defined in the agreement), or a voluntary resignation, or if an officer terminates his employment for good reason (as defined in the agreement), the officer in question shall be entitled to receive a lump sum severance payment equal to two times his base salary and of the continued payment of premiums for continuation of the officer's health and welfare benefits pursuant to COBRA or otherwise, for a period of two years from the date of termination, subject to earlier discontinuation if the officer is eligible for comparable coverage from a subsequent employer. All severance payments, less applicable withholding, are subject to the officer's execution and delivery of a general release of us and our subsidiaries and affiliates and each of their officers, directors, employees, agents, successors and assigns in a form acceptable to us, and a reaffirmation of the officer's continuing obligation under the propriety information and inventions agreement (or an agreement without that title, but which pertains to the officer's obligations generally, without limitation, to maintain and keep confidential all of our proprietary and confidential information, and to assign all inventions made by the officer to us, which inventions are made or conceived during the officer's employment).

**Table of Contents****Executive Compensation**

The following table sets forth all cash compensation paid by us, as well as certain other compensation paid or accrued in 2009 to each of the following named executive officers.

**Summary Compensation of Named Executive Officers**

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$) <sup>(1)</sup>	Non-Equity Incentive Plan Compensation (\$)	Change in Pension Value and Nonqualified Deferred Compensation Earnings <sup>(2)</sup> (\$)	All Other Compensation (\$)	Total (\$)
David Bar-Or Chairman and CSO	2009	\$ 227,500							\$ 227,500
Donald B. Wingerter, Jr. CEO from December 2009	2009								
Bruce G. Miller COO and CEO from April 2009 to December 2009	2009	\$ 180,000							180,000

Our executive officers will be reimbursed by us for any out-of-pocket expenses incurred in connection with activities conducted on our behalf.

*Director Independence and Board Committees*

We are not currently subject to the director independence and board committee requirements established by any other national securities exchange. Our board of directors is currently composed of five members. In endeavoring to add independent members to our board of directors and establish board committees, we intended to demonstrate our commitment to the corporate governance standards established by the national securities exchanges. The rules of the national stock exchanges require that, subject to specified exceptions, each member of a listed company's audit, compensation and corporate governance and nominating committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended. Under the rules of the national stock exchanges, a director will only qualify as an independent director if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

In order to be considered to be independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries.

In August 2010, our board of directors undertook a review of its composition, the composition of its committees and the independence of each director. Based upon information provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that none of Messrs. Macaluso, Coelho and Giles, representing three of our five



## **Table of Contents**

directors, has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is independent as that term is defined by the national securities exchanges. Our board of directors also determined that Messrs. Giles, Coelho and Macaluso, who comprise our audit committee and our compensation committee, and Messrs. Giles and Coelho, who comprise our nominating and corporate governance committee, satisfy the independence standards for those committees established by applicable SEC rules and the national stock exchanges. In making this determination, our board of directors considered the relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

We intend to list our securities on a national securities exchange at such time as we meet the initial listing criteria of one of such exchanges.

## **Board Committees**

Our board of directors has an audit committee, a compensation committee and a corporate governance and nominating committee, each of which has the composition and the responsibilities described below. The audit committee, compensation committee and corporate governance and nominating committee all operate under charters approved by our board of directors, which charters are available on our website.

*Audit Committee.* Our audit committee oversees our corporate accounting and financial reporting process and assists the board of directors in monitoring our financial systems and our legal and regulatory compliance. Our audit committee is responsible for, among other things:

selecting and hiring our independent auditors;

appointing, compensating and overseeing the work of our independent auditors;

approving engagements of the independent auditors to render any audit or permissible non-audit services;

reviewing the qualifications and independence of the independent auditors;

monitoring the rotation of partners of the independent auditors on our engagement team as required by law;

reviewing our financial statements and reviewing our critical accounting policies and estimates;

reviewing the adequacy and effectiveness of our internal controls over financial reporting; and

reviewing and discussing with management and the independent auditors the results of our annual audit, our quarterly financial statements and our publicly filed reports.

The members of our audit committee are Messrs. Giles, Coelho and Macaluso. Mr. Giles is our audit committee chairman and was appointed to our audit committee on August 10, 2010. Our board of directors has determined that each member of the audit committee meets the financial literacy requirements of the national stock exchanges and the SEC, and Mr. Giles qualifies as our audit committee financial expert as defined under SEC rules and regulations. Our board of directors has concluded that the composition of our audit committee meets the requirements for independence under the current requirements of the national

## **Table of Contents**

stock exchanges and SEC rules and regulations. We believe that the functioning of our audit committee complies with the applicable requirements of SEC rules and regulations, and will comply with the applicable requirements of one of the national stock exchanges when such provisions apply to us.

*Compensation Committee.* Our compensation committee oversees our corporate compensation policies, plans and programs. The compensation committee is responsible for, among other things:

reviewing and recommending policies, plans and programs relating to compensation and benefits of our directors, officers and employees;

reviewing and recommending compensation and the corporate goals and objectives relevant to compensation of our Chief Executive Officer;

reviewing and approving compensation and corporate goals and objectives relevant to compensation for executive officers other than our Chief Executive Officer;

evaluating the performance of our executive officers in light of established goals and objectives;

developing in consultation with our board of directors and periodically reviewing a succession plan for our Chief Executive Officer; and

administering our equity compensations plans for our employees and directors.

The members of our compensation committee are Messrs. Coelho, Giles and Macaluso. Mr. Coelho is the chairman of our compensation committee. Each member of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended, is an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, or the IRC, and satisfies the independence requirements of the national stock exchanges if such requirements applied to us. We believe that the composition of our compensation committee meets the requirements for independence under, and the functioning of our compensation committee complies with, any applicable requirements of the national securities exchanges and SEC rules and regulations. In restructuring our board of directors, we will seek candidates who will meet the director independence requirements for compensation committee members referenced above.

Our compensation committee and our board of directors have not yet established a succession plan for our Chief Executive Officer.

*Corporate Governance and Nominating Committee.* Our corporate governance and nominating committee oversees and assists our board of directors in reviewing and recommending corporate governance policies and nominees for election to our board of directors. The corporate governance and nominating committee is responsible for, among other things:

evaluating and making recommendations regarding the organization and governance of the board of directors and its committees;

assessing the performance of members of the board of directors and making recommendations regarding committee and chair assignments;

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

recommending desired qualifications for board of directors membership and conducting searches for potential members of the board of directors; and

reviewing and making recommendations with regard to our corporate governance guidelines.

## **Table of Contents**

The members of our corporate governance and nominating committee are currently Messrs. Giles and Coelho. Mr. Coelho is the chairman of our corporate governance and nominating committee. Our board of directors has determined that each member of our corporate governance and nominating committee is independent within the meaning of the independent director guidelines of the national stock exchanges, if such requirements applied to us.

Our board of directors may from time to time establish other committees.

### **Director Compensation**

Prior to the merger with Chay Enterprises in March 2010, our predecessor did not pay any director fees. Following the August 2010 appointment of Mr. Giles to the board of directors and the establishment of board committees, our compensation committee established the following fees for payment to members of our board of directors or committees, as the case may be:

Members of the Board will receive:

\$20,000 cash retainer for the Chairman, to be paid on January 2 each year.

\$10,000 cash retainer for each non-employee director other than the Chairman, to be paid January 2 of each year.

\$10,000 restricted stock grant to each director, to be granted on the first trading day of the calendar year.

\$1,000 per meeting fee plus reimbursement of expenses for in-person attendance at meetings.

\$500 per meeting fee for telephonic or web-based attendance at meetings.

Members of the Audit Committee will receive:

\$20,000 cash retainer for the Chairman of the Audit Committee, to be paid on January 2 of each year.

\$12,000 cash retainer for each Audit Committee member except the Chairman, to be paid on January 2 of each year.

\$2,500 meeting fee for the Chairman of the Audit Committee for each meeting attended in- person.

\$1,500 meeting fee for the Chairman of the Audit Committee for each meeting attended telephonically or via the Internet.

\$1,500 meeting fee for members of the Audit Committee for each meeting attended in- person.

\$1,000 meeting fee for members of the Audit Committee for each meeting attended telephonically or via the Internet.

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

Members of the Compensation Committee and the Nominating and Governance Committee will each receive (*i.e.*, a separate cash retainer in the noted amount shall be paid to the Chair and members of each committee, and for each meeting of each committee, the meeting fees noted will be payable to each attending Chair or member):

\$20,000 cash retainer for the Chairman of each Committee, to be paid on January 2 of each year.

\$10,000 cash retainer for each member of each Committee, to be paid on January 2 of each year.

**Table of Contents**

\$2,500 meeting fee for the Chairman of each Committee for each meeting attended in- person.

\$1,500 meeting fee for the Chairman of each Committee for each meeting attended telephonically or via the Internet.

\$1,500 meeting fee for members of each Committee for each meeting attended in- person.

\$1,000 meeting fee for members of each Committee for each meeting attended telephonically or via the Internet.

**Code of Business Conduct and Ethics**

We have adopted a code of business conduct that is applicable to all of our employees, officers and directors. In addition, we have adopted a code of ethics that is applicable to our chief executive and senior financial officers.

**Compensation Committee Interlocks and Insider Participation**

None of the members of our compensation committee is an officer or employee of our company. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

---

**Table of Contents**

**RELATED PARTY TRANSACTIONS**

In addition to the director and executive compensation arrangements discussed above in Management, we, Life Sciences or BioSciences have been a party to the following transactions since October 1, 2008 in which the amount involved exceeded or will exceed \$120,000, and in which any director, executive officer or holder of more than 5% of any class of our voting stock, or any member of the immediate family of or entities affiliated with any of them, had or will have a material interest.

In April 2009, Life Sciences issued 3,500,000 shares of its common stock to BioSciences, an entity under common control, in connection with Life Sciences' purchase of certain of BioSciences' assets. Under the terms of the agreement, Life Sciences acquired office and lab equipment, cell lines and intellectual property including patents and license agreements. In conjunction with the asset purchase, Life Sciences recorded a distribution of \$252,015 to reflect liabilities assumed. Included in the assumed liabilities was a \$200,000 note payable to Life Sciences' founder, Michael Macaluso. The note payable was subsequently converted by Mr. Macaluso into 163,934 shares of Series A preferred stock at a conversion price of \$1.22 per share.

As of December 31, 2009, Life Sciences had \$100,000 in notes payable to Mike Macaluso, Life Sciences' founder, and \$100,000 payable to BioSciences. The related party notes payable are unsecured, bear interest at 6% and matured on April 30, 2010. These notes were extended through September 2, 2010, and additional borrowings of \$200,000 were made by us from BioSciences in the three months ended June 30, 2010. The \$300,000 in total borrowings from BioSciences were cancelled on our acquisition of BioSciences. The note payable to Mr. Macaluso has been extended to become due at the earlier of January 1, 2011, or on closing of a financing exceeding \$10 million.

BioSciences paid operating expenses on behalf of Life Sciences, and funds were advanced and repaid between Life Sciences and BioSciences, during 2009. Disbursements to BioSciences during 2009, including prepayment of liabilities assumed under the asset purchase agreement, totaled \$111,943. BioSciences owed \$7,261 to Life Sciences in a short-term non-interest bearing advance at December 31, 2009.

In April 2009, Life Sciences issued 7,350,000 shares of restricted common stock to its directors, officers and employees in exchange for \$7,350 in cash. One third of the restricted shares vested on the date of grant. The remaining two thirds vest on a monthly basis between the second and fourth anniversaries of the date of grant. Vesting is subject to acceleration upon achieving certain milestones.

Life Sciences issued 913,930 shares of its Series A preferred stock in April and May 2009 in exchange for \$1,115,020 in cash. Mr. Macaluso purchased 819,672 of such shares of preferred stock. All such preferred stock was converted into our common stock on the merger of Life Sciences with a subsidiary of Chay.

Life Sciences has a sponsored research agreement with Trauma Research LLC, or TRLLC, an entity owned by Dr. Bar-Or. Under the terms of the research agreement, Life Sciences is to provide personnel and equipment with an equivalent value of \$263,750 per year and to make monthly equipment rental payments of \$7,236 on behalf of TRLLC. In exchange, TRLLC will assign any intellectual property rights it develops under the research agreement. The research agreement expires in 2014 and may be terminated by either party on six months' notice or immediately if either party determines that the other is not fulfilling its obligations under the agreement. Life Sciences was current in its financial obligations under the research agreement at June 30, 2010.

Life Sciences has license agreements with the Institute for Molecular Medicine, Inc. a nonprofit research organization founded by Dr. Bar-Or, who also serves as its executive director. The license agreements were assigned to Life Sciences as a part of the asset purchase from BioSciences. Under the license agreements, Life Sciences pays the costs associated with obtaining and maintaining intellectual property subject to the license agreements. In the license covering certain Methylphenidate derivatives, Life Sciences is entitled to deduct twice the amounts it has paid to maintain the intellectual property from any amounts that may become due to the Institute for Molecular Medicine, Inc. under the license agreement, if and when the intellectual property becomes commercially viable and generates revenue. Life Sciences paid \$53,000 during 2009 in legal and patent fees to maintain the intellectual property of the Institute for Molecular Medicine, Inc.

---

## **Table of Contents**

Immediately prior to the closing of the merger between Life Sciences and a subsidiary of Chay, Chay accepted subscriptions for an aggregate of 1,325,000 shares of common stock from six officers and employees of Life Sciences, for a purchase price of \$150,000. Mr. Wingerter, our chief executive officer, purchased 325,000 of such shares for a purchase price of approximately \$36,800 which was advanced on his behalf by Life Sciences. Dr. Clift's spouse purchased 575,000 shares for a purchase price of approximately \$65,000 which was likewise advanced by Life Sciences. Life Sciences made advances to the other four non-executive officers and employees in the additional amount of approximately \$48,000 to facilitate these share purchases. These shares were issued immediately before the closing of the Chay merger but after the shareholders of Chay had approved the merger.

In August 2010, Michael Macaluso and Richard B. Giles, both members of our board of directors, together with an affiliate of Mr. Giles, purchased convertible debentures from us for \$430,000. The debentures were issued in principal amounts of \$230,000, \$100,000 and \$100,000, respectively, to Mr. Macaluso, Mr. Giles, and James A. Ludvik. Mr. Ludvik is the sole owner of Ludvik Electric Co., for which Mr. Giles serves as the chief financial officer. The debentures accrue interest at the rate of 8% per annum. The debentures are convertible into our common stock at the lower of (i) \$1.75 per share, or (ii) the per-share price at which we issue common stock in an underwritten offering. The conversion price may be adjusted pursuant to the other terms of the debentures. The debentures are due and payable at the earlier of one business day after the closing of an underwritten offering or January 31, 2011. The debenture terms specified that we were obligated to obtain an extension of the \$400,000 in principal amount of promissory notes previously issued to BioSciences to a due date consistent with the maturity date of the debentures, and required us to obtain a subordination agreement from BioSciences, Inc., such that the debentures will jointly constitute our senior unsecured indebtedness. The BioSciences debt will be extinguished on final closing of the BioSciences merger.

In conjunction with the issuance of the debentures, we issued warrants to the debenture purchasers representing the right to purchase an aggregate of 21,500 shares of our common stock at an exercise price equal to the price at which we sell common stock in an underwritten offering or if no offering, the lowest price between April 1, 2011 and May 31, 2011. The warrant exercise price is subject to adjustment for stock splits, stock dividends, and the like. We paid no commission in connection with the sale of the debentures and the warrants, and did not engage a placement agent to assist it in the sale of these unregistered securities.

In the event that we issue additional debentures on terms that are more favorable to the purchasers than the terms extended to Messrs. Macaluso, Giles and Ludvik, we have agreed that we will ascribe most favored nation status to the debenture holders and will conform the terms of the debentures such that the terms are as favorable to the initial purchasers as any other debenture issued thereafter until maturity.

### **Indemnification of Officers and Directors**

We have entered into indemnification agreements with each of our directors and executive officers. The indemnification agreements and our certificate of incorporation and bylaws require us to indemnify our directors and executive officers to the fullest extent permitted by Delaware law.

### **Policies and Procedures for Related Party Transactions**

We have adopted a formal written policy that our executive officers, directors, nominees for election as directors, beneficial owners of more than 5% of any class of our common stock and any member of the immediate family of any of the foregoing persons, are not permitted to enter into a related party transaction with us without the prior consent of our audit committee, subject to the pre-approval exceptions described below. If advance approval is not feasible then the related party transaction will be considered at the audit committee's next regularly scheduled meeting. In approving or rejecting any such proposal, our audit committee is to consider the relevant facts and circumstances available and deemed relevant to our audit committee, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related party's interest in the transaction. Our board of directors has delegated to the chair of our audit committee the authority to pre-approve or ratify any request for us to enter into a transaction with a related party, in which the amount involved is less than \$120,000 and where the chair is not the related party. Our audit committee has also reviewed certain types of related party transactions that it has deemed pre-approved even if the aggregate amount involved will exceed \$120,000 including, employment of executive officers, director compensation, certain transactions with other organizations, transactions where all stockholders receive proportional benefits, transactions involving competitive bids, regulated transactions and certain banking-related services. All of the transactions described above were entered into prior to the adoption of this policy.



**Table of Contents****PRINCIPAL STOCKHOLDERS**

The following table sets forth information regarding beneficial ownership of our common stock as of November 10, 2010 and as adjusted to reflect the issuance of the Merger Stock to the BioSciences shareholders, by:

each person or group of affiliated persons known by us to be the beneficial owner of more than 5% of our common stock;

each of our named executive officers;

each of our directors; and

all executive officers and directors as a group.

We have determined beneficial ownership in accordance with SEC rules. The information does not necessarily indicate beneficial ownership for any other purpose. Under these rules, the number of shares of common stock deemed outstanding includes shares issuable upon exercise of options and warrants held by the respective person or group which may be exercised or converted within 60 days after November 10, 2010. For purposes of calculating each person's or group's percentage ownership, stock options, debentures convertible, and warrants exercisable within 60 days after November 10, 2010 are included for that person or group but not the stock options, debentures, or warrants of any other person or group.

Applicable percentage ownership before the merger is based on 22,107,036 shares of common stock outstanding at November 10, 2010. Applicable percentage ownership after the merger gives effect to the issuance of 8,500,000 shares of our common stock in connection with the BioSciences acquisition that was closed in escrow pending the registration of the shares of common stock to be issued to the BioSciences shareholders.

Unless otherwise indicated and subject to any applicable community property laws, to our knowledge, each stockholder named in the following table possesses sole voting and investment power over the shares listed. Unless otherwise noted below, the address of each stockholder listed on the table is c/o Ampio Pharmaceuticals, Inc., 5445 DTC Parkway, P4, Greenwood Village, Colorado 80111.

<b>Name of Beneficial Owner</b>	<b>Number of Shares Beneficially Owned</b>	<b>Percentage of Shares Beneficially Owned</b>
Michael Macaluso	2,892,601	16.4%
Donald B. Wingerter, Jr.	525,000	3.0%
David Bar-Or	2,950,000	17.0%
Bruce G. Miller	1,500,000	8.8%
Philip H. Coelho	225,000	1.3%
Richard B. Giles	384,657	2.2%
Kristin Clift(1)	696,667	4.0%
Genesis Capital Management(2)	1,596,794	9.3%
All executive officers and directors as a group (seven persons)	7,593,925	40.6%

(1)

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

Ms. Clift is the spouse of Dr. Vaughan Clift, our Chief Regulatory Affairs Officer. Dr. Clift holds options to acquire 121,667 shares of common stock which are included in the noted shares.

- (2) Represents Ampio shares of common stock that are issuable to Genesis Capital Management, Biotechnology Fund and Genesis Investment Funds Limited, which are shareholders of BioSciences. The address of all such entities is Trust House, 112 Bonadie Street, Kingtown, Saint Vincent & The Grenadines.

**Table of Contents**

**DESCRIPTION OF CAPITAL STOCK**

**General**

The following is a summary of the rights of our common stock and preferred stock and of certain provisions of our certificate of incorporation and bylaws. For more detailed information, please see our certificate of incorporation and bylaws, which are filed as exhibits to the registration statement of which this prospectus is part.

*Authorized and Issued Capital Stock*

Our authorized capital stock consists of 100,000,000 shares of common stock, par value \$0.0001 per share, of which 17,107,036 shares are issued and outstanding, and 2,000,000 shares of undesignated preferred stock, \$0.0001 par value, of which no shares are issued or outstanding.

*Common Stock*

As of November 10, 2010, there were 17,107,036 shares of our common stock outstanding held by approximately 250 shareholders of record. Upon closing of the BioSciences acquisition, the number of shares of our common stock outstanding will increase to 22,107,036. Holders of common stock will have voting rights for the election of our directors and all other matters requiring stockholder action, except with respect to amendments to our certificate of incorporation that alter or change the powers, preferences, rights or other terms of any outstanding preferred stock if the holders of such affected series of preferred stock are entitled to vote on such an amendment. There is no cumulative voting with respect to the election of directors, with the result that the holders of more than 50% of the shares voted for the election of directors can elect all of the directors. Holders of common stock will be entitled to one vote per share on matters to be voted on by stockholders and also will be entitled to receive such dividends, if any, as may be declared from time to time by our board of directors in its discretion out of funds legally available therefor. The payment of dividends, if ever, on the common stock will be subject to the prior payment of dividends on any outstanding preferred stock, of which there is currently none. Upon our liquidation or dissolution, the holders of common stock will be entitled to receive *pro rata* all assets remaining available for distribution to stockholders after payment of all liabilities and provision for the liquidation of any shares of preferred stock at the time outstanding. Our stockholders have no conversion, preemptive or other subscription rights and there are no sinking fund or redemption provisions applicable to the common stock.

*Preferred Stock*

Our certificate of incorporation provides that shares of preferred stock may be issued from time to time in one or more series. Our board of directors will be authorized to fix the voting rights, if any, designations, powers, preferences, the relative, participating, optional or other special rights and any qualifications, limitations and restrictions thereof, applicable to the shares of each series. Our board of directors will be able to, without stockholder approval, issue preferred stock with voting and other rights that could adversely affect the voting power and other rights of the holders of the common stock and could have anti-takeover effects. The ability of our board of directors to issue preferred stock without stockholder approval could have the effect of delaying, deferring or preventing a change of control of us or the removal of existing management. We have no preferred stock outstanding at the date hereof. Although we do not currently intend to issue any shares of preferred stock, we cannot assure you that we will not do so in the future.

*Dividends*

We have not paid any dividends on our common stock to date. It is the present intention of our board of directors to retain any earnings for use in our business operations and, accordingly, we do not anticipate the board declaring any dividends in the foreseeable future.

## **Table of Contents**

### *Our Transfer Agent*

The transfer agent for our securities is Corporate Stock Transfer, Inc., 3200 Cherry Creek Drive South, Suite 430, Denver, Colorado 80209.

### *Certain Anti-takeover Provisions of Delaware Law and our Certificate of Incorporation and By-Laws*

As a Delaware corporation, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally has an anti-takeover effect for transactions not approved in advance by our board of directors. This may discourage takeover attempts that might result in payment of a premium over the market price for the shares of common stock held by stockholders. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a three-year period following the time that such stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A business combination includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; or

upon consummation of the transaction which resulted in the stockholder becoming an interested outstanding, shares owned by:

persons who are directors and also officers, and

employee stock plans, in some instances; or

at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

### *Staggered board of directors*

Our Delaware certificate of incorporation and by-laws provide that our board of directors will be classified into three classes of directors of approximately equal size at a date selected by the board. As a result, in most circumstances, a person can gain control of our board only by successfully engaging in a proxy contest at two or more annual meetings.

### *Stockholder action; special meeting of stockholders*

Our Delaware certificate of incorporation provides that following an underwritten offering, our stockholders may not take any action by written consent, but only take action at duly called annual or special meetings of stockholders. Our by-laws further provide that special meetings of our stockholders may be only called by our board of directors with a majority vote of our board of directors, by our chief executive officer or our chairman.

### *Advance notice requirements for stockholder proposals and director nominations*

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

Our Delaware by-laws provide that stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders, must provide timely notice of their intent in writing. To be timely, a stockholder's notice needs to be delivered to our principal executive offices not later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual

## **Table of Contents**

meeting of stockholders. For the 2011 annual meeting of stockholders, a stockholder's notice shall be timely if delivered to our principal executive offices not later than the 90th day prior to the scheduled date of the annual meeting of stockholders or the 10th day following the day on which public announcement of the date of our annual meeting of stockholders is first made or sent by us. Our by-laws also specify certain requirements as to the form and content of a stockholders' meeting. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders.

### *Authorized but unissued shares*

Our authorized but unissued shares of common stock and preferred stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

### *Removal of directors*

Our Delaware certificate of incorporation provides that a director on our board of directors may be removed from office only for cause and only by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of our directors.

### *Limitation on Liability and Indemnification of Directors and Officers*

Our Delaware certificate of incorporation and by-laws provide that our directors and officers will be indemnified by us to the fullest extent authorized by Delaware law as it now exists or may in the future be amended, against all expenses and liabilities reasonably incurred in connection with their service for or on our behalf. In addition, our certificate of incorporation provides that our directors will not be personally liable for monetary damages to us for breaches of their fiduciary duty as directors, unless they violated their duty of loyalty to us or our stockholders, acted in bad faith, knowingly or intentionally violated the law, authorized unlawful payments of dividends, unlawful stock purchases or unlawful redemptions, or derived an improper personal benefit from their actions as directors. Our by-laws also permit us to secure insurance on behalf of any officer, director or employee for any liability arising out of his or her actions, regardless of whether Delaware law would permit indemnification.

These provisions may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. Furthermore, a stockholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. We believe that these provisions, insurance and the indemnity agreements are necessary to attract and retain talented and experienced directors and officers.

There is no pending litigation or proceeding involving any of our directors or officers where indemnification by us would be required or permitted. We are not aware of any threatened litigation or proceeding that might result in a claim for such indemnification. Insofar as indemnification for liabilities arising under the Securities Act of 1933 (the "Act") may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

### *Registration rights*

Redwood Consultants, LLC has certain "piggy-back" registration rights under which we have agreed to pay the expenses of registering shares of common stock owned by Redwood on the filing of a registration statement. All such shares were transferred by Redwood to Constellation Asset Management LLC and Sunrise Capital LLC on or about July 14, 2010. We believe the beneficial owners of Redwood also control Constellation but have not verified this belief.

**Table of Contents***Listing*

We intend to apply to have our common stock listed on a national stock exchange at such time as our common stock qualifies for a listing. Our common stock is traded in the over-the-counter market and is now quoted on the OTC Bulletin Board, an NASD-sponsored and operated inter-dealer automated quotation system for equity securities.

*Securities Authorized for Issuance Under Equity Compensation Plans*

At the special meeting of our shareholders on March 1, 2010, our shareholders approved the adoption of our Stock and Option Award Plan, under which 2,500,000 shares are reserved for future issuance under restricted stock awards, options, and other equity awards. The plan permits grants of equity awards to employees, directors and consultants. On August 15, 2010, the number of shares issuable under the plan was increased to 4,500,000 shares by consent of our majority stockholders. The following table displays equity compensation plan information as of November 10, 2010.

*Equity Compensation Plan Information*

	<b>Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (a)</b>	<b>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)</b>	<b>Number of Securities Remaining Available for Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)</b>
Equity compensation plans approved by security holders	4,500,000	\$	1,600,000
Equity compensation plans not approved by security holders			
<b>Total</b>	<b>4,500,000</b>	<b>\$</b>	<b>1,600,000</b>

**Table of Contents**

**SHARES ELIGIBLE FOR FUTURE SALE**

To date there has been a very limited public market for shares of our common stock. Future sales of substantial amounts of shares of our common stock, including shares issued upon the exercise of outstanding options, in the public market after the closing of the BioSciences merger, or the possibility of these sales occurring, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future.

On closing of the BioSciences merger, a total of 22,107,036 shares of common stock will be outstanding, assuming that there are no exercises of options or warrants after November 10, 2010. Of these shares, the 8,500,000 shares of common stock issued to the BioSciences shareholders will be freely tradable in the public market without restriction or further registration under the Securities Act, unless these shares are held by affiliates, as that term is defined in Rule 144 under the Securities Act. A total of 300,000 shares of common stock that were sold in a previous registered public offering by Chay are also freely tradable.

The remaining 13,307,036 shares of common stock are restricted securities, as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below.

Subject to the lock-up agreements described in the Underwriting section below and the provisions of Rules 144 and 701 under the Securities Act, these restricted securities will be available for sale in the public market as follows:

Date	Number of shares
On the date of this prospectus	0
By March 3, 2011	
By May 31, 2011	

In addition, of the 2,900,000 shares of our common stock that were subject to stock options outstanding as of November 10, 2010, options to purchase 1,820,000 shares of common stock were vested as of November 10, 2010.

**Rule 144**

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell such shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144. Our affiliates or persons selling shares on behalf of our affiliates are entitled to sell, within any three-month period beginning 90 days after the date of this prospectus, a number of shares that does not exceed the greater of:

1% of the number of shares of common stock then outstanding, which will equal approximately 221,000 shares; or



## **Table of Contents**

the average weekly trading volume of the common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

### **Rule 701**

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701.

### **Stock Options**

We intend to file a registration statement on Form S-8 under the Securities Act covering all of the shares of our common stock subject to options outstanding or reserved for issuance under our stock plan and shares of our common stock issued upon the exercise of options. We expect to file this registration statement in 2011. However, the shares registered on Form S-8 will be subject to volume limitations, manner of sale, notice and public information requirements of Rule 144.

### **Lock-Up Agreements**

BioSciences shareholders owning in the aggregate 6,807,695 shares of our common stock have agreed, pursuant to individual lock-up agreements, not to (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or securities convertible into or exercisable or exchangeable for any shares of our common stock, or (ii) enter into any swap or other arrangement that transfers, in whole or in part, any of the economic consequences associated with the ownership of any shares of common stock or any such other securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of common stock or such other securities, without our prior written consent until May 31, 2011

The foregoing restrictions on sales will not apply to (A) shares of common stock acquired in open market transactions; (B) transfers of shares of common stock or any other securities (i) to an immediate family member or a trust formed for the direct or indirect benefit of the stockholder or an immediate family member of the stockholder or (ii) by bona fide gift, will or intestacy; (C) if the stockholder is a business entity, distributions of shares of common stock or any other securities to (i) members, partners, stockholders or other equity owners of the stockholder, (ii) wholly-owned subsidiaries or any affiliates of the stockholder, or (iii) any business entity that is managed and governed by the same management company as the stockholder or any business entity that is controlled by, under common control with, managed or advised by the same management company or registered investment advisor (or an affiliate of such management company or registered investment advisor) as the stockholder; (D) if the stockholder is a trust, transfers of shares of common stock or any other securities to a trustor or beneficiary of the trust; provided that in the case of any transfer or distribution pursuant to clauses (B), (C) or (D), each transferee, donee or distributee shall execute and deliver to us a lock-up agreement of like tenor.

**Table of Contents**

**MATERIAL UNITED STATES FEDERAL INCOME TAX AND ESTATE TAX**

**CONSEQUENCES TO NON-U.S. HOLDERS**

The following is a summary of the material U.S. federal income tax and estate tax consequences of the ownership and disposition of our common stock to non-U.S. holders, but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon the provisions of the Internal Revenue Code, Treasury regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income or estate tax consequences different from those set forth below.

This summary does not address the tax considerations arising under the laws of any non-U.S., state or local jurisdiction or under U.S. federal gift and estate tax laws, except to the limited extent below. In addition, this discussion does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

banks, insurance companies or other financial institutions;

persons subject to the alternative minimum tax;

tax-exempt organizations;

controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;

dealers in securities or currencies;

traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;

persons that own, or are deemed to own, more than five percent of our capital stock, except to the extent specifically set forth below;

certain former citizens or long-term residents of the United States;

persons who hold our common stock as a position in a hedging transaction, straddle, conversion transaction or other risk reduction transaction;

persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Internal Revenue Code (generally, for investment purposes); or

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

persons deemed to sell our common stock under the constructive sale provisions of the Internal Revenue Code.

In addition, if a partnership or entity classified as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships that hold our common stock, and partners in such partnerships, should consult their tax advisors.

**YOU ARE URGED TO CONSULT YOUR TAX ADVISOR WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO YOUR PARTICULAR SITUATION, AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX RULES OR UNDER THE LAWS OF ANY STATE, LOCAL, NON-U.S. OR OTHER TAXING JURISDICTION OR UNDER ANY APPLICABLE TAX TREATY.**

## **Table of Contents**

### **Non-U.S. Holder Defined**

For purposes of this discussion, you are a non-U.S. holder if you are any holder, other than a partnership or entity classified as a partnership for U.S. federal income tax purposes, which is not:

an individual citizen or resident of the United States;

a corporation or other entity taxable as a corporation created or organized in the United States or under the laws of the United States or any political subdivision thereof;

an estate whose income is subject to U.S. federal income tax regardless of its source; or

a trust (x) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (y) which has made an election to be treated as a U.S. person.

### **Distributions**

We have not made any distributions on our common stock and we do not plan to make any distributions for the foreseeable future. However, if we do make distributions on our common stock, those payments will constitute dividends for U.S. tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, they will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock.

Any dividend paid to you generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. In order to receive a reduced treaty rate, you must provide us with an IRS Form W-8BEN or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate. A non-U.S. holder of shares of our common stock eligible for a reduced rate of U.S. withholding tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by filing an appropriate claim for refund with the IRS. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

Dividends received by you that are effectively connected with your conduct of a U.S. trade or business, and, if an income tax treaty applies, attributable to a permanent establishment maintained by you in the United States, are exempt from such withholding tax. In order to obtain this exemption, you must provide us with an IRS Form W-8ECI or other applicable IRS Form W-8 properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are generally taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. In addition, if you are a corporate non-U.S. holder, dividends you receive that are effectively connected with your conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty.

## **Table of Contents**

### **Gain on Disposition of Common Stock**

You generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

the gain is effectively connected with your conduct of a U.S. trade or business, and, if an income tax treaty applies, the gain is attributable to a permanent establishment maintained by you in the United States;

you are an individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met; or

our common stock constitutes a U.S. real property interest by reason of our status as a United States real property holding corporation, or a USRPHC, for U.S. federal income tax purposes, at any time within the shorter of the five-year period preceding the disposition or your holding period for our common stock.

We believe that we are not currently and will not become a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as a U.S. real property interest only if you actually or constructively hold more than five percent of such regularly traded common stock at any time during the applicable period described above.

If you are a non-U.S. holder described in the first point above, you will generally be required to pay tax on the gain derived from the sale, net of certain deductions or credits, under regular graduated U.S. federal income tax rates, and corporate non-U.S. holders described in the first bullet above may be subject to branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. If you are an individual non-U.S. holder described in the second bullet above, you will be required to pay a flat 30% tax on the gain derived from the sale, which tax may be offset by U.S. source capital losses, even though you are not considered a resident of the United States. You should consult any applicable income tax or other treaties that may provide for different rules.

### **Federal Estate Tax**

Our common stock beneficially owned by an individual who is not a citizen or resident of the United States, as defined for U.S. federal estate tax purposes, at the time of death will generally be includable in the decedent's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax treaty provides otherwise.

### **Backup Withholding and Information Reporting**

Generally, we must report annually to the IRS the amount of dividends paid to you, your name and address, and the amount of tax withheld, if any. A similar report will be sent to you. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence.

Payments of dividends or of proceeds on the disposition of stock made to you may be subject to additional information reporting and backup withholding at a current rate of 28% unless you establish an exemption, for example by properly certifying your non-U.S. status on a Form W-8BEN or another appropriate version of IRS Form W-8. Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or our paying agent has actual knowledge, or reason to know, that you are a U.S. person.

**Table of Contents**

Backup withholding is not an additional tax; rather, the U.S. income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

**Recently Enacted Legislation Affecting Taxation of Our Common Stock Held By or Through Foreign Entities**

Recently enacted legislation generally will impose a U.S. federal withholding tax of 30% on dividends and the gross proceeds of a disposition of our common stock paid after December 31, 2012 to a foreign financial institution, as specially defined under these rules, unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution, which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners. The legislation also will generally impose a U.S. federal withholding tax of 30% on dividends and the gross proceeds of a disposition of our common stock paid after December 31, 2012 to a non-financial foreign entity unless such entity provides the withholding agent with a certification identifying the direct and indirect U.S. owners of the entity. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of this legislation on their investment in our common stock.

**THE PRECEDING DISCUSSION OF U.S. FEDERAL TAX CONSIDERATIONS IS FOR GENERAL INFORMATION ONLY. IT IS NOT TAX ADVICE. EACH INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, STATE AND LOCAL AND NON-U.S. TAX CONSEQUENCES OF HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.**

**Table of Contents**

**LEGAL MATTERS**

The validity of the shares of common stock offered hereby will be passed upon for us by Richardson & Patel, Los Angeles, California. A lawyer who is of counsel to Richardson & Patel, LLP holds options to acquire 75,000 shares of our common stock, and Richardson & Patel, LLP holds options to acquire 25,000 shares of our common stock.

**EXPERTS**

The Ampio Pharmaceuticals, Inc. consolidated financial statements as of December 31, 2008 and 2009 and for each of the two years in the period ended December 31, 2009 included in this prospectus have been so included in reliance on the report of Ehrhardt Keefe Steiner & Hottman PC, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting. The DMI BioSciences, Inc. consolidated financial statements as of September 30, 2008 and 2009 and for each of the two years in the period ended September 30, 2009 included in this prospectus have been so included in reliance on the report of Ehrhardt Keefe Steiner & Hottman PC, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

**WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock we are registering. The registration statement, including the attached exhibits, contains additional relevant information about us and our common stock. This prospectus does not contain all of the information set forth in the registration statement and the exhibits thereto. The rules and regulations of the SEC allow us to omit from this prospectus certain information included in the registration statement.

For further information about us and our common stock, you may inspect a copy of the registration statement and the exhibits to the registration statement without charge at the offices of the SEC at 100 F Street, N.E., Washington, D.C. 20549. You may obtain copies of all or any part of the registration statement from the Public Reference Section of the SEC, 100 F Street, N.E., Washington, D.C. 20549 upon the payment of the prescribed fees.

You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website at [www.sec.gov](http://www.sec.gov) that contains reports, proxy and information statements and other information that we and other public companies file electronically with the SEC. You can also inspect our registration statement and our other public filings on this website, and may review future filings we make with the SEC at this website.

**Table of Contents**

**AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**(A Development Stage Company)**

**Consolidated Financial Statements**

**and**

**Independent Auditors Report**

**December 31, 2009 and 2008**

F-1



**Table of Contents**

**AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**(A Development Stage Company)**

**Table of Contents**

	<b>Page</b>
<u>Independent Auditors Report</u>	F-3
Consolidated Financial Statements	
<u>Balance Sheets</u>	F-4
<u>Statements of Operations</u>	F-5
<u>Statement of Changes in Stockholders Equity</u>	F-6
<u>Statements of Cash Flows</u>	F-7
<u>Notes to Consolidated Financial Statements</u>	F-8

F-2

**Table of Contents**

**INDEPENDENT AUDITORS REPORT**

Board of Directors and Stockholders

Ampio Pharmaceuticals, Inc. and Subsidiaries

Greenwood Village, CO

We have audited the accompanying balance sheets of DMI Life Sciences, Inc. ( a development stage company) as of December 30, 2008 and 2009, and the related statements of operations, changes in stockholders equity and cash flows for the years then ended. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of DMI Life Sciences, Inc. as of December 31, 2008 and 2009, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

Ehrhardt Keefe Steiner & Hottman PC

March 8, 2010

Denver, Colorado

**Table of Contents****AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES**

(A Development Stage Company)

**Consolidated Balance Sheets**

	June 30, 2010 (unaudited)	December 31, 2009                      2008	
<b>Assets</b>			
Current assets			
Cash and cash equivalents	\$ 131,035	\$ 71,983	\$
Restricted cash	105,000		
Prepaid expenses	49,523	7,036	
Related party receivable	7,238	7,261	
<b>Total current assets</b>	<b>292,796</b>	<b>86,280</b>	
Fixed Assets	2,423		
<b>Total assets</b>	<b>\$ 295,219</b>	<b>\$ 86,280</b>	<b>\$</b>
<b>Liabilities and Stockholders Equity (Deficit)</b>			
Current liabilities			
Accounts payable	357,234	\$ 79,445	\$
Accrued salaries	196,353	73,391	
Accrued interest	7,595	1,414	
Related party notes payable	400,000	200,000	
<b>Total current liabilities</b>	<b>961,182</b>	<b>354,250</b>	
<b>Total liabilities</b>	<b>961,182</b>	<b>354,250</b>	
Stockholder equity			
Common Stock, par value \$0.0001 in 2010 and \$0.001 in 2009 and 2008; shares authorized - 100,000,000 shares in 2010 and 15,000,000 shares in 2009 and 2008, shares issued and outstanding - 17,107,036 in 2010 and 11,930,000 and 1,080,000, respectively in 2009 and 2008	1,711	11,930	1,080
Series A Preferred Stock, \$.001 par value; 2,000,000 shares authorized, shares issued and outstanding - 1,077,864 in 2009 and none in 2008 (liquidation preference of \$1,314,942)		1,078	
Common stock subscribed		170,003	
Additional paid in capital	4,664,552	1,313,942	
Issuances for promotion	(788,958)		
Advances to shareholders	(150,183)		
Deficit accumulated in the development stage	(4,393,085)	(1,764,923)	(1,080)
<b>Total stockholders equity (deficit)</b>	<b>(665,963)</b>	<b>(267,970)</b>	
<b>Total liabilities and stockholders equity (deficit)</b>	<b>\$ 295,219</b>	<b>\$ 86,280</b>	<b>\$</b>

See notes to financial statements.

F-4

**Table of Contents****AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES****(A Development Stage Company)****Consolidated Statements of Operations**

	Six Month Ended June 30		Year ended December 31, 2009	December 18,	December 18,
	2010 (unaudited)	2009 (unaudited)		(inception) through December 31, 2008	(inception) through June 30, 2009
<b>Expenses</b>					
Research and development	589,999	258,725	\$ 1,070,370	\$	\$ 1,660,369
General and administrative	2,032,560	148,934	441,135	1,080	2,473,695
Total operating expenses	2,622,559	407,659	1,511,505	1,080	4,134,044
<b>Other income (expense)</b>					
Interest income	578	252	1,091		1,669
Interest expense	(6,181)		(1,414)		(7,595)
Total other income (expense)	(5,603)	252	(323)		(5,926)
<b>Net loss</b>	<b>\$ (2,628,162)</b>	<b>\$ (407,407)</b>	<b>\$ (1,511,828)</b>	<b>\$ (1,080)</b>	<b>\$ (4,139,990)</b>
Weighted average number of common shares outstanding	15,456,332	10,022,308	8,787,650	1,080,000	
Basis and diluted net loss per common share	\$ (0.17)	\$ (0.04)	(0.17)	(0.00)	

See notes to financial statements.

Table of Contents

## AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES

(A Development Stage Company)

## Consolidated Statements of Stockholders Equity

	Series A Preferred Stock		Common Stock		Additional Paid in Capital	Common Stock Subscribed	Additional Issuances	Receivable From Stockholders	Deficit Accumulated During the Development Stage	Total Stockholders Equity
	Shares	Amount	Shares	Amount						
Balance - December 18, 2008 (date of inception)		\$		\$	\$	\$	\$			
Issuance of common stock to founder in December 2008			1,080,000	1,080			1,080			
Net loss						(1,080)	(1,080)			
Balance - December 31, 2008			1,080,000	1,080		(1,080)				
Issuance of common stock and assumption of liabilities in asset acquisition			3,500,000	3,500		(252,015)	(248,515)			
Issuance of Series A Preferred Stock in exchange for cancellation of a note payable in April 2009	163,934	164			199,836		200,000			
Issuance of restricted Common Stock in exchange for cash in April 2009	913,930	914	7,350,000	7,350			7,350			
Issuance of Series A Preferred Stock in exchange for cash in April							1,115,020			

Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

and May 2009									
Net loss						(1,511,828)		(1,511,828)	
Balance - December 31, 2009	1,077,864	\$ 1,078	11,930,000	\$ 11,930	\$ 1,313,942	\$ (1,764,923)		\$ (437,973)	
Conversion of equity in reverse merger acquisition (unaudited)	(1,077,864)	(1,078)	3,068,958	(10,430)		11,691			183
Common stock subscribed in March 2010 (unaudited)					7,000				7,000
Issuance of common stock in exchange for cash in March and June 2010, net of offering costs of \$350,000 (unaudited)			1,078,078	108	(177,003)	1,536,522			1,359,627
Issuance of common stock for services (unaudited)			1,030,000	103		1,802,397	(788,958)		1,013,542
Loans to shareholders (unaudited)							(150,183)		(150,183)
Net loss (unaudited)							(2,628,162)		(2,628,162)
Balance - June 30, 2010 (unaudited)		\$	17,107,036	\$ 1,711	\$	\$ 4,664,552	\$ (788,958)	\$ (150,183)	\$ (4,393,085) \$ (665,963)

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

**Table of Contents****AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES**

(A Development Stage Company)

**Consolidated Statements of Cash Flows**

	Six Months Ended June 30, 2010 (unaudited)	Six Months Ended June 30, 2009 (unaudited)	Year ended December 31, 2009	December 18, 2008 (inception) through December 31, 2008	December 18, 2008 (inception) through June 30, 2009 (unaudited)
Cash flows from operating activities:					
Net loss	\$ (2,628,162)	\$ (407,407)	\$ (1,511,828)	\$ (1,080)	\$ (4,139,990)
Common stock issued for services	1,013,542				1,013,542
Adjustments to reconcile net loss to cash used in operating activities:					
(Increase) in prepaid expenses	(42,487)	(10,002)	(7,036)		(49,523)
Decrease (increase) in related party receivable	23	(8,445)	(7,261)		(7,238)
Increase (decrease) in accounts payable	277,789	(11,343)	79,445		357,234
Increase in accrued salaries	122,962		73,391		196,353
Increase in accrued interest payable	6,181		1,414		7,595
Net cash used in operating activities	(1,250,152)	(437,197)	(1,371,875)	(1,080)	(2,622,027)
Cash flow used in investing activities					
Purchase of fixed assets	(2,423)				(2,423)
Net cash used in investing activities	(2,423)				(2,423)
Cash used in financing activities:					
Proceeds from related party notes payable	200,000		200,000		400,000
Proceeds from sale of common stock	1,359,627	7,125	7,350	1,080	1,366,977
Proceeds from sale of Series A preferred stock		1,115,020	1,115,020		1,115,020
Advances made to shareholders	(150,183)				(150,183)
Proceeds from common stock subscribed	7,000		170,003		177,003
Transfer of funds into escrow	(125,000)				(125,000)
Payment of liabilities assumed in asset purchase		(48,515)	(48,515)		(48,515)
Release of funds from escrow	20,000				20,000
Increase in cash from acquisition	183				183
Net cash provided by financing activities	1,311,627	1,073,630	1,443,858	1,080	2,755,485
Net change in cash and cash equivalents	59,042	636,433	71,983		131,035
Cash and cash equivalents at beginning of period	71,983				
Cash and cash equivalents at end of period	\$ 131,035	\$ 636,433	\$ 71,983	\$	\$ 131,035

Supplementary cash flow information:



Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

Interest paid	\$	\$	\$	\$	\$
Income taxes paid	\$	\$	\$	\$	\$
Interest received			\$ 1,091	\$	
Non cash transactions:					
Note payable assumed in asset purchase, recorded as a distribution	\$	\$ 200,000	\$ 200,000	\$	\$ 200,000
Accounts payable assumed in asset purchase, recorded as a distribution	\$	\$ 48,515	\$ 48,515	\$	\$ 48,515
Conversion		200,000			200,000
Common stock	177,003				177,003
Deferred change	1,802,500				1,802,500
Conversion of notes payable to Series A preferred stock	\$	\$ 200,000	\$ 200,000	\$	\$ 200,000
		See notes to financial statements.			

F-7

**Table of Contents**

**AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**(A Development Stage Company)**

**Notes to Consolidated Financial Statements**

**(Information as to June 30, 2010 and 2009 is unaudited)**

**Note 1 Description of Business and Summary of Significant Accounting Policies**

***Nature of Operation***

These financial statements represent the consolidated financial statements of Ampio Pharmaceuticals, Inc. (Ampio), formerly known as Chay Enterprises, Inc. (Chay), and its wholly owned subsidiaries, DMI Life Sciences, Inc. (DMI) and DMI Acquisition Corp.

On March 2, 2010, DMI merged with Chay Acquisitions, a wholly-owned subsidiary of Chay Enterprises, Inc., a public company (the Merger). Chay issued 15,068,942 shares of common stock to acquire DMI, which resulted in the stockholders of DMI owning approximately 95.7% of Chay's outstanding common stock after the consummation of the Merger and before taking into account the issuance of 1,325,000 additional shares of common stock as described in Footnote 8 Related Party Transactions. In conjunction with the Merger, Chay purchased 263,624 shares of its common stock from the Chay Control Shareholders for \$150,000 in cash.

As a result of the Merger, DMI became a wholly owned subsidiary of Chay. For accounting purposes, the merger was treated as a reverse acquisition with DMI as the acquirer and Chay as the acquired party. As a result, the business and financial information included in the report is the business and financial information of DMI. The accumulated deficit of Chay has been included in additional paid in capital. Pro-forma information has not been presented as the financial information of Chay was significant.

Subsequent to the Merger, Chay Enterprises, Inc. was renamed Ampio Pharmaceuticals, Inc.

The preparation of our consolidated financial statements and related disclosures in conformity with generally accepted accounting principles in the United States (GAAP) requires us to make estimates and judgments that affect the amounts reported in our financial statements and accompanying notes. The statements reflect all normal recurring adjustments, which, in the opinion of the Ampio's management, are necessary for the fair presentation of financial position, results of operations and cash flows for the periods presented.

***Cash and Cash Equivalents***

Ampio considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents consist primarily of money market investments. Ampio maintains balances from time to time in excess of the federally insured limits.

***Restricted Cash***

Restricted cash of \$105,000 as of June 30, 2010 represents cash placed in escrow pursuant to the put agreement described in the commitments and contingencies footnote.

***Patents***

Costs of establishing patents consisting of legal fees paid to third parties are expensed as incurred.

***Use of Estimates***

The preparation of financial statements in accordance with Generally Accepted Accounting Principles in the United States ( GAAP ) requires management to make estimates and assumptions that affect the reported amounts assets and liabilities, disclosures of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from these estimates.

*Income Taxes*

Ampio uses the liability method for accounting for income taxes. Under this method, Ampio recognizes deferred assets and liabilities based on the differences between the tax basis of assets and liabilities and their reported amounts in the financial statements that will result in taxable or deductible amounts in future years. Ampio establishes a valuation allowance for all deferred tax assets for which there is uncertainty regarding realization.

---

**Table of Contents**

**AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**(A Development Stage Company)**

**Notes to Consolidated Financial Statements**

**Note 1 Description of Business and Summary of Significant Accounting Policies**

***Net Loss per Common Share***

GAAP provides for the calculation of Basic and Diluted earnings per share. Basic earnings per share include no dilution and are computed by dividing income available to common stockholders by the weighted-average number of shares outstanding during the period. Diluted earnings per share reflect the potential of securities that could share in the earnings of the Company, similar to fully diluted earnings per share. Basic and diluted loss per share was the same in 2009 and 2008. Although there were common stock equivalents of 1,227,864 shares zero shares, zero shares and \$1,077,864 outstanding at December 31, 2009 and 2008 and June 30, 2010 (unaudited) and 2009 (unaudited), respectively, consisting of stock options and convertible Series A Preferred Stock; they were not included in the calculation of earnings per share because they would have been anti-dilutive.

***Stock-Based Compensation***

Ampio accounts for share based payments by recognizing compensation expense based upon the estimated fair value of the awards on the date of grant. Ampio determines the estimated grant fair value using the Black-Scholes option pricing model and recognizes compensation costs ratably over the vesting period using the straight-line method.

***Research and Development***

Research and development costs are expensed as incurred and totaled \$1,070,370 and \$0 for 2009 and 2008, respectively; and \$589,999 and \$258,725 for the six months ended June 30, 2010 (unaudited) and 2009 (unaudited), respectively.

***Fair Value of Financial Instruments***

GAAP defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value hierarchy established by GAAP prioritizes the inputs into valuation techniques used to measure fair value. Accordingly, the Company uses valuation techniques that maximize the use of observable inputs when determining fair value. The three levels of the hierarchy are as follows:

- Level 1: Inputs that reflect unadjusted quoted prices in active markets that are accessible to us for identical assets or liabilities;
- Level 2: Inputs include quoted prices for similar assets and liabilities in active or inactive markets or that are observable for the asset or liability either directly or indirectly; and
- Level 3: Unobservable inputs that are supported by little or no market activity.

Ampio has no assets or liabilities that were measured using quoted prices for similar assets and liabilities or significant unobservable inputs (Level 2 and Level 3 assets and liabilities) as of December 31, 2009. Ampio's financial instruments include cash and cash equivalents, prepaid expenses, accounts payable, accrued salaries and accrued interest payable. The carrying amounts of these financial instruments approximate their fair value due to their short maturities. The carrying value of cash held in money market funds totaling \$69,357, \$0, \$130,783, \$700,240 as of December 31, 2009 and 2008 and June 30, 2010 (unaudited) and 2009 (unaudited), respectively, is included in cash and cash equivalents on the Balance Sheet and approximates market values based on quoted market prices, or Level 1 Inputs.



**Table of Contents****AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES****(A Development Stage Company)****Notes to Consolidated Financial Statements****Note 2 Income Taxes**

DMI's effective tax rate differs from the U.S. federal corporate income tax rate for 2009 and 2010 of 34% as follows:

Statutory rate	(34.0)%
State income taxes, net of federal income tax impact	(3.3)
Research and development credits	4.5
Increase in valuation allowance	32.8
<b>Effective tax rate</b>	<b>0.0%</b>

As of December 31, 2009, Ampio provided a full valuation allowance against the deferred tax asset based on the weight of available evidence, both positive and negative, including the Ampio's operating loss, which indicated that it is more likely than not that such benefits will not be realized.

Deferred tax assets comprised of the following:

	2010	June 30, 2009	December 31, 2009
<b>Deferred tax assets</b>			
Net operating loss and credit carryforwards	\$ 1,465,000	\$ 229,000	\$ 494,000
Research and development credits	185,000	9,000	67,748
Accrued liabilities	68,000		22,000
<b>Total deferred tax asset</b>	<b>1,709,000</b>	<b>238,000</b>	<b>583,748</b>
Valuation allowance	(1,709,000)	(238,000)	(583,748)
<b>Net deferred tax asset</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>

As of December 31, 2009, DMI had an available net operating loss (NOL) carry forward of approximately \$1,422,000 for federal and state purposes, expiring in 2029, and research and development credit carryforwards of approximately \$67,000. Under the provisions of the Internal Revenue Code, certain substantial changes in the Company's ownership may result in limitations on the amount of the NOL carryforwards which can be utilized in future years.

The Company classifies penalty and interest expense related to income tax liabilities as general and administrative expense and therefore is recognized in the statement of operations.

The Company files tax returns in the United States and in the state of Colorado. The tax years since inception remain open to examinations by the major taxing jurisdictions to which the Company is subject.

Income taxes for 2008 were immaterial.

F-10

---

**Table of Contents**

**AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**(A Development Stage Company)**

**Notes to Consolidated Financial Statements**

**Note 3 Related Party Notes Payable**

As of December 31, 2009, Ampio had \$100,000 in notes payable to DMI's founder and \$100,000 payable to DMI BioSciences, Inc (BioSciences). As of June 30, 2010, Ampio had \$100,000 in notes payable to DMI's founder and \$300,000 payable to DMI BioSciences, Inc. The related party notes payable are unsecured, bear interest at 6% and mature on September 2, 2010. The Company accrued interest on these notes of \$1,414, \$0, \$6,181 and \$0 for the years ended December 2009 and 2008 and the six months ended June 30, 2010 (unaudited) and 2009 (unaudited), respectively.

**Note 4 Equity**

***Capital Transactions***

Ampio issued 1,080,000 shares of Common Stock to its founder in December 2008 at a value of \$.001 per share.

Ampio issued 3,500,000 shares of Common Stock to BioSciences, an entity under common control, in April 2009 in connection with an Asset Purchase Agreement. Under the terms of the agreement, Ampio acquired office and lab equipment, cell lines and intellectual property including patents and license agreements, while the Company valued those assets in excess of \$300,000, for financial reporting purposes the assets and liabilities have been recorded at predecessor cost. In conjunction with the asset purchase, Ampio recorded a distribution of \$252,015 to reflect liabilities assumed. Included in the assumed liabilities was a \$200,000 note payable to Ampio's founder. The note payable was converted into 163,934 shares of Series A preferred stock at a value of \$1.22 per share.

Ampio issued 7,350,000 shares of restricted Common Stock to its directors, officers and employees in exchange for \$7,350 in cash in April 2009. The restricted common stock is subject to vesting as set forth below.

Ampio issued 913,930 shares of Series A Preferred Stock in April and May 2009 in exchange for \$1,115,020 in cash.

Ampio received \$170,002 in December 2009 in connection with a private placement for the purchase of 97,144 shares of common stock. Ampio had not issued the shares as of December 31, 2009 and has therefore recorded the proceeds as a liability.

As set forth in Note 1 Basis of Presentation and Merger, DMI and Chay completed a reverse merger in March 2010. In conjunction with the Merger, DMI's Series A Preferred Stock was automatically converted into common stock. As result of the Merger, related stock transactions and the conversion of Series A Preferred Stock, Ampio common stock outstanding increased by 3,068,958 shares.

Ampio issued 1,031,078 shares of common stock in March 2010 for \$1,454,380 in cash (net of \$350,000 in offering costs), of which \$170,003 had been received in 2009 and previously classified as common stock subscribed.

Ampio issued 1,030,000 shares of common stock in January, February and March 2010 in exchange for services. The shares were recorded at their fair value, \$1.75 per share or \$1,802,500. Ampio recorded \$363,125 and \$1,013,542 as expense in the three and six months ended June 30, 2010, respectively. The remaining \$788,958 is reflected as a deferred charge in stockholders' equity, and will be recognized into expense as the services are provided.

Ampio issued 47,000 shares of Common Stock in April 2010 for \$82,250 in cash, of which \$7,000 had been received in March 2010 and was previously classified as common stock subscribed.



## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

Immediately prior to the Merger, Chay accepted subscriptions for an aggregate of 1,325,000 shares of common stock from six officers and employees of DMI, for a purchase price of \$150,183. DMI made advances to the six officers and employees in the aggregate amount of \$150,183 to facilitate the share purchases by the six purchasers. These shares were issued immediately before the closing of the Merger. The advances are non-interest bearing and due on demand and are classified as a reduction to stockholder's equity.

### ***Restricted Common Stock***

Total shares of 7,350,000 sold to Ampio's employees are restricted. One third of the restricted shares vested on the date of grant, April 17, 2009. The remaining two thirds vest on a monthly basis between the second and fourth anniversaries of the date of grant. Vesting is subject to acceleration upon achieving certain milestones.

### ***Series A Preferred Stock***

The holders of the Series A Preferred Stock have rights and preferences summarized as follows. In conjunction with the merger, DMI's Series A Preferred Stock was automatically converted into Common Stock.

**Table of Contents**

**AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**(A Development Stage Company)**

**Notes to Consolidated Financial Statements**

**Note 4 Equity (continued)**

***Series A Preferred Stock (continued)***

*Dividends*

The Series A Preferred Stock carries an 8% non-cumulative dividend.

*Conversion*

The Series A Preferred Stock is convertible to Common Stock on a 1 for 1 basis at the option of the Series A Preferred Shareholders. The Series A Preferred Stock automatically converts to Common Stock on any public offering, any merger with a publicly traded shell corporation, or with the consent of holders of a majority of the Series A Preferred Stock.

*Liquidation Preference*

The Series A Preferred Stockholders are entitled to receive \$1.22 per share (as adjusted for stock splits) plus declared but unpaid dividends prior to any distribution to the holders of the Common Stock.

*Voting*

The Series A Preferred Stockholders are entitled to vote on an as-if converted to Common Stock basis.

*Protective Provisions*

As long as 20% of the Series A Preferred Stock remains outstanding, the consent of the holders of a majority of the Series A Preferred Stock will be required to amend the certificate of incorporation or bylaws, declare any dividend or redeem any shares, or sell the company.

***Equity Incentive Plan***

Ampio adopted the 2009 Equity Incentive Plan (the Plan) during 2009. Under the Plan, Ampio may issue stock awards to employees, directors and consultants. Ampio is authorized to grant up to 550,000 shares of stock awards. Pricing and vesting are determined by the board of directors and, and awards are evidenced by an award agreement extended to the recipient. Stock options generally vest over four years and terminate 10 years from the date of grant.

Ampio adopted a stock plan in March 2010. The stock plan reserves up to 2,500,000 shares of common stock for issuance to officers, directors, employees and consultants through various means, including incentive stock options, non-qualified stock options, restricted stock grants, and other forms of equity equivalents. As of August 12, 2010, Ampio had issued options with respect to all 2,500,000 shares reserved under the plan.

***Stock-Based Compensation***

Stock based compensation related to common stock issued to third party vendors in exchange for services of \$363,125 and \$1,013,542 in the three and six months ended June 30, 2010, respectively, was included in general and administrative expenses in the statement of operations. The common stock was recorded at its fair value at the dates Ampio became obligated to issue the shares, and is recognized as expense as the

services are provided.

F-12

---

**Table of Contents**

**AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**(A Development Stage Company)**

**Notes to Consolidated Financial Statements**

**Note 5 Related Party Transactions**

Ampio entered into an Asset Purchase Agreement during 2009 with BioSciences. Under the Asset Purchase Agreement, Ampio acquired office and lab equipment, cell lines and intellectual property including patents and license agreements and assumed liabilities as set forth in Note 5 Equity. This transaction was accounted for as a reverse merger and the assets acquired and liabilities assumed were recorded at predecessor cost. The assets had \$0 carrying value on the predecessor financial statements and liabilities totaled \$252,015. In conjunction with the Asset Purchase Agreement, the parties entered into a Royalty Agreement which granted Ampio with a 10% revenue royalty based upon license revenue that BioSciences receives, subject to Ampio committing to additional funding.

BioSciences paid operating expenses on behalf of Ampio, and funds have been advanced and repaid between Ampio and BioSciences during 2009. Disbursements to BioSciences during 2009, including prepayment of liabilities assumed under the Asset Purchase Agreement totaled \$111,943. BioSciences owed \$7,261 to DMI in a short-term non-interest bearing advance at December 31, 2009.

Ampio entered into a number of financing transactions with related parties as set forth in Note 3 Related Party Notes Payable and Note 4 Equity.

Related party receivable at June 30, 2010 consisted of \$1,527 receivable from OMI Bio Sciences, Inc. and \$5,711 from the Chay Control Shareholders.

Ampio has a Sponsored Research Agreement with Trauma Research LLC (TRLLC), a related for-profit research organization. Under the terms of the Sponsored Research Agreement, Ampio is to provide personnel and equipment with an equivalent value of \$263,750 per year and to make monthly equipment rental payments of \$7,236 on behalf of TRLLC. In exchange, TRLLC will assign any intellectual property rights it develops under the Sponsored Research Agreement. The Sponsored Research Agreement expires in 2014 and may be terminated by either party on six months notice or immediately if either party determines that the other is not fulfilling its obligations under the agreement. There were no outstanding liabilities related to the Sponsored Research Agreement at December 31, 2009 or June 30, 2010.

Ampio has license agreements with the Institute for Molecular Medicine, Inc. a related nonprofit research organization. The license agreements were assigned to Ampio as a part of the Asset Purchase Agreement with BioSciences. Under the license agreements, Ampio pays the costs associated with maintaining intellectual property subject to the license agreements. In return, Ampio is entitled to deduct twice the amounts it has paid to maintain the intellectual property from any amounts that may become due to the Institute for Molecular Medicine, Inc. under the license agreements, if and when the intellectual property becomes commercially viable and generates revenue. Ampio paid \$53,000 during 2009 in legal and patent fees to maintain the intellectual property of the Institute for Molecular Medicine, Inc.

**Note 6 Commitments and Contingencies**

As condition of the Merger, Ampio and certain of its stockholders (the Guarantors) and the Chay Control Shareholders entered into a Securities Put and Guarantee Agreement, or the Put Agreement. The Put Agreement provides that if Ampio is not successful in obtaining a minimum of \$5.0 million in financing, within 150 days after the closing of the Merger, the Chay Control Shareholders will have the right to put back to Ampio all of the Chay common stock then owned by the Chay Control Shareholders for a put price of \$250,000, subject to adjustment. Under the Put Agreement, the Guarantors agreed to jointly guarantee the payment of the put price by Ampio if the put right becomes exercisable in accordance with its terms. In addition, Ampio placed into escrow a cash deposit of \$125,000 that will be paid to the Chay Control Shareholders in the event the put right becomes exercisable by its terms. If paid to the Chay Control Shareholders in accordance with the escrow agreement, such payment will reduce the amount the Guarantors would be required to pay on exercise of the put right by the Chay Control Shareholders. The Chay Control Shareholders released to Ampio \$20,000 of the funds in escrow in June 2010 and \$75,000 in July 2010. The Chay Control Shareholders have not exercised their put right.

**Note 7 Subsequent Events**

F-13

**Table of Contents**

**AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**(A Development Stage Company)**

**Notes to Consolidated Financial Statements**

**Note 6 Subsequent Events (continued)**

During August 2010, Ampio issued \$430,000 in principal amount of 8% Senior Convertible Unsecured Debentures due January 31, 2011 (the Debentures ) together with warrants to related parties.

The Debentures are convertible into the Ampio s common stock at the lower of \$1.75 per share, or the per-share price at which the Company issues common stock in an underwritten offering of \$10,000,000 (the Offering). The Debentures are due and payable at the earlier of one business day after the closing of the Offering or January 31, 2011. The Debenture terms specify that Ampio is obligated to obtain an extension of the \$400,000 in principal amount of promissory notes previously issued to DMI BioSciences, Inc., to a due date consistent with the maturity date of the Debentures, and require Ampio to obtain a subordination agreement from DMI BioSciences, Inc., such that the Debentures will jointly constitute the senior unsecured indebtedness of Ampio.

In conjunction with the issuance of the Debentures, the Company issued Warrants to the purchasers of the Debentures giving them the right to purchase an aggregate of 21,500 shares of the Company s common stock at an exercise price equal to the price at which the Company sells common stock in the Offering.

During August 2010, Ampio issued options to purchase 2,500,000 shares of common stock to its officers, directors and general counsel. The stock options have an exercise price of \$1.01 per share and have a term of ten years.

During August 2010, Ampio entered into employment agreements with one of its officers. Ampio expects to enter into employment agreements with two additional officers on or about August 18, 2010. Under the employment agreements, the officers are collectively entitled to receive \$415,000 in annual salaries. Upon completion of a financing of \$10,000,000 or more, the annual salaries will collectively increase to \$780,000. The employment agreements have terms of three years.

**Table of Contents**

**AMPIO PHARMACEUTICALS, INC.**

**Financial Statements**

**and**

**Independent Auditors Report**

F-15

**Table of Contents**

**DMI BIOSCIENCES, INC.**

**Table of Contents**

	<b>Page</b>
<u>Independent Auditors Report</u>	F-17
Financial Statements	
<u>Balance Sheets</u>	F-18
<u>Statements of Operations</u>	F-19
<u>Statement of Changes in Stockholders Equity</u>	F-20
<u>Statements of Cash Flows</u>	F-21
<u>Notes to Financial Statements</u>	F-22
<u>Selected Unaudited Pro Forma Consolidated Financial Data</u>	F-33
<u>Pro Forma Unaudited Consolidated Statement of Operations</u>	F-34 to F-37
<u>Pro Forma Unaudited Consolidated Balance Sheet</u>	F-38

F-16



**Table of Contents**

**INDEPENDENT AUDITORS REPORT**

Board of Directors and Stockholders

DMI BioSciences, Inc.

Denver, Colorado

We have audited the accompanying balance sheets of DMI BioSciences, Inc. ( BioSciences ) as of September 30, 2009 and 2008, and the related statements of operations, changes in stockholders equity, and cash flows for the years then ended. These financial statements are the responsibility of BioSciences management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company s internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of BioSciences as of September 30, 2009 and 2008, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Ehrhardt Keefe Steiner & Hottman PC

September 2, 2010

Denver, Colorado

F-17

**Table of Contents****DMI BIOSCIENCES, INC.****Balance Sheets**

	September 30, 2009	September 30, 2008	June 30, 2010 (unaudited)	June 30, 2009 (unaudited)
<b>Assets</b>				
Cash	\$ 1,702,204	\$ 9,100	\$ 517,393	\$ 408,455
Accounts receivable		25,000		
Prepaid patent fees			33,605	12,981
Prepaid income tax			34,118	
Related party notes receivable			300,000	
Accrued interest receivable			3,880	
<b>Total assets</b>	<b>\$ 1,702,204</b>	<b>\$ 34,100</b>	<b>\$ 888,996</b>	<b>\$ 421,436</b>
<b>Liabilities and Stockholders Deficit</b>				
<b>Current liabilities</b>				
Accounts payable	\$ 607,659	\$ 905,282	\$ 85,047	\$ 702,427
Accrued liabilities	47,876			47,876
Accrued wages payable	1,039,906	1,039,375	1,039,807	1,039,906
Accrued interest	443,937	388,935	450,149	429,888
Deferred revenue	625,000			845,590
Current portion of capital leases	16,487	16,302	16,399	17,879
Due to related party	8,312		1,527	
<b>Total current liabilities</b>	<b>2,789,177</b>	<b>2,349,894</b>	<b>1,592,929</b>	<b>3,083,566</b>
Notes payable	530,000	635,000	430,000	530,000
Capital leases, less current portion	16,163	34,270		19,434
<b>Total liabilities</b>	<b>3,335,340</b>	<b>3,019,164</b>	<b>2,022,929</b>	<b>3,633,000</b>
<b>Stockholders deficit</b>				
Preferred Stock; 50,000,000 shares authorized, none outstanding				
Common Stock; no par value, 9,195,695 shares authorized, 9,171,282 and 11,288,310 shares outstanding at September 30, 2009 and 2008, respectively, and 9,171,282 shares outstanding at both June 30, 2010 (unaudited) and 2009 (unaudited)				
	8,809,537	10,546,504	8,819,962	8,809,537
Common Stock Class B; no par value, 8,804,305 shares authorized, 8,804,305 and 0 shares outstanding at September 30, 2009 and 2008, respectively, and 8,804,305 shares outstanding at both June 30, 2010 (unaudited) and 2009 (unaudited)				
	8,445,097		8,445,097	8,445,097
Treasury stock	(327,355)	(327,355)	(327,355)	(327,355)
Accumulated deficit	(18,560,415)	(13,204,213)	(18,071,637)	(20,138,843)
<b>Total stockholders deficit</b>	<b>(1,633,136)</b>	<b>(2,985,064)</b>	<b>(1,133,933)</b>	<b>(3,211,564)</b>
<b>Total liabilities and stockholders deficit</b>	<b>\$ 1,702,204</b>	<b>\$ 34,100</b>	<b>\$ 888,996</b>	<b>\$ 421,436</b>

See notes to financial statements.



**Table of Contents****DMI BIOSCIENCES, INC.****Statement of Operations**

	<b>For the Years Ended September 30,</b>		<b>For the Nine Months Ended June 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2010 (unaudited)</b>	<b>2009 (unaudited)</b>
<b>Revenue</b>				
License fees	\$ 875,000	\$ 500,000	\$ 625,000	\$ 654,410
Royalty fees	58,750	75,000		58,751
Milestone payments	1,500,475			
Other revenue	111,943	36,865		111,943
<b>Total revenue</b>	<b>2,546,168</b>	<b>611,865</b>	<b>625,000</b>	<b>825,104</b>
<b>Operating expenses</b>				
Research and development	1,095,221	153,397	93,085	1,057,668
General and administrative	7,013,867	1,041,569	11,213	6,922,410
<b>Total operating expenses</b>	<b>8,109,088</b>	<b>1,194,966</b>	<b>104,298</b>	<b>7,980,078</b>
<b>Loss from operations</b>	<b>(5,562,920)</b>	<b>(583,101)</b>	<b>520,702</b>	<b>(7,154,974)</b>
<b>Other income (expense)</b>				
Interest expense	(57,520)	(60,650)	(38,026)	(43,084)
Loss on disposal		(513,000)		
Other income	1,568	1,566	6,102	762
<b>Total other income (expense)</b>	<b>(55,952)</b>	<b>(572,084)</b>	<b>(31,924)</b>	<b>(42,322)</b>
<b>Net (loss) income</b>	<b>\$ (5,618,872)</b>	<b>\$ (1,155,185)</b>	<b>\$ 488,778</b>	<b>\$ (7,197,296)</b>

See notes to financial statements.

**Table of Contents****DMI BIOSCIENCES, INC.****Statement of Changes in Stockholders' Equity****For the Periods ended September 30, 2009 and 2008 and June 30, 2010 (unaudited)**

		Common Stock		Common Stock	Class B	Treasury	Accumulated	Total
		Shares	Amount	Shares	Amount	Stock	Deficit	Stockholders
								Deficit
Balance	September 30, 2007	11,163,310	\$ 10,384,114		\$	\$ (327,355)	\$ (12,049,028)	\$ (1,992,269)
Conversion of debt to common stock		60,000	60,000					60,000
Issuance of common stock for cash		65,000	65,000					65,000
Stock-based compensation			37,390					37,390
Net loss							(1,155,185)	(1,155,185)
Balance	September 30, 2008	11,288,310	10,546,504			(327,355)	(13,204,213)	(2,985,064)
Issuance of restricted common stock in exchange for services		5,383,689	5,383,689					5,383,689
Issuance of common stock in exchange for services		1,278,588	1,278,588					1,278,588
Issuance of common stock in exchange for cell lines		25,000	25,000					25,000
Exchange of common stock for Class B shares (Note 7)		(8,804,305)	(8,445,097)	8,804,305	8,445,097			
Stock-based compensation			20,853					20,853
Contribution from stockholders							262,670	262,670
Net loss							(5,618,872)	(5,618,872)
Balance	September 30, 2009	9,171,282	8,809,537	8,804,305	8,445,097	(327,355)	(18,560,415)	(1,633,136)
Stock-based compensation (unaudited)			10,425					10,425
Net income (unaudited)							488,778	488,778
Balance	June 30, 2010 (unaudited)	9,171,282	\$ 8,819,962	8,804,305	\$ 8,445,097	\$ (327,355)	\$ (18,071,637)	\$ (1,133,933)

See notes to financial statements.

**Table of Contents****DMI BIOSCIENCES, INC.****Statements of Cash Flows**

	For the Years Ended September 30,		For the Nine Months Ended June 30,	
	2009	2008	2010 (unaudited)	2009 (unaudited)
<b>Cash flows from operating activities</b>				
Net (loss) income	\$ (5,618,872)	\$ (1,155,185)	\$ 488,778	\$ (7,197,296)
Adjustments to reconcile net loss to cash used in operating activities				
Loss on disposal of assets		513,000		
Depreciation		35,537		
Common stock issued for services	6,662,277			6,662,277
Common stock issued for cell lines	25,000			25,000
Stock-based compensation	20,853	37,390	10,425	20,850
Change in operating assets and liabilities				
Accounts receivable	25,000	(25,000)	(300,000)	25,000
Interest receivable			(3,880)	
Prepaid patents		76,414	(33,605)	(12,981)
Prepaid income tax			(34,118)	
Due from related party	8,312	(310,600)	(6,785)	
Accounts payable	(297,623)	362,236	(522,612)	(202,855)
Accrued interest	55,002	55,482	6,212	40,953
Accrued wages	531	34,798	(99)	531
Accrued expenses	110,546		(47,876)	110,546
Deferred revenue	625,000		(625,000)	845,590
Net cash provided by (used in) operating activities	1,616,026	(375,928)	(1,068,560)	317,615
<b>Cash flows from financing activities</b>				
Proceeds from notes payable and advances	125,000	165,000		125,000
Payments on advances	(30,000)		(100,000)	(30,000)
Payments on capital leases	(17,922)	(65,260)	(16,251)	(13,260)
Issuance of common stock		65,000		
Net cash provided by (used in) financing activities	77,078	164,740	(116,251)	81,740
Net change in cash and cash equivalents	1,693,104	(211,188)	(1,184,811)	399,355
Cash and cash equivalents at beginning of period	9,100	220,288	1,702,204	9,100
Cash and cash equivalents at end of period	\$ 1,702,204	\$ 9,100	\$ 517,393	\$ 408,455
Non cash transactions:				
Exchange of note for common stock	\$	\$ 60,000	\$	\$
Sale of assets in exchange for common stock of Life Sciences (Note 2)	\$ 262,670	\$	\$	\$ 262,670

**Table of Contents**

**DMI BIOSCIENCES, INC.**

**Notes to Financial Statements**

**Note 1 Summary of Significant Accounting Policies**

***Nature of Operation***

DMI BioSciences, Inc., ( BioSciences or the Company ), a Colorado Corporation, was formed in 1990. BioSciences is a privately held, clinical-stage pharmaceutical company that develops therapeutic products to treat human sexual dysfunction. The Company's most advanced product is a drug to delay ejaculation.

***Use of Estimates***

The preparation of financial statements in conformity with generally accepted accounting principles ( GAAP ) in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

***Unaudited Interim Information***

The accompanying unaudited interim financial statements included herein have been prepared by the management of the Company pursuant to the rules and regulations of the United States Securities and Exchange Commission. Certain information and note disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to these rules and regulations, although the Company believes that the disclosures are adequate to make the information not misleading. In the opinion of management, the unaudited interim financial statements contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly, in all material respects, the Company's financial position as of June 30, 2010, the interim results of operations for the nine months ended June 30, 2010 and June 30, 2009, and the cash flows for the nine months ended June 30, 2010 and June 30, 2009. These interim statements have not been audited.

***Cash and Cash Equivalents***

The Company considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents consist primarily of money market investments. The Company maintains balances from time to time in excess of the federally insured limits.

***Property and Equipment***

Property and equipment is recorded at cost. Depreciation is calculated using the straight-line method over the estimated useful lives for owned assets, ranging from five to seven years or, for leasehold improvements, the term of the related lease.

**Table of Contents**

**DMI BIOSCIENCES, INC.**

**Notes to Financial Statements**

**Note 1 Summary of Significant Accounting Policies (continued)**

***Patents and Patent Applications***

Costs of establishing patents consisting of legal fees paid to third parties are expensed as incurred until such time as the patent is deemed viable and will produce a source of revenue.

***Impairment of Long-Lived Assets and Assets to be Disposed***

Long-lived assets and certain identifiable intangibles are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Recoverability of assets to be held and used is generally measured by a comparison of the carrying amount of an asset to future net undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amounts of the assets exceed the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. There has been no impairment loss recognized during the periods ended September 30, 2009 and 2008 or June 30, 2010 (unaudited) and 2009 (unaudited).

***Revenue Recognition***

Revenues from royalties and license agreements are recognized when all of the following criteria have been met: (a) persuasive evidence of an arrangement exists, (b) delivery has occurred or services have been rendered, (c) the price is fixed or determinable, and (d) collectability is reasonably assured. Milestone payments are received and earned in accordance with the terms of the specific contracts and the Company providing the required information in accordance with the terms of the contracts. Revenue is recognized upon completion of each milestone.

***Research and Development***

Research and development cost are expensed as incurred.

***Income Taxes***

The Company uses the liability method for accounting for income taxes. Under this method, the Company recognizes deferred assets and liabilities based on the differences between the tax basis of assets and liabilities and their reported amounts in the financial statements that will result in taxable or deductible amounts in future years. The Company establishes a valuation allowance for all deferred tax assets for which there is uncertainty regarding realization.



---

**Table of Contents**

**DMI BIOSCIENCES, INC.**

**Notes to Financial Statements**

**Note 1 Summary of Significant Accounting Policies (continued)**

***Income Taxes (continued)***

In December 2009, the Company adopted the Financial Accounting Standards Board released guidance on uncertain tax positions. This new guidance prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of an uncertain tax position taken or expected to be taken in a tax return. It requires that the Company recognize in its financial statements the impact of uncertain tax positions. In addition, it also provides guidance on de-recognition, classification, interest and penalties, and disclosure. The Company has evaluated the impact of the adoption on its financial position and results of operations and determined it not to be significant.

***Stock-Based Compensation***

The Company accounts for share based payments by recognizing compensation expense based upon the estimated fair value of the awards on the date of grant. The Company determines the estimated grant fair value using the Black-Scholes option pricing model and recognizes compensation costs ratably over the vesting period using the straight-line method.

***Fair Value of Financial Instruments***

GAAP defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value hierarchy established by GAAP prioritizes the inputs into valuation techniques used to measure fair value. Accordingly, the Company uses valuation techniques that maximize the use of observable inputs when determining fair value. The three levels of the hierarchy are as follows:

- Level 1: Inputs that reflect unadjusted quoted prices in active markets that are accessible to us for identical assets or liabilities;
- Level 2: Inputs include quoted prices for similar assets and liabilities in active or inactive markets or that are observable for the asset or liability either directly or indirectly; and
- Level 3: Unobservable inputs that are supported by little or no market activity.

The Company has no assets or liabilities that were measured using quoted prices for similar assets and liabilities or significant unobservable inputs (Level 2 and Level 3 assets and liabilities) as of September 30, 2009 or 2008 or June 30, 2010 (unaudited) and 2009 (unaudited). The Company's financial instruments include cash and cash equivalents, accounts payable, accrued salaries, and accrued interest payable. The carrying amounts of these financial instruments approximate their fair value due to their short maturities. The carrying value of cash held in money market funds totaling \$1,701,204, \$30, \$512,229, and \$405,551 as of September 30, 2009 and 2008 and June 30, 2010 (unaudited) and 2009 (unaudited), respectively, is included in cash and cash equivalents and approximates market values based on quoted market prices, or Level 1 inputs.

**Table of Contents****DMI BIOSCIENCES, INC.****Notes to Financial Statements****Note 2 Sale of Certain Assets**

On April 16, 2009, the Company entered into an Asset Purchase Agreement with DMI Life Sciences, Inc. ( Life Sciences ) to sell certain assets and relinquish certain liabilities. Under the Asset Purchase Agreement, BioSciences sold office and lab equipment, cell lines and intellectual property, including patents and license agreements, and relinquished certain liabilities to Life Sciences in exchange for 3,500,000 shares of common stock of Life Sciences. The assets had no remaining book value and the liabilities consisted of a \$200,000 note payable to a related party and \$62,670 of accrued liabilities. In conjunction with the Asset Purchase Agreement, the parties entered into a Royalty Agreement which granted Life Sciences a 10% royalty based upon license revenue that BioSciences receives, subject to Life Sciences committing to providing additional funding. The accounting for this transaction resulted in a deemed contribution to BioSciences by its stockholders in the amount of \$262,670 which represents the historical value of the assets transferred to Life Sciences as the transactions was a recapitalization of Life Sciences as of the date of this transaction.

In March 2010, Life Sciences became a wholly owned subsidiary of Chay Enterprises, Inc., a public company. Chay Enterprises, Inc. subsequently changed its name to Ampio Pharmaceuticals, Inc. ( Ampio ).

**Note 3 Property and Equipment**

The Company's property and equipment consists of the following:

	September 30, 2009	September 30, 2008	June 30, 2010 (unaudited)	June 30, 2009 (unaudited)
Computer equipment	\$	\$ 28,092	\$	\$
Lab equipment		33,768		
Furniture and fixtures	110,000	110,000	110,000	110,000
Less accumulated depreciation	(110,000)	(171,860)	(110,000)	(110,000)
	\$	\$	\$	\$

**Table of Contents****DMI BIOSCIENCES, INC.****Notes to Financial Statements****Note 4 Notes Payable**

The Company's notes payable consists of the following:

	September 30, 2009	2008	June 30, 2010 (unaudited)	2009 (unaudited)
Note payable to a stockholder, due on March 17, 2000. The note carries an interest rate of 10%, or in the event of default, 12%, and is uncollateralized.	\$ 300,000	\$ 300,000	\$ 300,000	\$ 300,000
Note payable to a stockholder with no maturity date and carrying interest at 7%, uncollateralized.	75,000	75,000	75,000	75,000
Note payable to a stockholder with no maturity date and carrying interest at 7%, uncollateralized.	55,000	55,000	55,000	55,000
Note payable to a stockholder with no maturity date and carrying interest at 9%, uncollateralized.	100,000	100,000		100,000
Note payable to an individual with no maturity date and carrying interest at 3.26%, uncollateralized.		30,000		
Note payable to a related party with no maturity date and carrying interest at 10%, uncollateralized.		75,000		
	\$ 530,000	\$ 635,000	\$ 430,000	\$ 530,000

**Note 5 Capital Leases**

The Company has acquired an asset under the provision of a long-term lease. For financial reporting purposes, minimum lease payments relating to the asset have been capitalized. The lease expires May 5, 2011. Amortization of the leased property is included in depreciation expense.

**Table of Contents****DMI BIOSCIENCES, INC.****Notes to Financial Statements****Note 5 Capital Leases (continued)**

The asset under capital lease had cost and accumulated amortization as follows:

	September 30,		June 30,	
	2009	2008	2010 (unaudited)	2009 (unaudited)
Cost	\$ 88,600	\$ 88,600	\$ 88,600	\$ 88,600
Less accumulated amortization	(88,600)	(88,600)	(88,600)	(88,600)
	\$	\$	\$	\$

Maturities of capital lease obligations are as follows:

<u>Year Ending September 30,</u>		
2010		\$ 16,487
2011		16,163
Total minimum lease payments		32,650
Less current portion		(16,487)
Long-term capital lease obligation		\$ 16,163

**Note 6 Income Taxes**

BioSciences' effective tax rate differs from the U.S. federal corporate income tax rate of 34% as shown in the below table, which reflects the rate for the year ended September 30, 2009 and 2008 and the nine months ended June 30, 2010 (unaudited) and 2009 (unaudited).

Statutory rate	34.0%
State income taxes, net of federal income tax impact	2.7%
Permanent items	(4.5)%
Increase in valuation allowance	(32.1)%
Effective tax rate	0.0%

For the years ended September 30, 2009 and 2008, and the nine months ended June 30, 2010 (unaudited) and 2009 (unaudited), the Company provided a full valuation allowance against the deferred tax asset based on the weight of available evidence, both positive and negative, including the Company's operating losses, which indicated that it is more likely than not that such benefits will not be realized.

**Table of Contents****DMI BIOSCIENCES, INC.****Notes to Financial Statements****Note 6 Income Taxes (continued)**

The Company's deferred tax assets are comprised of the following:

	September 30,		June 30,	
	2009	2008	2010 (unaudited)	2009 (unaudited)
Deferred tax assets				
Net operating loss and credit carryforwards	\$ 6,500,000	\$ 4,700,000	\$ 6,500,000	\$ 7,100,000
Valuation allowance	(6,500,000)	(4,700,000)	(6,500,000)	(7,100,000)
	\$	\$	\$	\$

As of September 30, 2009 and June 30, 2010 (unaudited), the Company had an available net operating loss ( NOL ) carry forward of approximately \$16,500,000 and \$12,700,000 (unaudited) respectively, for federal and state purposes, expiring through 2025. Under the provisions of the Internal Revenue Code, certain substantial changes in the Company's ownership may result in limitations on the amount of the NOL carryforwards which can be utilized in future years.

The Company classifies penalty and interest expense related to income tax liabilities as general and administrative expense and therefore is in the statement of operations.

The Company filed tax returns in the United States and in the state of Colorado. The tax years ended September 30, 2007 through the current period remain open to examinations by the major taxing jurisdictions to which the Company is subject.

**Note 7 Equity****Common Stock**

The Company issued 5,383,689 shares of Restricted common stock to its directors, officers, and employees in exchange for service in 2009. The shares were valued at \$1 per share. The Company issued 1,278,588 shares of common stock to stockholders in exchange for services and 25,000 shares of common stock in exchange for property in 2009. The shares were valued at \$1 per share (Note 2). The Company converted notes payable in the amount of \$60,000 to 60,000 shares of common stock in 2008. During 2008, the Company issued 65,000 shares of common stock for \$65,000 in cash.

Common stockholders have voting privileges and one hundred percent ownership rights in all assets of the Company.

**Table of Contents****DMI BIOSCIENCES, INC.****Notes to Financial Statements****Note 7 Equity (continued)*****Class B Common Stock***

During 2009, the Company exchanged 8,804,305 shares of common stock for an equivalent number of shares of Class B common stock in conjunction with the sale of certain assets to Life Sciences (Note 2). The terms of the Class B Common Stock will be identical to the terms of our common stock except that holders of Class B Common Stock will not be entitled to receive any shares of Life Sciences common stock, or proceeds from the sale of shares of Life Sciences common stock, distributed to holders of our common stock.

***Equity Incentive Plan***

The Company adopted the 1999 Stock Incentive plan during 1999. Under the Plan, the Option Committee may grant Options to purchase shares of Common Stock to employees and consultants. The Option Committee is authorized to grant up to 2,000,000 shares of common stock. Pricing and vesting are determined by the Option Committee, and awards are evidenced by an award agreement extended to the recipient. Stock options generally vest over four years and terminate 10 years from the date of grant.

The fair value of options granted under the Plan during 2009 were valued using the Black-Scholes option pricing model. In order to calculate the fair value of the options, assumptions were made regarding the estimated fair value of the underlying common stock, risk-free interest rate, volatility, expected dividend yield, and expected option life. Changes to the assumptions could cause significant adjustments to valuation. The Company estimated a volatility factor utilizing comparable published volatilities of peer companies. An estimated forfeiture rate of zero was based upon the small number of participants and their expected longevity and the expected term was based on the average of the vesting term and the contractual term of the options. The risk-free rate is based on the U.S. Treasury yield in effect at the time of the grant for the treasury securities of similar maturity. Accordingly, the Company has calculated the fair value options granted during 2009 and 2008 using the following assumptions:

Expected volatility	87.52 - 91.05%
Risk free interest rate	1.65 - 4.24%
Expected term (years)	4 - 6.25
Dividend yield	0%
Forfeiture rate	0%

The Company uses estimated volatility factors implied from related industry sources, and historical data to estimate the expected term and forfeitures of awards due to employee terminations in order to estimate compensation cost for awards expected to vest.

**Table of Contents****DMI BIOSCIENCES, INC.****Notes to Financial Statements****Note 7 Equity (continued)****Equity Incentive Plan (continued)**

The following table presents the composition of options outstanding and exercisable as of September 30, 2009:

Range of Exercise Prices	Options Exercisable and Outstanding		
	Number	Price	Life
\$0.01	314,720	\$ 0.01	5.5
\$0.90	448,000	\$ 0.90	2.1
\$2.50 - \$3.00	163,350	\$ 2.53	1.1

\* Price and life reflect the weighted average exercise price and weighted average remaining contractual life, respectively. Stock options activity was as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Outstanding at September 30, 2007	1,903,059	\$ 1.15	5.8
Granted	222,250	0.97	
Exercised			
Canceled			
Forfeited	(12,000)	2.50	
Outstanding at September 30, 2008	2,113,309	1.13	5.3
Granted	1,041	0.01	
Exercised	(25,000)	0.01	
Canceled	(18,750)	0.01	
Forfeited	(449,250)	1.52	
Outstanding at September 30, 2009	1,621,350	1.05	5.1
Granted			
Exercised			
Canceled	(396,000)	1.51	
Forfeited	(299,000)	0.97	
Outstanding and Exercisable at June 30, 2010 (unaudited)	926,350	\$ 0.88	4.2





**Table of Contents****DMI BIOSCIENCES, INC.****Notes to Financial Statements****Note 7 Equity (continued)****Equity Incentive Plan (continued)**

The weighted average fair value of the options granted for the year ended September 30, 2009 and 2008 was \$1.01 and \$0.97 per share, respectively. Compensation expense was \$20,853 and \$37,390 for the year ended September 30, 2009 and 2008, respectively; and \$10,425 and \$32,308 for the nine months ended June 30, 2010 (unaudited) and 2009 (unaudited), respectively. Unrecognized compensation expense was \$93,913 at September 30, 2009 and \$0 at June 30, 2010 (unaudited).

**Warrants**

On November 6, 1998, the Company issued 350,000 warrants, in conjunction with the issuance debt. The warrants were exercisable at \$1.50 per share and expired in November 2008.

On January 31, 2007, the Company issued 100,000 warrants, in conjunction with the issuance of debt to purchase common stock. The warrants are exercisable at \$1.00 per share and expire on January 2, 2012. The remaining contract life is 2.25 and 3.25 at September 30, 2009 and 2008, respectively and 1.50 (unaudited) and 2.50 (unaudited) at June 30, 2010 and 2009, respectively. Interest expense associated with the fair value of the warrants was deemed to be immaterial.

The following table presents the activity for warrants outstanding:

	Number of Shares	Weighted Average Exercise Price
Outstanding at September 30, 2007	450,000	\$ 1.50
Issued		
Forfeited/canceled		
Exercised		
Outstanding at September 30, 2008	450,000	1.40
Issued		
Forfeited/canceled		
Exercised		
Outstanding at September 30, 2009	450,000	1.40
Issued		
Forfeited/canceled	(350,000)	1.50
Exercised		
Outstanding at June 30, 2010 (unaudited)	100,000	\$ 1.00



**Table of Contents**

**DMI BIOSCIENCES, INC.**

**Notes to Financial Statements**

**Note 8 Related Party Transactions**

Prior to April 16, 2009, the Company had a Sponsored Research Agreement with Trauma Research LLC ( TRLLC ), a related research organization. Under the terms of the Sponsored Research Agreement, the Company was to provide personnel and equipment with an equivalent value of \$600,000 per year and to make monthly equipment rental payments of \$7,236 on behalf of TRLLC. In exchange, TRLLC will assign any intellectual property rights it develops. The Sponsored Research Agreement expires in 2014 and may be terminated by either party on six months notice or immediately if either party determines that the other is not fulfilling its obligations under the agreement. There were no outstanding liabilities related to the Sponsored Research Agreement at September 30, 2009 and the nine months ended June 30, 2010. The obligations under this agreement were transferred through issuance of a new agreement between TRLLC and Life Sciences effective April 16, 2009.

Prior to April 16, 2009, the Company had license agreements with the Institute for Molecular Medicine, Inc. a related nonprofit research organization. Under the license agreements, the Company paid the costs associated with maintaining intellectual property subject to the license agreements. In return, the Company was entitled to deduct twice the amounts it has paid to maintain the intellectual property from any amounts that may become due to the Institute for Molecular Medicine, Inc. under the license agreements, if and when the intellectual property becomes commercially viable and generates revenue. The Company paid \$28,460, \$5,000, \$0 (unaudited) and \$28,460 (unaudited) during the year ended September 30, 2009 and 2008 and nine months ended June 30, 2010 and 2009, respectively, in legal and patent fees to maintain the intellectual property of the Institute of Molecular Medicine, Inc. These costs are included in the accompanying financial statements as this contract was assumed by Life Sciences as part of the Assets sold.

As of June 30, 2010, the Company has a note receivable of \$300,000 from Ampio. The note is unsecured, bears interest at 6% and matures on September 2, 2010.

As of June 20, 2010 and September 30, 2009, the Company had noninterest bearing advances of \$1,527 and \$8,312, from Ampio and Life Sciences, respectively, with no set maturity date.

**Note 9 Subsequent Events**

Subsequent to June 30, 2010, the Company's board of directors approved a definitive merger agreement to exchange all of the outstanding shares of the Company for stock in Ampio. The merger is expected to take place upon approval of the definite merger agreement by the Company's stockholders and is structured as a tax free exchange of stock.

The Company has evaluated subsequent events through September 2, 2010, the date the financial statements were available for issuance, and has identified no other events or transactions requiring financial statement recognition or disclosure.

**Table of Contents**

**AMPIO PHARMACEUTICALS, INC. AND DMI BIOSCIENCES, INC.**

**SELECTED UNAUDITED PRO FORMA CONSOLIDATED FINANCIAL DATA**

**Explanatory Notes**

The unaudited pro forma financial data set forth below at and for the year ended December 31, 2009 and the six months ended June 30, 2010 and 2009 is based upon Ampio's historical financial statements, adjusted to give effect to the acquisition and merger with DMI Bio Sciences, Inc. 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, 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 proforma 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 unaudited 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.

**Table of Contents****Ampio Pharmaceuticals, Inc.****Pro Forma Unaudited Consolidated Statement of Operations**

	<b>Historical Six Months Ended June 30, 2010 Ampio (unaudited)</b>	<b>Historical Six Months Ended June 30, 2010 DMI BioSciences (unaudited)</b>	<b>Total Before Pro Forma Adjustments</b>	<b>Pro Forma Adjustments</b>	<b>Pro Forma Consolidated</b>
<b>Revenues</b>					
License fees	\$	\$ 404,410	\$ 404,410	\$	\$ 404,410
<b>Total revenue</b>		404,410	404,410		404,410
<b>Expenses</b>					
Research and development	589,999	47,420	637,419		637,419
General and administrative	2,032,560	13,649	2,046,209		2,046,209
<b>Total expenses</b>	2,622,559	61,069	2,683,628		2,683,628
Operating income (loss)	(2,622,559)	343,341	(2,279,218)		(2,279,218)
<b>Other income (expenses)</b>					
Interest income	578	6,193	6,771	(3,205)(1)	3,566
Interest expense	(6,181)	(24,329)	(30,510)	3,205(1) 22,250(3)	(5,055)
<b>Total other income (expenses)</b>	(5,603)	(18,136)	(23,739)		(1,489)
<b>Net (loss)</b>	\$ (2,628,162)	\$ 325,205	\$ (2,302,957)	\$	\$ (2,280,707)
<b>Weighted average number of common shares outstanding</b>					
	15,456,332		15,456,332	5,000,000(2)	20,456,332
<b>Basic and diluted net loss per common share</b>	\$ (0.17)		\$ (0.15)		\$ (0.11)

**Pro Forma Adjustments**

- (1) to eliminate intercompany interest.
- (2) to reflect common stock issued with acquisition.
- (3) to reverse interest on notes payable exchanged for common stock in connections with acquisition.

**Table of Contents****Ampio Pharmaceuticals, Inc.****Pro Forma Unaudited Consolidated Statement of Operations**

	<b>Historical Six Months Ended June 30, 2009 Ampio (unaudited)</b>	<b>Historical Six Months Ended June 30, 2009 DMI BioSciences (unaudited)</b>	<b>Total Before Pro Forma Adjustments</b>	<b>Pro Forma Adjustments</b>	<b>Pro Forma Consolidated</b>
<b>Revenues</b>					
License fees	\$	\$ 404,410	\$ 404,410	\$	\$ 404,410
Royalty fees		33,750	33,750		33,750
Other revenue		111,943	111,943		111,943
<b>Total revenue</b>		<b>550,103</b>	<b>550,103</b>		<b>550,103</b>
<b>Expenses</b>					
Research and development	258,725	786,260	1,044,985		1,044,985
General and administrative	148,934	6,808,382	6,957,316	(5,383,689) (1)	1,573,627
<b>Total expenses</b>	<b>407,659</b>	<b>7,594,642</b>	<b>8,002,301</b>	<b>(5,383,689)</b>	<b>2,618,612</b>
Operating income (loss)	(407,659)	(7,044,539)	(7,452,198)	5,383,689	(2,068,509)
<b>Other income (expenses)</b>					
Interest income	252	762	1,014		1,014
Interest expense		(28,801)	(28,801)	16,053 (2)	(12,748)
<b>Total other income (expenses)</b>	<b>252</b>	<b>(28,039)</b>	<b>(27,787)</b>	<b>16,053</b>	<b>(11,734)</b>
<b>Net (loss)</b>	<b>\$ (407,407)</b>	<b>\$ (7,072,578)</b>	<b>\$ (7,479,985)</b>	<b>\$ 5,399,742</b>	<b>\$ (2,080,243)</b>
<b>Weighted average number of common shares outstanding</b>					
	5,575,856		5,575,856	5,000,000 (3)	10,575,856
<b>Basic and diluted net loss per common share</b>	<b>\$ (0.07)</b>		<b>\$ (1.34)</b>		<b>\$ (0.20)</b>

**Notes to ProForma Consolidated Financial Information**

- (1) to reverse stock compensation expense on management shares surrendered with acquisition.
- (2) to reverse interest on notes payable exchanged for common stock in connections with acquisition.
- (3) To reflect common stock issued with acquisition.

**Table of Contents****Ampio Pharmaceuticals, Inc.****Pro Forma Unaudited Consolidated Statement of Operations**

	<b>Historical Year Ended December 31, 2009 Ampio</b>	<b>Historical Year Ended September 30, 2009 DMI BioSciences</b>	<b>Total Before Pro Forma Adjustments</b>	<b>Pro Forma Adjustments</b>	<b>Pro Forma Consolidated</b>
<b>Revenue</b>					
License fee	\$	\$ 875,000	\$ 875,000	\$	\$ 875,000
Royalty fees		58,750	58,750		58,750
Milestone payments		1,500,475	1,500,475		1,500,475
Other revenues		111,943	111,943		111,943
<b>Total revenue</b>		2,546,168	2,546,168		2,546,168
<b>Expenses</b>					
Research and development	1,070,370	1,095,221	2,165,591		2,165,591
General and selling	442,215	7,013,867	7,456,082	(5,383,689) (1)	2,072,393
<b>Total expenses</b>	1,512,585	8,109,088	9,621,673	(5,383,689)	4,237,984
<b>Operating loss</b>	(1,512,585)	(5,562,920)	(7,075,505)	5,383,689	(1,691,816)
<b>Other income (expenses)</b>					
Interest income	1,091	1,568	2,659		2,659
Interest expense	(1,414)	(57,520)	(58,934)	674 (2)	(13,160)
				45,100 (4)	
<b>Total other income (expenses)</b>	(323)	(55,952)	(56,275)	674	(55,601)
<b>Net loss</b>	\$ (1,512,908)	\$ (5,618,872)	\$ (7,131,780)	\$ 5,384,363	\$ (1,747,417)
<b>Weighted average number of common shares outstanding</b>	8,787,650		8,787,650	5,000,000(3)	13,787,650
<b>Basic and diluted net loss per common share</b>	\$ (0.17)		\$ (0.81)		\$ (0.13)

**Pro Forma Adjustments**

- (1) to reverse stock compensation expense on management shares surrendered with acquisition.
- (2) to eliminate intercompany interest.
- (3) to reflect common stock issued with acquisition.
- (4) to reverse interest on notes payable exchanged for common stock in connections with acquisition.

**Table of Contents****Ampio Pharmaceuticals, Inc.****Pro Forma Unaudited Consolidated Statement of Operations**

	Historical Year Ended December 31, 2008 Ampio	Historical Year Ended September 30, 2008 DMI BioSciences	Total Before Pro Forma Adjustments	Pro Forma Adjustments	Pro Forma Consolidated
<b>Revenue</b>					
License fee	\$	\$ 500,000	\$ 500,000	\$	\$ 500,000
Royalty fees		75,000	75,000		75,000
Other revenues		36,865	36,865		36,865
<b>Total revenue</b>		<b>611,865</b>	<b>611,865</b>		<b>611,865</b>
<b>Expenses</b>					
Total revenue					
Research and development		153,397	153,397		153,397
General and selling	1,080	1,041,569	1,042,649	(1)	1,042,649
<b>Total expenses</b>	<b>1,080</b>	<b>1,194,966</b>	<b>1,196,046</b>		<b>1,196,046</b>
Operating loss	(1,080)	(583,101)	(584,181)		(584,181)
<b>Other income (expenses)</b>					
Interest income		1,566	1,566		1,566
Loss on disposal		(513,000)	(513,000)		(513,000)
Interest expense		(60,650)	(60,650)	674(2)	(14,876)
				45,100(4)	
<b>Total other income (expenses)</b>		<b>(572,084)</b>	<b>(572,084)</b>	<b>45,774</b>	<b>(526,310)</b>
<b>Net loss</b>	<b>\$ (1,080)</b>	<b>\$ (1,155,185)</b>	<b>\$ (1,156,265)</b>	<b>\$ 45,774</b>	<b>\$ (1,110,491)</b>
Weighted average number of common shares outstanding	1,080,000		1,080,000	5,000,000(3)	6,080,000
Basic and diluted net loss per common share	\$ (0.00)		\$ (1.07)		\$ (0.18)

**Pro Forma Adjustments**

- (1) to reverse stock compensation expense on management shares surrendered with acquisition.
- (2) to eliminate intercompany interest.
- (3) to reflect common stock issued with acquisition.
- (4) to reverse interest on notes payable exchanged for common stock in connections with acquisition.



**Table of Contents****Pro Forma Unaudited Consolidated Balance sheet**

	June 30, 2010		Total Before	Pro Forma	Pro Forma
	Ampio	DMI BioSciences	Pro Forma	Adjustments	Combined
	(unaudited)	(unaudited)	Adjustments		
<b>Current assets</b>					
Cash	\$ 131,035	\$ 517,393	\$ 648,428	\$	\$ 648,428
Restricted cash	105,000		105,000		105,000
Prepaid expenses	49,523	67,723	117,246		117,246
Related party receivable	7,238	300,000	307,238	(301,527)(1)	5,711
Accrued interest receivable		3,880	3,880	(3,880)(1)	
<b>Total current assets</b>	<b>292,796</b>	<b>888,996</b>	<b>1,181,792</b>	<b>(305,407)</b>	<b>876,385</b>
In-process research and development				8,000,000(5)	8,000,000
Goodwill				3,713,977(5)	3,713,977
Fixed assets	2,423		2,423		2,423
<b>Total assets</b>	<b>\$ 295,219</b>	<b>\$ 888,996</b>	<b>\$ 1,184,215</b>	<b>\$ 11,408,570</b>	<b>\$ 12,592,785</b>
<b>Current liabilities</b>					
Accounts payable	\$ 357,234	\$ 85,047	\$ 442,281	\$	\$ 442,281
Accrued wages payable	196,353	1,039,807	1,236,160	(1,039,807)(3)	196,353
Accrued interest	7,595	450,149	457,744	(450,149)(4)	3,715
				(3,880)(1)	
Related party notes payable	400,000		400,000	(300,000)(1)	100,000
Current portion of capital leases		16,399	16,399		16,399
Due to related party		1,527	1,527	(1,527)(1)	
<b>Total current liabilities</b>	<b>961,182</b>	<b>1,592,929</b>	<b>2,554,111</b>	<b>(1,795,363)</b>	<b>758,748</b>
Note payable		430,000	430,000	(430,000)(4)	
<b>Total liabilities</b>	<b>961,182</b>	<b>2,022,929</b>	<b>2,984,111</b>	<b>(2,225,363)</b>	<b>758,748</b>
<b>Stockholder' equity (deficit)</b>					
Common stock, par value \$0.0001	1,711		1,711	500(2)	2,211
Common stock class A, no par		8,819,962	8,819,962	(8,819,962)(7)	
Common stock class B, no par		8,445,097	8,445,097	(8,445,097)(6)	
Treasury stock		(327,355)	(327,355)	327,355(7)	
Additional paid in capital	4,664,552		4,664,552	12,499,500(2)	17,164,052
Issuances for promotion	(788,958)		(788,958)		(788,958)
Advances to shareholders	(150,183)		(150,183)		(150,183)
Deficit accumulated in the development stage	(4,393,085)		(4,393,085)		(4,393,085)
Accumulated deficit		(18,071,637)	(18,071,637)	18,071,637(7)	
<b>Total stockholders' equity (deficit)</b>	<b>(665,963)</b>	<b>(1,133,933)</b>	<b>(1,799,896)</b>	<b>13,633,933</b>	<b>11,834,037</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 295,219</b>	<b>\$ 888,996</b>	<b>\$ 1,184,215</b>	<b>\$ 11,408,570</b>	<b>\$ 12,592,785</b>

**Notes to Pro Forma Consolidated Financial Information**

## Edgar Filing: Ampio Pharmaceuticals, Inc. - Form S-1

- (1) to eliminate related intercompany receivables and payables.
- (2) to reflect 5,000,000 Ampio shares issued upon merger (8,500,000 new shares issued, less 3,500,000 shares owned by BioSciences) at fair value of \$2.50 per share.
- (3) to reflect forgiveness of accrued wages by BioSciences officers and employees.
- (4) to reflect retirement of notes payable and accrued interest in exchange for Ampio common stock.
- (5) to reflect goodwill and fair value of BioSciences in-process research and development.
- (6) to reflect retirement of common stock class B by BioSciences' officers and employees
- (7) to eliminate BioSciences' capital structure.

F-38

**Table of Contents**

**8,500,000 Shares**

**Ampio Pharmaceuticals, Inc.**

**Common Stock**

, 2010

**Table of Contents****PART II****INFORMATION NOT REQUIRED IN THE PROSPECTUS****Item 13. Other expenses of issuance and distribution.**

The following table sets forth the various expenses to be incurred in connection with the registration of the common stock effected hereby, all of which will be borne by us (except any expenses incurred in disposing of the shares). All amounts shown are estimates except the SEC registration fee.

SEC registration fee	\$ 1,219
Printing and engraving expenses	40,000
Legal fees and expenses	100,000
Accounting fees and expenses	50,000
Transfer Agent Fees	1,000
Miscellaneous fees and expenses	7,781
<b>Total</b>	<b>\$ 200,000</b>

**Item 14. Indemnification of Directors and Officers.**

The Registrant's certificate of incorporation contains provisions that eliminate, to the maximum extent permitted by the General Corporation Law of the State of Delaware, the personal liability of the Registrant's directors and executive officers for monetary damages for breach of their fiduciary duties as directors or officers. The Registrant's certificate of incorporation and bylaws provide that the Registrant must indemnify its directors and executive officers and may indemnify its employees and other agents to the fullest extent permitted by the General Corporation Law of the State of Delaware.

Sections 145 and 102(b)(7) of the General Corporation Law of the State of Delaware provide that a corporation may indemnify any person made a party to an action by reason of the fact that he or she was a director, executive officer, employee or agent of the corporation or is or was serving at the request of a corporation against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with such action if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of an action by or in right of the corporation, no indemnification may generally be made in respect of any claim as to which such person is adjudged to be liable to the corporation.

The Registrant has entered into indemnification agreements with its directors and executive officers, in addition to the indemnification provided for in its amended and restated certificate of incorporation and bylaws, and intends to enter into indemnification agreements with any new directors and executive officers in the future.

The Registrant has purchased and intends to maintain insurance on behalf of each and any person who is or was a director or officer of the Registrant against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

The Underwriting Agreement, to be attached as Exhibit 1.1, provides for indemnification by the underwriters of the Registrant and its executive officers and directors, and by the Registrant of the underwriters, for certain liabilities, including liabilities arising under the Securities Act.

See also the undertakings set out in response to Item 17 herein.



**Table of Contents****Item 15. Recent sales of unregistered securities.**

During the last three years, we sold the following unregistered securities:

- (1) In connection with the Chay Merger, on March 2, 2010, we issued an aggregate of 15,736,752 shares of our common stock to the Life Sciences shareholders contemporaneously with the merger of our wholly-owned subsidiary into Life Sciences. As a result of the Merger, Life Sciences became our wholly-owned subsidiary. Immediately prior to the Merger, Life Sciences issued an additional 1,230,000 shares of its common stock to the following persons or entities, who received our shares at the time of the Merger:

Aloha Property Management	100,000
David Brenman	100,000
Eric Weidner	15,000
Redwood Consultants, LLC	815,000
Sunrise Capital, LLC	200,000

We also issued an aggregate of 1,325,000 shares of our common stock to the following persons at the time of the Merger, each of whom was an affiliate of Life Sciences at the time of such issuance. These issuances occurred on March 2, 2010, after our shareholders approved the Merger.

Dr. Daniel Navot	200,000
Donald B. Wingerter, Jr.	325,000
Kristin Clift	575,000
Gregory Thomas	75,000
Kristin Salottolo	75,000
Leonard Rael	75,000

The issuance of such securities was exempt from registration pursuant to Section 4(2) of, and Regulation D promulgated under the Securities Act.

- (2) From March 15, 2010 through September 20, 2010, we granted options under our 2010 Stock Incentive Plan to purchase 2,900,000 shares of common stock to our employees, directors and consultants, having exercise prices ranging from \$1.03 to \$1.70 per share.

- (3) In August 2010, we sold and issued \$430,000 in principal amount of convertible debentures to two of our directors and an affiliate of one of the directors. Warrants to purchase 21,500 shares of common stock were issued in conjunction with such debentures.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering, and the registrant believes that each transaction was exempt from the registration requirements of the Securities Act in reliance on the following exemptions:

with respect to the transactions described in paragraphs (1), (2) and (3), Rule 701 promulgated under the Securities Act as transactions pursuant to a compensatory benefit plan approved by the registrant's board of directors; and

with respect to the transactions described in paragraphs (4) and (5), Section 4(2) of the Securities Act, or Rule 506 of Regulation D promulgated thereunder, as transactions by an issuer not involving a public offering. Each recipient of the securities in these transactions represented his or her intention to acquire the securities for investment only and not with a view to, or for resale in connection with, any distribution thereof, and appropriate legends were affixed to the share certificates issued in each such transaction. In each case, the recipient received adequate information about the registrant or had adequate access, through his or her relationship with the registrant, to information about the registrant.



**Table of Contents**

There were no underwriters employed in connection with any of the transactions set forth in Item 15.

**Item 16. Exhibits**

<b>Exhibit number</b>	<b>Exhibit title</b>
3.1	Certificate of Incorporation of the Registrant, as currently in effect(1)
3.2	Amendment to Certificate of Incorporation(1)
3.3	Plan of Conversion of Chay Enterprises, Inc. to a Delaware corporation(1)
3.4	Bylaws of the Registrant, as currently in effect(1)
4.1*	Specimen Common Stock Certificate of the Registrant file by Amendment
4.2	Form of Senior Convertible Unsecured Debenture (2)
4.3	Form of Warrant issued with Senior Convertible Unsecured Debenture (2)
5.1*	Opinion of Richardson & Patel, LLP file by Amendment
10.1	Form of Director and Executive Officer Indemnification Agreement(3)
10.2	2010 Stock Incentive Plan and forms of option agreements (4)
10.3	Agreement and Plan of Merger dated March 2, 2010(4)
10.4	Securities Put and Guarantee Agreement dated March 2, 2010(3)
10.5	Employment Agreement dated April 17, 2009, by and between DMI Life Sciences, Inc. and David Bar-Or, M.D.(4)
10.6	Employment Agreement dated April 17, 2009, by and between DMI Life Sciences, Inc. and Bruce G. Miller (4)
10.7	Sponsored Research Agreement dated September 1, 2009 (4)
10.8	Exclusive License Agreement, dated July 11, 2005(4)
10.9	First Amendment to Exclusive License Agreement, dated April 17, 2009 (4)
10.10	Exclusive License Agreement, dated February 17, 2009 (4)
10.11	Consulting Agreement by and between Redwood Consultants, LLC and the Registrant(4)



**Table of Contents**

- 10.12\* Form of Lock-up Agreement
- 10.13 Extension Agreement for Notes Payable dated May 13, 2010(5)
- 10.14 Extension Agreement for Notes Payable dated May 13, 2010(5)
- 10.15 Notes Payable dated June 23, 2010 (6)
- 10.16 Employment Agreement, dated August 12, 2010, between the Registrant and Donald B. Wingerter, Jr. (7)
- 21.1\* List of subsidiaries of the Registrant
- 23.1\* Consent of Ehrhardt Keefe Steiner &Hottman PC, Independent Registered Public Accounting Firm
- 23.2\* Consent of Richardson & Patel, LLP (included in Exhibit 5.1)
- 24.1 Power of Attorney (see page II-6 to this registration statement on Form S-1)

- (1) Incorporated by reference from Registrant s Form 8-K filed March 30, 2010.
- (2) Incorporated by reference from Registrant s From 8-K filed August 16, 2010.
- (3) Incorporated by reference from Registrant s From 8-K filed March 8, 2010.
- (4) Incorporated by reference from Registrant s From 8-K/A filed March 17, 2010.
- (5) Incorporated by reference from Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.
- (6) Incorporated by reference from Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2010.
- (7) Incorporated by reference from Registrant s Form 8-K/A filed August 17, 2010.

\* Filed herewith.  
Previously filed.

\*\* Confidential treatment has been applied for with respect to certain portions of these exhibits.

\*\*\* This exhibit is a management contract or compensatory plan or arrangement.

**Table of Contents**

**Item 17. Undertakings.**

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933, as amended, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933, as amended, and will be governed by the final adjudication of such issue.

We hereby undertake that:

(a) We will provide to the underwriters at the closing as specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(b) For purposes of determining any liability under the Securities Act of 1933, as amended, the information omitted from a form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933, as amended, shall be deemed to be part of this registration statement as of the time it was declared effective.

(c) For the purpose of determining any liability under the Securities Act of 1933, as amended, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that the registrant meets all of the requirements for filing on Form S-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Greenwood Village, Colorado, on this 12th day of November, 2010.

**AMPIO PHARMACEUTICALS, INC.**

By: /s/ Donald B. Wingerter, Jr.  
 Donald B. Wingerter, Jr.  
 Chief Executive Officer

**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Donald B. Wingerter, Jr. as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her, and in his or her name, place and stead, in any and all capacities, to sign the Registration Statement on Form S-1 of Ampio Pharmaceuticals, Inc. and any or all amendments (including post-effective amendments) thereto and any new registration statement with respect to the offering contemplated thereby filed pursuant to Rule 462(b) of the Securities Act, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Donald B. Wingerter, Jr. Donald B. Wingerter, Jr.	Chief Executive Officer and Director (Principal Executive Officer)	November 12, 2010
/s/ Bruce G. Miller Bruce G. Miller	Chief Financial Officer (Principal Accounting Officer) (Principal Financial Officer)	November 12, 2010
* David Bar-Or	Director	November 12, 2010
* Philip H. Coelho	Director	November 12, 2010
* Richard B. Giles	Director	November 12, 2010
* Michael Macaluso	Chairman of the Board of Directors	November 12, 2010

\*By: /s/ Donald B. Wingerter, Jr.,  
 Attorney-in-Fact

