

Ampio Pharmaceuticals, Inc.

Form 10-K

March 06, 2013

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2012

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

Commission File Number 333-146542

**AMPIO PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**26-0179592**  
(I.R.S. Employer  
Identification Number)

**5445 DTC Parkway**  
**Suite 925**  
**Greenwood Village, Colorado**  
(Address of principal executive offices)

**80111**  
(Zip Code)

**(720) 437-6500**  
(Registrant's telephone number, including area code)

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

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K ☐

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

Large Accelerated Filer ☐ Accelerated Filer ☒  
Non-Accelerated Filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐  
Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of common stock held by non-affiliates of the Registrant as of June 30, 2012 was \$133,153,013.

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: As of March 6, 2013, 37,085,784 shares of common stock were outstanding.



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This Report on Form 10-K refers to trademarks, such as Optina, Ampion, Zertane and Vasaloc, which are protected under applicable intellectual property laws and are our property or the property of our subsidiaries. This Form 10-K 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 Form 10-K 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.

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*Unless otherwise indicated or unless the context otherwise requires, references in this Form 10-K to the Company, Ampio, we, us, or our are to Ampio Pharmaceuticals, Inc. and its subsidiaries; references to Life Sciences are to DMI Life Sciences, Inc., our predecessor; and references to BioSciences are to DMI BioSciences, Inc.*

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA**

**Forward Looking Statements**

This Annual Report on Form 10-K, or Annual Report, includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our anticipated future clinical and regulatory events, future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. Forward looking statements are generally written in the future tense and/or are preceded by words such as may, will, should, forecast, could, expect, suggest, believe, estimate, continue, anticipate, intend, plan, or similar words, or the negatives of such terms or other variations on such comparable terminology. Such forward-looking statements include, without limitation, statements regarding the potential future commercialization of our product candidates, the anticipated start dates, durations and completion dates, as well as the potential future results, of our ongoing and future clinical trials, the anticipated designs of our future clinical trials, anticipated future regulatory submissions and events, our anticipated future cash position and future events under our current and potential future collaborations. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including without limitation the risks described in Risk Factors in Part I, Item 1A of this Annual Report. These risks are not exhaustive. Other sections of this Annual Report include additional factors that could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. We assume no obligation to update or supplement forward-looking statements.

We obtained statistical data, market and product data, and forecasts used throughout this Form 10-K 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.

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**AMPIO PHARMACEUTICALS, INC.**

**PART I**

**Item 1. Business**

Ampio Pharmaceuticals, Inc. is a biopharmaceutical company focused on the rapid development of therapies to treat prevalent inflammatory conditions for which there are limited treatment options. We are primarily focused on providing medicines to improve the health and quality of life of patients with minimal side effects. We are developing compounds that decrease inflammation by (i) inhibition of specific pro-inflammatory compounds by affecting specific pathways at the protein expression and at the transcription level or (ii) activation of a specific phosphatase or depletion of the available phosphate needed for the inflammation process. We are also focused on monetizing our sexual dysfunction portfolio and a diagnostic device.

Our disciplined innovation process is built on clinical observations and patient data gathered under Institutional Review Board supervision from clinicians at two Level I trauma centers in the State of Colorado, who conduct over 120,000 emergency room consultations annually, and collaborate with Dr. Bar-Or, Ampio's Chief Scientific Officer and Director. Our discovery activities are conducted by Trauma Research LLC (TRLLC), a limited liability company owned by Dr. Bar-Or, which conducts drug and biomarker discovery and development programs at its research facilities under a sponsored research agreement with us. These internal discoveries are assessed for promising in vitro results or clinical efficacy for one or more potential indications. We then focus our development work on advancing product candidates that we believe offer significant therapeutic advantages over currently available treatments, represent large potential markets, and, if possible, a relatively quick path to commercialization by way of previously established clinical data.

We intend to maintain a diversified product candidate pipeline to mitigate risks associated with pharmaceutical development and increase the likelihood of commercial success which capitalizes on our own internal discoveries and our intellectual property. This intellectual property 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 molecular entities (NMEs), new indications for previously approved drugs, and rapid point-of-care tests for diagnosis, monitoring and screening.

During the clinical development of our product candidates, we plan to outsource manufacturing, and, when deemed appropriate, out-license a product candidate's cost of clinical trials to collaborators for the rights to sell and market product candidates that receive regulatory approval within or outside the United States. Although such outsourcing may reduce future income derived from any sales of approved products, our business model is premised on carefully controlling fixed overhead and development costs. If a product candidate that we have not licensed receives regulatory approval and may have the potential to be successfully commercialized, we would evaluate the current business and regulatory environments in order to decide whether to engage in the manufacturing, distribution, marketing and sale of a product candidate or to enter into one or more collaboration agreements for commercialization.

We are currently in the clinical stage of development on product candidates that were discovered by Dr. Bar-Or and chosen from our pre-clinical pipeline based upon market potential and our belief that these candidates have a relatively shorter pathway to commercialization: (i) Ampion™, a biologic to treat inflammatory conditions and autoimmune disorders; (ii) Optina™, a low dose form of orally administered danazol for diabetic macular edema; (iii) Zertane™ and Zertane-ED for sexual dysfunction; (iv) Oxidation Reduction Potential (ORP), a diagnostic which measures oxidative stress in the blood; and (v) methylphenidate derivatives for cancer which are in pre-clinical development. We have also conducted early research into how copper chelating peptides can be used to treat Acute Coronary Syndrome, or ACS, strokes, and Wilson's disease. Given the depth of our pre-clinical pipeline, which is described further in the Intellectual Property Summary, we may choose to collaborate, license, or sell discoveries that we choose not to develop internally.

We have not generated any revenue from product sales to date, and we may never generate any revenue from product sales. We have funded our operations primarily through private and public offerings of our common stock and through the \$500,000 up-front payment we received from Daewoong Pharmaceuticals Co., Ltd. (Daewoong) in September 2011 in connection with a license, development and commercialization agreement we entered into with Daewoong. We have incurred cumulative net losses of \$39.5 million through December 31, 2012, and we expect to incur substantial additional losses for the foreseeable future as we pursue regulatory approval for, and, if approved, commercial launch of our product candidates, and continue to finance clinical and preclinical studies of our existing and potential future product candidates and our corporate overhead costs.

**Corporate History**

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Our predecessor, DMI Life Sciences, Inc. ( "Life Sciences" ), was formed by Michael Macaluso, our chief executive officer and chairman of our Board of Directors, 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 pending patent applications, business products and tangible property) from DMI BioSciences, Inc. ( "BioSciences" ), a scientific discovery, privately-held Colorado corporation formed in May 1990 by Dr. David Bar-Or. Life Sciences issued 3,500,000 shares of

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our common stock to BioSciences, and assumed certain liabilities, as consideration for the assets purchased from BioSciences. In March 2010, Life Sciences merged with a subsidiary of Chay Enterprises, Inc. ( "Chay" ), a publicly-traded company incorporated in Colorado. Simultaneous with the merger, we changed our name to Ampio Pharmaceuticals, Inc. ( "Ampio" ), and reincorporated in Delaware. As a result of the Chay merger, we became a publicly-traded company and 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. For accounting and financial reporting purposes, Life Sciences was considered the acquirer and the Chay merger was treated as a reverse acquisition. All financial information presented in this Form 10-K for periods prior to the Chay merger reflects only that of Life Sciences, 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 April 2010, we announced the execution of a letter of intent to acquire BioSciences. We and BioSciences executed a definitive merger agreement on September 4, 2010 which was adopted and approved by consent of a majority of the Ampio shareholders on November 9, 2010. The final consent agreement was approved by both parties January 5, 2011 and the merger closed on March 23, 2011. BioSciences owned the rights to one product, Zertane<sup>TM</sup>, and held 32 issued patents and 31 pending patent applications related to the product. The purpose of the BioSciences acquisition was to unify our management team and ownership as (i) BioSciences owned and donated back to Ampio, 3,500,000 shares of Ampio common stock, or approximately 20% of the outstanding Ampio shares of common stock, (ii) Ampio's Zertane<sup>TM</sup> Product Manager, Bruce G. Miller, was also the president, a director and a principal Class B shareholder of BioSciences, (iii) Ampio's chief scientific officer and director, Dr. David Bar-Or, was a former executive officer and director, and a principal Class B shareholder of BioSciences, (iv) Richard B. Giles, a shareholder of BioSciences, is a member of the Board of Directors and shareholder of Ampio, and (v) several other Ampio investors were also shareholders of BioSciences. The aggregate consideration paid by Ampio to BioSciences shareholders in the merger was 8,473,789 shares of Ampio common stock which is net of shares exchanged for options in settlement of a dispute with three option holders of BioSciences. This consideration includes the shares payable to holders of in-the-money BioSciences stock options and warrants, and holders of two BioSciences promissory notes, outstanding immediately prior to the effective time of the merger. 435,717 out-of-the-money options to purchase Ampio shares at an average price of \$1.54 were also issued as consideration.

## **Our Product Pipeline**

### **Ampion<sup>TM</sup>: Biologic to Treat Inflammatory Conditions and Autoimmune Diseases**

#### ***Market Statistics***

Osteoarthritis ( "OA" ) is the most common form of arthritis, affecting 27 million people in the U.S. according to the American College of Rheumatology. In the Journal of Rheumatology, it was reported that symptomatic OA of the knee occurs in 10-13% of individuals over the age of 60. OA is caused by inflammation of the soft tissue and bony structures of the joint which worsens over time and leads to progressive thinning of articular cartilage, narrowing of the joint space, synovial membrane thickening, osteophyte formation and increased density of subchondral bone, according to Oxford Journals: Rheumatology. These changes eventually result in chronic pain and disability, and deterioration of the joint despite drug therapy and may eventually require surgery or total joint replacement. Current drug treatment for OA of the knee relies on pain control with analgesics, anti-inflammatory treatment with NSAIDs, and intra-articular injections of steroids or hyaluronates. An article published in the American Academy of Orthopedic Surgeons adds that current drug treatments have been shown to have mixed results and may have significant limitations due to various adverse effects such as gastrointestinal irritation and bleeding.

#### ***Current Treatment Options***

There are a variety of pharmacological treatments for the symptoms of OA, including oral NSAIDs and COX-2 inhibitors, as well as topical NSAIDs, injectable steroids and injectable hyaluronic acids. We believe that Ampion<sup>TM</sup> will compete directly with the injectables, but depending upon the ultimate safety and efficacy of the product, it might also replace some of the other forms of treatment. One of the market leader hyaluronic acids, Genzyme's Synvisc, reported over \$300,000,000 in revenues in 2011, and clinical studies have shown modest efficacy relative to control. Steroid injections are generic, effectively off-label, and concerns have been expressed that chronic steroid injections could lead to joint destruction and tissue atrophy. However, there are numerous clinical areas in need of improved anti-inflammatory medications.

#### ***Ampion<sup>TM</sup>***

Ampion<sup>TM</sup> is a non-steroidal anti-inflammatory biologic that has the potential to be used in a broad array of inflammatory conditions and autoimmune diseases. The active ingredient is aspartyl-alanyl diketopiperazine, referred to as DA-DKP, which is derived from two amino acids from human albumin and appears to have a significant role in the homeostasis of inflammation. We have published a number of studies and articles on the anti-inflammatory activity of DA-DKP.



***Completed Clinical Trials***

In October 2011, we released a preliminary analysis of our 60 patient Ampion™ clinical trial for patients with osteoarthritis of the knee in Australia. Sixty patients were injected with a steroid (standard of care) with or without Ampion™. Initial results showed Ampion™ was well tolerated with no additional difference in adverse events and further demonstrated synergistic efficacy in

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combination with the steroid. These results permitted expansion of the trial to 32 patients with an addition of two arms comparing Ampion™ as a mono-therapy versus vehicle (normal saline). In May 2012, we announced results of the expanded trial, which showed statistically significant pain relief of osteoarthritis 84 days after a single injection. One method of analysis we use is to determine if any change from baseline is significant (each patient serves as their own control). The change from baseline for patients treated with Ampion™ was statistically significant at both 30 and 84 days after injection ( $p < 0.05$  for day 30 and day 84) and the change from baseline for the placebo treated patients was not statistically significant ( $p = 0.08$  day 30,  $p = 0.34$  at day 84). In addition, Ampion™ showed a statistically significant ( $p = 0.04$ ) difference in pain relief compared to vehicle. Moreover, percentage of responders in the group who received Ampion was more than twice the percentage of those who received saline (53% vs. 24%) and this approached statistical significance ( $p = 0.06$ ). A responder was defined as someone who experienced a two or more points shift improvement in pain relief as measured by the numerical pain scale (scale of 1-10).

### ***Upcoming Clinical Trial***

In December 2012, we submitted an IND to the FDA for the Phase III pivotal trial based upon the guidance received at the pre-IND meeting with the FDA in May 2012. Our prior IND submission and FDA guidance suggested we would complete two Phase III studies (AP-003 and AP-004) with respect to Ampion, each having approximately 800 patients. In February 2013, we received new formal guidance from the FDA indicating that the Company should conduct a dose ranging study as a Phase II dose-escalation study or as a run-in study for one of the Phase III studies. Now, as currently proposed in our revised IND, one of our Phase III studies

(AP-004) will be conducted as a run-in study following the first study (AP-003A) with 320 patients. The size of the AP-004 study will be determined by statistical power based on the AP-003A study. The run-in allowance that the FDA has provided Ampio means that data can be presented anytime enough data is collected to support the hypothesis, which will allow for a rapid turn-around.

### **Optina™ : Oral Danazol for Diabetic Macular Edema (DME)**

#### ***Market Statistics***

Diabetic Macular Edema (DME) is a swelling of the retina in diabetic patients due to leaking of fluid from blood vessels within the macula. The macula is the part of the eye responsible for sharp central vision. According to the American Diabetes Association, there are approximately 26 million people in the United States with diabetes and DME can occur in both Type 1 and Type 2 diabetes. According to the Digital Journal of Ophthalmology by Harvard University, up to 10% of diabetics will develop DME during their lifetime and up to 75,000 new cases of DME are estimated to occur each year in the United States.

The systemic nature of diabetes which affects, among other things, the microvascular system is manifested by local and systemic inflammation. The known prevalent systemic complications of diabetes are DME and retinopathy, myocardial ischemia and infarction, nephropathy and peripheral neuropathy. Early indications also suggest that low dose danazol may also be efficacious in decreasing vascular permeability in the kidneys of diabetic patients and, therefore, potentially delaying the onset of diabetic nephropathy. Development of Vasaloc™, another of our product candidates, as a separate indication is pending supportive data from the Optina™ trial and discussion with regulators.

#### ***Current Treatment Options***

Current treatments include anti-vascular endothelial growth factor ( VEGF ) drugs, corticosteroid-based regimens, and laser surgery that helps seal the leaky blood vessels. Drug delivery by injection into the vitreous of the eye is a limitation of these new treatments because of the potential complications due to repeated injections into the eye such as infection, pain, hemorrhage and increased intraocular pressure.

#### ***Optina™***

Optina is a drug based on a low dose of the weak androgen, low-molecular-weight, very lipophilic steroid danazol. Our in vitro data suggest that danazol has a biphasic effect on endothelial cells, which means at low doses, danazol decreases vascular leakage, while at higher concentrations an increase in vascular permeability is observed. This biphasic effect was supported by the efficacy of danazol in vivo at various BMIs. From Ampio's previously announced results, Optina™ appears to reduce DME in a BMI dosage-adjusted manner and appears to trend toward improved visual acuity and seems to be safe with few side effects shown in our studies.

#### ***Completed Clinical Trials***

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In 2012, we released results of the human clinical trial, A Randomized, Double-masked, Placebo-Controlled, Parallel Treatment Group, Dose-Ranging, Efficacy and Safety Study of Oral Optina™ Capsules in Subjects with Diabetic Macular Edema, conducted at St. Michael's Hospital in Toronto, Canada. The study was double masked and included 32 patients with moderate to severe diabetic macular edema (range 316-707microns) that were treated orally with either placebo or one of three doses of Optina. The results confirm a significant interaction between the patient's body mass index (BMI) and efficacy at the different doses of Optina. For higher BMI (BMI=35) patients, higher doses of Optina were more effective and for lower BMI (BMI=26) patients, lower doses

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were more effective. Defined a priori, and supported by an American Ophthalmological Society thesis published in 2010, a decrease in retinal thickness exceeding 11% was considered clinically significant. In the subgroup of patients whose retinal thickness decreased by more than 11%, the inverse linear relationship between change from baseline BCVA and percent change in baseline retinal thickness was statistically significant, ( $r^2=0.52$ ,  $p=0.01$ ). Using the ICD-9-CM Categories for visual acuity defined as: severe vision loss (BCVA score: 35-54); moderate vision loss (BCVA score: 55-74); and mild vision loss (BCVA score: 75-94), 47% (7/15) of subjects treated with Optina improved at least one category (3.3 fold over placebo).

### ***Upcoming Clinical Trial***

The FDA granted Optina™ 505(b)(2) status in July, 2012, and we commenced enrollment in the clinical trial in February 2013. Drugs designated under this pathway can be approved on a single trial. The planned multicenter trial is designed to evaluate the safety and efficacy of oral Optina™ compared with placebo given over a period of 12 weeks in adult patients with DME. Patients will be randomized to receive one of two doses of Optina (0.5mg per BMI and 1.0mg per BMI per day) or placebo. After patients have completed 4 weeks of initial treatment, an interim analysis will occur to determine the best dose of Optina™. Following the 12 week active treatment period, there will be a further 4 week washout period to determine regression of treatment effect. The primary endpoint is improvement in visual acuity (VA), defined by responder status, compared to placebo. Secondary endpoints are (i) measurements of changes in VA and central macular thickness (CMT) in treated patients compared to placebo, and (ii) safety and tolerability of the two Optina doses. Following treatment and washout, patients will be assessed for vision regression and a 12 week open label extension study will be offered to evaluate the duration of effect of the optimal dose. A total of 450 patients are expected to enroll.

### **Sexual Dysfunction Portfolio - Zertane and PE-ED Combo**

According to Australia's Keough Institute of Medical Research, premature ejaculation (PE) 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 may be large and, depending on the definition used (less than one minute or less than two minutes); the incidence is estimated to be 3 to 23% of males suffering from PE. At present, no drug has been approved by the FDA for the treatment of PE. Zertane™ is an orally disintegrating tablet (ODT) formulation of tramadol hydrochloride. Our Phase III clinical trial for Zertane™ was a randomized, double-blind, placebo-controlled, multi-center study to evaluate the efficacy and safety of two doses of Zertane™ for the treatment of PE. The clinical study demonstrated statistically significant efficacy and safety for Zertane™ in treating PE, utilizing co-primary endpoints of Intravaginal Ejaculatory Latency Time (IELT) and a Premature Ejaculation Profile (PEP).

We are in the process of preparing our regulatory dossier for Zertane™ and expect to submit the dossier to the Australian regulatory authority, the TGA, in 2013. In the second quarter of 2012 we held a pre-IND meeting with the FDA where they provided necessary guidance on the design to conduct two concurrent phase III pivotal clinical trials of approximately 15 weeks in duration with the caveat that one of the two co-primary endpoints, the patient reported outcome questionnaire, must be validated. We completed the seven week validation trial and submitted the results to the FDA in late 2012 and are waiting to hear back from the FDA. Once the FDA officially validates the questionnaire, the two phase III pivotal trials are set to begin. We are actively seeking partners to commercialize Zertane™ worldwide. For example, in September 2011, we entered into a license, development and commercialization agreement with Daewoong Pharmaceuticals Co., Ltd., in South Korea, which grants the pharmaceutical company exclusive rights to market Zertane™ in South Korea for the treatment of PE and for a combination drug to be developed, utilizing a combination of Zertane™ and a class of erectile dysfunction drugs known as PDE-5 inhibitors. We are in active discussions with other parties regarding potential licensing, marketing, and distribution opportunities worldwide as well as an outright asset purchase of the sexual dysfunction portfolio.

### **ORP (Oxidation Reduction Potential): Point of Care Diagnostic**

We are developing a handheld Oxidation-Reduction Potential (ORP) diagnostic device for use at home or in healthcare facilities that will measure the oxidants/antioxidant balances in human blood and plasma. ORP is a tightly controlled bodily parameter, and abnormal changes in oxidation-reduction potential are closely associated with poor outcomes in critically ill patients, and oxidative stress is often a marker for inflammation, which in turn indicates the presence of disease-related processes or developing conditions. The ORP device, a battery-powered unit using a drop of whole blood or plasma exposed to a disposable electrode, is intended to provide the first integrated measure of total oxidative stress status for clinical practice. We announced in April 2012 that we completed enrollment in a multiple indication study. The clinical trials include patients presenting to the emergency department with chest pain and undergoing clinical evaluation including the performance of Positron Emission Tomography coupled to Computerized Axial Tomography (PET/CT) to detect the presence or absence of myocardial ischemia (523 patients enrolled), patients presenting with stroke symptoms (850 patients enrolled) and in trauma patients including traumatic brain injury where we already published favorable results (more than 3500 patients enrolled).



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In February 2013, we announced the incorporation and initiation of operations of Luoxis Diagnostics, Inc. ( Luoxis ), a wholly-owned subsidiary, focused on commercialization of ORP. The new diagnostic company, with a separate management team, plans to begin preparing a 510(k) submission and CE Mark approval application upon completion of data analysis, expected in the near future.

### **NCE001: Methylphenidate Derivative for Oncology**

#### ***Market Statistics***

The methylphenidate derivatives are being considered for the treatment of Glioblastoma multiforme (a fatal brain cancer), renal cell carcinoma, inflammatory breast cancer, and for autoimmune/inflammatory conditions, including ophthalmic disorders. Ampio is currently sponsoring the pre-clinical work required to determine the most appropriate indication(s) for NCE001.

#### ***Current Treatment Options***

Generally speaking, there are three methods to fight cancer other than surgery: (i) radiation therapy, (ii) chemotherapy and (iii) enzyme therapy. Enzyme therapy mostly consists of a group of molecules called kinase inhibitors. NCE001 would fall outside of this category denoted a phosphatase promoter. We believe there are no phosphatase promoters on the market or nearing commercialization.

#### ***NCE001***

NCE001 activates a specific intracellular phosphatase largely involved in inflammation, angiogenesis and cell proliferation pathways and has demonstrated remarkable anti-angiogenesis and anti-metastasis properties in vitro on aggressive cancer cells of three lineages: glioblastoma multiforme, renal cell carcinoma and inflammatory breast cancer. We believe it may play an important role in treating these particularly aggressive cancers.

#### ***Ongoing Pre-Clinical Work***

We have entered into a master services agreement with Syngene International (Bangalore, India) to evaluate and test comparative compounds in the methylphenidate derivative family with the potential of proceeding to determine its ultimate safety profile before submitting an IND application to the FDA.

### **Government Regulation**

#### ***FDA Approval Process***

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical and biologic product development in the US typically involves 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 current good manufacturing practices, or cGMP, a quality system regulating manufacturing, the submission and acceptance of an Investigational New Drug ( IND ) application which must become effective before human clinical trials may begin in the US, 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, adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug or biologic for each indication for which FDA approval is sought, and the submission to the FDA for review and approval of a New Drug Application ( NDA ) or Biologic License Application ( BLA ). Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

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 (in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the

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roles of clinical trial sponsors), analytical data and the clinical trial protocol (detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated), 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

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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 or Ethics Committee ( EC ). 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. The FDA or and IRB/EC may order the temporary, or permanent, discontinuation of a clinical trial or a specific clinical trial site to be halted at any time, or impose other sanctions for failure to comply with requirements under the appropriate entity jurisdiction.

Clinical Trials to support NDAs and BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. 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. During Phase II trials, 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 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 and adequate information for labeling of the drug or biologic.

After completion of the required clinical testing, a NDA or BLA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting a NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding \$1.8 million and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees, currently approximately \$0.1 million per product and \$0.5 million per establishment. These fees are typically increased annually.

The FDA has 60 days from its receipt of a NDA to determine whether the application will be accepted for filing based on the FDA's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for standard review drug products are reviewed within ten months; most applications for priority review drugs are reviewed in six months. We expect the FDA to amend each of these goals to extend them by two months for applications received after September 2012. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited only for drugs intended to treat a serious or life-threatening disease relative to the currently approved products. The review process for both standard and priority review may be extended by FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA may also refer applications for novel drug products, or drug products which present difficult questions of safety or efficacy, to an advisory committee typically a panel that includes clinicians and other experts for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving a NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.





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### ***Fast Track Designation***

The FDA has developed Fast Track policies, which provide the potential for expedited review of an NDA. Fast Track status is potentially 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. 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.

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.

### ***Accelerated Approval***

Under the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit. In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

### ***Foreign Regulatory Approval***

Outside of the United States, our ability to market our 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.

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.

### ***The Hatch-Waxman Act***

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In seeking approval for a drug through a NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the

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listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as generic equivalents to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: 1) the required patent information has not been filed; 2) the listed patent has expired; 3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or 4) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any non-patent exclusivity listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active ingredients during which ANDAs for generic versions of those drugs cannot be submitted, unless the submission contains a Paragraph IV challenge to a listed patent in which case the submission may be made four years following the original product approval. Federal law provides for a period of three years of exclusivity during which FDA cannot grant effective approval of an ANDA based on the approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use; the approval of which was required to be supported by new clinical trials conducted by, or for, the applicant.

### ***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 the contract manufacturers we use for manufacture of clinical supplies and commercial supplies 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.

### **Intellectual Property Summary**

As of December 31, 2012, we owned or were the exclusive licensee under 21 issued United States patents, 46 U.S. pending patent applications, 201 issued international patents, and 149 pending international patent applications.



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Ampion™. As of December 31, 2012, we owned or were the exclusive licensee under five issued United States patents, 11 U.S. pending patent applications, 35 issued international patents, and 31 pending international patent applications that are relevant to Ampion™.

Optina™. As of December 31, 2012, we owned or were the exclusive licensee under one issued United States patent, eight U.S. pending patent applications, 40 issued international patents, and 49 pending international patent applications that are relevant to Optina™.

Zertane™. As of December 31, 2012, we owned or were the exclusive licensee under one issued United States patent, five U.S. pending patent applications, 69 issued international patents, and 22 pending international patent applications that are relevant to Zertane™.

ORP. As of December 31, 2012, we owned or were the exclusive licensee under 2 issued United States patent, 8 U.S. pending patent applications, 0 issued international patents, and 4 pending international patent applications that are relevant to ORP.

Methylphenidate derivatives. As of December 31, 2012, we owned or were the exclusive licensee under 1 issued United States patent, 2 U.S. pending patent applications, 21 issued international patents, and 5 pending international patent applications that are relevant to methylphenidate derivatives.

Copper Chelating Peptides. As of December 31, 2012, we owned or were the exclusive licensee under 7 issued United States patent, 2 U.S. pending patent applications, 10 issued international patents, and 15 pending international patent applications that are relevant to copper chelating peptides.

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.

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 an application for 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

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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

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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.

We cannot assure you that any of our products that we successfully develop will be clinically superior or scientifically preferable to products developed or introduced by our competitors.

Many of our actual and potential competitors have substantially longer operating histories and possess greater name recognition, product portfolios, and significantly greater experience in discovering, developing, manufacturing, and marketing products as well as 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 strategic partners. 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: (i) potential advantages over existing or alternative therapies or tests, (ii) the actual or perceived safety of similar classes of products, (iii) the effectiveness of sales, marketing, and distribution capabilities, and (iv) 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 on our behalf 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.

For the years ended December 31, 2012, 2011 and 2010, we recorded \$7.5 million, \$6.6 million and \$2.0 million, respectively, of research and development expenses. Research and development expenses represented 63.1 %, 59.6% and 29.4% of total operating expenses in the years ended December 31, 2012, 2011 and 2010, respectively. More information regarding our research and development activities can be found in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" under Item 7 of this Annual Report.

### **Manufacturing**

Our business strategy is to use cGMP compliant contract manufacturers for manufacture of clinical supplies as well as for commercial supplies if required by our commercialization plans, and to transfer manufacturing responsibility to our collaboration partners when possible.





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### **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 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 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.

### **Employees**

As of March 6, 2013, we had 13 full-time employees and utilized the services of a number of consultants on a temporary 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.

### **Available Information**

Our principal executive offices are located at 5445 DTC Parkway, Suite 925, Greenwood Village, Colorado 80111 USA, and our phone number is (720) 437-6500.

We maintain a website on the internet at [www.ampiopharma.com](http://www.ampiopharma.com). We make available free of charge through our website, by way of a hyperlink to a third-party site that includes filings we make with the SEC website ([www.sec.gov](http://www.sec.gov)), our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports electronically filed or furnished pursuant to Section 15(d) of the Exchange Act. The information on our website is not, and shall not be deemed to be, a part of this annual report on Form 10-K or incorporated into any other filings we make with the SEC. In addition, the public may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington D.C., 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. Our Code of Conduct and Ethics and the charters of our Nominating and Governance Committee, Audit Committee, and Compensation Committee of our Board of Directors may be accessed within the Investor Relations section of our website. Amendments and waivers of the Code of Conduct and Ethics will also be disclosed within four business days of issuance on the website. Information found in our website is neither part of this annual report on Form 10-K nor any other report filed with the SEC.

### **Item 1A. Risk Factors** **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 inception. As of December 31, 2012, we had an accumulated deficit of approximately \$39.8 million. We expect our annual net losses to continue over the next several years as we advance development programs and incur significant clinical development costs.

We have not received, and do not currently expect to receive, any revenues from the commercialization of our product candidates. We have entered into and may enter into additional licensing and collaboration arrangements, which may provide us with potential milestone payments and royalties and those arrangements, if obtained, will be our primary source of revenues for the coming years. For example, in September 2011,

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we entered into a license, development and commercialization agreement with a major Korean pharmaceutical company with respect to Zertane in South Korea, which provided for a \$500,000 upfront payment and future milestone payments that are contingent upon achievement of regulatory approvals and cumulative net sales targets. We cannot be certain that this or other licensing or collaboration arrangements will be concluded, or that the terms of those arrangements will result in our receiving material revenues. To obtain revenues from 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.

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

A key aspect of our current strategy is to selectively enter into collaborations with third parties to conduct clinical testing, as well as to commercialize and manufacture product candidates. We currently have only one collaboration agreement in effect, which relates to Zertane in South Korea. 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 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, the collaborators 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;

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, our former 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 and thereafter terminated the collaboration agreement. 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 we experienced in the above 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 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.

***We will need additional funding and if we are unable to raise capital when needed, it would harm our product development and commercialization efforts.***

We will require additional capital to fund our operations, including to:

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continue to fund, or initiate funding for, clinical trials of Ampion and Optina;

prepare for and apply for regulatory approval for our product candidates;

further develop and assess the clinical utility of the oxidation reduction potential (ORP) diagnostic device, or the ORP device;

develop additional product candidates;

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conduct additional clinical research and development;

pursue existing and new claims covered by intellectual property we own or license; and

sustain our corporate overhead requirements, and hire and retain necessary personnel.

Until we can generate revenue from collaboration agreements to finance our cash requirements, which we may not accomplish, we expect to finance future cash needs primarily through offerings of our debt or equity securities. We currently have only one collaboration agreement in effect, which relates to Zertane in South Korea.

We do not know whether additional funding will be available to us on acceptable terms, or at all. If we are unable to secure additional funding when needed, we may have to delay, reduce the scope, or eliminate development of one or more of our product candidates, or substantially curtail or close our operations altogether. Alternatively, we may have to obtain a collaborator for one or more of our product candidates at an earlier stage of development, which could lower the economic value of those product candidates to us.

***Ampion, Optina and the ORP Device are currently undergoing, or are expected to 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 continue to work toward completion and analysis of clinical trials for three primary products: Ampion, Optina and the ORP device. An unfavorable outcome in one or more trials for Ampion, Optina or the ORP Device would be a major set-back for the development programs for these product candidates and for us. 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 us and the value of our common stock.

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;

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

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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.

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*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 could take from six to 24 months to complete, but the completion of trials for our product candidates may be delayed for a variety of reasons, including delays in:

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

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

manufacturing sufficient quantities of a product candidate;

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

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

determining dosing and making related adjustments; and

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

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

lack of effectiveness of product candidates during clinical studies;

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

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;



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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 clinical trials or requests for supplemental information with respect to 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

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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 delay, 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. We cannot be certain 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.

In addition, 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. 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;

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 this 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;

withdrawals of previously approved marketing applications; and

finances, civil penalties, and criminal prosecutions.

***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 or repositioned product are complex, require a number of years and involve the expenditure of substantial resources. We cannot assure you that any of our product candidates will receive FDA approval in the future, and the time for receipt of any such approval is currently incapable of estimation.

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

Assuming successful completion of clinical trials, we expect to submit NDAs to the FDA at various times in the future under §505(b)(2) of the Food, Drug and Cosmetic Act, as amended, or the FDCA. NDAs submitted under this section are eligible 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

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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 the application may lead the FDA to request more information or require us to perform additional clinical

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trials, thus adding to 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 it submits, 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 the 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. 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 the 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 the 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 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, its reputation in the marketplace may suffer, and we could face lawsuits.

We also are 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, 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



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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. If we fail to achieve 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 December 31, 2012, we had cash and cash equivalents of approximately \$17.7 million. Based upon our current expectations, we believe our capital resources at December 31, 2012 will be sufficient to fund our currently planned operations for the next 12 months. We have not received, and do not expect to receive for several years, any revenues from the commercialization of our product candidates. In July 2012, we obtained a total of \$15.4 million in net proceeds from the sale of our common stock in an underwritten public offering. We anticipate we will require significant additional financing to continue to fund our operations beyond the next 12 months. Our future capital requirements will depend on, and could increase significantly as a result of, many factors including:

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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;

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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 collaboration arrangements, 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 shareholders 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 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, in January 2013, we announced that we entered into a Master Service Agreement and Scope of Work with a clinical research organization with respect to our clinical trial for Ampion, and also entered into a Master Services Agreement and Scope of Work with a clinical research organization in connection with our clinical trial of Optina. We also 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.

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### ***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 the product candidate in commercial quantities. While we believe there are a number of alternative sources available to manufacture our product candidates, if and when regulatory approvals are received, we may not be able to secure manufacturing arrangements on a timely basis when required, or at a reasonable cost. We cannot estimate any delay in manufacturing or unanticipated manufacturing costs with certainty but, if either occurs, our commercialization efforts may be impeded or our costs may increase.

Once regulatory approval is obtained, a marketed product and its manufacturer are subject to continual review. The discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer or manufacturing facility, including withdrawal of the product from the market. Any manufacturers with which we contract are required to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs. A failure of any of our contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in the launch of products based on our product candidates into the market. Failure by 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 currently maintain an organization for the sale, marketing and distribution of pharmaceutical products and may 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 may 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 us.***

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 of new combinations of previously approved drugs, or which 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 us. 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;

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obtain patent and/or other proprietary protection for our product candidates;

obtain required regulatory approvals; and

obtain collaboration arrangements to commercialize our product candidates.

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

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 product candidates.***

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 is 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 any collaborator's ability to educate the medical community about the safety and effectiveness of the product;

the reimbursement policies of government and third party payors pertaining to the product; and

the market price of our product relative to competing treatments.

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

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

our or our collaborators' ability to set a price we believes 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, and could cause an increase in our compliance, manufacturing, or other operating expenses. 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.

## **Risks Related to Our Intellectual Property**

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

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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 December 31, 2012, we owned or were the exclusive licensee under 21 issued United States patents, 46 U.S. pending patent applications, 201 issued international patents, and 149 pending international patent applications.

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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 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 developed 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 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 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 prosecution, maintenance or enforcement of patents covering 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.***



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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.

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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 the pharmaceutical 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 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 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

us 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.

***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.

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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.

### **Risks Related to Our Common Stock**

*The price of our stock has been extremely volatile and may continue to be so, and investors in our stock could incur substantial losses.*

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 common stock:

any actual or perceived adverse developments in clinical trials for Ampion, Optina or the ORP device;

any licensee's termination of a license, such as that experienced with Zertane 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 of our product candidates when compared to existing treatments;

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;

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 introduction of 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 collaborators, or our competitors;

economic and other external factors beyond our control; and

sales of stock by us or by our shareholders.

***The price of our stock may be vulnerable to manipulation.***

In December 2011, our common stock was the subject of significant short selling efforts by certain market participants. Short sales are transactions in which a market participant sells a security that it does not own. To complete the transaction, the market participant must borrow the security to make delivery to the buyer. The market participant is then obligated to replace the security borrowed by purchasing the security at the market price at the time of required replacement. If the price at the time of replacement is lower than the price at which the security was originally sold by the market participant, then the market participant will realize a gain on the transaction. Thus, it is in the market participant's interest for the market price of the underlying security to decline as much as possible during the period prior to the time of replacement.

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Because our unrestricted public float (not subject to lockup restrictions) has been small relative to other issuers, previous short selling efforts have impacted, and may in the future continue to impact, the value of our stock in an extreme and volatile manner to the detriment of our shareholders and our Company. In addition, market participants with admitted short positions in our stock have published, and may in the future continue to publish, negative information regarding our Company and our management team on internet sites or blogs that we believe is inaccurate and misleading. We believe that the publication of this negative information has led, and may in the future continue to lead, to significant downward pressure on the price of our stock to the further detriment of our shareholders and our Company. These and other efforts by certain market participants to manipulate the price of our common stock for their personal financial gain may cause our stockholders to lose a portion of their investment, may make it more difficult for us to raise equity capital when needed without significantly diluting existing stockholders, and may reduce demand from new investors to purchase shares of our stock.

***If we cannot continue to satisfy the NASDAQ Capital Market listing maintenance requirements and other rules, including the director independence requirements, our securities may be delisted, which could negatively impact the price of our securities.***

Although our common stock is listed on the NASDAQ Capital Market, we may be unable to continue to satisfy the listing maintenance requirements and rules. If we are unable to satisfy the NASDAQ Capital Market criteria for maintaining our listing, our securities could be subject to delisting. To qualify for continued listing on the NASDAQ Capital Market, we must continue to meet specific criteria, including the following:

The minimum bid price of our shares must be at least \$1.00;

We must have at least 300 public shareholders (excluding officers, directors and beneficial holders of more than 10% of our outstanding shares);

We must have at least 500,000 publicly held shares;

The market value of our publicly held shares must be at least \$1,000,000;

(i) Our stockholders' equity must be at least \$2,500,000; (ii) our market value of listed securities must be at least \$35,000,000; or (iii) our net income from continuing operations must be at least \$500,000 in the most recently completed fiscal year or in two of the three most recently completed fiscal years; and

We must have adopted the exchange's mandated corporate governance measures, including maintaining a board of directors comprised of a majority of independent directors, an audit committee and compensation committee comprised solely of independent directors, and the adoption of a code of ethics, among other requirements.

If the NASDAQ Capital Market delists our securities, we could face significant consequences, including:

a limited availability for market quotations for our securities;

reduced liquidity with respect to our securities;

a determination that our common stock is a penny stock, which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in reduced trading;

activity in the secondary trading market for our common stock;

limited amount of news and analyst coverage; and

a decreased ability to issue additional securities or obtain additional financing in the future.

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In addition, we would no longer be subject to the NASDAQ Capital Market rules, including rules requiring us to have a certain number of independent directors and to meet other corporate governance standards.

### ***Concentration of our ownership limits the ability of our shareholders to influence corporate matters.***

As of December 31, 2012, our directors, executive officers and their affiliates beneficially owned approximately 21.6% of our outstanding common stock. These shareholders may control effectively the outcome of actions taken by us that require shareholder approval.

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

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

requiring supermajority shareholder voting to effect certain amendments to our certificate of incorporation and bylaws;

restricting the ability of shareholders to call special meetings of shareholders;

prohibiting shareholder 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 shareholders at shareholder 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, may create difficulties for companies such as ours in understanding and complying with these laws and regulations. As a result of these difficulties 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 securities analysts do not publish research or reports about our business or if they downgrade our stock after instituting coverage, the price of our common 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 us, or if an industry analyst institutes coverage and later decides to cease covering us, 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 that stock, our stock price would likely decline rapidly in response.

### ***We have no plans to pay dividends on our common stock.***



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We have no plans to pay dividends on our common stock. We generally intend to invest 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 our Board of Directors deem relevant. Any future credit facilities or preferred stock financing we obtain may further limit our ability to pay dividends on our common stock.

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**Item 1B.    *Unresolved Staff Comments***

None.

**Item 2.     *Properties***

We maintain our headquarters in leased space in Greenwood Village, Colorado, for a monthly rental of approximately \$8,900. The lease expires in July 2014. We anticipate that the lease can be renewed on terms similar to those now in effect.

**Item 3.     *Legal Proceedings***

We are currently not a party to any material legal or administrative proceedings and are not aware of any material pending or threatened legal or administrative proceedings in which we will become involved.

**Item 4.     *Mine Safety Disclosures.***

Not applicable.

**Table of Contents****PART II****Item 5. *Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***  
**Market Data**

On May 19, 2011, our common stock began trading on the NASDAQ Capital Market under the ticker symbol **AMPE**. It was previously quoted on the Over-the-Counter Bulletin Board under the symbol **AMPE.OB**. The following table sets forth the high and low last reported sale price information for our common stock for each quarter for the past two fiscal years.

	<b>Common Stock</b>	
	<b>High</b>	<b>Low</b>
First quarter 2010	\$ 1.50	\$ 1.50
Second quarter 2010	\$ 4.50	\$ 0.75
Third quarter 2010	\$ 3.50	\$ 1.00
Fourth quarter 2010	\$ 3.00	\$ 2.01
First quarter 2011	\$ 8.75	\$ 2.20
Second quarter 2011	\$ 8.61	\$ 2.80
Third quarter 2011	\$ 9.19	\$ 4.32
Fourth quarter 2011	\$ 8.26	\$ 3.77
First quarter 2012	\$ 4.51	\$ 2.68
Second quarter 2012	\$ 5.08	\$ 2.56
Third quarter 2012	\$ 5.43	\$ 2.65
Fourth quarter 2012	\$ 4.12	\$ 3.14

As of February 5, 2013, there were of record approximately 4,075 holders of our common stock.

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.

**Performance Graph**

We have presented below the cumulative total return to our stockholders during the period from March 31, 2010 (the date our common stock commenced trading on the NASDAQ Capital Market) through December 31, 2012 in comparison to the cumulative total return of the NASDAQ Composite Index and the NASDAQ Biotechnology Index. All values assume a \$100 initial investment on March 31, 2010, and the reinvestment of the full amount of all dividends and are calculated as of the last stock trading day of each year. The comparisons are based on historical data and are not indicative of, nor intended to forecast, the future performance of our common stock.

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The information under Performance Graph is not deemed to be soliciting material or filed with the Securities and Exchange Commission or subject to Regulation 14A or 14C, or to the liabilities of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference in any filing of Ampio Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K and irrespective of any general incorporation language in those filings.

**Unregistered Sales of Equity Securities and Use of Proceeds**

Information regarding unregistered sales of equity securities and use of proceeds is incorporated by reference to Item 15 of Part IV, Notes to Consolidated Financial Statements Note 6 Short Term Debt and Note 11 Common Stock of this annual report on Form 10K.

**Equity Compensation Plan Information**

At the special meeting on March 1, 2010, our shareholders approved the adoption of a stock and option award plan (the 2010 Plan), under which 2,500,000 shares were reserved for future issuance under restricted stock awards, options, and other equity awards. The 2010 Plan permits grants of equity awards to employees, directors and consultants. On August 15, 2010, the number of shares issuable under the 2010 Plan was increased to 4,500,000 shares by consent of our majority shareholders. At the annual shareholders meeting, held December 3, 2011, the number of shares issuable under the 2010 Plan was increased to 5,700,000. At the annual shareholders meeting held December 15, 2012, the number of shares issuable under the 2010 Plan was further increased to 8,200,000. The following table displays equity compensation plan information as of December 31, 2012.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders	4,922,815	\$ 2.25	2,257,065
Equity compensation plans not approved by security holders			
Total	4,922,815	\$ 2.25	2,257,065

**Table of Contents****Item 6. Selected Financial Data**

Our selected consolidated financial data shown below should be read together with Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and respective notes included in Item 8 Financial Statements and Supplementary Data referencing Item 15 of Part IV. The data shown below is not necessarily indicative of results to be expected for any future period.

	Years Ended December 31,				December 18, 2008 (Inception) through December 31, 2008
	2012	2011	2010	2009	
<b>Selected Statements of Operations Data:</b>					
License revenue	\$ 50,000	\$ 18,750	\$	\$	\$
Research and development	7,493,824	6,614,384	1,883,150	962,679	
Research and development -related party (Note 13)		34,013	88,984	107,691	
General and administrative	4,376,932	4,504,494	4,732,271	441,135	1,080
Interest income	21,943	6,684	815	1,091	
Interest expense		8,358	19,545	1,414	
Unrealized gain (loss) on fair value of debt instruments		(5,585,422)	37,511		
Derivative income (expense)	205,768	(1,555,497)	(1,367,771)		
Net loss, before income tax	(11,593,045)	(18,276,734)	(8,053,395)	(1,511,828)	(1,080)
Foreign tax expense		82,500			
Net loss	\$ (11,593,045)	\$ (18,359,234)	\$ (8,053,395)	\$ (1,511,828)	\$ (1,080)
<b>Per share data:</b>					
Weighted average number of common shares outstanding	33,983,590	26,013,838	16,288,468	14,793,068	
Basic and diluted net loss per common share	\$ (0.34)	\$ (0.71)	\$ (0.49)	\$ (0.10)	\$
<b>Selected Balance Sheets Data:</b>					
Cash and cash equivalents	\$ 17,682,517	\$ 11,362,325	\$ 671,279	\$ 71,983	\$
Prepaid expenses	164,890	43,120	60,534	7,036	
Related party receivable			5,711	7,261	
Fixed assets, net	59,290	76,230			
In-process research and development	7,500,000	7,500,000			
Patents, net	420,468	465,924			
Deposits	20,000	35,000			
Total assets	25,847,165	19,482,599	737,524	86,280	
Accounts payable	1,201,122	630,622	464,453	79,445	
Deferred revenue	50,000	50,000			
Accrued salaries and other liabilities			526,733	73,391	
Accrued interest			19,693	1,414	
Related party payable			193,821		
Senior convertible unsecured related party debentures			608,846		
Senior unsecured mandatorily convertible debentures			2,133,743		
Warrant derivative liability	384,771	610,911	398,671		
Related party notes payable			400,000	200,000	
Long-term deferred revenue	381,250	431,250			
Total liabilities	2,017,143	1,722,783	4,745,960	354,250	
Total stockholders' equity (deficit)	23,830,022	17,759,816	(4,008,436)	(267,970)	1,080

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### **Item 7. 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 elsewhere in this report. Some of the information contained in this discussion and analysis, 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 Form 10-K 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 biopharmaceutical company focused on the rapid development of therapies to treat prevalent inflammatory conditions for which there are limited treatment options. We are focused on providing medicines to improve the health and quality of life of patients with minimal side effects. We are developing compounds that decrease inflammation by (i) inhibition of specific pro-inflammatory compounds by affecting specific pathways at the protein expression and at the transcription level or (ii) activation of a specific phosphatase or depletion of the available phosphate needed for the inflammation process. We are also focused on monetizing our sexual dysfunction portfolio and a diagnostic device.

#### **Financing Activities**

On September 30, 2011 Ampio filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission ( SEC ) to register Ampio common stock and warrants in an aggregate amount of up to \$80 million for offering from time to time in the future. The registration statement also registers for possible resale up to one million shares of common stock to be sold by directors and management (as selling shareholders) in future public offerings. On October 13, 2011 Ampio filed an amendment to identify potential selling stockholders and the number of shares they would be eligible to sell in the event of a future public offering. The shelf registration was declared effective on October 28, 2011 by the SEC. At December 31, 2012 Ampio had \$53.7 million available for future public offerings along with 714,900 shares remaining for future sale by named selling shareholders.

In July 2012 Ampio completed an underwritten public offering for the sale of 5,203,860 shares of common stock at a price of \$3.25 per share. Gross proceeds to Ampio were \$16,912,545 with net proceeds of \$15,353,150 after underwriter fees and cash offering expenses. Ampio also issued warrants to purchase 138,462 shares of common stock to the underwriters. These warrants have an exercise price of \$4.0625 and can be exercised from the period July 12, 2013 through July 12, 2017. Certain shareholders also became selling shareholders and received gross proceeds of \$926,575 from the offering of 285,100 shares as provided in the registration statement. The net proceeds of the 2012 offering have been or will be used for general corporate purposes and working capital, including completion of the Ampio and Optina clinical trials and costs related to the regulatory approval and commercialization of Zertane.

#### **Management Update**

On December 15, 2012, Ampio entered into an employment agreement with Joshua R. Disbrow to serve as the Chief Operating Officer ( COO ).

Effective January 9, 2012, at the request of Donald B. Wingerter, Jr., Chief Executive Officer ( CEO ), Ampio granted a compassionate leave to him from all his duties as CEO, member of the Board of Directors and as an employee. Ampio's Chairman of the Board, Michael Macaluso, was appointed CEO concurrent with Mr. Wingerter's departure.

#### **Known Trends or Future Events; Outlook**

We have not generated any significant revenues and have therefore incurred significant net losses totaling \$39.5 million since our inception in December 2008. The assets we purchased from BioSciences in April 2009 generated minimal revenues prior to their acquisition. We expect to generate operating losses for the foreseeable future, but intend to try to limit the extent of these losses by entering into co-development or collaboration agreements with one or more strategic partners. Although we have raised capital in the past and raised net proceeds of \$15.4 million and \$19.4 million through the sale of common stock in 2012 and 2011, respectively, we cannot assure you that we will be able to secure such additional financing, if needed, or that it will be adequate to execute our business strategy. Even if we obtain additional financing, it may be costly and may require us to agree to covenants or other provisions that will favor new investors over existing shareholders.

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Our primary focus is advancing the clinical development of our core assets: Ampion and Optina. We have filed the proposed protocol for the upcoming Ampion study based on the new guidance received by the FDA in February 2013 with the FDA and are waiting for their response. We have previously announced the initiation of a 505(b)(2) clinical trial of Optina in diabetic macular edema. These trials will be blinded and conducted by third party clinical research organizations and we have announced that the costs associated with these contracts will be \$6.0 million for the Optina trial and less than \$3.0 million for the Ampion trial. In addition, we are involved in active discussions with other parties regarding potential licensing, marketing, and distribution opportunities worldwide as well as an outright asset purchase of the sexual dysfunction portfolio. Luoxis Diagnostics, Inc., a wholly-owned subsidiary, focused on commercialization of ORP is currently seeking private financing. We are also sponsoring the pre-clinical development of NCE001 and hope to file an IND with the FDA by the end of 2013 in order to pursue clinical development of this product candidate for the treatment of cancer. Vasaloc, another one of our product candidates whose formulation is the same as Optina, for diabetic nephropathy will be evaluated for clinical development after completion and evaluation of the Optina trial. At this time, due to the risks inherent in the clinical trials and the stage of development of our product candidates, we are unable to estimate with any certainty the additional costs we will incur for the continued development of our product candidates for commercialization as clinical development timelines, probability of success, and development costs vary widely.

We are also focused on monetizing several of our other assets: our sexual dysfunction portfolio, ORP, and copper chelating peptides. However, we cannot forecast with any degree of certainty which product candidates will be subject to future collaborative or licensing arrangements, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our product candidate plans and capital requirements.

## **Significant Accounting Policies and Estimates**

Our consolidated financial statements have been prepared in accordance with accounting policies generally accepted in the United States of America. The preparation of the consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. On an on-going basis, management evaluates its estimates and judgments, including those related to recoverability of long-lived assets, fair value of our derivative instruments, allowances and contingencies. 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 consolidated financial statements.

## ***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. The \$500,000 fair value of the Zertane patents acquired in connection with the March 2011 acquisition of BioSciences is being amortized over the remaining U.S. patent lives of approximately 11 years beginning April 2011.

## ***In-Process Research and Development***

In-process research and development ( IPRD ) relates to the Zertane product and clinical trial data acquired in connection with the March 2011 business combination of BioSciences. The \$7,500,000 recorded was based on an independent third party appraisal of the fair value of the assets acquired. IPRD is considered an indefinite-lived intangible asset and its fair value will be assessed for impairment annually and written down if impaired. Once the Zertane product obtains regulatory approval and commercial production begins, IPRD will be amortized over its estimated useful life. If the commercialization of Zertane becomes impracticable or we abandon this drug, we will expense the \$7.5 million IPRD asset.

## ***Product Technology License***

Ampio acquired a Product Technology License for an orally disintegrating table ( ODT ) formulation for Zertane. The \$2 million license/asset purchase was expensed since the ODT formulation has not been petitioned for regulatory approval and the license does not have an alternative future use.

## ***Research and Development***

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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.



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### ***Stock-Based Compensation***

We account for stock-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 of options 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 requisite service period.

### ***Derivatives***

We account for hybrid financial instruments (debentures with embedded derivative features – conversion options, down-round protection and a mandatory conversion provision) and related warrants by recording the fair value of each hybrid instrument in its entirety and recording the fair value of the warrant derivative liability. The fair value of the hybrid financial instruments and warrants was calculated using a binomial-lattice-based valuation model. We recorded a derivative expense at the inception of each instrument reflecting the difference between the fair value and cash received. Changes in the fair value in subsequent periods were recorded as unrealized gain or loss on fair value of derivative instruments for the hybrid financial instruments and to derivative income or expense for the warrants.

### ***Income Taxes***

We use the liability method of accounting for income taxes. Under this method, we recognize 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. We establish a valuation allowance for all deferred tax assets for which there is uncertainty regarding realization.

### **Results of Operations Year Ended December 31, 2012, 2011 and 2010 See Notes to Consolidated Financial Statements.**

Results of operations for the years ended December 31, 2012, 2011 and 2010 reflected losses of \$ 11.6 million, \$18.4 million and \$8.1 million, respectively. These losses include non-cash charges related to depreciation and amortization expense, derivative expense, stock-based compensation and losses on the fair value of debt instruments in the amount of \$1.5 million in 2012, \$9.1 million in 2011 and \$4.4 million in 2010.

### ***Revenue***

We are a development stage enterprise and have not generated material revenue in our operating history. The \$50,000 and \$18,750 license revenue recognized in 2012 and 2011, respectively, represents the amortization of the upfront payment received on our license agreement. The initial payment of \$500,000 from the license agreement with a Korean pharmaceutical company was deferred and being recognized over 10 years.

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

Research and development costs consist of labor, research and development of patents and intellectual property, stock-based compensation as well as drug development and clinical trials. These costs are summarized as follows:

	Year Ended December 31,		
	2012	2011	2010
Labor	\$ 1,424,000	\$ 1,364,000	\$ 889,000
Patent costs	1,449,000	962,000	399,000
Stock-based compensation	396,000	316,000	381,000
Clinical trials and sponsored research	3,756,000	1,694,000	239,000
Technology license		2,000,000	
Consultants	469,000	312,000	64,000
	\$ 7,494,000	\$ 6,648,000	\$ 1,972,000

*Comparison of Years Ended December 31, 2012 and 2011*

Research and development expenses increased approximately 13% in 2012 over 2011. This was due primarily to costs associated with FDA pre-IND filings for our three major drug candidates, the IND submissions for Ampion and Optina, and clinical trials of Ampion and Optina. We also incurred costs related to the production of the study drugs for the Ampion and Optina trials. We continue to maintain and strengthen our patent portfolio while labor and stock compensation costs were relatively flat. These represent costs solely related to research and development without an allocation of general and administrative expenses.

*Comparison of Years Ended December 31, 2011 and 2010*

Research and development expenses increased approximately 237% in 2011 over 2010 as we refocused from building our corporate foundation to the corporate objective of research and development of drug candidates. The increase in expenses in 2011 relates to our primary product candidates as we began Ampion and Optina clinical trials early in 2011 and acquired a \$2,000,000 product technology license related to our Zertane product. We also continued to maintain and strengthen our patent portfolio on our primary product candidates. Labor costs increased as a result of several employees having job responsibilities change from administrative to research and development.

**General and Administrative**

General and administrative expenses consist of personnel costs for employees in executive, business development and operational functions; professional fees including legal, auditing and accounting; occupancy, travel and other including rent, governmental and regulatory compliance; and outside director fees. These costs are summarized as follows:

	Year Ended December 31,		
	2012	2011	2010
Labor	\$ 1,308,000	\$ 888,000	\$ 775,000
Stock-based compensation	1,227,000	1,671,000	2,715,000
Professional fees	399,000	656,000	863,000
Occupancy, travel and other	1,191,000	932,000	225,000
Directors fees	252,000	357,000	154,000
	\$ 4,377,000	\$ 4,504,000	\$ 4,732,000

*Comparison of Years Ended December 31, 2012 and 2011*

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There was an overall decrease of approximately 3% in general and administrative costs in 2012 from 2011. Labor costs increased in 2012 as the result of the employment agreement payout to our former CEO upon the granting of an indefinite compassionate leave of absence in January 2012. Stock-based compensation decreased in 2012 due to longer vesting periods being incorporated into new awards, resulting in straight line amortization of the fair value over a longer period. Professional fees consist primarily of legal, audit

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and accounting costs, costs related to the Chay Enterprises merger, public company compliance costs, and consulting related to capital formation. Professional fees decreased in 2012 as compared to 2011 since we had only routine filing and reporting requirements in 2012. In 2011 we had additional professional fees related to the filing of a Form S-4 with the SEC and the acquisition of BioSciences. Travel and investor/public relations costs increased in 2012 as we pursued business development and financing opportunities. Directors' fees decreased because only regularly scheduled meetings were held during 2012, compared to 2011 when additional meetings were required. No general and administrative costs are currently being allocated to the research and development activities.

### *Comparison of Years Ended December 31, 2011 and 2010*

General and administrative expenses decreased by 5% in 2011 from the 2010 expenses. Labor costs increased in 2011 over 2010 as we added new positions and transitioned from consultants to employees as workloads necessitated. Stock-based compensation decreased. Expansion of operations resulted in an increase of occupancy, travel and other costs increase in 2011. The director fees resulted from the adoption of a compensation plan for independent directors in August 2010. With the acceleration of research and development, job responsibilities of several existing employees changed from administrative functions so that the costs associated with those employees were more appropriately allocated to research and development beginning April 1, 2011.

### *Derivative Expense*

We recorded approximately \$206,000, (\$1.6) million and (\$1.4) million in non-cash derivative income (expense) in 2012, 2011 and 2010, respectively, in connection with our hybrid financial instruments consisting of debentures and related warrants. The expense relates to the fair value at inception and subsequent changes in fair value of the debentures issued in 2011 and 2010 stemming from the embedded derivative features (conversion options, down-round protection and mandatory conversion provisions) and the changes in fair value of warrants issued in conjunction with the debentures. The debentures were redeemed in 2011 and any related unexercised warrants will expire on December 31, 2013.

### *Unrealized loss on fair value of debt instruments*

We recorded \$5.6 million in non-cash unrealized loss on fair value of debt instruments in the first quarter of 2011 and \$38,000 of non-cash unrealized gain in 2010. The expense reflects the change in fair value of our debentures prior to their conversion to common stock in February 2011 and stemmed primarily from the increase in our common stock price between December 31, 2010 and February 28, 2011, when the debentures were converted.

### *Foreign income tax expense*

The \$82,500 of foreign income tax expense is the amount of Korean income taxes withheld in connection with the \$500,000 payment received for the signing of the license agreement with the Korean pharmaceutical company.

### *Net Cash Used in Operating Activities*

During 2012 our operating activities used approximately \$9.7 million in cash. The use of cash was \$1.5 million lower than the net loss due to non-cash charges for stock-based compensation, depreciation and amortization and also non-cash deferred revenue and derivative income. Net cash used in operating activities also included a \$121,770 increase in prepaid expenses and cash provided by a \$570,500 increase in accounts payable.

During 2011 our operating activities used approximately \$9.1 million in cash. The use of cash was significantly lower than the \$18.4 million net loss, primarily as a result of non-cash charges for depreciation and amortization, stock-based compensation, and derivative and unrealized loss on fair value of debt instruments of \$9.2 million. Net cash used in operating activities included the receipt of revenue to be recognized over a ten year period, but was offset by the payment of deferred salaries.

During 2010 our operating activities used approximately \$2.6 million in cash. The use of cash was significantly lower than the \$8.1 million net loss, primarily as a result of non-cash charges of \$3.1 million for common stock issued for services and stock-based compensation, and derivative expense of \$1.4 million. Net cash used in operating activities was also lower as a result of \$1.0 million related to changes in non-cash working capital, primarily an increase in accounts payables of \$385,000 relating to professional fees and other expenses, an increase in accrued salaries and other liabilities of \$453,000 resulting from deferral of salaries by our management team and fees by our directors, and an increase of \$194,000 representing funds advanced from BioSciences.

***Net Cash from Financing Activities***

Net cash provided by financing activities in 2012 was \$16 million. During the year, Ampio completed an underwritten public offering, with net proceeds of \$15.4 million, options exercised of \$618,000 and warrants exercised of \$12,322. We also received a repayment of \$36,883 related to the stockholders advances from BioSciences made in 2010.

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Net cash provided by financing activities in 2011 was \$20 million. During the year, Ampio completed private placement and registered direct offerings, with net proceeds of \$19.4 million, debentures were issued for \$382,000, options exercised of \$109,045 and warrants exercised of \$155,171. We also received a repayment of \$22,660 related to the stockholders advances from BioSciences made in 2010.

Net cash provided by our financing activities was \$3.2 million for 2010. During 2010, Ampio received \$2.0 million in loans from related parties and debentures and approximately \$1.4 million from the sale and subscription of common stock. Immediately prior to the Chay merger, we made advances of \$150,183 to stockholders who were also executive and non-executive officers of Ampio. Those advances are non-interest bearing and due on demand. Pursuant to the terms of the Chay merger agreement, we were also required to place \$125,000 in restricted cash into an escrow account, all of which was released during 2010. The escrow terminated on December 31, 2010 under the terms of the agreement with Chay.

**Contractual Obligations and Commitments**

The following table summarizes the commitments and contingencies as of December 31, 2012 which are described below:

Contractual Obligations	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Sponsored Research Agreement with Related Party	439,583	263,750	175,833		
Clinical Research Obligations	663,293	663,293			
Operating Leases (Office)	173,296	108,924	64,372		
Officers employment agreements	1,290,729	659,479	631,250		
<b>Total</b>	<b>2,566,901</b>	<b>1,695,446</b>	<b>871,455</b>		

***Clinical Research Obligations***

In connection with upcoming clinical trials, Ampio has a remaining commitment of \$115,000 on contracts related to the Ampion study drug and \$136,660 remaining contract commitments related to the Optina study drug. Ampio also has a contract related to the production of the Zertane study drug with a remaining unrecorded commitment of \$414,633. Ampio has subsequently entered into agreements with clinical research organizations for upcoming trials.

***Sponsored Research Agreement with Related Party***

Ampio entered into a Sponsored Research Agreement with Trauma Research LLC, a related party, in September 2009. Under the terms of the Sponsored Research Agreement, Ampio is to provide personnel and pay for leased equipment. The Sponsored Research Agreement may be terminated without cause by either party on 180 day notice.

***Leases***

On May 20, 2011 Ampio entered into a 38 month non-cancellable operating lease for office space effective June 1, 2011. Commitments include the annual operating expense increase for 2013.

***Employment Agreements***

As of December 31, 2012, Ampio has employment agreements with four of its executive officers. Under the employment agreements, the executive officers are collectively entitled to receive \$955,000 in annual salaries. The employment agreements expire July 2013 with respect to our chief scientific officer and chief regulatory affairs officer, January 2015 with respect to our chief executive officer and December 2015 with respect to our chief operating officer. The portion of the salary due to our chief scientific officer that is included in the Sponsored Research Agreement with Trauma Research LLC is excluded from the officers' employment agreements commitment.

**Liquidity and Capital Resources**

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As a development stage biopharmaceutical company, we have not generated significant revenue as our primary activities are focused on research and development, advancing our primary product candidates, and raising capital. As of December 31, 2012, we had cash

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and cash equivalents totaling \$17.7 million available to fund our operations and \$1.2 million in payables. Based upon our current expectations, we believe our capital resources at December 31, 2012 will be sufficient to fund our currently planned operations for the next 12 months. This estimate is based on a number of assumptions that may prove to be wrong, and we could exhaust our available cash and cash equivalents earlier than presently anticipated. We may be required or choose to seek additional capital within the next 12 months to expand our clinical development activities for Ampion™ and Optina™ based on the positive results of our ongoing clinical trials to fund costs of planning for a commercial launch of Ampion™ or Optina™, if we face challenges or delays in connection with our clinical trials, or to maintain minimum cash balances that we deem reasonable and prudent. In addition, we intend to evaluate the capital markets from time to time to determine whether to raise additional capital in the form of equity, convertible debt or otherwise, depending on market conditions relative to our need for funds at such time, and we may seek to raise additional capital within the next 12 months should we conclude that such capital is available on terms that we consider to be in the best interests of us and our stockholders.

We have prepared a budget for 2013 which reflects cash requirements for fixed, on-going expenses such as payroll, legal and accounting, patents and overhead at an average cash burn rate of between \$550,000 and \$600,000 per month. Additional funds in the amount of approximately \$9.0 million are planned for regulatory approvals, completion of clinical trials, and planning for commercialization of Zertane during 2013. To the extent we decide to further expand our clinical trials, it will be necessary to raise additional capital and/or enter into licensing or collaboration agreements. At this time, we expect to satisfy our future cash needs through private or public sales of our securities or debt financings. We cannot be certain that financing will be available to us on acceptable terms, or at all. Over the last two years, volatility in the financial markets has adversely affected the market capitalizations of many pharmaceutical companies and generally made equity and debt financing more difficult to obtain. This volatility, coupled with other factors, may limit our access to additional financing.

If we cannot raise adequate additional capital in the future when we require it, we will be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. We also may be required to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. This may lead to impairment or other charges, which could materially affect our balance sheet and operating results.

### **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.

### **Recently Issued Accounting Pronouncements**

#### ***New accounting pronouncements to be adopted***

In July 2012, the FASB issued ASU 2012-02, Intangibles—Goodwill and Other (Topic 350)—Testing Indefinite-Lived Intangible Assets for Impairment. The guidance is intended to simplify impairment testing of indefinite-lived intangible assets such as IPRD by first assessing qualitative factors to determine whether it is more likely than not that the fair value of an asset is less than its carrying amount as a basis for determining whether it is necessary to perform a quantitative impairment test. The more-likely-than-not threshold is defined as having a likelihood of more than 50%. This guidance is effective for annual and interim tests performed for fiscal years beginning after September 15, 2012. The adoption of this guidance is not expected to have a significant impact on the Company's financial position or results of operations.

In May, 2011, the FASB issued ASU 2011-04 Fair Value Measurement (Topic 820): The guidance is designed to achieve fair value measurement and disclosure requirements between U.S. GAAP and International Financial Reporting Standards. The amendments were effective for Ampio beginning in the first quarter of 2012. The adoption of this guidance did not have a material impact on Ampio's consolidated financial statements.

### **Impact of Inflation**

In general, we believe that, as a development stage company, our operating expenses can be negatively impacted by increases in the cost of clinical trials due to inflation and rising health care costs.



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**Item 7A. *Quantitative and Qualitative Disclosures about Market Risks***

Our business is not currently subject to material market risk related to financial instruments, equity or commodities.

**Item 8. *Financial Statements and Supplementary Data***

Our Financial Statements and Supplementary Data are incorporated by reference to Item 15 of Part IV, *Index to Financial Statements* at page F-1 of this annual report on Form 10-K.

**Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***  
**None**

**Item 9A. *Controls and Procedures***  
**Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the *Exchange Act*), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of senior management, including the chief executive officer and the chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rules 13a-15(b) and 15d-15(b). Based upon this evaluation, the chief executive officer and the chief financial officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective at the reasonable assurance level.

**Management's Annual Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Rules 13a-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2012. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework*. Our management has concluded that, as of December 31, 2012, our internal control over financial reporting is effective based on these criteria.

EKS&H LLLP, the independent registered public accounting firm, that audited our consolidated financial statements included in this annual report on Form 10-K, has issued an attestation report on our internal control over financial reporting, which is included herein at F-2.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal controls over financial reporting, known to the chief executive officer or the chief financial officer that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. *Other Information***  
**None.**



**Table of Contents****PART III****Item 10. Directors and Executive Officers, and Corporate Governance**

The following table sets forth the names, ages and positions of our executive officers and directors as of February 12, 2013.

			Principal Occupation and Areas of	
Name	Age	Position With Ampio	Relevant Experience For Directors	Director Since
Michael Macaluso	61	Chief Executive Officer and Chairman of the Board	Mr. Macaluso founded Life Sciences and has been a member of 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 in March 2010 and our Chief Executive Officer since January 9, 2012. 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. 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.	March 2010
			Mr. Macaluso's experience in executive management and marketing within the pharmaceutical industry, monetizing company opportunities, and corporate finance led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.	
David Bar-Or, M.D.	64	Chief Scientific Officer and Director	Dr. Bar-Or has served as our chief scientific officer since March 2010. Dr. Bar-Or also served as our chairman of the board from March 2010 until May 2010. From April 2009 until March 2010, 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	March 2010

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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.

Among other experience, qualifications, attributes and skills, Dr. Bar-Or's medical training, extensive involvement in researching and developing our product candidates, and leadership role in his hospital affiliations led to the conclusion of our board that he should serve as a director of our company in light of our business and structure.

Philip H. Coelho<sup>(1)(2)(3)</sup>

69 Director

Mr. Coelho is 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

April 2010

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Name	Age	Position With Ampio	Principal Occupation and Areas of	Director Since
			<p><b>Relevant Experience For Directors</b></p> <p>October 2009. From August 2007 through May 2008, Mr. Coelho served as the Chief Technology Architect of ThermoGenesis Corp., a medical products company he founded in 1986 that focused on the regenerative medicine market. From 1989 through July 2007, he was Chairman and Chief Executive Officer of ThermoGenesis Corp. Mr. Coelho served as Vice President of Research &amp; 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 Mediware 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.</p>	
			<p>Mr. Coelho's long tenure as a chief executive officer of a public medical device company, as director of a public pharmaceutical company, prior and current public company board experience, and knowledge of corporate finance and governance as an executive and director, as well as his demonstrated success in developing patented technologies, led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.</p>	
Richard B. Giles <sup>(1)(2)(3)</sup>	63	Director	<p>Mr. Giles is 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 &amp; Company, then a Denver, Colorado CPA firm, and during the 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</p>	August 2010

is also a member of the American Institute of Certified Public Accountants and the Construction Financial Management Association.

Mr. Giles' experience in executive financial management, accounting and financial reporting, and corporate accounting and controls led to the conclusion of our board that he should serve as a director of our company in light of our business and structure.

**Table of Contents****Principal Occupation and Areas of**

<b>Name</b>	<b>Age</b>	<b>Position With Ampio</b>	<b>Relevant Experience For Directors</b>	<b>Director Since</b>
David R. Stevens,  Ph.D. <sup>(1)(2)</sup>	63	Director	Dr. Stevens has served as a member of our Board of Directors since June 2011. Dr. Stevens is currently Executive Chairman of Cedus, Inc., a privately-held development stage biopharmaceutical company and a board member of Micro-Imaging Solutions, LLC, a private medical device company. He has served on the boards of several other public and private life science companies, including Poniard Pharmaceuticals, Inc. (2006-2012), Aqua Bounty Technologies, Inc. (2002-2012), and Smart Drug Systems, Inc. (1999-2006), and was an advisor to Bay City Capital from 1999-2006. Dr. Stevens was previously President and CEO of Deprenyl Animal Health, Inc., a public veterinary pharmaceutical company, from 1990 to 1998, and Vice President, Research and Development, of Agrion Corp., a private biotechnology company, from 1986 to 1988. He began his career in pharmaceutical research and development at the former Upjohn Company, where he contributed to the preclinical evaluation of Xanax and Halcion. Dr. Stevens received B.S. and D.V.M. degrees from Washington State University, and a Ph.D. in comparative pathology from the University of California, Davis. He is a Diplomate of the American College of Veterinary Pathologists. Dr. Stevens has worked in the pharmaceutical and biotechnology industries since 1978. Dr. Stevens' experience in executive management in the pharmaceutical industry, and knowledge of the medical device industry led to the conclusion of our Board of Directors that he should serve as a director of our Company in light of our business and structure.	June 2011
Dr. Vaughan L. Clift	51	Chief Regulatory  Affairs Officer	Dr. Clift has been employed by us since March 2010 and was employed by Life Sciences from May 2009 until March 2010. From 2005 to 2009, Dr. Clift was the chief executive officer of Detectachem LLC, a Houston, Texas-based manufacturer of a hand-held explosive and narcotics detection device. Dr. Clift was the Vice President of Operations for Isolagen from 2002 until 2005. From January 2001 to May 2002, Dr. Clift researched home oxygen therapy systems while developing an oxygen system for NASA. From July 1997 to January 2001, he was Chief Scientist of DBCD, Inc., a medical device company that manufactures a range of blood diagnostic products for the human and veterinary market. From May 1992 to June 1997, Dr. Clift was Chief Scientist for the Science Payload Development, Engineering and Operations project at Lockheed Martin's Human Spaceflight Division. Dr. Clift has received a number of international and federal awards and was nominated as one of NASA's top ten inventors in 1995.	

**Table of Contents****Principal Occupation and Areas of**

<b>Name</b>	<b>Age</b>	<b>Position With Ampio</b>	<b>Relevant Experience For Directors</b>	<b>Director Since</b>
Mark D. McGregor	71	Chief Financial Officer	<p>Mark D. McGregor has been employed by us since April 2011. Mr. McGregor is a certified public accountant with over 30 years financial experience in a variety of industries. Mr. McGregor served in various financial capacities with Louisville, Colorado-based Storage Technology Corporation, or StorageTek, from February 1985 until October 2005. During this period, Mr. McGregor held three positions with StorageTek, including director of revenue management (1985-1987), assistant corporate controller (1987-1993), and vice president, corporate treasurer and corporate development (1993-2005). In these positions, Mr. McGregor's responsibilities included treasury and risk management, developing financial strategic plans, cash management and investments, managing foreign currency and interest rate exposures, credit provider and credit rating agency relations, and insurance risk management. His responsibilities also included corporate and international consolidation and reporting, SEC and management reporting, financial integration, disbursements operations, evaluating potential acquisitions, conducting financial due diligence, negotiating credit line provisions to promote operating flexibility, optimizing capital structures, and implementing stock buy-back programs to enhance stockholder value. Mr. McGregor was directly involved in two divestitures and four acquisitions while with StorageTek, in addition to leading the deal team in connection with the sale of StorageTek to Sun Microsystems in 2005. After leaving StorageTek, Mr. McGregor served as the chief financial officer of Integrated Management Information, Inc., or IMI, from February 2006 to November 2007. IMI is a publicly-traded provider of identification, verification and communications solutions for the agriculture, livestock, and food industries based in Castle Rock, Colorado. Since retiring as chief financial officer of IMI in November 2007, Mr. McGregor has been engaged part-time in the real estate business as an agent with Keller Williams Realty in Castle Rock, Colorado. He began his career with Price Waterhouse, now PricewaterhouseCoopers LLP, where he spent 13 years with the Audit Department. Mr. McGregor holds a BBA degree in accounting from Texas A&amp;M University and served in the United States Army from 1964 to 1966, where he attained the rank of First Lieutenant.</p>	
Joshua R. Disbrow	37	Chief Operating Officer	<p>Joshua R. Disbrow has been employed by us since December, 2012. Prior to joining Ampio, he served as the Vice-President of Commercial Operations at Arbor Pharmaceuticals, a specialty pharmaceutical company, from May 2007 through October 2012. He joined Arbor as that company's second full-time employee and led the company's commercial efforts from its inception to \$127 million in net sales in 2011 and led the growth of the commercial organization to comprise over 150 people in sales, marketing and other commercial functions. Mr.</p>	



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Disbrow has spent nearly 17 years in the pharmaceutical, diagnostic and medical device industries and has held positions of increasing responsibility in sales, marketing, sales management, commercial operations and commercial strategy. Prior to joining Arbor, Mr. Disbrow served as Regional Sales Manager with Cyberonics, Inc., a medical device company focused on neuromodulation therapies from June 2005 through April 2007. Mr. Disbrow holds an MBA from Wake Forest University and BS in Management from North Carolina State University.

- (1) Member of our Audit Committee
- (2) Member of our Compensation Committee
- (3) Member of our Nominating and Governance Committee

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### **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. Rick Giles, a non-executive employee, is the son of Richard B. Giles, one of our directors.

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our executive officers, directors and persons who beneficially own greater than 10% of a registered class of its equity securities to file certain reports with the SEC with respect to ownership and changes in ownership of the Common Stock and our other equity securities. Prior to our listing on the NASDAQ Capital Market, our common stock was registered pursuant to Section 15(d) of the Exchange Act and, accordingly, our executive officers, directors and greater than 10% stockholders were not subject to the obligation to file Forms 3, 4 and 5 pursuant to Section 16(a) of the Exchange Act. Upon our listing on the NASDAQ Capital Market, our executive officers, directors and greater than 10% shareholders became subject to the filing obligations described in Section 16(a).

On January 8, 2013, Joshua Disbrow, our chief operating officer filed a Form 3 and a Form 4 pursuant to Section 16(a) of the Exchange Act. These reports were not timely filed. The Form 3 was due within 10 days after December 15, 2012 when Mr. Disbrow became an executive officer of the Company, and the Form 4 was due within 2 days December 15, 2012 when Mr. Disbrow received a grant of options from the Company.

Other than as described above, none of our executive officers or directors engaged in any transaction that would have been required to be reported under Section 16(a) of the Exchange Act during the period starting on the date the reports were originally due and ending on the date such reports were filed. To our knowledge, no shareholder beneficially owns more than 10% of our Common Stock.

### **Code of Business Conduct and Ethics**

We have adopted a code of business conduct and ethics that is applicable to all of our employees, officers and directors. The code is available on our web site, [www.ampiopharma.com](http://www.ampiopharma.com), under the Investor Relations tab. We intend to disclose future amendments to, or waivers from, certain provisions of our code of ethics, if any, on the above website within four business days following the date of such amendment or waiver.

### **Meetings**

During the year ended December 31, 2012, there were held (i) five meetings of the Board of Directors, (ii) five meetings of the Audit Committee, (iii) five meetings of the Compensation Committee, and (iv) two meetings of the Nominating and Governance Committee. No incumbent director attended fewer than seventy-five percent (75%) of the aggregate of (1) the total number of meetings of the Board, and (2) the total number of meetings held by all committees of the Board during the period that such director served.

### **Annual Meeting Attendance, Executive Sessions and Shareholder Communications**

Commencing January 1, 2011, our policy has been that directors attend the annual meeting of stockholders. We previously did not have a policy concerning director attendance at annual meetings. Commencing January 1, 2011, our policy has been that our non-employee directors are also required to meet in separate sessions without management on a regularly scheduled basis four times a year. Generally, these meetings are expected to take place in conjunction with regularly scheduled meetings of the Board throughout the year.

We have not implemented a formal policy or procedure by which our shareholders can communicate directly with our Board of Directors. Nevertheless, every effort has been made to ensure that the views of shareholders are heard by the Board of Directors or individual directors, as applicable, and that appropriate responses are provided to shareholders in a timely manner. We believe that we are responsive to shareholder communications, and therefore have not considered it necessary to adopt a formal process for shareholder communications with our Board. During the upcoming year, our Board will continue to monitor whether it would be appropriate to adopt such a policy. Communications will be distributed to the Board, or to any individual director or directors as appropriate, depending on the facts and circumstances outlined in the communications. Items that are unrelated to the duties and responsibilities of the Board may be excluded, such as:

junk mail and mass mailings

resumes and other forms of job inquiries

surveys

solicitations or advertisements.

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In addition, any material that is unduly hostile, threatening, or illegal in nature may be excluded, provided that any communication that is excluded will be made available to any outside director upon request.

### **Involvement in Certain Legal Proceedings**

No director, executive officer, promoter or control person of our company has, during the last ten years: (i) been convicted in or is currently subject to a pending a criminal proceeding (excluding traffic violations and other minor offenses); (ii) been a party to a civil proceeding of a judicial or administrative body of competent jurisdiction and as a result of such proceeding was or is subject to a judgment, decree or final order enjoining future violations of, or prohibiting or mandating activities subject to any Federal or state securities or banking or commodities laws including, without limitation, in any way limiting involvement in any business activity, or finding any violation with respect to such law, nor (iii) any bankruptcy petition been filed by or against the business of which such person was an executive officer or a general partner, whether at the time of the bankruptcy or for the two years prior thereto.

In addition, we are not engaged in, nor are we aware of any pending or threatened, litigation in which any of our directors, executive officers, affiliates or owner of more than 5% of our common stock is a party adverse to us or has a material interest adverse to us.

### **Leadership Structure of the Board**

The Board of Directors does not currently have a policy on whether the same person should serve as both the chief executive officer and chairman of the board or, if the roles are separate, whether the chairman should be selected from the non-employee directors or should be an employee. The Board believes that it should have the flexibility to make these determinations at any given point in time in the way that it believes best to provide appropriate leadership for us at that time. Our current chairman, Michael Macaluso, was appointed our chief executive officer effective January 9, 2012. Mr. Macaluso has served as a member of our Board since March 2010, and has been a member of the Board of Directors of Life Sciences from December 2009.

### **Risk Oversight**

The Board oversees risk management directly and through its committees associated with their respective subject matter areas. Generally, the Board oversees risks that may affect our business as a whole, including operational matters. The Audit Committee is responsible for oversight of our accounting and financial reporting processes and also discusses with management our financial statements, internal controls and other accounting and related matters. The Compensation Committee oversees certain risks related to compensation programs and the Nominating and Governance Committee oversees certain corporate governance risks. As part of their roles in overseeing risk management, these committees periodically report to the Board regarding briefings provided by management and advisors as well as the committees' own analysis and conclusions regarding certain risks faced by us. Management is responsible for implementing the risk management strategy and developing policies, controls, processes and procedures to identify and manage risks.

### **Board Committees**

Our Board of Directors has an Audit Committee, a Compensation Committee and a Nominating and Governance Committee, each of which has the composition and the responsibilities described below. The Audit Committee, Compensation Committee and Nominating and Governance 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 Stevens. 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 securities exchanges and the SEC, and Mr. Giles qualifies as our

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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 NASDAQ Capital Market 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 applicable requirements of the NASDAQ Capital Market.

*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 Stevens. 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 NASDAQ Capital Market. 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 NASDAQ Capital Market and SEC rules and regulations.

Our Compensation Committee and our Board of Directors have not yet established a succession plan for our chief executive officer.

In fulfilling its responsibilities, the Committee is permitted under the Compensation Committee charter to delegate any or all of its responsibilities to a subcommittee comprised of members of the Compensation Committee or the Board, except that the Committee may not delegate its responsibilities for any matters that involve compensation of any officer or any matters where it has determined such compensation is intended to comply with Section 162(m) of the Code or is intended to be exempt from Section 16(b) under the Exchange Act pursuant to Rule 16b-3 by virtue of being approved by a committee of independent or nonemployee directors.

*Nominating and Governance Committee.* Our Nominating and Governance 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 Nominating and Governance Committee is responsible for, among other things:

evaluating and making recommendations regarding the organization and governance of the Board of Directors and its committees;

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assessing the performance of members of the Board of Directors and making recommendations regarding committee and chair assignments;

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.

The members of our Nominating and Governance Committee are currently Messrs. Giles and Coelho. Mr. Coelho is the chairman of our Nominating and Governance Committee. Our Board of Directors has determined that each member of our Nominating and Governance Committee is independent within the meaning of the independent director guidelines of the NASDAQ Capital Market.

Our Board of Directors may from time to time establish other committees.

**Table of Contents****Non-Employee 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:

	Committee or Committees	Cash Compensation	Common Stock
<b>Board Annual Retainer:</b>			
Chairman		\$ 20,000	
Each non-employee director		10,000	
<b>Board Meeting Fees:</b>			
Each meeting attended in-person		\$ 1,000	
Each meeting attended telephonically or via web		500	
<b>Committee Annual Retainer:</b>			
Chairman of each committee	Audit; Compensation; Nominating and Governance	\$ 20,000	
Each non-chair member	Audit	12,000	
Each non-chair member	Compensation; Nominating and Governance	10,000	
<b>Committee Chairman Meeting Fees:</b>			
Each meeting attended in-person	Audit; Compensation; Nominating and Governance	\$ 2,500	
Each meeting attended telephonically or via web	Audit; Compensation; Nominating and Governance	1,500	
<b>Committee Member Meeting Fees:</b>			
Each meeting attended in-person	Audit; Compensation; Nominating and Governance	\$ 1,500	
Each meeting attended telephonically or via web	Audit; Compensation; Nominating and Governance	1,000	
<b>Annual Stock Award:</b>			\$ 10,000

**Director Compensation for 2012**

The table below summarizes the compensation paid by us to non-employee directors for the year ended December 31, 2012.

Name	Fees Earned or Paid in Cash	Stock Option Awards (1)(2)	All Other Compensation (3)	Total
Michael Macaluso	\$ 32,500	\$ 352,128	\$ 10,000	\$ 42,500
Philip H. Coelho	89,500	203,822	10,000	451,628
Richard B. Giles	78,000	203,822	10,000	291,822
David Stevens, PhD	52,000	203,822	10,000	265,822

- (1) The amounts in this column reflect the grant date fair values of the stock awards based on the last reported sale price of the common stock at the dates of grant. Please see Item 15 of Part IV, Notes to Consolidated Financial Statements Note 12 Stock-Based Compensation.
- (2) At December 31, 2012, Messrs. Macaluso, Coelho, Giles and Dr. Stevens held options to acquire 550,000 (issued when non-employee director) 515,554, 500,000 and 225,000 shares of common stock, respectively.
- (3) Annual restricted stock award.

In January 2012, each of Messrs. Macaluso, Coelho and Giles and Dr. Stevens were awarded 2,268 shares of common stock pursuant to the 2010 Plan, at a price of \$4.41 per share, which was the closing price of the Company's common stock on the date of grant (January 3, 2012).





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In May 2012, each of Messrs. Coelho and Giles and Dr. Stevens were granted options to purchase 100,000 shares of common stock. These options have an exercise price of \$2.76 per share, which was the closing price of the Company's common stock on the date of grant (May 7, 2012). The options vest in 36 equal monthly installments from the grant date and have a term of 10 years from the grant date.

Also in May 2012, Mr. Coelho was granted an option to purchase 75,000 shares of common stock. This option has an exercise price of \$2.76 per share, which was the closing price of the Company's common stock on the date of grant (May 7, 2012). The option was fully vested as of the grant date and has a term of 10 years from the grant date.

### **Item 11. *Executive Compensation*** **Executive Compensation**

#### **Compensation Discussion and Analysis**

*Overview.* The following Compensation Discussion and Analysis describes the material elements of compensation for our executives identified in the Summary Compensation Table (Named Executive Officers). The Compensation Committee of the Board of Directors assists the Board of Directors in discharging the Board's responsibilities regarding compensation of our executives, including the Named Executive Officers. In particular, the Compensation Committee makes recommendations to the Board of Directors regarding the corporate goals and objectives relevant to executive compensation, evaluates executives' performance in light of such goals and objectives, and recommends the executives' compensation levels to the Board of Directors based on such evaluations. The Compensation Committee's recommendations relating to compensation matters are subject to approval by the Board.

*Compensation Philosophy and Objectives.* Our executive compensation program is designed to retain our executive officers and to motivate them to increase stockholder value on both an annual and longer term basis. These objectives are to be accomplished primarily by positioning us to maximize our product development efforts and to transform, over time, those efforts into collaboration revenues and income. To that end, compensation packages include significant incentive forms of stock-based compensation to ensure that each executive officer's interest is aligned with the interests of our stockholders.

#### **Named Executive Officers**

For our most recently completed fiscal year (the year ended December 31, 2012), our Named Executive Officers were: (i) Michael Macaluso, our Chief Executive Officer, who has served as our Chief Executive Officer since January 9, 2012, (ii) Mark D. McGregor, our current Chief Financial Officer, who has served as our Chief Financial Officer since April 2011, (iii) David Bar-Or, M.D., our current Chief Scientific Officer, who has served as our Chief Scientific Officer since March 2010, (iv) Vaughan Clift, our current Chief Regulatory Affairs Officer, who has served as our Chief Regulatory Affairs Officer since March 2010, and (v) Joshua Disbrow, our current Chief Operating Officer, who has served as our Chief Operating Officer since December 15, 2012. Donald B. Wingerter, Jr., our former Chief Executive Officer, served as Chief Executive Officer until January 9, 2012. We had no other executive officers serving during the year ended December 31, 2012.

#### **Executive Compensation Components**

Our compensation program for our Named Executive Officers consists of three components: (i) a base salary, (ii) discretionary bonuses based on performance, and (iii) equity compensation. Each of these components is reflected in the Summary Compensation Table below.

*Salaries.* The cash salaries paid to Messrs. Macaluso, Disbrow and Wingerter and Drs. Bar-Or and Clift were established at the time they became officers. Each of these persons has (or, in the case of Mr. Wingerter, had) an employment agreement with us, a copy of which is an exhibit to, or incorporated by reference herein. Mr. McGregor is an at-will employee and does not have an employment agreement with us. Since the respective dates of their becoming Named Executive Officers, any increases in the salaries of our Named Executive Officers have been made at the discretion of the Compensation Committee. Mr. Macaluso and Dr. Bar-Or receive no additional compensation for serving on our Board of Directors.

*Cash Incentive Compensation.* Cash incentive or bonus compensation is discretionary under our employment agreements with Drs. Bar-Or and Clift and Messrs. Macaluso and Disbrow. However, each employment agreement contains performance objectives tailored to the individual officer's duties, and provides for a target bonus of 50% of the officer's base salary, which is to take into account both employee performance and company performance. All cash incentive compensation grants are intended to be paid in accordance with Section 162(m) of the Code. In 2012, we paid a cash bonus to Dr. Bar-Or of \$105,000, to Mr. Wingerter of \$48,000 and to Dr. Clift and Messrs. Macaluso and McGregor of \$5,000.

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each, which were awarded on a discretionary basis by the Compensation Committee based on the Compensation Committee's assessment of 2012 performance.

*Equity Compensation.* In 2012, we granted stock options to certain of our officers, directors and consultants for their services, all of which were granted pursuant to written agreements under the 2010 Plan. All future grants are expected to be made under the 2010 Plan. The vesting period for option grants varies, but the grants made to our Named Executive Officers on May 7, 2012 provided that the options vest in 36 equal monthly installments from the date of grant.

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*Perquisites.* We offer health benefits received by all of our employees. None of our Named Executive Officers receives any further perquisites.

*Why Each Element of Compensation is Paid; How the Amount of Each Element is Determined.* The Compensation Committee intends to pay each of these elements in order to ensure that a desirable overall mix is established between base compensation and incentive compensation, cash and non-cash compensation, and annual and long-term compensation. The Compensation Committee also intends to evaluate on a periodic basis the overall competitiveness of our executive compensation packages as compared to packages offered in the marketplace for which we compete with executive talent. Overall, our Compensation Committee believes that our executive compensation packages are currently appropriately balanced and structured to retain and motivate our Named Executive Officers, while necessarily taking into account our presently limited financial resources.

*How Each Compensation Element Fits into Overall Compensation Objectives and Affects Decisions Regarding Other Elements.* In establishing compensation packages for executive officers, numerous factors are considered, including the particular executive's experience, expertise and performance, our operational and financial performance as a company, and compensation packages available in the marketplace for similar positions. In arriving at amounts for each component of compensation, our Compensation Committee strives to strike an appropriate balance between base compensation and incentive compensation. The Compensation Committee also endeavors to properly allocate between cash and non-cash compensation and between annual and long-term compensation.

*Risk Assessment.* Our Compensation Committee has reviewed our compensation program and believes that the program, including our cash incentive compensation and equity incentive compensation, does not encourage our Named Executive Officers to engage in any unnecessary or excessive risk-taking. As a result, the Compensation Committee has to date not implemented a provision for recovery by us of cash or incentive compensation bonuses paid to our Named Executive Officers.

*Role of Compensation Consultants in Executive Compensation Decisions.* The Compensation Committee has the authority to retain the services of third-party executive compensation specialists in connection with the establishment of the Company's compensation policies. The Compensation Committee did not use a compensation consultant in connection with setting 2012 executive compensation, and relied upon the professional and market experience of the Committee members in determining 2012 executive compensation. The Compensation Committee may engage a compensation consultant in the future if it deems such services to be appropriate and cost-justified.

*Role of Executives in Executive Compensation Decisions.* The Compensation Committee seeks input and specific recommendations from our Chief Executive Officer when discussing the performance of, and compensation levels for, executives other than himself. The Chief Executive Officer provides recommendations to the Compensation Committee regarding each executive officer's level of individual achievement other than himself. However, he is not a member of the Compensation Committee and does not vote. The Compensation Committee also works with our Chief Executive Officer and our Chief Financial Officer to evaluate the financial, accounting, tax and retention implications of our various compensation programs. Neither our Chief Executive Officer nor any of our other executives participates in deliberations relating to his or her own compensation.

## **Tax and Accounting Implications**

*Deductibility of Executive Compensation.* Section 162(m) of the Internal Revenue Code limits the tax deduction to \$1 million for compensation paid to certain executives of public companies. However, performance-based compensation that has been approved by stockholders is not subject to the \$1 million limit under Section 162(m) if, among other requirements, the compensation is payable only upon attainment of pre-established, objective performance goals, and the Board of Directors committee that establishes such goals consists only of outside directors. All members of the Compensation Committee qualify as outside directors. Additionally, stock options will qualify for the performance-based exception where, among other requirements, the exercise price of the option is not less than the fair market value of the stock on the date of the grant, and the plan includes a per-executive limitation on the number of shares for which options may be granted during a specified period.

## **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.

## **Compensation Committee Report**

The Compensation Committee of the Board of Directors has reviewed and discussed the Compensation Discussion and Analysis required by Item 402(b) of Regulation S-K with management and, based on such review and discussions, the Compensation Committee recommended to the

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Board of Directors that the Compensation Discussion and Analysis be included in this Annual Report on Form 10-K and in the Company's Proxy Statement.

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Submitted by the Compensation Committee of the Board of Directors

Richard B. Giles  
Philip H. Coelho  
David R. Stevens, Ph.D.

The following table sets forth all cash compensation earned, as well as certain other compensation paid or accrued in 2012, 2011 and 2010, to each of the following named executive officers.

**Summary Compensation of Named Executive Officers**

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Award (\$)	Option Award (\$)(1)	Change in Pension Value and Nonqualified All Other Compensation				Total (\$)
						Non-Equity Incentive Plan Compensation (\$)(g)	Deferred Compensation (\$)(h)	Other Compensation (\$)(i)		
(a) Current Named Executive Officers	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	
Michael Macaluso Chief Executive Officer  effective January 2012	2012	190,938	5,000		509,556					705,494
David Bar-Or, M.D. Chief Scientific Officer and Former Chairman	2012	300,000	105,000		407,645					812,645
	2011	281,875	5,000							286,875
	2010	227,500(2)			451,968					679,468
Vaughan Clift, M.D. Chief Regulatory Affairs Officer	2012	250,000	5,000		305,734					560,734
	2011	228,003	5,000							233,003
	2010	198,000(3)	29,500		235,669					463,169
Mark D. McGregor Chief Financial Officer since April, 2011	2012	150,000	5,000		152,867					307,867
	2011	111,932	5,000		155,420					272,352
Joshua R. Disbrow Chief Operating Officer since December, 2012	2012	11,375			1,167,346					1,178,721
Former Named Executive Officers										
Donald B. Wingerter, Jr. (4) Chief Executive Officer to December 2011	2012	555,729	48,000							603,729
	2011	242,500	71,250							313,750
	2010	145,333	29,000		385,179					559,512
Bruce G. Miller (5) Former Chief Financial Officer and Chief Operating Officer and Chief Executive Officer	2012	125,000								125,000
	2011	180,000	5,000							185,000
	2010	180,000(6)	10,000							190,000

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- (1) Option awards are reported at fair value at the date of grant. See Item 15 of Part IV, Notes to Consolidated Financial Statements Note 12 Stock-Based Compensation.
- (2) Excludes \$85,313 in salary deferred by Dr. Bar-Or in prior years paid in 2011.
- (3) Excludes \$42,333 in salary deferred by Dr. Clift at December 31, 2010 paid in 2011.
- (4) Mr. Wingerter served as the Company's Chief Executive Officer from December 2009 to January 2012.
- (5) Mr. Miller served as the Company's Chief Financial Officer and Chief Operating Officer from January 2010 to April 2011 and the Company's Chief Operating Officer and Chief Executive Officer from April 2009 to December 2009. Mr. Miller retired on August 15, 2012.

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(6) Includes \$54,000 in salary deferred by Mr. Miller at December 31, 2010.

The above-noted salary deferrals were necessitated by our limited financial resources in 2010. All deferred salaries were paid in 2011.

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

### **Grants of Plan-Based Awards**

The following table sets forth certain information regarding grants of plan-based awards to the Named Executive Officers as of December 31, 2012:

Name	Grant Date	All Other Option Awards:	Exercise Price of Option Awards (\$/Share)	Grant Date Fair Value of Option Awards
		Number of Securities Underlying Options (#)		
Current Named Exective Officers				
Michael Macaluso	5/7/2012	250,000	\$ 2.76	\$ 509,556
David Bar-Or, M.D.	5/7/2012	200,000	\$ 2.76	\$ 407,645
Vaughan Clift, M.D.	5/7/2012	150,000	\$ 2.76	\$ 305,734
Mark D. McGregor	5/7/2012	75,000	\$ 2.76	\$ 152,867
Joshua R. Disbrow	12/15/2012	450,000	\$ 3.53	\$ 1,167,346
Former Named Executive Officers				
Donald B. Wingerter, Jr.				
Bruce G. Miller (1)	5/7/2012	100,000	\$ 2.76	\$ 203,822

(1) Option award grant expired or forfeited at December 31, 2012.



**Table of Contents****Outstanding Equity Awards**

The following table provides a summary of equity awards outstanding for each of the Named Executive Officers as of December 31, 2012:

Name (a)	Option Awards				Stock Awards				
	Number of Securities Underlying Unexercised Options Exercisable (#) (b)	Number of Securities Underlying Unexercisable Options (#) (1) (c)	Equity Incentive Plan Awards:		Option Price (\$ (e)	Option Expiration Date (f)	Equity Incentive Plan Awards:		
			Number of Securities Underlying Unexercised Unearned Options (#) (d)	Option Exercise			Equity Incentive Plan Awards:		
							Shares, Units or Other Rights That Have Not Vested (#) (i)	Market Value of Shares or Units of Stock That Have Not Vested (\$) (h)	Other Rights That Have Not Vested (\$ (j)
Michael Macaluso (1)	48,611	201,389		2.76	5/7/2022				
David Bar-Or, M.D. (1)	38,889	161,111		2.76	5/7/2022				
David Bar-Or, M.D.	700,000			1.03	8/12/2020				
Vaughan Clift, M.D. (1)	29,167	120,833		2.76	5/7/2022				
Vaughan Clift, M.D.	365,000			1.03	8/12/2020				
Mark D. McGregor (1)	14,583	60,417		2.76	5/7/2022				
Mark D. McGregor	100,000			2.50	4/4/2021				
Joshua R. Disbrow (2)	100,000	350,000		3.53	12/15/2022				

*Former Named Executive Officers*

Donald B. Wingerter, Jr. (3)

- (1) Unexercisable options vest monthly and become fully vested May 7, 2015.
- (2) Unexercisable option vests annually and becomes fully vested December 15, 2015.
- (3) All option awards have been exercised.

**Employment Agreements**

In August, 2010, we entered into employment agreements with Mr. Wingerter, our former chief executive officer, Dr. David Bar-Or, our chief scientific officer, and Dr. Vaughan Clift, our chief regulatory affairs officer. The employment agreement with Dr. Bar-Or supersedes his prior agreement with Life Sciences. Dr. Clift's employment agreement was amended on October 1, 2010 and May 26, 2011 and Mr. Wingerter's employment agreement was amended on May 26, 2011 and subsequently terminated on January 6, 2012 with the granting of a compassionate leave of absence. The terms of the employment agreements with Mr. Wingerter, Dr. Bar-Or, and Dr. Clift are substantially identical except as noted below. Each agreement has an initial term ending July 31, 2013. The agreements provide for annual salaries of \$300,000 for Dr. Bar-Or, and \$250,000 for Dr. Clift, which automatically increased from annual salaries of \$227,500, and \$198,000, respectively, following our completion of a financing in March and April of 2011. We entered into an employment agreement with Mr. Michael Macaluso, our chief

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executive officer, effective January 9, 2012 which provides for an annual salary of \$195,000, with an initial term ending January 9 2015. We entered into an employment agreement with Mr. Joshua Disbrow, our chief operating officer, effective December 15, 2012. This agreement has an initial term ending December 15, 2015 and provides for an annual salary of \$210,000.

Each officer is eligible to receive a discretionary 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, (iv) the sale of intellectual property not selected for clinical trials by the Company at prices, and times, approved by the Board of Directors and (v) making significant scientific discoveries acceptable to the Board of Directors. The targeted amount of each officer's annual bonus shall be 50% of the applicable base salary, although the actual bonus may be higher or lower.

The employment agreements provide for an initial grant of stock options to Mr. Wingerter, Dr. Bar-Or, and Dr. Clift in the amount of 675,000, 700,000 and 365,000 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 options have all vested. Mr. Disbrow was granted 450,000 stock options which vest as follows: (i) 100,000 options to purchase common stock vested on the grant date of December 15, 2012; (ii) 100,000 options to purchase common stock vest 365 days after the grant date; (iii) 125,000 options to purchase common stock vest 730 days after the grant date; and (iv) 125,000 options to purchase common stock vest 1095 days after the grant date; and are exercisable for a period of ten years at an exercise price per share equal to the quoted closing price of our common stock on December 14, 2012. In the event of a change in control or in the event of termination without cause or for good reason (as such terms are defined in the employment agreement), all outstanding stock options held by Mr. Disbrow will become fully vested and exercisable.

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### **Potential Payments upon Termination or Change in Control**

If the employment of Mr. Disbrow, Dr. Bar-Or, or Dr. Clift is terminated at our election at any time, for reasons other than death, disability or cause (as defined in the employment agreements), or if an officer terminates his employment for good reason (as defined in the employment agreements), 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. Mr. Macaluso is not entitled to any such termination payments pursuant to the terms of his employment agreement. 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). If the employment is terminated for cause, no severance shall be payable by us.

Good Reason means:

a material reduction or change in the officer's title or job duties inconsistent with his position and his prior duties, responsibilities and requirements;

any reduction of the officer's then-current base salary or his target bonus;

relocation of the officer to a facility or location more than 30 miles from our current offices in Greenwood Village, Colorado; or

a material breach by Ampio of the employment agreement.

Cause means:

conviction of a felony or a crime involving fraud or moral turpitude;

commission of theft, a material act of dishonesty or fraud, intentional falsification of employment or company records, or a criminal act that impairs the officer's ability to perform his duties;

intentional or reckless conduct or gross negligence materially harmful to Ampio or its successor;

willful failure to follow lawful instructions of the Board; or

gross negligence or willful misconduct in the performance of duties.

Change in Control means: the occurrence of any of the following events:

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Any person (other than persons who are employees of Ampio at any time more than one year before a transaction) becomes the beneficial owner, directly or indirectly, of securities of Ampio representing 50% or more of the combined voting power of Ampio's then outstanding securities. In applying the preceding sentence, (A) securities acquired directly from Ampio or its affiliates by or for the person shall not be taken into account, and (B) an agreement to vote securities shall be disregarded unless its ultimate purpose is to cause what would otherwise be Change in Control, as reasonably determined by the Board;

Ampio consummantes a merger, or consolidation of Ampio with any other corporation unless: (a) the voting securities of Ampio outstanding immediately before the merger or consolidation would continue to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) at least 50% of the combined voting power of the voting securities of Ampio or such surviving entity outstanding immediately after such merger or consolidation; and (b) no person (other than persons who are employees at any time more than one year before a transaction) becomes a beneficial owner, directly or indirectly, of securities of Ampio representing 50% or more of the combined voting power of Ampio's then outstanding securities;

The stockholders of Ampio approve an agreement for the sale or disposition by Ampio of all, or substantially all, of Ampio's assets; or

The stockholders of Ampio approve a plan or proposal for liquidation or dissolution of Ampio.

Notwithstanding the foregoing, a Change in Control shall not be deemed to have occurred by virtue of the consummation of any transaction or series of integrated transactions immediately following which the record holders of the common stock of Ampio immediately prior to such transaction or series of transactions continue to have substantially the same proportionate ownership in an entity which owns all or substantially all of the assets of Ampio immediately following such transaction or series of transactions.

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The employment agreements also provide for the payment of a gross-up payment if the officer becomes entitled to certain payments and benefits and equity acceleration under his employment agreement and those payments and benefits constitute parachute payments under Section 280G of the Internal Revenue Code. In addition, in accordance with Ampio's stock incentive plan, all outstanding stock options held by Mr. Disbrow, Dr. Bar-Or and Dr. Clift (and all other option holders with grants under that plan) become fully vested in connection with a Change in Control. All outstanding stock options held by Mr. Macaluso will also become fully vested in connection with a Change in Control.

The following table provides estimates of the potential severance and other post-termination benefits that each of Mr. Disbrow, Dr. Bar-Or and Dr. Clift would have been entitled to receive assuming their respective employment was terminated as of December 31, 2012 for the reason set forth in each of the columns. Messrs. Macaluso and McGregor are not entitled to receive any such payments.

Recipient and Benefit	Termination Due to Death	Termination Due to Disability	Termination by Registrant for Cause or by Named Executive Officer Other than for Cause	Termination by Registrant without Cause or by Named Executive Officer for Cause
David Bar-Or				
Salary	\$ 0	\$ 600,000	\$ 0	\$ 600,000
Value of health benefits provided after termination(1)	\$ 0	\$ 39,182	\$ 0	\$ 39,182
Total	\$ 0	\$ 639,182	\$ 0	\$ 639,182
Vaughan Clift				
Salary	\$ 0	\$ 500,000	\$ 0	\$ 500,000
Value of health benefits provided after termination(1)	\$ 0	\$ 53,414	\$ 0	\$ 53,414
Total	\$ 0	\$ 553,414	\$ 0	\$ 553,414
Joshua Disbrow				
Salary	\$ 0	\$ 420,000	\$ 0	\$ 420,000
Value of health benefits provided after termination(1)		\$ 53,414		\$ 53,414
Total	\$ 0	\$ 473,414	\$ 0	\$ 473,414

- (1) The value of such benefits is determined based on the estimated cost of providing health benefits to the Named Executive Officer for the remaining term of the employment agreement.

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On January 9, 2012, we announced that Mr. Wingerter requested a compassionate leave from all of his duties as chief executive officer and a board member of Ampio in order to attend to the serious illnesses affecting both of his parents. The Board of Directors of the Company unanimously granted his request, which became effective on January 9, 2012. In connection with his departure, Mr. Wingerter received certain compensation and benefits which became payable in connection with a termination of his employment without cause for good reason in accordance with his employment agreement including: a lump sum payment of two years' salary totaling \$550,000, a supplemental payment of \$48,000, two years of continued health benefits totaling approximately \$1,500 per month to be paid by Ampio, and full acceleration of the vesting of 200,000 stock options at an exercise price of \$1.03. Following such acceleration, Mr. Wingerter's total holdings in the Company's stock were 325,000 shares and 600,000 vested options to purchase shares at an exercise price of \$1.03.

**Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.***

The following table sets forth information regarding beneficial ownership of our common stock as of December 31, 2012 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 December 31, 2012. For purposes of calculating each person's or group's percentage ownership, stock options, debentures convertible, and warrants exercisable within 60 days after December 31, 2012 are included for that person or group but not the stock options, debentures, or warrants of any other person or group.

Applicable percentage ownership is based on 37,009,695 shares of common stock outstanding at December 31, 2012.

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, Suite 925, 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 (1)	2,669,363	6.7%
David Bar-Or (2)	3,438,889	8.5%
Vaughn Clift (3)	916,367	2.4%
Philip H. Coelho (4)	471,811	1.3%
Richard B. Giles (5)	654,271	1.7%
David R. Stevens (6)	113,379	0.3%
Mark D. McGregor(7)	134,583	0.4%
Joshua R. Disbrow (8)	100,000	0.3%

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All executive officers and directors (eight persons)	8,498,663	21.6%
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- (1) Includes an aggregate of 625,990 shares of common stock issuable to Mr. Macaluso by virtue of (i) exercise of currently exercisable stock options, (ii) exercise of warrants, and (iii) his service as a non-management director and currently as an officer.
- (2) Includes 738,889 shares of common stock which Dr. Bar-Or has the right to acquire through the exercise of stock options. Excludes 945,283 shares of common stock owned of record by Raphael Bar-Or, Dr. Bar-Or's son, as to which Dr. Bar-Or disclaims beneficial ownership.
- (3) Includes (i) 394,167 shares of common stock Dr. Clift has the right to acquire on exercise of currently exercisable stock options, and (ii) 522,200 shares of common stock owned of record by Kristin Clift, Dr. Clift's spouse after selling 52,800 shares in the underwritten offering in July 2012.
- (4) Includes 434,998 shares of common stock issuable to Mr. Coelho on exercise of currently exercisable stock options.

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- (5) Includes 481,779 shares of common stock issuable to Mr. Giles by virtue of (i) exercise of currently exercisable stock options, and (ii) 50,417 shares of common stock issuable to Barbara Giles, Mr. Giles' spouse, on exercise of currently exercisable options, and (iii) exercise of warrants.
- (6) Includes 111,111 shares of common stock issuable to Dr. Stevens on exercise of currently exercisable stock options.
- (7) Includes 114,583 shares of common stock issuable to Mr. McGregor on exercise of currently exercisable stock options.
- (8) Includes 100,000 shares of common stock issuable to Mr. Disbrow on exercise of currently exercisable stock options.

### **Item 13. *Certain Relationships, Related Transactions, and Director Independence*** **Related Party Transactions**

In addition to the director and executive compensation arrangements discussed above in Item 11. Executive Compensation Executive Compensation and Employment Agreements, we or Life Sciences have been a party to the following transactions since January 1, 2010 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.

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 lease payments of \$7,236 on behalf of TRLLC. Lease commitments expired as of January 2011. In exchange, TRLLC will assign any intellectual property rights it develops on our behalf 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 December 31, 2010 and June 30, 2011.

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. We paid \$141,436, \$122,599 and \$61,000 during the years ended 2012, 2011 and 2010, respectively, in legal and patent fees to maintain the intellectual property of the Institute for Molecular Medicine, Inc.

Immediately prior to the closing of the merger between Life Sciences and a subsidiary of Chay in March 2010, 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 former 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. \$22,600 was repaid in 2011, and an additional \$36,883 was repaid in 2012. These shares were issued immediately before the closing of the Chay merger but after the shareholders of Chay had approved the merger. Life Sciences was not a public company at the time such advances were made.

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 accrued interest at the rate of 8% per annum. The principal and accrued interest of the debentures were converted into our common stock at a conversion price of \$1.75 per share on February 28, 2011, on the same terms under which convertible debentures issued to non-affiliates were converted. In conjunction with the issuance of the debentures, we issued warrants to Messrs. Macaluso, Giles and Ludvik representing the right to purchase an aggregate of 21,500 shares of our common stock. 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. Upon closing of our bridge financing in November 2010, we reserved an additional 27,643 shares for issuance to Messrs. Macaluso, Giles and Ludvik for most favored nation adjustments to the warrants previously issued to these persons.

In 2010, Messrs. Bar-Or, Miller and Clift deferred salaries in the amounts of \$85,313, \$67,500, and \$64,833, respectively, due to the limited financial resources available to us during these periods. These deferred salaries were paid in April 2011 following the closing of the 2011 Private Placement.



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Mr. McGregor purchased 20,000 shares of common stock in the 2011 Private Placement in March 2011, prior to his becoming our Chief Financial Officer on April 4, 2011. Mr. Giles purchased 32,000 shares of common stock in the 2011 Private Placement. Such purchases were on terms identical to those extended to unaffiliated purchasers in the 2011 Private Placement.

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Upon the formation of Life Sciences, shares of common stock issued to Bruce Miller, James Winkler, M.D., Raphael Bar-Or and Wannell Crook were subject to vesting requirements under which one-third of the shares vested immediately, one-third vested monthly from April 16, 2010 to April 16, 2011, and the remainder vesting monthly through April 16, 2012. The second and third tranches were subject to accelerated vesting based on development milestones being achieved by Life Sciences. In April 2011, the Board of Directors determined that the milestones for accelerated vesting had been met and that the portion of the shares that was unvested would vest immediately. All vested shares remain subject to contractual lockup agreements entered into in connection with the acquisition of BioSciences in March 2011.

### **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.

### **Director Independence**

Our common stock is listed on the NASDAQ Capital Market. The listing rules of the NASDAQ Capital Market require that a majority of the members of the board of directors be independent. The rules of the NASDAQ Capital Market require that, subject to specified exceptions, each member of our Audit, Compensation and Nominating and Governance 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 NASDAQ Capital Market, 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 2011, 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 at the time none of Messrs. Macaluso, Coelho, Giles and Stevens, representing four of our six 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 NASDAQ Capital Market. Since Mr. Macaluso became our chief executive officer on January 9, 2012, and Mr. Wingerter departed, we now have three independent directors out of five directors, represented by Messrs. Coelho, Giles and Stevens. Our Board of Directors also determined that Messrs. Giles, Coelho and Stevens, who comprise our Audit Committee and our Compensation Committee, and Messrs. Giles and Coelho, who comprise our Nominating and Governance Committee, satisfy the independence standards for those committees established by applicable SEC rules and the NASDAQ Capital Market rules. 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. The Board of Directors also has determined that Mr. Giles qualifies as an audit committee financial expert, as defined in Item 401(h) of Regulation S-K promulgated under the Exchange Act.

### **Item 14. *Principal Accountant Fees and Services***

EKS&H LLLP has served as our independent auditors since March 16, 2010 and has been appointed by the Audit Committee of the Board of Directors to continue as our independent auditors for the fiscal year ending December 31, 2012.

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The following table presents aggregate fees for professional services rendered by our independent registered public accounting firm, EKS&H LLP for the audit of our annual consolidated financial statements for the respective periods.

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	Year Ended December 31,		
	2012	2011	2010
Audit fees (1)	\$ 80,000	\$ 163,141	\$ 94,881
Audit-related fees (2)	20,767	120,698	80,028
Tax fees (3)	15,385	12,490	4,950
Total fees	\$ 116,152	\$ 296,329	\$ 179,859

- (1) Audit fees are comprised of annual audit fees and quarterly review fees.
- (2) Audit-related fees for fiscal years 2012, 2011 and 2010 are comprised of fees related to registration statements and accounting consultation fees.
- (3) Tax fees are comprised of tax compliance, preparation and consultation fees.

**Policy on Audit Committee Pre-Approval of Services of Independent Registered Public Accounting Firm**

Our Audit Committee has responsibility for appointing, setting compensation and overseeing the work of the independent registered public accounting firm. In recognition of this responsibility, the Audit Committee has established a policy to pre-approve all audit and permissible non-audit services provided by the independent registered public accounting firm. Prior to engagement of the independent registered public accounting firm for the following year's audit, management will submit to the Audit Committee for approval a description of services expected to be rendered during that year for each of following four categories of services:

*Audit services* include audit work performed in the preparation and audit of the annual financial statements, review of quarterly financial statements, reading of annual, quarterly and current reports, as well as work that generally only the independent auditor can reasonably be expected to provide, such as the provision of consents and comfort letters in connection with the filing of registration statements.

*Audit-related services* are for assurance and related services that are traditionally performed by the independent auditor, including due diligence related to mergers and acquisitions and special procedures required to meet certain regulatory requirements.

*Tax services* consist principally of assistance with tax compliance and reporting, as well as certain tax planning consultations.

*Other services* are those associated with services not captured in the other categories. We generally do not request such services from our independent auditor.

Prior to the engagement, the Audit Committee pre-approves these services by category of service. The fees are budgeted, and the Audit Committee requires the independent registered public accounting firm and management to report actual fees versus the budget periodically throughout the year by category of service. During the year, circumstances may arise when it may become necessary to engage the independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, the Audit Committee requires specific pre-approval before engaging the independent registered public accounting firm.

The Audit Committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the Audit Committee at its next scheduled meeting.

None of the services described above for 2012, 2011 or 2010 provided by EKS&H LLLP were approved by the Audit Committee pursuant to paragraph (c)(7)(i)(C) of Rule 2-01 of Regulation S-X.

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**PART IV**

**Item 15. Exhibits and Financial Statement Schedules**

**(a)(1) Financial Statements**

The following documents are filed as part of this Form 10-K, as set forth on the Index to Financial Statements found on page F-1.

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2012 and 2011

Consolidated Statements of Operations for the years ended December 31, 2012, 2011 and 2010

Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2012, 2011 and 2010

Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011 and 2010

Notes to Consolidated Financial Statements

**(a)(2) Financial Statement Schedules**

Not Applicable.

**(a)(3) Exhibits**

<b>Exhibit number</b>	<b>Exhibit title</b>
2.1	Agreement and Plan of Merger, dated March 2, 2010 (1)
2.2	Securities Put and Guarantee Agreement dated March 2, 2010 (1)
2.3	Agreement and Plan of Merger, dated September 4, 2010 (2)
2.4	Amendment to Agreement and Plan of Merger, effective December 31, 2010 (3)
2.5	Amendment to Agreement and Plan of Merger, dated March 22, 2011 (14)
3.1	Certificate of Incorporation of the Registrant, as currently in effect (4)
3.2	Certificate of Amendment to Certificate of Incorporation(4)

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3.3	Plan of Conversion of Chay Enterprises, Inc. to a Delaware corporation(4)
3.4	Bylaws of the Registrant, as currently in effect (4)
4.1	Specimen Common Stock Certificate of the Registrant (11)
4.2	Form of Unsecured Senior Convertible Debenture (5)
4.3	Form of Warrant issued with Unsecured Senior Convertible Debenture (5)
4.4	Form of Senior Unsecured Mandatorily Convertible Debenture (6)
4.5	Form of Warrant issued with Senior Unsecured Mandatorily Convertible Debenture (6)
4.6	Form of Underwriter Warrant (19)
10.1	Form of Director and Executive Officer Indemnification Agreement (7)
10.2	2010 Stock Incentive Plan and forms of option agreements (7)**
10.3	Employment Agreement, dated April 17, 2009, by and between DMI Life Sciences, Inc. and David Bar-Or, M.D.(7)**
10.4	Employment Agreement, dated April 17, 2009, by and between DMI Life Sciences, Inc. and Bruce G. Miller (7)**
10.5	Employment Agreement, effective August 1, 2010, by and between Ampio Pharmaceuticals, Inc. and Donald B. Wingerter, Jr. (8)**
10.6	Employment Agreement, effective August 1, 2010, by and between Ampio Pharmaceuticals, Inc. and David Bar-Or, M.D.(6)**
10.7.1	Employment Agreement, effective August 1, 2010, by and between Ampio Pharmaceuticals, Inc. and Vaughan Clift, M.D.(12)**

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<b>Exhibit number</b>	<b>Exhibit title</b>
10.7.2	Amendment to Employment Agreement, effective October 1, 2011, by and between Ampio Pharmaceuticals, Inc. and Vaughan Clift, M.D. (12)**
10.7.3	Letter Agreement, effective May 31, 2011, by and among Ampio Pharmaceuticals, Inc., on the one hand, and Donald B. Wingerter, Jr. and Vaughan Clift, M.D., on the other hand (16)
10.8	Sponsored Research Agreement dated September 1, 2009 (7)***
10.9	Exclusive License Agreement, dated July 11, 2005(7)***
10.10	First Amendment to Exclusive License Agreement, dated April 17, 2009 (7)***
10.11	Exclusive License Agreement, dated February 17, 2009 (7)***
10.12	Extension Agreement for Notes Payable dated May 13, 2010 (9)
10.13	Extension Agreement for Notes Payable dated May 13, 2010 (9)
10.14	Extension Agreement for Notes Payable effective January 31, 2011(12)
10.15	Extension Agreement for Notes Payable effective January 31, 2011 (12)
10.16	Note Extension and Subordination Agreement, executed February 15, 2011, by and between Ampio Pharmaceuticals, Inc. and DMI BioSciences, Inc. (12)
10.17	Note Extension and Subordination Agreement, executed February 15, 2011, by and between DMI Life Sciences, Inc., a subsidiary of the Company, and DMI BioSciences, Inc. (12)
10.18	Note Extension and Subordination Agreement, executed February 15, 2011, by and between DMI Life Sciences, Inc., a subsidiary of the Company, and Michael Macaluso (12)
10.19	Promissory Note, dated June 23, 2010 (10)
10.20	Irrevocable Instructions to Transfer Agent, dated March 10, 2011 (13)
10.21	Lease Agreement by and between Ampio Pharmaceuticals, Inc. and CSHV Denver Tech Center, LLC, dated May 20, 2011 (15)
10.22	License, Development and Commercialization Agreement between Ampio Pharmaceuticals, Inc. and Daewoong Pharmaceuticals Co., Ltd, effective as of August 23, 2011 (17)
10.23	Asset Purchase Agreement by and between Ampio Pharmaceuticals, Inc. and Valeant International (Barbados) SRL, effective as of December 2, 2011 (23)***
10.24	Employment Agreement, effective January 9, 2012, by and between Ampio Pharmaceuticals, Inc. and Michael Macaluso (20)**
10.25	Employment Agreement, effective December 15, 2012, by and between Ampio Pharmaceuticals, Inc. and Joshua R. Disbrow (21)**
10.26	Clinical Batch Manufacturing Agreement between Ethypharm S.A. and Ampio Pharmaceuticals, Inc. dated September 10, 2012 (22)***
10.27	Manufacturing and Supply Agreement between Ethypharm S.A. and Ampio Pharmaceuticals, Inc. dated September 10, 2012 (22)***
16.1	Letter Regarding Change in Certifying Accountant, dated March 16, 2010 (7)
21.1	List of subsidiaries of the Registrant (18)
23.1*	Consent of EKS&H LLLP
31.1*	Certificate of the Chief Executive Officer of Ampio Pharmaceuticals, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certificate of the Chief Financial Officer of Ampio Pharmaceuticals, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.





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<b>Exhibit number</b>	<b>Exhibit title</b>
32.1*	Certificate of the Chief Executive Officer and the Chief Financial Officer of Ampio Pharmaceuticals, Inc. pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document+
101.SCH	XBRL Taxonomy Extension Schema Document+
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document+
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document+
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document+
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document+

- (1) Incorporated by reference from Registrant s Form 8-K filed March 8, 2010.
- (2) Incorporated by reference from Registrant s Amendment No. 1 to Form 8-K filed January 7, 2011.
- (3) Incorporated by reference from Registrant s Amendment No. 2 to Form 8-K filed January 7, 2011.
- (4) Incorporated by reference from Registrant s Form 8-K filed March 30, 2010.
- (5) Incorporated by reference from Registrant s Form 8-K filed August 16, 2010.
- (6) Incorporated by reference from Registrant s Form 8-K filed November 12, 2010.
- (7) Incorporated by reference from Registrant s Form 8-K/A filed March 17, 2010.
- (8) Incorporated by reference from Registrant s Form 8-K/A filed August 17, 2010.
- (9) Incorporated by reference from Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.
- (10) Incorporated by reference from Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2010.
- (11) Incorporated by reference from Registrant s Registration Statement on Form S-4 filed January 7, 2011.
- (12) Incorporated by reference from Registrant s Form 8-K filed February 15, 2011.
- (13) Incorporated by reference from Registrant s Form 8-K filed March 16, 2011.
- (14) Incorporated by reference from Registrant s Form 8-K filed March 25, 2011.
- (15) Incorporated by reference from Registrant s Registration Statement on Form S-1/A filed May 23, 2011.
- (16) Incorporated by reference from Registrant s Form 8-K filed June 8, 2011.
- (17) Incorporated by reference from Registrant s Form 8-K/A filed October 5, 2011.
- (18) Incorporated by reference from Registrant s Registration Statement on Form S-1 filed November 12, 2010.
- (19) Incorporated by reference from Registrant s Form 8-K filed July 13, 2012.
- (20) Incorporated by reference from Registrant s Form 8-K filed September 13, 2012.
- (21) Incorporated by reference from Registrant s Form 8-K filed December 20, 2012.
- (22) Incorporated by reference from Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.
- (23) Incorporated by reference from Registrant s Annual Report on Form 10-K for the year ended December 31, 2011.

\* Filed herewith.

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

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

+ Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

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**SIGNATURES**

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

**AMPIO PHARMACEUTICALS, INC.**

Date: March 6, 2013

By: /s/ Michael Macaluso  
Michael Macaluso

*Chief Executive Officer*

(Principal Executive Officer)

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**POWER OF ATTORNEY**

Each person whose signature appears below constitutes and appoints and hereby authorizes Michael Macaluso and, severally, such person's true and lawful attorneys-in-fact, with full power of substitution or resubstitution, for such person and in his name, place and stead, in any and all capacities, to sign on such person's behalf, individually and in each capacity stated below, any and all amendments, including post-effective amendments to this Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Commission granting unto said attorney-in-fact, 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, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorney-in-fact, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant in the capacities indicated, on March 6, 2013.

<b>Signature</b>	<b>Title</b>
<b>/s/ Michael Macaluso</b>	Chairman of the Board and Chief Executive Officer
Michael Macaluso	
<b>/s/ Mark D. McGregor</b>	Chief Financial Officer (Principal Financial and Accounting Officer)
Mark D. McGregor	
<b>/s/ David Bar-Or</b>	Director
David Bar-Or	
<b>/s/ Philip H. Coelho</b>	Director
Philip H. Coelho	
<b>/s/ Richard B. Giles</b>	Director
Richard B. Giles	
<b>/s/ David R. Stevens</b>	Director
David R. Stevens	

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders

Ampio Pharmaceuticals, Inc. and Subsidiaries

Greenwood Village, Colorado

We have audited the accompanying consolidated balance sheets of Ampio Pharmaceuticals, Inc. and Subsidiaries (a development stage company, the Company) as of December 31, 2012 and 2011, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2012, and for the period from December 18, 2008 (inception) to December 31, 2012. We also have audited the Company's internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting included in Item 9A. Our responsibility is to express an opinion on these consolidated financial statements and an opinion on the Company's internal control over financial reporting 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Ampio Pharmaceuticals, Inc. and Subsidiaries (a development stage company) as of December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2012, and for the period from December 18, 2008 (inception) through December 31, 2012, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, Ampio Pharmaceuticals, Inc. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

EKS&H LLLP

March 6, 2013

Denver, Colorado



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

	December 31,	
	2012	2011
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 17,682,517	\$ 11,362,325
Prepaid expenses	164,890	43,120
Total current assets	17,847,407	11,405,445
Fixed assets, net	59,290	76,230
In-process research and development	7,500,000	7,500,000
Patents, net	420,468	465,924
Deposits	20,000	35,000
	7,999,758	8,077,154
Total assets	\$ 25,847,165	\$ 19,482,599
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable	\$ 1,201,122	\$ 630,622
Deferred revenue	50,000	50,000
Warrant derivative liability	384,771	610,911
Total current liabilities	1,635,893	1,291,533
Long-term deferred revenue	381,250	431,250
Total liabilities	2,017,143	1,722,783
Commitments and contingencies (Note 10)		
Stockholders' equity		
Preferred Stock, par value \$.0001; 10,000,000 shares authorized; none issued		
Common Stock, par value \$.0001; 100,000,000 shares authorized; shares issued and outstanding - 37,009,695 in 2012 and 31,081,434 in 2011	3,701	3,108
Additional paid-in capital	63,687,558	46,061,783
Advances to stockholders	(90,640)	(127,523)
(Deficit) accumulated in the development stage	(39,770,597)	(28,177,552)
Total stockholders' equity	23,830,022	17,759,816
Total liabilities and stockholders' equity	\$ 25,847,165	\$ 19,482,599

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





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

	Years Ended December 31,			December 18, 2008 (Inception) through December 31, 2012
	2012	2011	2010	
License revenue	\$ 50,000	\$ 18,750	\$	\$ 68,750
Expenses				
Research and development	\$ 7,493,824	\$ 6,614,384	\$ 1,883,150	\$ 16,954,037
Research and development - related party (Note 13)		34,013	88,984	230,688
General and administrative	4,376,932	4,504,494	4,732,271	14,055,912
Total operating expenses	11,870,756	11,152,891	6,704,405	31,240,637
Other income (expense)				
Interest income	21,943	6,684	815	30,533
Interest expense		(8,358)	(19,545)	(29,317)
Unrealized gain (loss) on fair value of debt instruments		(5,585,422)	37,511	(5,547,911)
Derivative income (expense)	205,768	(1,555,497)	(1,367,771)	(2,717,500)
Total other income (expense)	227,711	(7,142,593)	(1,348,990)	(8,264,195)
Net loss, before income tax	\$ (11,593,045)	\$ (18,276,734)	\$ (8,053,395)	\$ (39,436,082)
Foreign tax expense		82,500		82,500
Net loss	\$ (11,593,045)	\$ (18,359,234)	\$ (8,053,395)	\$ (39,518,582)
Weighted average number of common shares outstanding	33,983,590	26,013,838	16,288,468	
Basic and diluted net loss per common share	\$ (0.34)	\$ (0.71)	\$ (0.49)	

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

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

	Series A Preferred Stock		Common Stock		Common Stock	Additional Paid	Additional	Advances	Deficit	Total
	Shares	Amount	Shares	Amount	Subscribed	in Capital	Issuances	to Stockholders	Accumulated in the Development Stage	Stockholders Equity (Deficit)
Balance - December 18, 2008 (date of inception)		\$		\$	\$	\$	\$	\$	\$	\$
Issuance of common stock to founder December, 2008			1,080,000	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			7,350,000	7,350						7,350
Issuance of Series A Preferred Stock in exchange for cash in April and May 2009	913,930	914					1,114,106			1,115,020
Common stock subscribed in November and December 2009					170,003					170,003
Net loss									(1,512,908)	(1,512,908)
Balance - December 31, 2009	1,077,864	\$ 1,078	11,930,000	\$ 11,930	\$ 170,003	\$ 1,313,942	\$	\$	\$ (1,764,923)	\$ (267,970)
Conversion of equity in reverse merger acquisition	(1,077,864)	(1,078)	3,068,958	(10,430)			11,691			183
Common stock subscribed in March 2010					7,000					7,000
Issuance of common stock in exchange for cash			1,078,078	108	(177,003)		1,536,522			1,359,627

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in March and June 2010, net of offering costs of \$350,000									
Issuance of common stock for services	1,030,000	103		1,802,397	(3,281)				1,799,219
Stock-based compensation				1,297,083					1,297,083
Loans to shareholders					(150,183)				(150,183)
Net loss							(8,053,395)		(8,053,395)

Balance - December 31, 2010	\$	17,107,036	\$	1,711	\$	5,961,635	\$	(3,281)	\$	(150,183)	\$	(9,818,318)	\$	(4,008,436)
Stock-based compensation		13,635		1		1,983,784								1,983,785
Issuance of common stock for services								3,281						3,281
Conversion of debentures		1,281,852		128		9,423,947								9,424,075
Shares issued for cash		1,714				3,000								3,000
Options exercised, net		301,604		30		109,015								109,045

Issuance of common stock for acquisition of DMI BioSciences, Inc., net of 3,500,000 shares of Ampio common stock exchanged		5,167,905		517		7,852,220								7,852,737
Issuance of common stock in exchange for cash in March and April, net of offering costs of \$2,704,328		5,092,880		509		10,916,029								10,916,538
Warrants exercised		88,669		8		784,356								784,364
Shares received in exchange for options issued		(98,416)		(9)		574,009								574,000
Escrow shares claimed		(95,700)		(9)		9								
Repayment of advance								22,660						22,660
Issuance of common stock in exchange for cash in December, net of offering costs of \$982,083		2,220,255		222		8,453,779								8,454,001
Net loss										(18,359,234)				(18,359,234)

Balance - December 31, 2011	\$	31,081,434	\$	3,108	\$	46,061,783	\$	(127,523)	\$	(28,177,552)	\$	17,759,816
Issuance of common stock for services		24,072		3		100,147						100,150
Options exercised, net		680,809		68		617,932						618,000

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Warrants exercised, net	19,520	2	32,692	32,694
Stock-based compensation			1,522,374	1,522,374
Repayment of advance			36,883	36,883
Issuance of common stock in exchange for cash in July, net of offering costs of \$1,739,589	5,203,860	520	15,352,630	15,353,150
Net loss			(11,593,045)	(11,593,045)
Balance - December 31, 2012	\$ 37,009,695	\$ 3,701	\$ 63,687,558	\$ (90,640) \$ (39,770,597) \$ 23,830,022

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

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

	Years Ended December 31,			December 18, 2008 (Inception) through December 31, 2012
	2012	2011	2010	
<b>Cash flows from operating activities:</b>				
Net loss	\$ (11,593,045)	\$ (18,359,234)	\$ (8,053,395)	\$ (39,518,582)
Depreciation and amortization	62,396	42,551		104,947
Common stock issued for services	100,150	3,281	1,799,219	1,902,650
Stock-based compensation expense	1,522,374	1,983,785	1,297,083	4,803,242
Derivative (income) expense	(205,768)	1,555,497	1,367,771	2,717,500
Unrealized (gain) loss on fair value of debt instruments		5,585,422	(37,511)	5,547,911
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:				
(Increase) Decrease in prepaid expenses	(121,770)	17,414	(53,498)	(164,890)
Decrease in related party receivable		5,711	1,550	
Increase (Decrease) in related party payable		(84,032)	193,821	109,789
Increase in accounts payable	570,500	166,171	385,008	1,201,124
Increase (Decrease) in deferred revenue	(50,000)	481,250		431,250
Increase (Decrease) in accrued salaries		(526,733)	453,342	
Increase (Decrease) in accrued interest payable		(2,745)	18,279	16,948
Net cash and cash equivalents used in operating activities	(9,715,163)	(9,131,662)	(2,628,331)	(22,848,111)
<b>Cash flows used in investing activities:</b>				
Purchase of fixed assets		(84,705)		(84,705)
Deposits	15,000	(35,000)		(20,000)
Net cash and cash equivalents provided by (used in) investing activities	15,000	(119,705)		(104,705)
<b>Cash flows from financing activities:</b>				
Proceeds from related party notes payable and debentures		382,000	2,011,000	2,593,000
Proceeds from sale of common stock	17,542,867	22,435,500	1,359,627	41,346,424
Costs related to sale of common stock	(1,559,395)	(2,797,747)		(4,357,142)
Proceeds from common stock subscribed			7,000	177,003
Proceeds from sales of Series A Preferred Stock				1,115,020
Advances (to) from shareholders	36,883	22,660	(150,183)	(90,640)
Payment of liabilities assumed in asset purchase				(48,515)
Payment of related party notes		(100,000)		(100,000)
Increase in cash from acquisition			183	183
Net cash and cash equivalents provided by financing activities	16,020,355	19,942,413	3,227,627	40,635,333
Net change in cash and cash equivalents	6,320,192	10,691,046	599,296	17,682,517
Cash and cash equivalents at beginning of period	11,362,325	671,279	71,983	
Cash and cash equivalents at end of period	\$ 17,682,517	\$ 11,362,325	\$ 671,279	\$ 17,682,517

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Supplementary cash flow information:				
Interest paid	\$	\$	8,358	\$ 8,358
Income taxes paid	\$	\$	82,500	\$ 82,500
Non-cash transactions:				
Liabilities assumed in asset purchase, recorded as a distribution	\$	\$		\$ 248,515
Conversion of notes payable to Series A Preferred Stock	\$	\$		\$ 200,000
Common stock issued for common stock subscriptions received	\$	\$	177,003	\$ 177,003
Deferred charge recorded for common stock issued in exchange for services	\$	\$	1,802,500	\$ 1,802,500
Common stock issued for acquisition of DMI BioSciences, Inc.	\$	\$	7,852,737	\$ 7,852,737
Conversion of debentures to common stock	\$	\$	9,424,075	\$ 9,424,075
Warrant compensation from common stock offering costs	\$ 180,194	\$	888,664	\$ 1,068,858
Merger liability - shares exchanged for options	\$	\$	574,000	\$ 574,000
Debenture warrant exercise fair value adjustment	\$ 20,372	\$	629,193	\$ 649,565

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

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### **AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**(A Development Stage Company)**

#### **Notes to Consolidated Financial Statements**

##### **Note 1 Business, Basis of Presentation and Merger**

These financial statements represent the consolidated financial statements of Ampio Pharmaceuticals, Inc. ( *Ampio* or the Company ), formerly known as Chay Enterprises, Inc. ( *Chay* ), and its wholly owned subsidiaries, DMI Life Sciences, Inc.( *Life Sciences* ), DMI Acquisition Corp. and DMI BioSciences, Inc. ( *BioSciences* ). Ampio is engaged in developing innovative, proprietary pharmaceutical drugs and diagnostic products to identify, treat and prevent a broad range of human diseases including metabolic disorders, eye disease, kidney disease, acute and chronic inflammation diseases and male sexual dysfunction.

Life Sciences was incorporated in the state of Delaware on December 18, 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. The assets that Life Sciences 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 purchased. On March 2, 2010, Life Sciences 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 Life Sciences, which resulted in the stockholders of Life Sciences 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 Note 13 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, Life Sciences became a wholly owned subsidiary of Chay. For accounting purposes, the Merger was treated as a reverse acquisition with Life Sciences as the acquirer and Chay as the acquired party. The business and financial information included in this report is the business and financial information of Life Sciences. 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 insignificant.

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

On March 23, 2011, Ampio acquired BioSciences (the *BioSciences Merger* ). Bioscience 's principal asset consisted of the worldwide rights to Zertane, as to which BioSciences held 32 issued patents and 31 pending patent applications. Zertane is a repurposed drug to treat male sexual dysfunction pertaining to premature ejaculation (PE) in men. See Note 3 Acquisition of DMI BioSciences for terms of the acquisition.

Ampio 's activities, being primarily research and development and raising capital, have not generated significant revenue to date. Ampio is considered to be a development stage company.

##### **Note 2 Summary of Significant Accounting Policies**

###### ***Principals of Consolidation***

These consolidated financial statements include the accounts of Ampio and its wholly owned subsidiaries. All material intercompany transactions and balances have been eliminated.

###### ***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 fund investments. Ampio 's investment policy is to preserve principal and maintain liquidity. Ampio periodically monitors its positions with, and the credit quality of, the financial institutions with which it invests. Periodically, throughout the year, Ampio has maintained balances in excess of federally insured limits.

###### ***Revenue Recognition/Deferred Revenue***

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Payments made upon signing of the license agreements are for the right to use the license and are deferred and amortized over the lesser of the license term or patent life of the licensed drug. Milestone payments relate to obtaining regulatory approval in the territory, cumulative sales targets, and other projected milestones and are recognized at the time the milestone requirements are achieved. Royalties will be recognized as revenue when earned.

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**Table of Contents****Fixed Assets**

Fixed assets are recorded at cost and are depreciated on the straight-line method over estimated useful lives, generally five years. Fixed assets consist of the following:

	December 31,	
	2012	2011
Office furniture and equipment	\$ 84,705	\$ 84,705
Less accumulated depreciation	(25,415)	(8,475)
<b>Fixed assets, net</b>	<b>\$ 59,290</b>	<b>\$ 76,230</b>

The Company recorded the following depreciation expense in the respective periods:

	Year Ended December 31,			December 18, 2008 (Inception) through December 31, 2012
	2012	2011	2010	
Depreciation Expense	\$ 16,940	\$ 8,475	\$	\$ 25,415

**Patents**

Costs of establishing patents, consisting of legal and filing fees paid to third parties, are expensed as incurred. The fair value of the Zertane patents, determined by an independent, third party appraisal to be \$500,000, acquired in connection with the March 2011 acquisition of BioSciences is being amortized over the remaining U.S. patent lives of approximately 11 years beginning April 1, 2011. Patents consist of the following:

	December 31,	
	2012	2011
Patents	\$ 500,000	\$ 500,000
Less accumulated amortization	(79,532)	(34,076)
<b>Patents, net</b>	<b>\$ 420,468</b>	<b>\$ 465,924</b>

The Company recorded the following amortization expense in the respective periods:

	Year Ended December 31,			December 18, 2008 (Inception) through December 31, 2012
	2012	2011	2010	
Amortization Expense	\$ 45,456	\$ 34,076	\$	\$ 79,532

Future amortization is as follows:

2013	\$ 45,456
2014	45,456

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2015	45,456
2016	45,456
2017	45,456
Thereafter	193,188
	\$ 420,468

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### ***In-Process Research and Development***

In-process research and development ( IPRD ) relates to the Zertane product and clinical trial data acquired in connection with the March 2011 business combination of BioSciences Note 3 Acquisition of DMI BioSciences. The \$7,500,000 recorded was based on an independent third party appraisal of the fair value of the assets acquired. IPRD is considered an indefinite-lived intangible asset and its fair value will be assessed annually and written down if impaired. Once the Zertane product obtains regulatory approval and commercial production begins, IPRD will be reclassified to an intangible that will be amortized over its estimated useful life.

### ***Use of Estimates***

The preparation of consolidated financial statements in accordance with Generally Accepted Accounting Principles in the United States of America ( GAAP ) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosures of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. Significant items subject to such estimates and assumptions include the fair value of warrant derivative liability, hybrid debt instruments, valuation allowances, deferred income tax assets, stock-based compensation and assumptions in evaluating impairment of indefinite lived assets. Actual results could differ from these estimates.

### ***Derivatives***

Ampio accounted for hybrid financial instruments (debentures with embedded derivative features conversion options, down-round protection and mandatory conversion provisions) and related warrants by recording the fair value of each hybrid instrument in its entirety and recording the fair value of the warrant derivative liability. The fair value of the hybrid financial instruments and related warrants was calculated using a binomial-lattice-based valuation model. Ampio recorded a derivative expense at the inception of each instrument reflecting the difference between the fair value and cash received. Changes in the fair value in subsequent periods were recorded as unrealized gain or loss on fair value of debt instruments for the hybrid financial instruments and to derivative income or expense for the warrants. Accounting for hybrid financial instruments and derivatives is discussed more fully in Note 6 Short Term Debt Conversion. The fair value of warrants issued in connection with the common stock offerings was valued using a Black-Scholes option pricing model.

### ***Income Taxes***

Deferred taxes are provided on an asset and liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry forwards and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

The amount of income taxes and related income tax positions taken are subject to audits by federal and state tax authorities. Ampio has adopted accounting guidance for uncertain tax positions which provides that in order to recognize an uncertain tax benefit, the taxpayer must be more likely than not of sustaining the position, and the measurement of the benefit is calculated as the largest amount that is more than 50% likely to be realized upon recognition of the benefit. Ampio believes that it has no material uncertain tax positions and has fully reserved against Ampio s future tax benefit with a valuation allowance and do not expect significant changes in the amount of unrecognized tax benefits that occur within the next twelve months. Ampio s policy is to record a liability for the difference between the benefits that are both recognized and measured pursuant to FASB ASC 740-10, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109* ( ASC 740-10 ) and tax position taken or expected to be taken on the tax return. Then, to the extent that the assessment of such tax positions changes, the change in estimate is recorded in the period in which the determination is made. Ampio reports tax-related interest and penalties as a component of income tax expense. During the periods reported, management of Ampio has concluded that no significant tax position requires recognition under ASC 740-10. The Company is no longer subject to income tax examinations for federal income taxes before 2009 or for Colorado before 2008.

**Table of Contents*****Net Loss per Common 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 Ampio. Basic and diluted loss per share was the same in 2012, 2011 and 2010. Although there were common stock equivalents of 5,677,186, 4,509,882 and 3,136,969 shares outstanding at December 31, 2012, 2011 and 2010, respectively, consisting of stock options and warrants; they were not included in the calculation of earnings per share because they would have been anti-dilutive. Ampio also had convertible debt and warrants to purchase common stock outstanding at December 31, 2010, however the conversion price of the debt, the exercise price of the warrants and number of applicable common shares was contingent upon future events outside of Ampio's control at December 31, 2010 and, therefore, were not included as common stock equivalents.

***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 with expense recorded in the respective periods as follows:

	Year Ended December 31,			December 18, 2008 (Inception) through December 31, 2012
	2012	2011	2010	
Research and development costs	\$ 7,493,824	\$ 6,648,397	\$ 1,972,134	\$ 17,184,725

***Fair Value of Financial Instruments***

The carrying amounts of financial instruments, including cash and cash equivalents, accounts payable and other current assets and liabilities are carried at cost which approximates fair value due to the short maturity of these instruments. Hybrid financial instruments such as convertible debentures and related warrants are recorded at estimated fair value based on a binomial-lattice based valuation model.

***Impairment of Long-Lived Assets***

Ampio routinely performs an evaluation of the recoverability of the carrying value of its long-lived assets to determine if facts and circumstances indicate that the carrying value of assets or intangible assets may be impaired and if any adjustment is warranted. Based on Ampio's evaluation as of December 31, 2012, no impairment existed for long-lived assets.

***Newly Issued Accounting Pronouncements***

In July 2012, the FASB issued ASU 2012-02, Intangibles—Goodwill and Other (Topic 350)—Testing Indefinite-Lived Intangible Assets for Impairment. The guidance is intended to simplify impairment testing of indefinite-lived intangible assets such as In-Process Research and Development by first assessing qualitative factors to determine whether it is more likely than not that the fair value of an asset is less than its carrying amount as a basis for determining whether it is necessary to perform a quantitative impairment test. The more-likely-than-not threshold is defined as having a likelihood of more than 50%. This guidance is effective for annual and interim tests performed for fiscal years beginning after September 15, 2012. The adoption of this guidance is not expected to have a significant impact on the Company's financial position or results of operations.

In May 2011, the FASB issued ASU 2011-04 Fair Value Measurement (Topic 820): The guidance is designed to achieve fair value measurement and disclosure requirements between U.S. GAAP and International Financial Reporting Standards. The amendments were effective for Ampio beginning in the first quarter of 2012. The adoption of this guidance did not have a material impact on Ampio's consolidated financial statements.

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**Table of Contents****Note 3 Acquisition of DMI BioSciences**

On March 23, 2011, Ampio acquired all of the outstanding stock of BioSciences for 8,667,905 shares of Ampio common stock (the "merger stock"). Ampio acquired BioSciences in order to obtain all rights to Zertane, BioSciences' male sexual dysfunction drug for PE. The business combination occurred following the satisfaction or waiver of all conditions to closing. As called for in the merger agreement, Ampio issued 405,066 shares of merger stock to holders of BioSciences in-the-money stock options and warrants, 500,000 shares of merger stock to holders of two BioSciences promissory notes in extinguishment of the notes, and placed 250,000 shares of merger stock in an indemnification escrow until December 31, 2011. The remaining 7,512,839 shares of merger stock were issued to the holders of BioSciences common stock on a pro rata basis. As required by the merger agreement, at the closing BioSciences donated back to Ampio's capital 3,500,000 shares of Ampio common stock formerly owned by BioSciences which were subsequently cancelled. Ampio separately issued 212,693 options in replacement of 250,850 Biosciences options that were out-of-the-money as of the date of execution of the merger agreement.

As a component of the purchase price, Ampio recorded a liability of \$574,000 to reflect the potential settlement with three in-the-money option holders that threatened litigation to have their BioSciences options carried over versus being issued Ampio stock in exchange for these options. The dispute involved 263,000 options that were converted to 98,416 shares of Ampio common stock. The liability was estimated based on a fair value calculation of the difference between the Ampio stock trading price and the value of Ampio options using the Black-Scholes option price model with an exercise price of \$0.90. On June 17, 2011 a formal agreement was executed whereby Ampio issued 223,024 stock options with an exercise price of \$0.90 and an expiration date of February 22, 2014 in exchange for the 98,416 previously issued shares of Ampio stock. The \$574,000 liability has been eliminated and credited to stockholders' equity. Ampio subsequently filed a claim on the indemnification escrow and was awarded 95,700 shares of Ampio stock to reflect the full value of the 223,024 options issued in exchange for the shares relinquished. The remaining 154,300 indemnification escrow shares were allocated to the appropriate shareholders on December 31, 2011. The 98,416 shares relinquished with the agreement and the 95,700 escrow shares awarded were cancelled. After these adjustments, the net merger stock issued was 8,473,789.

The following table summarizes the amounts of estimated fair value of net assets acquired at the acquisition date:

Notes receivable from Ampio	\$ 300,000
Non-interest bearing advances and accrued interest receivable from Ampio	127,000
In-process research and development	7,500,000
Patents	500,000
Liabilities	(574,000)
	\$ 7,853,000

The fair value of IPRD and patents was based on an independent third party appraisal.

**Note 4 Asset Purchase Agreement/Product Technology License**

On December 2, 2011, Ampio entered into a \$2,000,000 Asset Purchase Agreement with Valeant International (Barbados) SRL (formerly BioVail Laboratories International) ("Valeant"). The agreement provides for the sale and transfer of all of Valeant's rights, title and interest in and to a license agreement containing patented technology, specified data, information, manufacturing rights and know-how relating to an ODT formulation for Zertane, including samples of the Zertane product, in exchange for cash of \$2,000,000. This Product License is a major component for documenting the manufacturing process for regulatory approval and accelerating the timeline for commercialization of Zertane.

The ODT formulation has not been petitioned for regulatory approval and, since the License has no alternative future use, the cost of this purchase has been expensed.

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### **Note 5 License Agreement/Revenue Recognition**

On September 8, 2011, Ampio entered into a license, development and commercialization agreement, effective as of August 23, 2011, with a major Korean pharmaceutical company. The agreement grants the pharmaceutical company exclusive rights to market Zertane in South Korea for the treatment of PE and for a combination drug to be developed, utilizing Zertane and an erectile dysfunction drug. Upon signing of the agreement, Ampio received a \$500,000 upfront payment, the net proceeds of which were \$417,500 after withholding of Korean tax. The upfront payment has been deferred and is being recognized as license revenue over a ten year period. Milestone payments of \$3,200,000 will be earned and recognized contingent upon achievement of regulatory approvals and cumulative net sales targets, which may take several years. In addition, Ampio will earn a royalty based on 25% of net sales, as defined, if the royalty exceeds the transfer price of the Zertane product.

### **Note 6 Short Term Debt**

#### ***Related Party Notes Payable***

As of December 31, 2010, Ampio had \$300,000 in related party notes payable to BioSciences and \$100,000 to a director. The related party notes payable and accrued interest of \$16,948 owed to BioSciences were eliminated in consolidation subsequent to the acquisition of BioSciences. The \$100,000 related party note payable to a director was repaid together with accrued interest of \$8,219 on March 31, 2011.

#### ***Senior Convertible Unsecured Related Party Debentures***

On August 8, 2010, Ampio issued \$430,000 face value Senior Convertible Unsecured Debentures to two of its directors and an affiliate of one of those directors ( Related Party Debentures ) and warrants indexed to 21,500 shares of Ampio common stock for net cash proceeds of \$430,000. The Related Party Debentures accrued interest at 8% per annum. Both the principal and interest were payable upon the earlier of (i) one business day after the closing of a Public Offering or (ii) April 30, 2011. The principal amount of the Related Party Debentures was convertible into common stock at the lower of (i) \$1.75 per share or (ii) the per-share price at which Ampio common stock was sold in an underwritten public offering that was the subject of a registration statement on Form S-1. On February 28, 2011, the holders of the Related Party Debentures converted principal and accrued interest of \$430,000 and \$18,102, respectively, into 256,058 shares of common stock at \$1.75 per share.

Pursuant to the terms of the agreements, a total of 51,215 warrants were issued in connection with the Related Party Debentures which have an expiration date of December 31, 2013. The exercise price of the warrants is \$1.75 per share. The warrants are subject to adjustment for recapitalization events. The warrants are described more fully in Note 11 Common Stock.

#### ***Senior Unsecured Mandatorily Redeemable Debentures***

Ampio issued Senior Unsecured Mandatorily Redeemable Debentures ( 2011 Redeemable Debentures ) with a face value of \$382,000 between January 20, 2011 and January 31, 2011. Between October 22, 2010 and December 29, 2010, Ampio issued three tranches of Senior Unsecured Mandatorily Redeemable Debentures ( 2010 Redeemable Debentures ) with an aggregate face value of \$1,381,000. All Redeemable Debentures were issued on the same terms. Upon receipt of the principal amount, Ampio issued warrants that entitled the holder to acquire on exercise of the warrants an aggregate number of shares of the Company's common stock equal to 20% of the conversion shares issuable upon conversion of the debentures. The Redeemable Debentures accrued interest at 8% per annum. On February 28, 2011, pursuant to the terms of the debenture agreements, principal of \$1,763,000 and interest of \$32,146 were converted into 1,025,794 shares of common stock at a price of \$1.75 per share.

In connection with the conversion, Ampio issued warrants to purchase 205,174 shares of common stock which included accrued interest on both the 2010 and 2011 Redeemable Debentures. The warrants issued in connection with the 2011 and the 2010 Redeemable Debentures have an expiration date of December 31, 2013. The exercise price for the warrants became fixed at \$1.75 per share on February 28, 2011. The warrants are subject to adjustment for recapitalization events. During 2011, 88,669 warrants to purchase shares of common stock were exercised, resulting in \$155,171 proceeds to Ampio. The warrants are described more fully in Note 11 Common Stock.

#### ***Accounting for the Financings***

Because the economic characteristics and risks of the equity-linked conversion options are not clearly and closely related to a debt-type host, the conversion features require classification and measurement as a derivative financial instrument. The other embedded derivative features (down round protection feature and mandatory conversion provision) were also not considered clearly and closely related to the host debt instrument. Further, these features individually were not afforded the exemption normally available to





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derivatives indexed to a company's own stock. Accordingly, Ampio's evaluation resulted in the conclusion that a compound derivative financial instrument requires bifurcation and liability classification, at fair value. The compound derivative financial instrument consists of (i) the embedded conversion feature, (ii) down round protection feature and (iii) mandatory conversion provision. Current standards contemplate that the classification of financial instruments requires evaluation at each report date.

GAAP provides an election wherein companies that issue financial instruments with embedded features that require bifurcation may elect, as an alternative to bifurcation, fair value measurement of the hybrid financial instrument in its entirety. After reviewing all circumstances surrounding the issuance and impending redemptions or conversions, Ampio elected the alternative and recorded the Related Party Debentures and the Senior Convertible 2010 and 2011 Redeemable Debentures at fair value.

Ampio also concluded that the Warrants related to these financings which are derivatives by definition, did not meet the principal exemption to liability classification and measurement. Generally, freestanding financial instruments, such as the Warrants that are both indexed to a company's own stock and classified in stockholders' equity under certain conditions are exempt from derivative classification and measurement standards. The Warrants did not meet the definition of indexed to a company's own stock on the inception date because the exercise price was subject to adjustment. The Warrants also did not meet all of the eight conditions for classification in stockholders' equity. Accordingly, the Warrants are classified as a liability and subject to the classification and measurement standards for derivative financial instruments.

The following table reflects the allocation of the purchase of the 2011 and 2010 debentures at the time of financing:

	2011 Unsecured	Related Party	2010 Unsecured
<b>Purchase price allocation</b>			
Hybrid debt instruments	\$ 1,096,064	\$ 598,575	\$ 2,181,523
Warrants	211,073	21,332	318,744
Derivative loss, included in derivative expense	(925,137)	(189,907)	(1,119,267)
	<b>\$ 382,000</b>	<b>\$ 430,000</b>	<b>\$ 1,381,000</b>

## Note 7 - Derivative Financial Instruments

The components of warrant derivative liability as reflected in the consolidated balance sheets are as follows:

	December 31, 2012		December 31, 2011	
	Indexed Shares	Fair Values	Indexed Shares	Fair Values
<b>Ampio's financings giving rise to derivative financial instruments:</b>				
Warrants (dates correspond to hybrid financing):				
Tranche 1 - August 10, 2010	51,215	\$ 116,635	51,214	\$ 183,132
Tranche 2 - October 22, 2010-October 29, 2010			7,040	25,650
Tranche 3 - November 12, 2010-November 29, 2010	66,434	195,813	66,434	295,146
Tranche 4 - December 13, 2010-December 29, 2010	13,686	33,913	13,686	50,497
Tranche 5 - January 20, 2011-January 31, 2011	29,344	38,410	29,344	56,486
	<b>160,679</b>	<b>\$ 384,771</b>	<b>167,718</b>	<b>\$ 610,911</b>

Ampio elected to measure the Senior Convertible Debentures at fair value in their entirety, rather than bifurcating the conversion option. The fair value of the hybrid debt instrument comprises the present value of the principal and coupon enhanced by the conversion option. Both the Warrants and the conversion options embedded in the hybrid debt instruments were valued using a binomial-lattice-based valuation model. The lattice-based valuation technique was utilized because it embodies all of the requisite assumptions (including the underlying price, exercise price, term, volatility, and risk-free interest-rate) that are necessary to fair value these instruments. For forward contracts that contingently require net-cash settlement as the principal means of settlement, Ampio projects and discounts future cash flows applying probability-weighting to multiple possible outcomes. Estimating fair values of derivative financial instruments requires the development of significant and subjective

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estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. In addition, option-based techniques are highly volatile and sensitive to changes in the trading market price of Ampio's common stock, which has a high-historical volatility. Since derivative financial instruments are initially and subsequently carried at fair value, Ampio's income will reflect the volatility in these estimate and assumption changes.

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The following table summarizes the effects on Ampio's income (expense) associated with changes in the fair value of Ampio's derivative financial instruments by type of financing for the respective periods:

	Year Ended December 31,			December 18, 2008 (Inception) December 31, 2012
	2012	2011	2010	
Warrants (dates correspond to financing)				
Tranche 1 - August 10, 2010	\$ 66,497	\$ (134,375)	\$ (27,425)	\$ (95,303)
Tranche 2 - October 22, 2010-October 29, 2010	5,278	(103,027)	5,206	(92,543)
Tranche 3 - November 12, 2010-November 29, 2010	99,333	(329,780)	(34,313)	(264,760)
Tranche 4 - December 13, 2010-December 29, 2010	16,584	(25,917)	(2,065)	(11,398)
Tranche 5 - January 20, 2011-January 31, 2011	18,076	(37,260)		(19,184)
	205,768	(630,359)	(58,597)	(483,188)
Day-one derivative expense:				
Tranche 1 - August 10, 2010			(189,907)	(189,907)
Tranche 2 - October 22, 2010-October 29, 2010			(256,393)	(256,393)
Tranche 3 - November 12, 2010-November 29, 2010			(789,287)	(789,287)
Tranche 4 - December 13, 2010-December 29, 2010			(73,587)	(73,587)
Tranche 5 - January 20, 2011-January 31, 2011		(925,138)		(925,138)
	\$ 205,768	\$ (1,555,497)	\$ (1,367,771)	\$ (2,717,500)

The following tables summarize the effects on Ampio's unrealized gain (loss) associated with hybrid debt instruments recorded at fair value for the respective periods. All hybrid instruments were converted or eliminated in the first quarter of 2011 and, therefore, there are no ongoing charges.

	Year Ended December 31, 2011		
	Unrealized Gain	Unrealized (Loss)	Net Unrealized Gain (Loss)
Hybrid debt instruments (dates correspond to financing):			
Tranche 1 - August 10, 2010	\$	\$ (1,245,707)	\$ (1,245,707)
Tranche 2 - October 22, 2010-October 29, 2010		(578,744)	(578,744)
Tranche 3 - November 12, 2010-November 29, 2010		(2,901,987)	(2,901,987)
Tranche 4 - December 13, 2010-December 29, 2010		(330,829)	(330,829)
Tranche 5 - January 20, 2011-January 31, 2011		(528,155)	(528,155)
	\$	\$ (5,585,422)	\$ (5,585,422)

	Year Ended December 31, 2010		
	Unrealized Gain	Unrealized (Loss)	Net Unrealized Gain (Loss)
Hybrid debt instruments (dates correspond to financing):			
Tranche 1 - August 10, 2010	\$	\$ (10,271)	\$ (10,271)
Tranche 2 - October 22, 2010-October 29, 2010	81,008		81,008
Tranche 3 - November 12, 2010-November 29, 2010		(25,955)	(25,955)
Tranche 4 - December 13, 2010-December 29, 2010		(7,271)	(7,271)
Tranche 5 - January 20, 2011-January 31, 2011			
	\$ 81,008	\$ (43,497)	\$ 37,511

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	December 18, 2008 (Inception) through December 31, 2012		
	Unrealized Gain	Unrealized (Loss)	Net Unrealized Gain (Loss)
Hybrid debt instruments (dates correspond to financing):			
Tranche 1 - August 10, 2010	\$	\$ (1,255,978)	\$ (1,255,978)
Tranche 2 - October 22, 2010-October 29, 2010	81,008	(578,744)	(497,736)
Tranche 3 - November 12, 2010-November 29, 2010		(2,927,942)	(2,927,942)
Tranche 4 - December 13, 2010-December 29, 2010		(338,100)	(338,100)
Tranche 5 - January 20, 2011-January 31, 2011		(528,155)	(528,155)
	\$ 81,008	\$ (5,628,919)	\$ (5,547,911)

**Note 8 Fair Value Considerations**

Ampio's financial instruments include cash and cash equivalents, accounts payable, accrued salaries, accrued interest payable, related party payable, related party notes payable, senior convertible unsecured related party debentures, senior unsecured mandatorily convertible debentures (hybrid debt instruments, which include embedded derivative features) and warrant derivative liabilities. The carrying amounts of cash and cash equivalents, prepaid expenses, accounts payable, accrued salaries, accrued interest payable, related party payable, related party notes payable approximate their fair value due to their short maturities. Derivative financial instruments, as defined by GAAP, consist of financial instruments or other contracts that contain a notional amount and one or more underlying (e.g. interest rate, security price or other variable), require little to no initial net investment and permit net settlement. Derivative financial instruments may be free-standing or embedded in other financial instruments. Further, derivative financial instruments are initially, and subsequently, measured at fair value and recorded as liabilities or, in rare instances, assets, with changes in fair value recorded in earnings.

Ampio generally does not use derivative financial instruments to hedge exposures to cash-flow, market or foreign-currency risks. However, Ampio has entered into certain other financial instruments and contracts, such as Ampio's secured convertible debenture and warrant financing arrangements that are either (i) not afforded equity classification, (ii) embody risks not clearly and closely related to host contracts, or (iii) may be net-cash settled by the counterparty. As required by GAAP, these instruments are required to be carried as derivative liabilities, at fair value, in Ampio's financial statements. However, Ampio may elect fair value measurement of the hybrid financial instruments, on a case-by-case basis, rather than bifurcate the derivative. Ampio believes that fair value measurement of the hybrid convertible debenture financing arrangements provide a more meaningful presentation.

Authoritative guidance defines fair value as the price that would be received to sell an asset or transfer a liability (an exit price) in an orderly transaction between market participants at the measurement date. The guidance establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of Ampio. Unobservable inputs are inputs that reflect our assumptions of what market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. The hierarchy is broken down into three levels based on reliability of the inputs as follows:

- Level 1: Inputs that reflect unadjusted quoted prices in active markets that are accessible to Ampio 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's assets and liabilities which are measured at fair value are classified in their entirety based on the lowest level of input that is significant to their fair value measurement. Ampio's policy is to recognize transfers in and/or out of fair value hierarchy as of the date in which the event or change in circumstances caused the transfer. Ampio has consistently applied the valuation techniques discussed below in all periods presented.

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The following table presents Ampio's financial assets and liabilities that were accounted for at fair value on a recurring basis as of December 31, 2012 and 2011, by level within the fair value hierarchy:

	Level 1	Fair Value Measurements Using Level 2	Level 3	Total
<b>December 31, 2012</b>				
<b>LIABILITIES</b>				
Warrant derivative liabilities			384,771	384,771
<b>December 31, 2011</b>				
<b>LIABILITIES</b>				
Warrant derivative liabilities			610,911	610,911

Significant assumptions in valuing the warrant liability were as follows:

	December 31, 2012	December 31, 2011
<b>Warrants (All Tranches):</b>		
Exercise price	\$1.75	\$1.75
Volatility	148.60%	174.85%
Equivalent term (years)	0.61 - 1.08	1.61 - 2.08
Risk-free interest rate	0.16%	0.25%

Significant assumptions in valuing the warrant liability were as follows as of the inception dates:

	January 20, 2011	January 24, 2011	January 31, 2011	February 22, 2011
<b>Warrants (2011 Issuances):</b>				
Exercise price	\$1.75	\$1.75	\$1.75	\$1.75
Volatility	204.42%	204.42%	204.42%	204.42%
Equivalent term (years)	3.00	3.00	3.00	2.46 - 2.94
Risk-free interest rate	1.07%	1.05%	0.98%	0.74% - 1.22%

	2010 Inception Dates
<b>Warrants (2010 Issuances):</b>	
Exercise price	\$1.40 - \$1.75
Volatility	212.48%
Equivalent term (years)	3.08 - 3.47
Risk-free interest rate	0.53% - 1.02%

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The hybrid debt instruments were valued using the binomial lattice-based valuation methodology because that model embodies all of the relevant assumptions that address the features underlying these instruments. All hybrid instruments were converted/eliminated in the first quarter of 2011 and, therefore, significant assumptions were not applicable as of December 31, 2012 and 2011. Significant assumptions were as follows as of December 31, 2010:

<b>Hybrid Debt Instruments (All Tranches):</b>	<b>December 31, 2010</b>
Exercise price	\$1.75
Volatility	89.69% - 140.73%
Equivalent term (years)	0.087 - 0.253
Risk-free interest rate	0.19%

The hybrid debt instruments were valued using the binomial lattice-based valuation methodology because that model embodies all of the relevant assumptions that address the features underlying these instruments. Significant assumptions were as follows as of the inception dates:

<b>Hybrid Debt Instruments (All Tranches):</b>	<b>Inception Dates</b>
Exercise price	\$1.40 - \$1.75
Volatility	155.58% - 262.40%
Equivalent term (years)	0.296 - 0.483
Risk-free interest rate	0.19%

The following table sets forth a reconciliation of changes in the fair value of financial assets and liabilities classified as Level 3 in the fair valued hierarchy:

	<b>Derivative and Hybrid Debt Instruments</b>			
	2012	2011	2010	December 18, 2008 (Inception) through December 31, 2012
Balance as of January 1	\$ (610,911)	\$ (3,141,260)	\$	\$
Total losses (realized or unrealized):				
Included in earnings	205,768	(6,215,781)	(21,086)	(6,031,099)
Debt conversions		9,424,075		9,424,075
Debt issuances		(1,096,064)	(2,780,100)	(3,876,164)
Warrant exercises	20,372	629,192		649,564
Warrant issuances		(211,073)	(340,074)	(551,147)
Balance as of December 31	\$ (384,771)	\$ (610,911)	\$ (3,141,260)	\$ (384,771)
Change in unrealized gain (losses) included in earnings relating to derivatives and hybrid debt instruments held as of December 31	\$	\$ (5,585,422)	\$ 37,511	\$ (5,547,911)

**Note 9 Income Taxes**

Income tax benefit resulting from applying statutory rates in jurisdictions in which Ampio is taxed (Federal and State of Colorado) differs from the income tax provision (benefit) in Ampio's consolidated financial statements. The following table reflects the reconciliation for the respective periods:

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	Years Ended December 31,		
	2012	2011	2010
Benefit at federal statutory rate	(34.0)%	(34.0)%	(34.0)%
State, net of federal income tax impact	(3.1)%	(3.1)%	(3.1)%
Stock-based compensation	3.2 %	1.6 %	6.0 %
Research and development credits	%	%	(0.3)%
Change in valuation allowance	33.9 %	35.5 %	31.4 %
Effective tax rate	0.0 %	0.0 %	0.0 %

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Deferred income taxes arise from temporary differences in the recognition of certain items for income tax and financial reporting purposes. The approximate tax effects of significant temporary differences which comprise the deferred tax assets and liabilities are as follows for the respective periods:

	2012	2011	2010
<b>Current deferred income tax asset (liabilities):</b>			
Accrued Liabilities	\$	\$ 16,000	\$ 188,000
Deferred Revenue License Agreement	19,000	19,000	
Less: Valuation allowance	(19,000)	(35,000)	(188,000)
<b>Total current deferred income tax asset (liabilities)</b>			
<b>Long-term deferred income tax assets (liabilities):</b>			
Net operating loss carryforward	13,122,000	9,381,000	2,381,000
Derivative Expense			507,000
Section 197 license agreement	688,000	741,000	
Deferred revenue license agreement	141,000	159,000	
Share-based compensation expense	636,000	559,000	
Unrealized gain on fair value of debt instruments			(24,000)
Property and equipment, due to difference in depreciation	(22,000)		
Acquired patents	(156,000)	(185,000)	
Acquired in-process research and development	(2,780,000)	(2,767,000)	
Less: Valuation allowance	(11,629,000)	(7,888,000)	(2,864,000)
<b>Total long-term deferred income tax assets (liabilities)</b>			
<b>Total deferred income tax assets (liabilities)</b>	\$	\$	\$

For the years ended December 31, 2012 and 2010, Ampio's net provision for income taxes was zero for all jurisdictions. The Company recorded \$82,500 of foreign tax expense for the year ended December 31, 2011, which related to withholding of foreign income tax for a Korean license agreement that is more fully described at Note 5 License Agreement/Revenue Recognition. This \$82,500 represented Ampio's only tax expense for the year ended December 31, 2011.

As of December 31, 2012, Ampio has approximately \$36,000,000 in consolidated net operating loss carry forwards that, subject to limitation due to change in ownership, may be available in future tax years to offset taxable income. These consolidated net operating loss carry forwards expire in 2020 through 2032. As a result of certain realization requirements of ASC 718, the table of deferred tax assets and liabilities shown above does not include certain deferred tax assets as of December 31, 2012, 2011 and 2010 that arose directly from (or the use of which was postponed by) tax deductions related to equity compensation in excess of compensation expense recognized for financial reporting. Those deferred tax assets include approximately \$3,000,000 of net operating loss deductions. Equity will be increased if and when such deferred tax assets are ultimately realized.

Ampio provided a full valuation allowance against its deferred tax assets as it has determined it is not more likely than not that the recognition of such deferred tax assets will be utilized in the foreseeable future.

The amount of income taxes and related income tax positions taken are subject to audits by federal and state tax authorities. Ampio has adopted accounting guidance for uncertain tax positions which provides that in order to recognize an uncertain tax benefit, the taxpayer must be more likely than not of sustaining the position, and the measurement of the benefit is calculated as the largest amount that is more than 50% likely to be realized upon recognition of the benefit. Ampio believes that it has no material uncertain tax positions and has fully reserved against Ampio's future tax benefit with a valuation allowance and do not expect significant changes in the amount of unrecognized tax benefits that occur within the next twelve months. Ampio's policy is to record a liability for the difference between the benefits that are both recognized and measured pursuant to FASB ASC 740-10, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109* (ASC 740-10) and tax position taken or expected to be



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taken on the tax return. Then, to the extent that the assessment of such tax positions changes, the change in estimate is recorded in the period in which the determination is made. Ampio reports tax-related interest and penalties as a component of income tax expense. During the periods reported, management of Ampio has concluded that no significant tax position requires recognition under ASC 740-10. The Company is no longer subject to income tax examinations for federal income taxes before 2009 or for Colorado before 2008.

**Note 10 Commitments and Contingencies**

Commitments and contingencies are described below and summarized by the following table:

	Total	Due in Less than 1 Year	Due 1-3 Years	Due 3-5 Years	More than 5 Years
Clinical research obligations	\$ 663,293	\$ 663,293	\$	\$	\$
Sponsored research agreement with related party	439,583	263,750	175,833		
Office lease	173,296	108,924	64,372		
Officers employment agreements	1,290,729	659,479	631,250		
	\$ 2,566,901	\$ 1,695,446	\$ 871,455	\$	\$

**Clinical Research Obligations**

In connection with upcoming clinical trials, Ampio has a remaining commitment of \$115,000 on contracts related to the Ampion study drug and \$136,660 remaining contract commitments related to the Optina study drug. Ampio also has a contract related to the production of the Zertane study drug with a remaining unrecorded commitment of \$414,633. Ampio has subsequently entered into agreements with clinical research organizations for upcoming trials which are described in Note 14 Subsequent Events.

**Sponsored Research Agreement with Related Party**

Ampio entered into a Sponsored Research Agreement with Trauma Research LLC, a related party, in September 2009. Under the terms of the Sponsored Research Agreement, Ampio is to provide personnel and pay for leased equipment. The Sponsored Research Agreement may be terminated without cause by either party on 180 day notice.

**Leases**

On May 20, 2011 Ampio entered into a 38 month non-cancellable operating lease for office space effective June 1, 2011. Commitments include the annual operating expense increase for 2013. Rent expense for the respective periods follows:

	Years Ended December 31,			December 18, 2008 (Inception) through December 31, 2012
	2012	2011	2010	
Rent expense	\$ 100,495	\$ 92,989	\$ 62,975	\$ 288,892

**Employment Agreements**

As of December 31, 2012, Ampio has employment agreements with four of its executive officers. Under the employment agreements, the executive officers are collectively entitled to receive \$955,000 in annual salaries. The employment agreements expire July 2013 with respect to our chief scientific officer and chief regulatory affairs officer, January 2015 with respect to our chief executive officer and December 2015 with respect to our chief operating officer. The portion of the salary due to our chief scientific officer that is included in the Sponsored Research Agreement with Trauma Research LLC is excluded from the officers' employment agreements commitment.

Ampio has not recorded an accrual for compensated absences because the amount cannot be reasonably estimated.



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### **Note 11 Common Stock**

#### ***Capital Stock***

At December 31, 2012 and 2011, Ampio had 100,000,000 shares of common stock authorized with a par value of \$0.0001 per share and 10,000,000 shares of preferred stock authorized with a par value of \$0.0001.

#### ***Shelf Registration***

On September 30, 2011 Ampio filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission to register Ampio common stock and warrants in an aggregate amount of up to \$80 million for offering from time to time in the future. The registration statement also registers for possible resale up to one million shares of common stock to be sold by directors and management (as selling shareholders) in future public offerings. On October 13, 2011 Ampio filed an amendment to identify potential selling stockholders and the number of shares they would be eligible to sell in the event of a future public offering. The shelf registration was declared effective on October 28, 2011 by the Securities and Exchange Commission.

#### ***Underwritten Public Offering***

On July 18, 2012 Ampio completed an underwritten public offering for the sale of 5,203,860 shares of common stock at a price of \$3.25 per share. Gross proceeds to the Company were \$16,912,545 with net proceeds of \$15,353,150 after underwriter fees and cash offering expenses. Ampio also issued warrants to purchase 138,462 shares of common stock to the underwriters. These warrants have an exercise price of \$4.0625 and can be exercised from the period July 12, 2013 through July 12, 2017.

#### ***Registered Direct Offering***

On December 27, 2011, Ampio completed a registered direct offering of its common stock. A total of 2,220,255 shares were issued at \$4.25 per share resulting in gross proceeds of \$9,436,084 of which Ampio received net proceeds of \$8,454,001, after placement agent commissions, non-accountable expenses and other offering costs.

#### ***Private Placement Offering***

On March 31, April 8 and April 18, 2011, Ampio closed private placements of its common stock. A total of 5,092,880 shares of common stock were issued resulting in gross proceeds of \$12,732,200, of which the Company received net proceeds of \$10,916,538, after placement agent commissions, non-accountable expenses and other offering costs. In connection with the private placements, the placement agent also received 509,288 warrants to purchase common stock with a fair value of \$888,664, which amount has been included in total offering costs in the statement of change in stockholders' equity (deficit).

#### ***Capital Transactions***

Life Sciences issued 1,080,000 shares of Common Stock to its founder in December 2008 at a value of \$0.001 per share.

Life Sciences issued 3,500,000 shares of Common Stock to BioSciences in April 2009 in connection with an Asset Purchase Agreement. Under the terms of the agreement, Life Sciences acquired office and lab equipment, cell lines and intellectual property including patents and license agreements, while the Ampio 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, 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. The note payable was converted into 163,934 shares of Series A preferred stock at a value of \$1.22 per share.

Life Sciences 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 under *Restricted Common Stock*.

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

Life Sciences received \$170,003 in December 2009 in connection with a private placement for the purchase of 97,144 shares of common stock. Life Sciences had not issued the shares as of December 31, 2009 and therefore recorded the proceeds as a liability. The shares were issued in

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2010.

As set forth in Note 1 Business, Basis of Presentation and Merger, Life Sciences and Chay completed a reverse merger in March 2010, and Chay changed its name to Ampio Pharmaceuticals, Inc. In conjunction with the Merger, Life Sciences Series A Preferred

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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 (or its predecessors) issued 1,078,078 shares of common stock in March and April, 2010 for \$1,536,630 in cash (net of \$350,000 in offering costs), of which \$7,000 had been received in March 2010 and \$170,003 had been received in 2009 and was initially 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 \$1,799,219 as expense in 2010 see Note 12 Stock- Based Compensation. The remaining \$3,281 was reflected as a deferred charge in stockholders' equity at December 31, 2010, and was recognized into expense as the services are provided in the first quarter of 2011.

As further discussed in Note 3 Acquisition of DMI BioSciences, 8,667,905 shares of Ampio common stock were issued on March 23, 2011. At that time, the 3,500,000 shares issued in April 2009 to BioSciences in connection with the asset purchase were surrendered back to Ampio for cancellation.

### Restricted Common Stock

An aggregate of 7,350,000 shares of previously restricted stock owned by Ampio's employees are no longer restricted. One-third of the restricted shares vested on the grant date of April 17, 2009 and one-third vested on April 17, 2011. On April 23, 2011 the Ampio Board of Directors approved the acceleration of vesting of the remaining one-third, pursuant to the achievement of defined milestones.

### Common Stock Issued for Services

Ampio issued 9,072 shares with a value of \$40,000 to non-employee directors on January 3, 2012 as part of their director fees. In addition, Ampio issued 15,000 shares with a value of \$60,150 on October 1, 2012 for services rendered by as consultant. In 2011, Ampio issued 13,635 shares with a value of \$30,000 to non-employee directors as stipulated in directors' compensation.

### Warrants

Ampio issued warrants in 2012, 2011 and 2010 in conjunction with its 2012 Underwritten Public Offering, 2011 Private Placement and Related Party Debentures and its Redeemable Debentures as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding December 31, 2009 and 2008			
Warrants issued to Debenture holders	206,973	\$ 1.75	
Outstanding December 31, 2010	206,973	\$ 1.75	2.99
Warrants issued to Debenture holders	49,416	\$ 1.75	
Warrants exercised	(88,669)	(\$ 1.75)	
Warrants issued in connection with Private Placement	509,288	\$ 3.125	
Outstanding December 31, 2011	677,008	\$ 2.78	3.69
Warrants exercised - Debenture holders	(7,041)	(\$ 1.75)	
Warrants exercised - Private Placement	(54,058)	(\$ 3.125)	
Warrants issued in connection with Underwritten Offering	138,462	\$ 4.0625	
Outstanding December 31, 2012	754,371	\$ 3.00	3.01





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The exercise price of the warrants associated with Related Party Debentures and the Redeemable Debentures was fixed at \$1.75 per share. The warrants expire on December 31, 2013. The warrants issued to debenture holders in 2011 were associated with the \$382,000 of 2011 Debentures and in conjunction with accrued interest. Warrants issued in connection with the 2011 Private Placements are at \$3.125 per share and expire March 31, 2016.

In July 2012, Ampio issued warrants to purchase 138,462 shares of common stock at a price of \$4.0625, exercisable from July 12, 2013 through July 12, 2017 in connection with the Underwritten Public Offering. These warrants were valued using the Black-Scholes option pricing model. In order to calculate the fair value of the warrants, certain assumptions were made regarding components of the model, including the closing price of the underlying common stock, risk-free interest rate, volatility, expected dividend yield, and expected life. Changes to the assumptions could cause significant adjustments to valuation. Ampio estimated a volatility factor utilizing a weighted average of comparable published volatilities of peer companies. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for treasury securities of similar maturity. The offering costs and the additional paid-in capital for the warrants associated with the common stock offering was valued at \$180,194 using the Black-Scholes valuation methodology because that model embodies all of the relevant assumptions that address the features underlying these instruments. Significant assumptions were as follows:

Exercise price	\$ 4.0625
Expected volatility	72%
Equivalent term (years)	5
Risk-free interest rate	0.25%
Dividend Yield	0%

The 258,343 and 250,945 warrants issued in connection with the 2011 Private Placement in April and March 2011 were valued at \$466,007 and \$422,657, respectively, using the Black-Scholes option pricing model. In order to calculate the fair value of the warrants, certain assumptions were made regarding components of the model, including the closing price of the underlying common stock, risk-free interest rate, volatility, expected dividend yield, and expected life. Changes to the assumptions could cause significant adjustments to valuation. Since the expected life of five years was significantly longer than Ampio's stock trading history, Ampio estimated a volatility factor utilizing a weighted average of comparable published volatilities of peer companies. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for treasury securities of similar maturity. The offering costs and the additional paid-in capital for the warrants associated with the common stock offering was valued using the Black-Scholes valuation methodology because that model embodies all of the relevant assumptions that address the features underlying these instruments. Significant assumptions were as follows:

Exercise price	\$ 3.125
Expected volatility	73%
Equivalent term (years)	5
Risk-free interest rate	2.2%
Dividend Yield	0%

**Note 12 Stock-Based Compensation**

At the special meeting on March 1, 2010, Ampio shareholders approved the adoption of a stock and option award plan (the 2010 Plan), under which 2,500,000 shares were reserved for future issuance under restricted stock awards, options, and other equity awards. The 2010 Plan permits grants of equity awards to employees, directors and consultants. On August 15, 2010, the number of shares issuable under the 2010 Plan was increased to 4,500,000 shares by consent of our majority shareholders. At the annual shareholders' meeting, held December 3, 2011, the number of shares issuable under the 2010 Plan was increased to 5,700,000. At the annual shareholders' meeting held December 15, 2012, the number of shares issuable under the 2010 Plan was further increased to 8,200,000.

The Company granted options to purchase 2,930,000 shares in 2010, of which 1,820,000 vested immediately, and the remaining 1,110,000 options vested annually over two years.

During 2011, an additional 840,000 options were issued at a weighted average exercise price of \$3.95, with 638,333 vesting immediately. The remaining 201,667 options will vest annually over a period of from one to four years. In addition, Ampio issued options to purchase 435,717 shares to former BioSciences option holders. These were issued at a weighted average exercise price of \$1.54. 175,873 of these options had been exercised at December 31, 2012. The remaining options have an average life of 1.05 years.

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During 2012 an additional 2,095,000 options were granted at a weighted average exercise price of \$2.97 to officers, directors, employees and consultants. 1,430,000 of these options vest monthly over three years, 75,000 shares vested immediately, 450,000 vest over a three year period, 90,000 over a two year period and 50,000 over one year.

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Stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Aggregate Fair Value	Weighted Average Remaining Contractual Life
Outstanding December 31, 2009 and 2008				
Granted	2,930,000	\$ 1.13	\$ 1,875,535	
Outstanding December 31, 2010	2,930,000	\$ 1.13	\$ 1,875,535	9.63
Granted	840,000	\$ 3.95	\$ 1,898,598	
Exercised	(362,843)	(\$ 1.59)	\$ (312,158)	
Forfeited	(10,000)	(\$ 2.90)	\$ (18,359)	
Issued in connection with BioSciences merger	435,717	\$ 1.54		
Outstanding December 31, 2011	3,832,874	\$ 2.75	\$ 3,443,616	7.31
Granted	2,095,000	\$ 2.97	\$ 4,552,847	
Exercised	(715,476)	(\$ 1.07)	\$ (385,179)	
Forfeited	(256,250)	(\$ 4.04)	\$ (423,970)	
Expired	(33,333)	(\$ 5.96)	\$ (54,967)	
Outstanding December 31, 2012	4,922,815	\$ 2.25	\$ 7,132,347	8.36
Exercisable at December 31, 2012	3,468,508	\$ 1.86	\$ 3,978,441	7.39
Available for grant at December 31, 2012	2,257,065			

	Year Ended December 31,			December 18, 2008 (Inception) through December 31,
	2012	2011	2010	2012
Average fair value per share granted	\$ 2.17	\$ 2.26	\$ 0.64	\$ 1.42

Ampio has computed the fair value of all options granted using the Black-Scholes option pricing model. In order to calculate the fair value of the options, certain assumptions are made regarding components of the model, including 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. Ampio estimated a volatility factor utilizing a weighted average of comparable published volatilities of peer companies. Due to the small number of option holders, Ampio has estimated a forfeiture rate of zero. Ampio estimates the expected term based on the average of the vesting term and the contractual term of the options. The risk free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for treasury securities of similar maturity. Accordingly, Ampio has computed the fair value of all options granted during the respective years, using the following assumptions:

	Years Ended December 31,		
	2012	2011	2010
Expected volatility	72% - 93%	62% - 73%	72%
Risk free interest rate	0.18% - 1.15%	0.70% - 2.24%	1.48%
Expected term (years)	3.0 - 6.5	5.0 - 6.5	5.5 - 5.75
Dividend yield	0.0%	0.0%	0.0%

Stock-based compensation related to common stock issued to third party vendors in exchange for services was included in general and administrative expenses in the statement of operations as set forth in the table below. The common stock was recorded at its fair value at the

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dates Ampio became obligated to issue the shares, and is recognized as expense as the services are provided. Stock-based

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compensation expense related to the fair value of stock options was included in the statement of operations as research and development expenses and general and administrative expenses as set forth in the table below. Ampio determined the fair value as of the date of grant using the Black-Scholes option pricing method and expenses the fair value ratably over the vesting period.

	Years Ended December 31,			December 18, 2008 (Inception) through December 31, 2012
	2012	2011	2010	
Research and development expenses				
Stock options	\$ 395,644	\$ 315,524	\$ 381,093	\$ 1,092,261
General and administrative expenses				
Common stock issued for services	100,150	33,281	1,799,219	1,902,650
Stock options	1,126,730	1,638,261	915,990	3,710,981
	\$ 1,622,524	\$ 1,987,066	\$ 3,096,302	\$ 6,705,892
Unrecognized expenses at December 31, 2012	\$ 3,153,906			
Weighted average remaining years to vest	2.44			

The unrecognized compensation expense will be amortized on a straight-line basis over the remaining vesting periods.

**Note 13 Related Party Transactions**

In April 2009, Life Sciences issued 3,500,000 shares of its common stock to BioSciences, 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. The 3,500,000 shares of Life Sciences were surrendered to Ampio by BioSciences in conjunction with the BioSciences acquisition.

As of December 31, 2009, Life Sciences had \$100,000 in notes payable to Life Sciences' founder, and \$100,000 payable to BioSciences. The related party notes payable were unsecured, bore interest at 6% and initially were to mature on April 30, 2010. These notes were extended through September 2, 2010, and additional borrowings of \$200,000 were made by Ampio from BioSciences in the three months ended September 30, 2010, bringing the total amount owed by Ampio to BioSciences to \$300,000. The note evidencing the foregoing borrowing from Life Sciences' founder was paid in conjunction with the closing of the private placement on March 31, 2011 as discussed in Note 11 Common Stock. The \$300,000 owed to BioSciences was eliminated with the BioSciences Merger in 2011.

In October and November 2010, Ampio borrowed \$215,971 from BioSciences in non-interest bearing advances. As of December 31, 2010, non-interest bearing advances from BioSciences totaled \$193,821. This amount was eliminated with the BioSciences Merger in 2011.

Ampio has exclusive license agreements with the Institute for Molecular Medicine, Inc. (IMM), a nonprofit research organization founded by an officer and director of Ampio who also serves as IMM's executive director. The license agreements were assigned to Life Sciences as a part of the asset purchase from 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 specified amounts it has paid to maintain the intellectual property from any amounts that may become due to IMM under the license agreements, if and when the intellectual property becomes commercially viable and generates revenue. Ampio may cease funding the intellectual property costs and abandon the license agreements at any time. Ampio incurred \$141,436, \$122,599 and \$61,000 during the years ended December 31, 2012, 2011 and 2010, respectively, in legal and patent fees to maintain the intellectual property subject to the license agreement.

Immediately prior to the Chay Merger on March 2, 2010, 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 \$150,183. The purchase price was advanced to the six officers and employees by Chay at the time the subscriptions were accepted. These shares were issued immediately before

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the closing of the Chay Merger but after the shareholders of Chay had approved the merger. The advances are non-interest bearing and due on demand and are classified as a reduction to stockholders' equity. During the year ended December 31, 2011, one advance of \$22,660 was repaid. During the year ended December 31, 2012, an additional repayment of \$36,883 was received.

### **Note 14 Subsequent Events**

In January 2013, Ampio entered into a Master Service Agreement and Scope of Work (the "Ampion Agreement") with a clinical research organization (the "Ampion CRO"). Pursuant to the Ampion Agreement, the Ampion CRO will provide clinical trial services in connection with the Company's clinical trial of Ampio<sup>TM</sup> for the treatment of osteoarthritis of the knee. The consideration payable by Ampio to the Ampion CRO in connection with original scope of work was reported as \$6.8 million. However, as a result of an FDA request that we first conduct a dose ranging study, we are currently in the process of modifying the scope of work under this contract and do not expect it to exceed \$3.0 million. The Ampion Agreement went effective January 21, 2013 and continues until completion of the services, unless earlier terminated in accordance with the Ampion Agreement with or without cause upon 30 days written notice.

In January 2013, Ampio entered into a Master Service Agreement and Scope of Work (the "Optina Agreement") with a clinical research organization (the "Optina CRO"). Pursuant to the Optina Agreement, the Optina CRO will provide clinical trial services in connection with the Company's clinical trial of Optina<sup>TM</sup> for the treatment of diabetic macular edema. The consideration payable by Ampio to Optina CRO in connection with these services totals approximately \$6.0 million which is expected to be paid over the course of the next eleven months, based on specified milestones. The Optina Agreement went effective January 21, 2013 and continues until completion of the services, unless earlier terminated in accordance with the Optina Agreement.

In February 2013, we announced the incorporation and initiation of operations of Luoxis Diagnostics, Inc., a wholly-owned subsidiary, focused on commercialization of our ORP diagnostic device. The new diagnostic company is seeking private financing.