

Ampio Pharmaceuticals, Inc.  
Form 10-K  
February 16, 2011  
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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, 2010**

**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)

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

**5445 DTC Parkway**

**Penthouse 4**

**Greenwood Village, Colorado**

**26-0179592**  
(I.R.S. Employer

Identification Number)

**80111**

(Zip Code)

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(Address of principal executive offices)

(303) 418-1000

(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 December 31, 2010 was \$14,431,466.

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: As of February 14, 2010, 17,107,036 shares of common stock were outstanding.

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Exhibit 31.1Exhibit 31.2Exhibit 32.1

This Report on Form 10-K refers to trademarks, such as Optina, Ampion, and Vaseloc, 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**

This Report on Form 10-K contains forward-looking statements within the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Generally, the use of terms such as will, may, should, continue, believes, expects, intends, anticipates, estimates and similar identify forward-looking statements. All statements other than statements of historical fact contained in this Form 10-K, including statements regarding future events, our future financial performance, business strategy, and our plans and objectives, are forward-looking statements. Without limiting the generality of the preceding sentence, statements contained in this Form 10-K concerning the proposed acquisition of DMI BioSciences, Inc., which we refer to as BioSciences, including without limitation any statements as to the expected impact of the merger on Ampio's financial condition, any description of expected synergies, and other statements contained herein regarding matters that are not historical facts constitute forward-looking statements. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy.

These forward-looking statements involve known and unknown risks and uncertainties that are difficult to predict, including the risks outlined under Item 1A of Part I, Risk Factors, in this Form 10-K, which may cause our actual results, levels of activity, performance or achievements expressed or implied by these forward-looking statements to differ from expectations. Factors that could cause actual results to differ materially from those contemplated by the forward-looking statements include, among others, the following:

Ampio's and BioSciences ability to complete the merger;

Ampio's ability to realize synergies from the merger;

the results and timing of Ampio's clinical trials, particularly the Optina, Vasaloc and Ampion trials;

the regulatory review process and any regulatory approvals that are issued or denied by the FDA, the EMEA, or other regulatory agencies;

our need to secure collaborators to license, manufacture, market and sell any products for which we receive regulatory approval in the future;

the results of our internal research and development efforts;

the commercial success and market acceptance of any of our product candidates that are approved for marketing in the United States or other countries;

the safety and efficacy of medicines or treatments introduced by competitors that are targeted to indications which our product candidates have been developed to treat;

acceptance and approval of regulatory filings;

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our need for, and ability to raise, additional capital;

our collaborators' compliance or non-compliance with their obligations under our agreements with them, or decisions by our collaborators to discontinue clinical trials and return product candidates to us; and

our plans to develop other product candidates.

You should not place undue reliance on our forward-looking statements in this Form 10-K because the matters they describe are subject to known and unknown risks, uncertainties and other unpredictable factors, many of which are beyond our control. Our forward-looking statements are based on the information currently available to us and speak only as of the date of this Form 10-K. New risks and uncertainties arise from time to time, and it is impossible for us to predict these matters or their effect on us or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any forward-looking statements. Over time, our actual results, performance or achievements will likely differ from the anticipated results, performance or achievements that are expressed or implied by our forward-looking statements, and such differences might be significant and materially adverse to our investors. We have no duty to, and do not intend to, update or revise the forward-looking statements in this Form 10-K after the date of this Form 10-K except to the extent required by the federal securities laws. You should consider all risks and uncertainties disclosed in our filings with the SEC, all of which are accessible on the SEC's website at [www.sec.gov](http://www.sec.gov).

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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.

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

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**AMPIO PHARMACEUTICALS, INC.**

**PART I**

**Item 1. *Business*  
Overview and General Discussion of the Business**

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

In March 2010, Life Sciences merged with a subsidiary of Chay Enterprises, Inc., a publicly-traded company incorporated in Colorado. Contemporaneously with the merger, we changed our name to Ampio Pharmaceuticals, Inc., and reincorporated in the State of 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.

**Proposed Acquisition of BioSciences**

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. BioSciences is a privately-held Colorado corporation not currently engaged in active operations. BioSciences owns the rights to one product, Zertane, as to which BioSciences holds 32 issued patents and 31 pending patent applications. Zertane is a new use for tramadol hydrochloride, which was approved for marketing as a noncontrolled analgesic in 1995. The purpose of the BioSciences acquisition is to unify our management team and ownership as (i) BioSciences currently owns 3,500,000 shares of Ampio common stock, or approximately 20% of the outstanding Ampio shares of common stock, (ii) Ampio's chief financial officer, Bruce G. Miller, is also the president and a director of BioSciences and a principal Class B shareholder of BioSciences, (iii) Ampio's chief scientific officer and a director, Dr. David Bar-Or, is a former executive officer and director of BioSciences, and is a principal Class B shareholder of BioSciences, (iv) Richard B. Giles, a shareholder of BioSciences, is a member of the board of directors, shareholder and debenture holder of Ampio, and (v) several Ampio bridge investors are also shareholders of BioSciences.

The aggregate consideration that will be paid by Ampio to BioSciences shareholders in the merger is 8,667,905 shares of Ampio common stock. This consideration includes the consideration 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. The BioSciences acquisition is expected to close once the registration statement with respect to the shares of Ampio common stock to be issued in the merger is declared effective by the SEC, the BioSciences shareholders receive an information statement/prospectus in the form contained in the registration statement, and BioSciences shareholders holding in excess of 66<sup>2</sup>/3% of the outstanding BioSciences common stock consent to the merger.

**Business Model**

Our principal focus is developing pharmaceutical products that can achieve more rapid marketing approvals through identifying new applications, indications, dosing, and chemical combinations for compounds previously approved as safe and effective by the FDA or EMEA. Known as drug repositioning, this strategy reduces the risk of product failure due to adverse





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toxicology, leads to more modest investments during development, and may achieve more rapid marketing approval. Two of our most advanced product candidates are repositioned drugs (as is Zertane) for which we have secured or are securing U.S. and international patent protection covering their unique composition or application.

We operate in one business segment and intend to develop proprietary pharmaceutical drugs and diagnostic products which capitalize on our intellectual property. That 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 uses for repositioned drugs, new molecular entities, or NMEs, and rapid point-of-care tests for diagnosis, monitoring and screening.

### *Repositioned Drugs*

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

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

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

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

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

The market size for diabetic retinopathy, DME and wet AMD is difficult to measure but the demographics suggest a very large potential market exists. The American Diabetes Association reports that 20.8 million people in the U.S. have diabetes and another 54 million are pre-diabetic with 20% of type-2 diabetic patients having retinopathy when diagnosed. According to the World Health Organization, approximately 5 million individuals have diabetic retinopathy, accounting for 5 percent of world blindness. Over 360 million people worldwide are projected to have diabetes and its complications by 2030 with almost all patients with type-1 diabetes and more than 60% of patients with type-2 diabetes developing retinopathy. The International Diabetes Federation estimates that 285 million people around the world have diabetes and approximately 14% of people with diabetes have DME. According to the American Academy of Ophthalmology, the prevalence of DME increases to 29% for people with diabetes who use insulin for more than 20 years. By 2030, the incidence of diabetes is expected to rise to 438 million people worldwide, and the incidence of diabetes-related conditions like DME, diabetic retinopathy, and diabetic nephropathy are expected to continue to increase proportionately. We believe that an effective oral drug treatment of diabetic retinopathy, DME and wet AMD is a significant unmet medical need.

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If untreated, DME leads to moderate vision loss for one out of four people with diabetes over a period of three years and can lead to blindness over a period of seven years. Existing therapies for diabetic retinopathy, DME and wet AMD include focal and grid laser therapy, which is the current standard of care, as well as photodynamic therapy, surgery, and intravitreal treatment, or IVT, using Lucentis, Avastin, or Macugen. Lucentis is costly compared to alternative injection therapies, while Avastin is currently approved only for cancer treatment and is being used off-label by ophthalmologists to treat DME and wet AMD. Macugen recently completed a Phase III trial in which subjects were given injections in the eye as often as every six weeks in both the first and second year of the trial, which resulted in patients gaining 5.2 letters of vision compared to 1.2 letters for patients receiving a sham injection. There are currently no oral medications available for treatment of DME and wet AMD. We believe Optina has the potential to effectively treat DME and wet AMD without costly laser therapy and without requiring ongoing injections of pharmaceuticals in the eye. For these reasons, we believe Optina represents a significant Phase II stage clinical opportunity.

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

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

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

FDA 505(b)(2) regulatory approval can provide three years of market exclusivity in the U.S.

We previously entered into a contract with St. Michael's Hospital in Toronto, Canada, to conduct a clinical trial of Optina. Patient enrollment for this trial began in January 2011. The human clinical trial is titled, "A Randomized, Double-blind, Placebo-Controlled, Parallel Treatment Group, Dose-Ranging, Efficacy and Safety Study of Oral [Optina] Capsules in Subjects with Diabetic Macular Edema." We intend to prepare for a second clinical trial while examining formulation and manufacturing issues. On completion of the dose-ranging, efficacy and safety study, we will be positioned for a larger, pivotal FDA clinical trial to confirm safety and effectiveness. Based on our perception of the high unmet need for a drug such as Optina, the lack of pharmaceutical competition, and the history of the active pharmaceutical ingredient in Optina, we believe that Optina could potentially be available for marketing in approximately three years in the U.S., and could potentially be available for marketing earlier in some international markets.

*Vasaloc: Repositioned Drug to Treat Diabetic Nephropathy*

Untreated diabetic nephropathy leads to kidney damage or renal failure. Diabetes has become the most common single cause of end-stage renal disease, or ESRD, in the U.S. and Europe. While the exact cause of diabetic nephropathy is unknown, it is believed that excessive blood sugar damages nephrons. Once these structures are damaged, they begin to leak and protein (albumin) begins to pass into the urine. Standard modalities for the treatment of diabetic nephropathy include controlling blood glucose levels by using a variety of hormone therapies such as insulin, by stimulating the release of insulin using sulfonylureas, or through use of insulin derivatives. As high blood pressure is known to increase the rate of decline in renal function, diabetics are generally advised to control blood pressure using one or a combination of angiotensin-converting enzyme (ACE) inhibitors, Angiotensin II receptor blockers (ARBs), calcium channel blockers, diuretics, or beta-blockers. When renal failure occurs, dialysis is often required and a kidney transplant may become the only viable treatment option.

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

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

Ampion is a non-steroidal biologic, aspartyl-alanyl diketopiperazine, referred to as DA-DKP. This compound is comprised of two amino acids derived from human albumin, and is designed to treat chronic inflammatory and autoimmune diseases. Because it is a naturally occurring human molecule, DA-DKP is present in the body and can be detected in plasma. Ampion has significant effects on inflammation and other physiological and metabolic parameters. Dr. Bar-Or has published a number of studies and articles on the anti-inflammatory immune response of DA-DKP. We intend to conduct pilot clinical studies on the effect of DA-DKP in patients suffering from multiple sclerosis, an autoimmune disease caused by nerve damage attributable to inflammation. There is currently no cure for MS and it is unknown what triggers the body's

inflammatory response.

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We plan to conduct studies of Ampion in Australia and India commencing in the second or third quarter of 2011, and expect these studies will take approximately 24 months to complete. The trials in Australia will explore the efficacy of human albumin-derived Ampion in the treatment of two unrelated conditions. The Ampion-injection-into-knee (AIK) trial will be designed to assess the efficacy of Ampion in the reduction of pain and inflammation of osteoarthritis of the knee. The Wound Exudate Attenuation and Prevention (WEAP) trial will assess the efficacy of albumin-derived Ampion in the reduction of fluid loss across wounds. We expect the AIK trial to provide clinical data that will assist us in designing testing regimens for other inflammatory-related diseases such as rheumatoid arthritis and auto immune diseases, lupus, and multiple sclerosis, while the WEAP trial will provide us a model for evaluating early inflammatory changes related to fluid management.

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

### *New Molecular Entities, or NMEs*

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

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

The first class of NMEs we are testing are nine compounds which are derivatives of Methylphenidate, which is a drug approved for treatment of attention-deficit hyperactivity disorder, Postural Orthostatic Tachycardia Syndrome, and narcolepsy, most commonly known under the trade name Ritalin. Dr. Bar-Or has synthesized and applied for patents for these nine compounds, which have demonstrated anti-angiogenesis and anti-metastasis properties. We expect to seek a special protocol assessment from the FDA under which one or more of our Methylphenidate compounds can be administered under a compassionate need exception to patients suffering from advanced liver, ovarian, brain or other cancers. Methylphenidates may also have applications for macular degeneration and to Alzheimer's or other neurodegenerative disorders, as Methylphenidates have strong anti-inflammatory properties.

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

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

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

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

### *In Vitro Diagnostics*

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

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

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

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

The ORP device is currently being prototyped and the first prototypes are now being prepared for testing. We developed a disposable electrode for use in the ORP device and have calibrated the device to measure oxidants and antioxidants while taking into account various factors that may affect oxidative stress.

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

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### **Business Strategy**

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

Once product candidates are identified and clinical efficacy for one or more indications is initially determined, we focus our development work on advancing product candidates that we believe offer significant therapeutic advantages over currently available treatments and which represent large potential markets. We look to advance product candidates that also address multiple clinical indications, have proven safety profiles, and which can timely demonstrate clinical efficacy. We intend to continue to maintain a diversified product candidate pipeline to mitigate risks associated with pharmaceutical development and increase the likelihood of commercial success.

During the discovery process, we review pertinent scientific literature and conduct searches of patent records in order to make a preliminary determination of patentability. As many of our product candidates are repositioned drugs, the nature and extent of potentially available patent protection is central to our development decisions. Although we are in early clinical testing of two NMEs, we primarily target development of repositioned drugs because these drugs are based on compounds or medicines already approved by the FDA and/or the EMEA. We believe our repositioned drug product candidates may receive faster regulatory approvals than NMEs, thus extending the period during which these product candidates will enjoy patent protection for commercialization.

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

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

### **Regulation**

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

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

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

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

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

delays in clinical trials or commercialization;

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

product recalls or seizures;

suspension of manufacturing;

withdrawals of previously approved marketing applications; and

finances, civil penalties, and criminal prosecutions.

The ability to market a product outside of the United States is contingent upon receiving a marketing authorization from appropriate regulatory authorities. Foreign regulatory approval processes typically involve risks similar to those associated with obtaining FDA approval and may include additional risks. In addition, the requirements governing conduct of clinical trials and marketing authorizations, and the time required to obtain requisite approvals, may vary widely from country to country and differ from that required for FDA approval. We cannot assure you any of our product candidates will prove to be safe or effective, will receive regulatory approvals, or will be successfully commercialized.

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

If the FDA approves one or more of our product candidates, we and our contract manufacturers must provide certain updated safety and efficacy information to the FDA and other regulatory agencies. Product changes, as well as certain changes in the manufacturing process or facilities where the manufacturing occurs (or other post-approval changes) may necessitate additional FDA review and approval. The labeling, advertising, promotion, marketing and distribution of a drug product also must be in compliance with FDA and Federal Trade Commission, or FTC, requirements which include, among others, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA and FTC have very broad

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enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing us to correct deviations from regulatory standards and enforcement actions that can include seizures, fines, injunctions and criminal prosecution.

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



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### *Regulatory Approval Process for NMEs*

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

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

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

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

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

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

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

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

### *Preclinical Testing*

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

### *Clinical Trials*

Human clinical trials are typically conducted in three sequential phases:

- Phase 1. In Phase 1 clinical trials, a product candidate is typically introduced either into healthy human subjects or patients with the medical condition for which the new drug is intended to be used. The main purpose of the trial is to assess a product candidate's safety and the ability of the human body to tolerate the product candidate. Phase 1 clinical trials generally include less than 50 subjects or patients.

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

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

### *Post-Approval Regulation*

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

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

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

### *Fast Track Status and Orphan Drug*

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

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

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

### *Foreign Regulatory Approval*

Outside of the United States, our ability to market 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.

### *Europe*

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

## **Intellectual Property**

As of December 31, 2010, we owned or were the exclusive licensee under nine issued United States patents, 22 U.S. pending patent applications, 15 issued international patents, and 79 pending international patent applications. The following tabulates the U.S. and international patents owned or licensed by Ampio, including the jurisdiction for international issued patents, the expiration date, and the product candidate to which each relates.

**Table of Contents****Issued U.S. Patents**

United States Patent No.	Expiration Date	Description
5,330,898	October 3, 2011	Assay for bacterial vaginosis; unrelated to current product candidates
5,470,750	November 28, 2012	Assay for diagnosing appendicitis; unrelated to current product candidates
6,555,543	August 21, 2021	Ampion
6,615,162	January 18, 2022	Signal processing method and apparatus for reducing noise and enhancing resolution of signal data; unrelated to current product candidates
6,967,202	July 21, 2022	Method of synthesizing diketopiperazines
7,592,304	May 25, 2022	Metal-binding peptides that bind CuI/II metal ions for treating angiogenic disease or condition (method of use)
7,632,803	September 29, 2020	Metal-binding peptides that bind CuI/II metal ions (composition of matter)
7,732,403	May 14, 2024	Treatment of T-cell mediated diseases with diketopiperazines (methods of use)
7,575,929	July 5, 2025	Diagnostic for multiple sclerosis (method claims)

**Issued International Patents**

Country or Region	Patent No.	Expiration Date	Description
Australia	2001279313	August 2, 2021	Ampion
China	01815837.4	August 2, 2021	Ampion
South Africa	2003/0934	August 2, 2021	Ampion
United Kingdom	2,382,346	August 2, 2021	Method of synthesizing diketopiperazines
Australia	2004241101	May 14, 2024	Treatment of T-cell mediated diseases with diketopiperazines
New Zealand	542886	May 14, 2024	Treatment of T-cell mediated diseases with diketopiperazines
Singapore	116214	May 14, 2024	Treatment of T-cell mediated diseases with diketopiperazines
South Africa	2005/09184	May 14, 2024	Treatment of T-cell mediated diseases with diketopiperazines
Australia	770999	September 29, 2020	Metal binding peptides and uses
India	233058	September 29, 2020	Metal binding peptides (composition of matter)
New Zealand	518266	September 29, 2020	Metal binding peptides and uses
Australia	2003299568	November 25, 2023	Treatment of diseases and conditions mediated by increased phosphorylation using dephosphorylated phosvitin
India	241239	November 25, 2023	Treatment of diseases and conditions mediated by increased phosphorylation (kit claims)
Australia	2003279761	October 2, 2023	Diagnosis of diseases using diketopiperazines and truncated proteins
New Zealand	539735	October 2, 2023	Diagnosis of diseases using diketopiperazines and truncated proteins

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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 the patent may be narrowed or removed entirely, thus depriving us of adequate protection. As a result, we may face unanticipated competition, or conclude that without patent rights the risk of bringing product candidates to market exceeds the returns we are likely to obtain. We are generally aware of the scientific research being conducted in the areas in which we focus our research and development efforts, but patent applications filed by others are maintained in secrecy for at least 18 months and, in some cases in the United States, until the patent is issued. The publication of discoveries in scientific literature often occurs substantially later than the date on which the underlying discoveries were made. As a result, it is possible that patent applications for products similar to our drug or diagnostic candidates may have already been filed by others without our knowledge.

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

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### **Competition**

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

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

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

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

potential advantages over existing or alternative therapies or tests;

the actual or perceived safety of similar classes of products;

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

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

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

### **Research and Development**

Our strategy is to minimize fixed overhead by outsourcing much of our research and development activities. Through a sponsored research agreement, our discovery activities are conducted by Trauma Research LLC, or TRLLC, a limited liability company owned by Dr. David Bar-Or. Under the research agreement, TRLLC conducts drug and biomarker discovery and development programs at its research facilities, and we provide funding and some scientific personnel. Intellectual property from discovery programs conducted by TRLLC 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.

**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



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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 February 14, 2011, we had 11 full-time employees and utilized the services of a number of consultants on a part-time basis. Overall, we have not experienced any work stoppage and do not anticipate any work stoppage in the foreseeable future. Management believes that relations with our employees are good.

## **Corporate Information**

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

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.

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### **Item 1A. Risk Factors Risks Related to Our Business**

*There is substantial doubt as to our ability to continue as a going concern.*

We have experienced recurring losses since inception, resulting in cumulative losses of approximately \$9.8 million through December 31, 2010. Our financial statements have been prepared on the assumption that we will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. However, there is substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. We will need to obtain additional capital to continue as a going concern and to fund our operations, including to:

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

pursue a collaborator for Zertane, assuming closing of the BioSciences acquisition;

further develop and assess the clinical utility of the ORP device;

develop additional product candidates;

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 have no collaboration agreements currently in effect.

We do not know whether additional funding will be available to us on acceptable terms, or at all. If we are not able 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.

*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, 2010, we had an accumulated deficit of approximately \$9.8 million and a stockholders' deficit of approximately \$4.0 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 expect to receive for several years, any revenues from the commercialization of our product candidates. We anticipate that licensing and collaboration arrangements, which may provide us with potential milestone payments and royalties, will be our primary source of revenues for the next several years. We cannot be certain that additional licensing or collaboration arrangements will be concluded, or that the terms of those arrangements will result in 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.

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

A key aspect of our strategy is to selectively enter into collaborations with third parties to conduct clinical testing, commercialize and manufacture product candidates. We have no collaboration agreements currently in effect. Collaboration agreements typically call for milestone payments that depend on successful demonstration of efficacy and safety, obtaining regulatory approvals, and clinical trial results. Collaboration revenues such as those generated by BioSciences in the past 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.

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

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

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

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

Our product development programs are at various stages of development. We recently signed a contract with St. Michael's Hospital, Toronto, Canada, under which St. Michael's will conduct a Phase II trial for our product candidate Optina for the treatment of diabetic macular edema, an early stage of diabetic retinopathy. We intend also to commence a Phase II clinical trial for Vasaloc, our product candidate to treat diabetic nephropathy, by the first quarter of 2011. We are currently preparing to seek approval for a Phase II double-blind, placebo-controlled clinical trial of the product candidate Ampion for the treatment of chronic inflammatory and autoimmune disease. An unfavorable outcome in one or more trials for Optina, Vasaloc, or Ampion would be a major set-back for the development programs for these product candidates and for 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. We anticipate that clinical trials of Optina and Vasaloc will take at least six to nine months to complete, and clinical trials of Ampion will take

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between 18 to 24 months to complete.

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

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

a product candidate is ineffective, inferior to existing approved medicines, unacceptably toxic, or has unacceptable side effects;

patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;

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

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

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

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

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

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

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

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

manufacturing sufficient quantities of a product candidate;

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

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

determining dosing and making related adjustments; and

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

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

lack of effectiveness of product candidates during clinical studies;

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

inability to raise additional capital in sufficient amounts to continue clinical trials or development programs, which are very expensive;

the need to sequence clinical studies as opposed to conducting them concomitantly in order to conserve resources;

our inability to enter into collaborations relating to the development and commercialization of our product candidates;

failure by us or our collaborators to conduct clinical trials in accordance with regulatory requirements;

our inability or the inability of our collaborators to manufacture or obtain from third parties materials sufficient for use in preclinical and clinical studies;

governmental or regulatory delays and changes in regulatory requirements, policy and guidelines, including mandated changes in the scope or design of clinical trials or requests for supplemental information with respect to clinical trial results;

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failure of our collaborators to advance our product candidates through clinical development;

delays in patient enrollment, variability in the number and types of patients available for clinical studies, and lower-than anticipated retention rates for patients in clinical trials;

difficulty in patient monitoring and data collection due to failure of patients to maintain contact after treatment;

a regional disturbance where we or our collaborative partners are enrolling patients in our clinical trials, such as a pandemic, terrorist activities or war, or a natural disaster; and

varying interpretations of data by the FDA and similar foreign regulatory agencies.

Many of these factors may also ultimately lead to denial of regulatory approval of a current or potential product candidate. If we experiences 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.

***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 for Optina, Vasaloc, and Zertane 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 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 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.





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

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

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

Even if we receive regulatory approval for a product candidate, this approval may carry conditions that limit the market for the product or put 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 its 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 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

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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, 2010, we had cash of approximately \$671,000. In order to continue funding our operations, we obtained bridge financing in November 2010 totaling approximately \$1.38 million from 19 investors. The bridge financing converts automatically into our common stock on March 31, 2011, or earlier upon completion of an offering of \$10 million or more. We anticipate we will require significant additional financing to continue to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors including:

progress in, and the costs of, our preclinical studies and clinical trials and other research and development programs;

the scope, prioritization and number of Ampio's research and development programs;

the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we obtain;

the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;

the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;

the costs of securing manufacturing arrangements for commercial production; and

the costs of establishing or contracting for sales and marketing capabilities if we obtains regulatory clearances to market our product candidates.

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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, we contracted with St. Michael's Hospital, Toronto, Canada, to perform clinical trials for Optina, and a collaborator contracted by BioSciences performed clinical trials for Zertane. We rely primarily on Trauma Research, LLC, a related party, to conduct preclinical studies and provide assessments of clinical observations.

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

the third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines;

we replace a third party; or

the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory requirements, or for other reasons.

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

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

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

failure to receive regulatory clearances required to market them as drugs;

being subject to proprietary rights held by others;

being difficult or expensive to manufacture on a commercial scale;

having adverse side effects that make their use less desirable; or

failing to compete effectively with products or treatments commercialized by competitors.

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

We have no manufacturing facilities and have no experience in the manufacturing of drugs or in designing drug-manufacturing processes. If any of our product candidates are approved by the FDA or other regulatory agencies for sale, we will need to contract with a third party to manufacture 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.

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

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

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

our inability to exercise control over sales and marketing activities and personnel;

failure or inability of contracted sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;

disputes with third parties concerning sales and marketing expenses, calculation of royalties, and sales and marketing strategies; and

unforeseen costs and expenses associated with sales and marketing.

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

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



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

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

***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

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due to pre-existing conditions, establish health insurance exchanges, and provide additional support for medical research. Additional legislative proposals to reform healthcare and government insurance programs, along with the trend toward managed healthcare in the United States, could influence the purchase of medicines and reduce demand and prices for our products, if approved. This could harm our or our collaborators' ability to market any products and generate revenues. Cost containment measures that health care payors and providers are instituting and the effect of further health care reform could significantly reduce potential revenues from the sale of any of our product candidates approved in the future. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures at the federal and state level, as well as internationally, will continue and may increase, which may make it difficult for us to sell our potential products that may be approved in the future at a price acceptable to us or any of our future collaborators.

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

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

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

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

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

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

Our commercial success depends on obtaining and maintaining proprietary rights to our product candidates and compounds and their uses, as well as successfully defending these rights against third-party challenges. We will only be able to protect our product candidates, proprietary compounds, and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them. As of December 31, 2010, we owned or were the exclusive licensee under nine issued United States patents, 22 U.S. pending patent applications, 15 issued international patents, and 79 pending international patent applications. Our ability to obtain patent protection for our product candidates and compounds is uncertain due to a number of factors, including:

we may not have been the first to make the inventions covered by 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;

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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 patent prosecution, maintenance or enforcement of licensed compounds or products.

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

Because we operates 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 its proprietary technology and processes. However, trade secrets are difficult to protect. We enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. The failure to obtain or maintain trade secret protection could adversely affect our competitive position. We have entered into non-compete agreements with certain of its 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 repositioned drugs or compounds. We may need to resort to litigation to enforce a patent issued to us, to protect our trade secrets, or to determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel or consultants formerly employed by other companies involved in one or more areas similar to the



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activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

payment of damages, potentially treble damages, if we are found to have willfully infringed a party's patent rights;

injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or

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.

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

### **General Risks Related to Ampio**

***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:

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any actual or perceived adverse developments in clinical trials for Optina, Vasaloc or Ampion;

any licensee's termination of a license, such as BioSciences experienced with Zertane earlier in 2010;



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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 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.

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

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

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

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

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a price of less than \$5.00 (other than securities listed on a national securities exchange, provided that current price and volume information with respect to transactions in those securities are provided by the exchange or system). The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the penny stock rules, to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker-dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation. These disclosure requirements have the effect of reducing the level of trading activity for our common stock. As a result, investors may find it difficult to sell our common stock.

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

As of February 14, 2011, our directors, executive officers and their affiliates beneficially owned approximately 46.7% 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 you might otherwise receive a premium for your shares. These provisions include:

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

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

prohibiting stockholder action by written consent except in certain circumstances; and

establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

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

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

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

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

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our existing shareholders will experience immediate dilution upon the purchase of any shares of our common stock sold at a discount. For example, in November 2010, 19 investors purchased convertible debentures in the amount of \$1.38 million from us. In addition, as other capital raising opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of additional debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our shareholders will experience dilution and this dilution will be greater if we find it necessary to sell securities at a discount to prevailing market prices.

### ***We reported material weaknesses in our internal controls at December 31, 2010, and if we cannot remediate these weaknesses and maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired and investors' views of us could be harmed.***

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The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of its internal control over financial reporting to allow management to assess the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Even though our independent auditor is exempted

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by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 from having to currently opine on the effectiveness of our internal controls, our management team is still required to conduct an annual assessment of the effectiveness of our internal controls. We identified material weaknesses in our internal control over financial reporting as of December 31, 2010 based upon (i) a lack of segregation of duties in our financial reporting and accounting functions, and a related lack of implementation of measures that would prevent our chief executive officer and chief financial officer from overriding the internal control system, and (ii) there being ineffective controls over the accounting for, and reporting of, complex, non-routine transactions in derivative financial instruments. If we are unable to remediate the identified material weaknesses or otherwise fail to achieve and maintain an effective system of internal controls over financial reporting, we may be unable to accurately report our financial results, prevent or detect fraud, or provide timely and reliable financial information, which could have a material adverse effect on our business, results of operations, and financial condition. As a practical matter, we may be unable to remediate these material weaknesses until we have additional financial resources available to us, the amount and timing of which is uncertain. At December 31, 2010, we concluded that our disclosure controls and procedures were not effective at a reasonable assurance level because of the material weakness in our internal control over financial reporting that has continued to exist. If we are unable to comply with the requirements of Section 404 in a timely manner, or if we identify additional material weaknesses in our internal control over financial reporting, the market price of our common stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require us to expend additional financial and management resources.

***If securities analysts do not publish research or reports about our business or if they downgrade our stock after instituting coverage, the price of our 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, so you will not receive funds without selling your common stock.***

We have no plans to pay dividends on our common stock. We generally intend to invest 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 deems relevant. Any future credit facilities or preferred stock financing we obtain may further limit our ability to pay dividends on our common stock. Accordingly, you may have to sell some or all of your common stock in order to generate cash from an investment in our common stock. You may not receive a gain on your investment when you sell your common stock and whatever cash you realize may be worth less than the purchase price of the stock you owned.

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

Sales of a substantial number of shares of our common stock in the public market could cause the market price of our common stock to decline. If there are more shares of common stock offered for sale than buyers willing to purchase, then the market price of our common stock may decline to a market price at which buyers are willing to purchase the offered shares.

We currently have 17,107,036 shares of common stock outstanding. Of these shares, 356,587 shares are free-trading. In March 2011, approximately 2.6 million additional shares of our common stock will become free-trading. The remaining outstanding shares of our common stock are restricted securities as defined under Rule 144 under the Securities Act. We cannot predict the likelihood or timing of any future sales of the common stock issued to Ampio shareholders prior to this offering. Any sales by Ampio shareholders could depress the market price of Ampio common stock.

The 8,667,905 shares of common stock issuable in the merger to the BioSciences shareholders will be free-trading once the registration statement covering such shares of common stock is declared effective by the SEC, subject to the provisions of lock-up agreements under which such shareholders are prohibited from selling, pledging or hypothecating the Ampio common stock to be received by them until December 31, 2011. Executive and non-executive officers of BioSciences who receive Merger Stock, and executive and non-executive officers and employees of Ampio at the time of the merger, are required by the merger agreement, as amended, to sign lock-up agreements covering the Merger Stock, and any other Ampio shares owned by such persons, for a period through February 28, 2012.



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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 \$4,500. The lease expires in July 2011. 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 pending or threatened legal or administrative proceedings in which we will become involved.

**Item 4. *(Removed and Reserved)***

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

There is no established public trading market for our common stock. However, our common stock is quoted on the Over-the-Counter Bulletin Board under the symbol AMPE. The following table sets forth the high and low last reported sale price information for our common stock for the period from January 1, 2008 through December 31, 2010. The Over-the-Counter Bulletin Board quotations reflect inter-dealer prices, are without retail markup, markdowns or commissions, and may not represent actual transactions.

	Common Stock	
	High	Low
First quarter 2008	\$	\$
Second quarter 2008	\$	\$
Third quarter 2008	\$ 1.75	\$ 1.50
Fourth quarter 2008	\$ 1.50	\$ 1.50
First quarter 2009	\$ 1.50	\$ 1.50
Second quarter 2009	\$ 1.50	\$ 1.50
Third quarter 2009	\$ 1.50	\$ 1.50
Fourth quarter 2009	\$ 1.50	\$ 1.50
First quarter 2010	\$ 1.50	\$ 1.50
Second quarter 2010	\$ 4.50	\$ 0.75
Third quarter 2010	\$ 3.50	\$ 1.00
Fourth quarter 2010	\$ 3.00	\$ 2.01

As of February 14, 2011, there were of record approximately 250 holders of our common stock. This number is expected to increase on closing of the BioSciences acquisition by approximately 190 additional holders.

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.

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

See Item 15 of Part IV, Notes to Consolidated Financial Statements Note 3 Short Term Debt and Note 8 Common Stock.

**Equity Compensation Plan Information**

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



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	<b>Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (a)</b>	<b>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)</b>	<b>Number of Securities Remaining Available for Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)</b>
Equity compensation plans approved by security holders	2,930,000	\$	1,570,000
Equity compensation plans not approved by security holders			
<b>Total</b>	<b>2,930,000</b>	<b>\$</b>	<b>1,570,000</b>



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

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

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

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

In addition, when Life Sciences purchased intellectual property from BioSciences in April 2009, a transaction discussed further below, BioSciences received 3,500,000 shares of our common stock that represented approximately 20% of our outstanding shares. Because of this common ownership and the common management described above, we concluded that an acquisition of BioSciences would remove the potential for conflicts of interest between us and BioSciences, and would provide us with the opportunity to seek a new licensing partner for Zertane. That drug was returned to BioSciences in June 2010 by a major pharmaceutical company that had previously licensed the PE drug.

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

We have not generated any revenues since our inception in December 2008. The assets we purchased from BioSciences in April 2009 did generate minimal revenues prior to their acquisition. Since purchasing those assets from BioSciences in April 2009, which included patents, pending patent applications, proprietary know-how and minimal fixed assets, we have engaged in organizational activities, added to our management team, completed the merger with Chay Enterprises, and signed the letter of intent to acquire BioSciences. In addition, we conducted private placements in 2010 pursuant to which we raised \$2 million in debentures and related party notes payable, and \$1.4 million in common stock.

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

Since inception, we have incurred significant net losses and we expect to continue to experience significant losses as we invest in product candidate development, clinical trials, regulatory compliance, and building a portfolio of proprietary intellectual property. As of December 31, 2010, we had a deficit accumulated during the development stage of \$9.8 million.

Subject to receipt of sufficient capital, we expect to initiate and complete clinical trials for Optina, Vasaloc and Ampion in 2011. The timing of completion of the clinical trials may vary from our expectations, however, depending on our ability to raise additional capital, our success in identifying and contracting with potential collaborators, and the commencement and completion of patient enrollment.

### **Significant Accounting Policies and Estimates**

Our financial statements have been prepared in accordance with accounting policies generally accepted in the United States of America. The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of 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 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 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. A portion of the purchase price of BioSciences has been allocated to intellectual property acquired through the merger, meaning this portion of the purchase price has been capitalized as a result of the acquisition.

#### ***In-process Research and Development***

A portion of the purchase price of BioSciences will be allocated to in-process research and development acquired through the merger. As a result, this portion of the purchase price will be capitalized. In-process research and development is evaluated as to its future development and capitalized into the cost of the related drug when the patent is received, or expensed if abandoned. We will periodically assess the fair value of the in-process research and development and recognize an impairment if the carrying value exceeds the fair value.

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

We account for share-based payments by recognizing compensation expense based upon the estimated fair value of the awards on the date of grant. We determine the estimated grant fair value 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 service period.

### ***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.

### ***Research and Development***

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

### ***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.

## **Results of Operations Year Ended December 31, 2010 and 2009**

### ***Revenue***

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

### ***Expenses***

#### ***Research and Development***

Research and development costs were \$2.0 million and \$1.1 million in 2010 and 2009, respectively. 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. The increase in expenses in 2010 relates to the increase in business activity as we did not begin incurring operating expenses until April 2009. Also, we did not incur stock-based compensation costs in 2009. We have not capitalized any of our research and development costs. Research and development costs are summarized as follows:

	<b>Year Ended December 31,</b>	
	<b>2010</b>	<b>2009</b>
Labor	\$ 889,000	\$ 544,000
Patent fees	399,000	185,000
Stock-based compensation	381,000	
Clinical trials and sponsored research	239,000	117,000

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Consultants	64,000	193,000
All other		32,000
	\$ 1,972,000	\$ 1,071,000

**Table of Contents*****General and Administrative***

General and administrative costs are summarized as follows:

	<b>Year Ended December 31,</b>	
	<b>2010</b>	<b>2009</b>
Stock-based compensation	\$ 2,715,000	\$
Professional fees	863,000	23,000
Labor	775,000	401,000
Occupancy, travel and other	225,000	17,000
Directors fees	154,000	
	\$ 4,732,000	\$ 441,000

Professional fees consist primarily of legal, audit and accounting costs related to the Chay Enterprises merger, public company compliance costs, and consulting related to capital formation. Labor consists of compensation costs attributable to our administrative employees. The increase in expenses in 2010 relates to the increase in business activity as we did not begin incurring operating expenses until April 2009. We did not have stock-based compensation costs in 2009.

***Derivative Expense***

We recorded \$1.4 million in derivative expense in 2010 in connection with our debentures and related warrants. We had no derivatives in 2009. The expense relates to the fair value at inception and subsequent changes in fair value of the debentures issued in 2010 stemming from the embedded derivative features (conversion options, down-round protection and mandatory conversion provisions) and the warrants issued in conjunction with the debentures.

***Net Cash Used in Operating Activities***

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 than the net loss 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.

During the twelve months ended December 31, 2009, our operating activities used \$1.4 million of cash. This reflected a \$1.5 million net loss, an increase in accounts payables of \$80,000, accrued salaries and other liabilities of \$73,000, and accrued interest payable of \$1,000, partially offset by increases in prepaid expenses of \$7,000 and a related party receivable of \$7,000.

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### ***Net Cash from Financing Activities***

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 \$150,000 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.

Net cash provided by financing activities was \$1.4 million for the twelve months ended December 31, 2009. During this period, we received \$200,000 in proceeds from a related note payable and proceeds from the sale of common and preferred stock of \$1.3 million, offset partially by payment of assumed liabilities of \$48,000.

### **Liquidity and Capital Resources**

The accompanying financial statements have been prepared assuming that we will continue as a going concern. In the year ended December 31, 2010, we generated a net loss of approximately \$8.1 million, and experienced liquidity constraints due to our limited working capital. These liquidity constraints and our need for additional capital raise substantial doubt about our ability to continue as a going concern.

We had cash of \$671,000 at December 31, 2010. We raised approximately \$2.0 million in debt and \$1.4 million in common stock in private placements during 2010. As of December 31, 2010, we had \$400,000 in notes payable to shareholders, which mature on the earlier of a minimum financing of \$5,000,000 or April 30, 2011. Of these notes payable, \$300,000 was owed to BioSciences and will be cancelled upon consummation of the BioSciences acquisition.

During August 2010, two of our directors and an affiliate of one of those directors loaned an additional \$430,000 to us in the form of senior convertible unsecured related party debentures (the "related party debentures"). The related party debentures initially were to mature at the earlier of a minimum financing of \$10,000,000 or January 31, 2011. The maturity terms were later modified such that the related party debentures mature on closing of a minimum financing of \$5.0 million or April 30, 2011. In connection with the related party debentures, we issued to the lenders a total of 21,500 warrants to purchase shares of our common stock. On closing of the private placement described in the following paragraph, the number of shares purchasable on exercise of the warrants was increased by 27,643 shares, in order to match the terms of the warrants issued to non-affiliates in November 2010. The number of shares issuable on exercise of the warrants issued with the related party debentures may be increased if the exercise price is further adjusted and falls below \$1.75 per share. The exercise price will be equal to the lesser of \$1.75 per share or the per-share price of shares we sell in a public offering.

In November 2010, we raised an additional \$1.38 million from 19 accredited investors, a majority of whom were already shareholders of ours. These funds were received on issuance of senior unsecured mandatorily convertible debentures (the "convertible debentures") which will automatically convert into our common stock at the earlier of (i) completion of an underwritten offering of \$10 million or more, and (ii) March 31, 2011. The conversion price will be the lower of \$1.75 per share or the price paid by investors in the underwritten offering. In connection with the issuance of the convertible debentures, we issued to the convertible debenture purchasers an aggregate of 157,829 warrants to purchase shares of our common stock, which may be adjusted if the conversion price of the convertible debentures is less than \$1.75 per share.

Subsequent to December 31, 2010, we raised an additional \$382,000 in cash in exchange for convertible debentures and warrants to purchase 43,657 shares of common stock (subject to adjustment) on the same terms as set forth above. The purchasers of these convertible debentures had purchased convertible debentures in November 2010, and thus increased the principal amount of their prior investment. Additional loans from our shareholders and debenture holders may be a source of short-term liquidity. However, there is currently no formal commitment from our shareholders or debenture holders to provide additional short-term financing.

### **Off Balance Sheet Arrangements**

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



**Table of Contents****Contractual Obligations**

As condition of the merger with Chay Enterprises, or Chay, we and certain of our shareholders, referred to as the guarantors, and the principal shareholders of Chay entered into a securities put and guarantee agreement. The agreement provided that if Ampio was not successful in obtaining a minimum of \$5.0 million in financing within 150 days after the closing of the merger, the principal shareholders of Chay had the right to put back to Ampio all of the Chay common stock then owned by the Chay principal shareholders for a put price of \$250,000, subject to adjustment. Under the agreement, the guarantors agreed to jointly guarantee the payment of the put price by Ampio if the put right becomes exercisable in accordance with its terms. In addition, Ampio placed into escrow a cash deposit of \$125,000 that was to be paid to the Chay principal shareholders in the event the put right became exercisable by its terms. The Chay principal shareholders released \$125,000 of the funds in escrow prior to December 31, 2010. As of December 31, 2010, the securities and put agreement expired by its terms.

Ampio entered into a clinical research agreement with a hospital and a physician investigator effective April 1, 2010. Under the terms of the clinical research agreement, we agreed to fund and support a clinical trial to a minimum of \$600,000, based on a budget to be agreed upon by the parties. We have paid an initial down payment of \$50,000 and subsequently paid an additional \$25,000, however, the budget has not yet been finalized. The clinical research agreement will remain in full force until the clinical trial is completed or until terminated by the parties.

The following table summarizes contractual obligations and borrowings as of December 31, 2010 and the timing and effect that such commitments are expected to have on Ampio's liquidity and capital requirements in future periods. Ampio expects to fund these commitments primarily with existing cash balances and from additional financing obtained through the sale of equity or debt instruments.

**Contractual Obligations**

	Total	Due in Less than 1 Year	Due 1-3 Years	Due 3-5 Years	More than 5 years
Sponsored Research Agreement with Related Party(1)	\$ 973,870	\$ 270,537	\$ 703,333	\$	\$
Related Party Debt Obligations(2)	1,023,821	1,023,821			
Clinical Research Obligation(3)	533,893	533,893			
Operating Leases	31,423	31,423			
	\$ 2,563,007	\$ 1,859,674	\$ 703,333	\$	\$

- (1) Represents amounts due under our sponsored research agreement with Trauma Research LLC, or TRLLC. This commitment may increase if Ampio's board of directors requests TRLLC to perform additional research and development activities. Such a request is expected to be made only in conjunction with Ampio's receipt of additional financing. This agreement may be terminated without cause by either party with 180 days written notice.
- (2) For more information on our debt obligations, see Item 13 of Part III, Certain Relationships, Related Transactions, and Director Independence - Related Party Transactions. Of the amount shown, \$493,821 will be extinguished on closing of the BioSciences acquisition.
- (3) Represents obligations under a clinical research agreement with a hospital and physician investigator.

**Recently Issued Accounting Pronouncements*****New accounting pronouncements to be adopted***

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

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

believes that the escrowed shares should be reflected as a discount in the allocation of proceeds.

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

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

In December 2010, the FASB issued ASU 2010-29, *Business Combinations* (ASC Topic 805) - *Disclosure of Supplementary Pro Forma Information for Business Combinations*. This amendment expands the supplemental pro forma disclosures to include a description of the nature and amount of material, nonrecurring pro forma adjustments directly attributable to the business combination included in the reported pro forma revenue and earnings. This amendment is effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010. Early adoption is permitted. We intend to adopt this guidance in 2011. Other than requiring additional disclosures with respect to the BioSciences acquisition, the adoption of this new guidance will not have a material impact on our consolidated financial statements.

We expect that the adoption of the above updates will not have any significant impact on our financial position and results of operations. Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on our consolidated financial statements upon adoption.

### **Impact of Inflation**

In general, we believe that, over time, we will be able to increase prices to counteract the majority of the inflationary effects of increasing 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. Our outstanding indebtedness is limited currently to fixed rate instruments.

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

See Item 15 of Part IV, *Index to Financial Statements* at page F-1.

### **Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

On March 16, 2010, Schumacher & Associates, Inc. ( *SAI* ) was dismissed as our independent auditor. On March 16, 2010, we engaged Ehrhardt Keefe Steiner & Hottman PC ( *EKSH* ) as our independent auditor. This decision to engage EKSH was ratified by the majority approval of the Board of Directors on March 16, 2010. Our shareholders had previously authorized at the special meeting held March 1, 2010 the retention of EKSH as our auditor for the year ending December 31, 2010.

*SAI*'s report on our financial statements for the two most recent years contained a qualification based upon substantial doubt about our ability to continue as a going concern due to our recurring losses, negative working capital, and lack of business operations. With that exception, *SAI*'s report on the financial statements for the two most recent years did not contain an adverse opinion or a disclaimer of opinion, and was not qualified or modified as to uncertainty, audit scope, or accounting principles.

Our Board of Directors participated in and approved the decision to change independent accountants.

For the two most recent fiscal years and the interim period through *SAI*'s termination on March 16, 2010, there was no disagreement between us and *SAI* on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreement, if not resolved to the satisfaction of *SAI* would have caused it to make a reference to the subject matter of the disagreement in connection with its reports.

During the most recent audit period and the interim period through March 16, 2010 there have been no reportable events with us as set forth in Item 304(a)(i)(v) of Regulation S-K.

### **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 ineffective due to the material weaknesses in internal control noted below.

#### **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 that term is defined in Rule 13a-15(f) under the Exchange Act. Our 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 consistent with generally accepted accounting principles in the United States.



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Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives.

Our management, with the participation of chief executive officer and chief financial officer, evaluated the effectiveness of our internal control over financial reporting as of December 31, 2010. 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. Based on this evaluation, our management concluded that, as of December 31, 2010, our internal control over financial reporting was not effective due to material weaknesses in the system of internal control. A material weakness is a deficiency, or combination of deficiencies, that creates a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected in a timely manner.

The material weakness assessed by our management was that (1) we have not properly segregated duties as our chief executive officer or chief financial officer initiate, authorize, and complete all transactions, (2) we have not implemented measures that would prevent the chief executive officer or chief financial officer from overriding the internal control system, and (3) there were ineffective controls over the accounting for, and reporting of, complex, non-routine transactions in derivative financial instruments. We do not believe that these control weaknesses have resulted in deficient financial reporting because the chief executive officer and chief financial officer are aware of their responsibilities under the SEC's reporting requirements and personally certify our financial reports.

Accordingly, while we have identified certain material weaknesses in our system of internal control over financial reporting, we believe we have taken reasonable steps to ascertain that the financial information contained in this report is in accordance with generally accepted accounting principles. Our management has determined that current resources would be appropriately applied elsewhere and when resources permit, it will address and remediate material weaknesses through implementing various controls or changes to controls. At such time as we have additional financial resources available to us, we intend to enhance our controls and procedures. We will not be able to assess whether the steps we intend to take will fully remedy the material weakness in our internal control over financial reporting until we have fully implemented them and sufficient time passes in order to evaluate their effectiveness.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010.

### **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 14, 2010.

Name	Age	Position With Ampio	Principal Occupation and Areas of Relevant Experience For Directors	Director Since
Michael Macaluso <sup>(1)(2)</sup>	59	Chairman of the Board	<p>Founder and director of Life Sciences; prior to forming Life Sciences, Mr. Macaluso managed his personal investments. He served on the board of directors of Isolagen, Inc. (AMEX: ILE) from June 2001 until April 2005; served as both chief executive officer and president of Isolagen from June 2003 until September 2004; served as chief executive officer from August 2001 until September 2004; and served as president . from June 2001 to August 2001. From October 1998 until June 2001, he 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.</p> <p>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.</p>	March 2010
Donald B. Wingerter, Jr.	61	Chief Executive Officer and Director	<p>CEO of Ampio since March 2010 and Life Sciences since December 2009; from 2006 until 2009, he has served as a member of the board of directors of several private companies in which he holds personal investments. From June 2002 until 2006, he served as chief executive officer of Sound Surgical Technologies, Inc., a specialty medical device company that developed and marketed proprietary ultrasonic-based products to break up and remove fat deposits from the human body. Mr. Wingerter was engaged in managing his personal investments from 2001 until June 2002. From 1995 to 2001, Mr. Wingerter was chairman of the board and chief executive officer of ClearVision Laser Centers, a company he founded in 1995 that operated centers providing laser vision correction services to consumers. ClearVision had operations in 14 states consisting of 10 centers utilizing fixed excimer lasers and 42 centers serviced by mobile lasers. In 2001, ClearVision was acquired by affiliates of two private equity firms. Before founding ClearVision, Mr. Wingerter served as chief executive officer and president, respectively, of Western Imaging Technologies and Accel Holdings, medical imaging companies that sold and leased magnetic resonance imaging (MRI), positron emission tomography (PET), and computer tomography (CT) imaging equipment. He also spent 11 years in various sales positions with General Electric</p>	March 2010

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Medical Systems, the last of which was National Sales Manager for Digital Products. Mr. Wingerter holds a B.S. degree in biology from Lafayette College and a M.S. degree in physiology from Rutgers University.

Mr. Wingerter's experience in executive management, sales management, and marketing and sales, as well as his experience in 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.



**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 Bar-Or, M.D.	62	Chief Scientific Officer and Director	<p>Dr. Bar-Or has 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 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.</p> <p>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.</p>	March 2010
Bruce G. Miller	66	Chief Financial Officer	<p>Mr. Miller has served as our chief financial officer since April 2010 and served as our chief operating officer from December 2009. He also served as the chief executive officer of Life Sciences from April 2009 until December 2009, and as a member of the board of directors from April 2009 until the Chay merger. Thereafter, he served as a member of our board of directors until August 2010. Mr. Miller has been the chief executive officer of BioSciences since 1992. Mr. Miller was instrumental in BioSciences securing a license agreement for the PE drug, which generated significant revenues for BioSciences. Prior to joining BioSciences, Mr. Miller was a practicing attorney for over 24 years with experience in diverse aspects of business law ranging from start-ups to acquisitions. While practicing law, he was a shareholder for six years in the Denver office of Popham, Haik, Schonbrich &amp; Kaufman. Mr. Miller holds a J.D. degree from the University of Denver and a B.A. degree from Duke University.</p>	

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Name	Age	Position With Ampio	Principal Occupation and Areas of	
			Relevant Experience For Directors	Director Since
Dr. Vaughan L. Clift	49	Chief Regulatory Affairs Officer	Dr. Clift has been employed by Ampio 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.	
Philip H. Coelho <sup>(1)(2)(3)</sup>	67	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 October 2009. From August 2007 through May 2008, Mr. Coelho served as the Chief Technology Architect of ThermoGenesis Corp. From 1989 through July 30, 2007, he was Chairman and Chief Executive Officer of ThermoGenesis Corp. Mr. Coelho served as Vice President of Research & Development of ThermoGenesis from 1986 through 1989. Mr. Coelho has been in the senior management of high technology consumer electronic or medical device companies for over 30 years. He was President of Castleton Inc. from 1982 to 1986, and President of ESS Inc. from 1971 to 1982. Mr. Coelho currently also serves as a member of the Board of Directors of two Nasdaq-listed companies, Catalyst Pharmaceuticals Partners, Inc. (since October 2002), and 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.	April 2010
			Mr. Coelho's experience in executive management in the pharmaceutical industry, prior and current public company board experience, and knowledge of corporate finance and governance, 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.	



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**Principal Occupation and Areas of**

Name	Age	Position With Ampio	Relevant Experience For Directors	Director Since
Richard B. Giles <sup>(1)(2)(3)</sup>	61	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 is also a member of the American Institute of Certified Public Accountants and the Construction Financial Management Association.</p>	August 2010

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.

- (1) Member of our audit committee
- (2) Member of our compensation committee
- (3) Member of our corporate governance and nominating 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. Barbara Giles, a non-executive employee, is the spouse of Richard B. Giles, one of our directors.

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

Our common stock is registered pursuant to Section 15(d) of the Securities Exchange Act of 1934. Accordingly, our executive officers, directors and control persons are not currently subject to the obligation to file Forms 3, 4 and 5 pursuant to Section 16(a) of the Exchange Act. At such time as we secure a listing on a national securities exchange, our executive officers, directors and control persons will become subject to the filing obligations described in Section 16(a).

### **Meetings**

During the year ended December 31, 2010, there were held (i) four meetings of the board of directors, (ii) three meetings of the audit committee, (iii) two meetings of the compensation committee, and (iv) one meeting of the corporate governance and nominating 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, it will be Ampio's policy that directors attend the annual meeting of shareholders. Ampio previously did not have a policy concerning director attendance at annual meetings. Commencing January 1, 2011, Ampio's non-management directors will also be 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.

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.

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### **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, Ampio is not engaged in, nor is it aware of any pending or threatened, litigation in which any of its directors, executive officers, affiliates or owner of more than 5% of Ampio's common stock is a party adverse to Ampio or has a material interest adverse to Ampio.

### **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 Ampio at that time. Our current chairman, Michael Macaluso, is not an officer of Ampio or its subsidiaries. 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 Ampio's 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 governance and nomination 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 corporate governance and nominating committee, each of which has the composition and the responsibilities described below. The audit committee, compensation committee and corporate governance and nominating committee all operate under charters approved by our board of directors, which charters are available on our website.

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

selecting and hiring our independent auditors;

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

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

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reviewing the qualifications and independence of the independent auditors;

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

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

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

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

The members of our audit committee are Messrs. Giles, Coelho and Macaluso. Mr. Giles is our audit committee chairman and was appointed to our audit committee on August 10, 2010. Our board of directors has determined that each member of the audit committee meets the financial literacy requirements of the national securities exchanges and the SEC, and Mr. Giles qualifies as our audit committee financial expert as defined under SEC rules and regulations. Our board of directors has concluded that the composition of our audit committee meets the requirements for independence under the current requirements of the national securities exchanges and SEC rules and regulations. We believe that the functioning of our audit committee complies with the applicable requirements of SEC rules and regulations, and will comply with the applicable requirements of one of the national securities exchanges when such provisions apply to us.

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

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

reviewing and recommending compensation and the corporate goals and objectives relevant to compensation of our chief executive officer;

reviewing and approving compensation and corporate goals and objectives relevant to compensation for executive officers other than our chief executive officer;

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

developing in consultation with our board of directors and periodically reviewing a succession plan for our chief executive officer; and

administering our equity compensations plans for our employees and directors.

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

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members referenced above.

Our compensation committee and our board of directors have not yet established a succession plan for our chief executive officer.

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

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

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

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



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

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

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

**Non-Management 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; Corporate Governance and Nominating	\$ 20,000	
Each non-chair member	Audit	12,000	
Each non-chair member	Compensation; Corporate Governance and Nominating	10,000	
<b>Committee Chairman Meeting Fees:</b>			
Each meeting attended in-person	Audit; Compensation; Corporate Governance and Nominating	\$ 2,500	
Each meeting attended telephonically or via web	Audit; Compensation; Corporate Governance and Nominating	1,500	
<b>Committee Member Meeting Fees:</b>			
Each meeting attended in-person	Audit; Compensation; Corporate Governance and Nominating	\$ 1,500	
Each meeting attended telephonically or via web	Audit; Compensation; Corporate Governance and Nominating	1,000	
<b>Annual Restricted Stock Award:</b>			\$ 10,000

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The table below summarizes the compensation paid by us to non-employee directors for the year ended December 31, 2010.

Name	Fees Earned or Paid in Cash	Stock Option Awards (1) (2)	All Other Compensation	Total
Michael Macaluso	\$ 61,500	\$ 349,008	\$	\$ 410,508
Philip H. Coelho	58,000	142,776		200,776
Richard B. Giles	34,333	158,640		192,973

- (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, August 12 and 27, 2010. Please see Item 15 of Part IV, Notes to Consolidated Financial Statements Note 9 Stock-Based Compensation.
- (2) At December 31, 2010, Messrs. Macaluso, Coelho and Giles held options to acquire 550,000, 225,000 and 250,000 shares of common stock, respectively. Excludes January 2011 grants of 150,000 options each to Messrs. Coelho and Giles.

**Item 11. Executive Compensation**

The following table sets forth all cash compensation earned, as well as certain other compensation paid or accrued in 2010 and 2009, 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)	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Earnings Compensation	All Other Compensation	Total
Donald B. Wingerter, Jr CEO since December 2009	2010	\$ 145,333	\$ 29,000	\$	\$ 385,179	\$	\$	\$	\$ 559,512
David Bar-Or CSO and Former Chairman	2010	227,500	(2)		451,968				679,468
	2009	227,500	(3)						227,500
Bruce G. Miller CFO and COO since January 2010;	2010	180,000	(4)	10,000					190,000
COO and CEO from April 2009 to December 2009	2009	180,000	(5)						180,000
Vaughan Clift, M.D. Chief Regulatory Affairs Officer	2010	198,000	(6)	29,500	235,669				463,169
	2009	82,500	(7)						82,500

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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 9 Stock-Based Compensation.
- (2) Includes \$68,250 in salary deferred by Dr. Bar-Or at December 31, 2010.
- (3) Includes \$17,063 in salary deferred by Dr. Bar-Or at December 31, 2009.
- (4) Includes \$54,000 in salary deferred by Mr. Miller at December 31, 2010.
- (5) Includes \$13,500 in salary deferred by Mr. Miller at December 31, 2009
- (6) Includes \$42,333 in salary deferred by Dr. Clift at December 31, 2010.
- (7) Includes \$22,500 in salary deferred by Dr. Clift at December 31, 2009.

The above-noted salary deferrals were necessitated by our limited financial resources in 2010 and 2009. Our compensation committee has determined that all deferred salaries will be paid to the officers in question upon our completion of a financing in 2011 in the amount of \$5 million or more.

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

The following table provides a summary of equity awards outstanding for each of the Named Executive Officers as of December 31, 2010:

Named Executive Officer	Exercisable	Unexercisable (1)	Option Exercise Price	Option Expiration Date
Donald B. Wingerter, Jr. Chief Executive Officer	200,000	400,000	\$ 1.03	8/12/2020
David Bar-Or, M.D. Chief Scientific Officer	233,333	466,667	\$ 1.03	8/12/2020
Bruce G. Miller Chief Financial Officer				
Vaughan Clift, M.D. Chief Regulatory Affairs Officer	121,667	243,333	\$ 1.03	8/12/2020

(1) Each currently unexercisable option becomes exercisable by its terms 50% on August 12, 2011 and 50% on August 12, 2012.

**Employment Agreements**

Life Sciences previously entered into employment agreements with Dr. Bar-Or, Bruce G. Miller, and four non-executive officers, Dr. Vaughan Clift, Dr. James Winkler, Raphael Bar-Or, and Ms. Wannell Crook. In August and November, 2010 and January 2011, respectively, we entered into new employment agreements with Mr. Wingerter, our chief executive officer, Dr. Bar-Or, our chief scientific officer, and Dr. Clift, our chief regulatory affairs officer. The new employment agreement with Dr. Bar-Or supersedes the prior agreement with Life Sciences. 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 \$145,000 for Mr. Wingerter, \$227,500 for Dr. Bar-Or, and \$198,000 for Dr. Clift, which will automatically increase to annual salaries of \$275,000, \$300,000, and \$250,000, respectively, following our receipt of financing in the amount of \$5 million or more. The Compensation Committee established the current salary levels to reflect our presently limited financial resources.

The employment agreements originally provided for the increases to take effect once we obtained financing in the amount of \$10 million or more, but in January 2011 this provision was unilaterally reduced by the Compensation Committee to \$5 million or more. Dr. Clift's employment agreement was amended in January 2011 to reflect this reduction, and to reflect Dr. Clift's right to receive a monthly temporary housing reimbursement of \$3,000 which will extend through the time we receive a financing of \$5 million or more.

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

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The employment agreements provide for an immediate 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 day immediately prior to the effective date of the employment agreement. The options vest as follows: (i) one-third upon execution of the agreement, (ii) one-third on August 12, 2011, and (iii) one-third on August 12, 2012. The vesting of all options set forth above shall accelerate upon a change in control as defined in each agreement.

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

If the employment of Mr. Wingerter, Dr. Bar-Or, or Dr. Clift is terminated at our election at any time, for reasons other than death, disability, cause (as defined in the agreement), or a voluntary resignation, or if an officer terminates his employment for good cause, the officer in question shall be entitled to receive a lump sum severance payment equal to two times his base salary and of the continued payment of premiums for continuation of the officer's health and welfare benefits pursuant to COBRA or otherwise, for a period of two years from the date of termination, subject to earlier discontinuation if the officer is eligible for comparable coverage from a subsequent employer. All severance payments, less applicable withholding, are subject to the officer's execution and delivery of a general release of us and our subsidiaries and affiliates and each of their officers, directors, employees, agents, successors and assigns in a form acceptable to us, and a reaffirmation of the officer's continuing obligation under the proprietary 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.

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

- i. 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;
- ii. Ampio consummates 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 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;

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

iv. 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.

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 her 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. Wingerter, 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.

**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.

**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.

**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, 2010 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.

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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, 2010. 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, 2010 are included for that person or group but not the stock options, debentures, or warrants of any other person or group.

Applicable percentage ownership is based on 17,107,036 shares of common stock outstanding at December 31, 2010.

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

<b>Name of Beneficial Owner</b>	<b>Number of Shares Beneficially Owned</b>	<b>Percentage of Shares Beneficially Owned</b>
Michael Macaluso (1)	2,611,932	13.2%
David Bar-Or (2)	2,933,333	14.6%
Donald B. Wingerter, Jr. (3)	525,000	3.0%
Bruce G. Miller	1,500,000	8.1%
Vaughn Clift (4)	696,667	3.9%
Philip H. Coelho (5)	229,545	1.3%
Richard B. Giles (6)	439,031	2.5%
DMI BioSciences, Inc. (7)	3,500,000	17.0%
Wannell Crook (8)	1,100,000	6.0%
Raphael Bar-Or (8)	1,025,000	5.7%
James Winkler (8)	1,025,000	5.7%
All executive officers and directors (seven persons)	8,935,509	46.7%

- (1) Includes an aggregate of 712,260 shares of common stock issuable to Mr. Macaluso by virtue of (i) exercise of currently exercisable stock options, (ii) conversion of related party debentures held by him, (iii) exercise of warrants, and (iv) his service as a non-management director.
- (2) Includes 233,333 shares of common stock which Dr. Bar-Or has the right to acquire through the exercise of stock options. Excludes 1,025,000 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 200,000 shares of common stock issuable to Mr. Wingerter on exercise of currently exercisable stock options.
- (4) Includes (i) 121,667 shares of common stock Dr. Clift has the right to acquire on exercise of currently exercisable stock options, and (ii) 575,000 shares of common stock owned of record by Kristin Clift, Dr. Clift's spouse.
- (5) Includes 229,545 shares of common stock issuable to Mr. Coelho on exercise of currently exercisable stock options. Excludes options to acquire 150,000 shares of common stock granted in January 2011 which are not exercisable within 60 days of December 31, 2010.
- (6) Includes 345,022 shares of common stock issuable to Mr. Giles by virtue of (i) exercise of currently exercisable stock options, (ii) conversion of related party debentures held by him, (iii) exercise of warrants, and (iv) the BioSciences acquisition. Additionally, includes 40,000 shares of common stock issuable to Barbara Giles, Mr. Giles' spouse, on exercise of currently exercisable options. Excludes options to acquire 150,000 shares of common stock granted in January 2011 which are not exercisable within 60 days of December 31, 2010.
- (7) All such shares are to be donated to the capital of Ampio immediately prior to the closing of the acquisition of BioSciences pursuant to the terms of the agreement and plan of merger.
- (8) Such persons are non-executive officers of Ampio.



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**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 October 1, 2008 in which the amount involved exceeded or will exceed \$120,000, and in which any director, executive officer or holder of more than 5% of any class of our voting stock, or any member of the immediate family of or entities affiliated with any of them, had or will have a material interest.

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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 in excess of the fair value of assets received. Included in the assumed liabilities was a \$200,000 note payable to Life Sciences founder, Michael Macaluso. The note payable was subsequently converted by Mr. Macaluso into 163,934 shares of Life Sciences Series A preferred stock at a conversion price of \$1.22 per share, which was converted into our common stock upon the closing of the Chay merger.

As of December 31, 2009, Life Sciences had \$100,000 in notes payable to Mike Macaluso, Life Sciences' founder, and \$100,000 payable to BioSciences. The related party notes payable are unsecured, bear interest at 6% and 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 us from BioSciences in the three months ended June 30, 2010, bringing the total amount of notes payable owed by us to BioSciences to \$300,000. The notes evidencing the foregoing borrowings have been extended to become due at the earlier of March 2, 2011, or closing of a financing exceeding \$5 million.

BioSciences paid operating expenses on behalf of Life Sciences, and funds were advanced and repaid between Life Sciences and BioSciences, during 2009. Disbursements to BioSciences during 2009, including prepayment of liabilities assumed under the asset purchase agreement, totaled \$111,943. BioSciences owed \$7,236 us in short-term non-interest bearing advances at December 31, 2009. In October and November 2010, we borrowed \$215,971 from BioSciences in non interest bearing advances. As of December 31, 2010, non-interest bearing advances from BioSciences totaled \$193,821.

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

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

Life Sciences has a sponsored research agreement with Trauma Research LLC, or TRLLC, an entity owned by Dr. Bar-Or. Under the terms of the research agreement, Life Sciences is to provide personnel and equipment with an equivalent value of \$263,750 per year and to make monthly equipment rental payments of \$7,236 on behalf of TRLLC. In exchange, TRLLC will assign any intellectual property rights it develops under the research agreement. The research agreement expires in 2014 and may be terminated by either party on six months' notice or immediately if either party determines that the other is not fulfilling its obligations under the agreement. Life Sciences was current in its financial obligations under the research agreement at December 31, 2010.

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

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

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In August 2010, Michael Macaluso and Richard B. Giles, both members of our board of directors, together with an affiliate of Mr. Giles, purchased convertible debentures from us for \$430,000. The debentures were issued in principal amounts of \$230,000, \$100,000 and \$100,000, respectively, to Mr. Macaluso, Mr. Giles, and James A. Ludvik. Mr. Ludvik is the sole owner of Ludvik Electric Co., for which Mr. Giles serves as the chief financial officer. The debentures accrue interest at the rate of 8% per annum. The debentures are convertible into our common stock at the lower of (i) \$1.75 per share, or (ii) the per-share price at which we issue common stock in an underwritten offering. The conversion price may be adjusted pursuant to the other terms of the debentures. The debentures are due and payable at the earlier of one business day after the closing of an underwritten offering or April 30, 2011. The debenture terms specified that we were obligated to obtain an extension of the \$400,000 in principal amount of promissory notes previously issued to BioSciences to a due date consistent with the maturity date of the debentures, and required us to obtain a subordination agreement from BioSciences, Inc., such that the debentures will jointly constitute our senior unsecured indebtedness. The BioSciences debt will be extinguished on final closing of the BioSciences merger.

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

In the event that we issue additional debentures on terms that are more favorable to the purchasers than the terms extended to Messrs. Macaluso, Giles and Ludvik, we have agreed that we will ascribe most favored nation status to the debenture holders and will conform the terms of the debentures such that the terms are as favorable to the initial purchasers as any other debenture issued thereafter until maturity. Upon closing of our November 2010 bridge financing, 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 and 2009, 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. Our compensation committee has determined that all deferred salaries will be paid to the officers in question upon our completion of a financing in 2011 in the amount of \$5 million or more.

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

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

### **Director Independence**

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

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

In August 2010, our board of directors undertook a review of its composition, the composition of its committees and the independence of each director. Based upon information provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that none of Messrs. Macaluso, Coelho and Giles, representing three of our five directors, has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is independent as that term is defined by the national securities exchanges. Our board of directors also determined that Messrs. Giles, Coelho and Macaluso, who comprise our audit committee and our compensation committee, and Messrs. Giles and Coelho, who comprise our nominating and corporate governance committee, satisfy the independence standards for those committees established by applicable SEC rules and the national securities exchanges. In making this determination, our board of directors considered the relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. 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***

Ehrhardt Keefe Steiner & Hottman PC 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, 2011.

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The following table presents aggregate fees for professional services rendered by our independent registered public accounting firm, Ehrhardt Keefe Steiner & Hottman PC for the audit of our annual consolidated financial statements for the years ended December 31, 2010 and 2009.

	<b>Year Ended December 31,</b>	
	<b>2010</b>	<b>2009</b>
Audit fees (1)	\$ 69,381	\$ 32,243
Audit- related fees (2)	80,028	
Tax fees (3)	4,950	
All other fees		
<b>Total fees</b>	<b>\$ 154,359</b>	<b>\$ 32,243</b>

- (1) Audit fees are comprised of annual audit fees and quarterly review fees.
- (2) Audit-related fees for fiscal years 2010 and 2009 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 2010 or 2009 provided by Ehrhardt Keefe Steiner & Hottman PC 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, 2010 and 2009

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

Consolidated Statements of Stockholders' Deficit for the years ended December 31, 2010 and 2009

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

(a)(2) Notes to Consolidated Financial Statements  
**Financial Statement Schedules**

Not Applicable.

(a)(3) **Exhibits**

Exhibit number	Exhibit title
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	Amended Agreement and Plan of Merger, effective December 31, 2010 (3)
3.1	Certificate of Incorporation of the Registrant, as currently in effect (4)
3.2	Amendment to Certificate of Incorporation(4)
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 Senior Convertible Unsecured Debenture (5)
4.3	Form of Warrant issued with Senior Convertible Unsecured 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)
10.1	Form of Director and Executive Officer Indemnification Agreement (1)
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)**
10.7.2	Amendment to Employment Agreement, effective October 1, 2011, by and between Ampio Pharmaceuticals, Inc. and Vaughan Clift, M.D. (12)**
10.8	Sponsored Research Agreement dated September 1, 2009 (7)***
10.9	Exclusive License Agreement, dated July 11, 2005(7)***

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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 Consulting Agreement by and between Redwood Consultants, LLC and the Registrant (7)

10.13 Extension Agreement for Notes Payable dated May 13, 2010 (9)

10.14 Extension Agreement for Notes Payable dated May 13, 2010 (9)

10.15 Extension Agreement for Related Party Notes Payable dated May 13, 2010 (12)

10.16 Extension Agreement for Related Party Notes Payable dated May 13, 2010 (12)

10.17 Note Extension and Subordination Agreement, executed February 15, 2011, by and between 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 DMI BioSciences, Inc. (12)

10.19 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)

10.20 Notes Payable dated June 23, 2010 (10)

16.1 Letter Regarding Change in Certifying Accountant (7)

21.1 List of subsidiaries of the Registrant (7)

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.

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.

- (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 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.

\* 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.

**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: February 15, 2011

By: /s/ Donald B. Wingerter, Jr.  
Donald B. Wingerter, Jr.



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Chief Executive Officer

(Principal Executive Officer)

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**Table of Contents****POWER OF ATTORNEY**

Each person whose signature appears below constitutes and appoints and hereby authorizes Donald B. Wingerter, Jr. 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 February 15, 2011.

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

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AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of

Ampio Pharmaceuticals, Inc. and Subsidiaries

Greenwood Village, Colorado

We have audited the accompanying consolidated balance sheets of Ampio Pharmaceuticals, Inc. and subsidiaries (the Company) as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' deficit, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Ampio Pharmaceuticals, Inc. and subsidiaries as of December 31, 2010 and 2009, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has experienced recurring losses from operations which raises substantial doubt about its ability to continue as a going concern. Management's plans regarding those matters also are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Ehrhardt Keefe Steiner & Hottman PC

February 15, 2011

Denver, Colorado

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

	December 31,	
	2010	2009
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 671,279	\$ 71,983
Prepaid expenses	60,534	7,036
Related party receivable	5,711	7,261
Total current assets	737,524	86,280
Total assets	\$ 737,524	\$ 86,280
<b>Liabilities and Stockholders Deficit</b>		
Accounts payable	\$ 464,453	\$ 79,445
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	
Related party notes payable	400,000	200,000
Warrant derivative liability	398,671	
Total current liabilities	4,745,960	354,250
Total liabilities	4,745,960	354,250
Commitments and contingencies (Note 7)		
Stockholder deficit		
Common Stock, par value \$.0001 in 2010 and \$.001 in 2009; shares authorized - 100,000,000 shares in 2010 and 15,000,000 shares in 2009, shares issued and outstanding - 17,107,036 in 2010 and 11,930,000 in 2009	1,711	11,930
Preferred Stock, par value \$.0001 in 2010 and \$.001 in 2009; Series A Preferred Stock, shares authorized - none in 2010 and 2,000,000 in 2009, shares issued and outstanding - none in 2010 and 1,077,864 in 2009		1,078
Common stock subscribed		170,003
Additional paid in capital	5,961,635	1,313,942
Issuances for promotion	(3,281)	
Advances to stockholders	(150,183)	
Deficit accumulated in the development stage	(9,818,318)	(1,764,923)
Total stockholders deficit	(4,008,436)	(267,970)
Total liabilities and stockholders deficit	\$ 737,524	\$ 86,280

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



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

	Year Ended December 31,		December 18, 2008 (inception) through December 31, 2010
	2010	2009	
Expenses			
Research and development	\$ 1,972,134	\$ 1,070,370	\$ 3,042,504
General and administrative	4,732,271	441,135	5,174,486
Total operating expenses	6,704,405	1,511,505	8,216,990
Other (expense) income			
Interest income	815	1,091	1,906
Interest expense	(19,545)	(1,414)	(20,959)
Unrealized gain on fair value of debt instruments	37,511		37,511
Derivative expense	(1,367,771)		(1,367,771)
Total other (expense) income	(1,348,990)	(323)	(1,349,313)
Net loss	\$ (8,053,395)	\$ (1,511,828)	\$ (9,566,303)
Weighted average number of common shares outstanding	16,288,468	14,793,068	
Basic and diluted net loss per common share	\$ (0.49)	\$ (0.10)	

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

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

	Series A Preferred Stock		Common Stock		Common Stock Subscribed	Additional Paid in Capital	Additional Issuances	Receivable from Stockholders	Deficit Accumulated During the Development Stage	Total Stockholders Deficit
	Shares	Amount	Shares	Amount						
Balance -December 18, 2008 (date of inception)		\$		\$	\$	\$	\$	\$	\$	
Issuance of common stock to founder in December, 2008			1,080,000	1,080					1,080	
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)

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

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

	Year Ended December 31, 2010	Year Ended December 31, 2009	December 18, 2008 (inception) through December 31, 2010
<b>Cash flows from operating activities:</b>			
Net loss	\$ (8,053,395)	\$ (1,511,828)	\$ (9,566,303)
Common stock issued for services	1,799,219		1,799,219
Stock based compensation expense	1,297,083		1,297,083
Derivative expense	1,367,771		1,367,771
Unrealized gain on fair value of debt instruments	(37,511)		(37,511)
<b>Adjustments to reconcile net loss to cash used in operating activities:</b>			
(Increase) in prepaid expenses	(53,498)	(7,036)	(60,534)
Decrease (increase) in related party receivable	1,550	(7,261)	(5,711)
Increase in related party payable	193,821		193,821
Increase in accounts payable	385,008	79,445	464,453
Increase in accrued salaries and other liabilities	453,342	73,391	526,733
Increase in accrued interest payable	18,279	1,414	19,693
<b>Net cash used in operating activities</b>	<b>(2,628,331)</b>	<b>(1,371,875)</b>	<b>(4,001,286)</b>
<b>Cash used in financing activities:</b>			
Proceeds from related party notes payable and debentures	2,011,000	200,000	2,211,000
Proceeds from sale of common stock	1,359,627	7,350	1,368,057
Proceeds from common stock subscribed	7,000	170,003	177,003
Proceeds from sales of series A preferred stock		1,115,020	1,115,020
Advances made to shareholders	(150,183)		(150,183)
Payment of liabilities assumed in asset purchase		(48,515)	(48,515)
Increase in cash from acquisition	183		183
<b>Net cash provided by financing activities</b>	<b>3,227,627</b>	<b>1,443,858</b>	<b>4,672,565</b>
<b>Net change in cash and cash equivalents</b>	<b>599,296</b>	<b>71,983</b>	<b>671,279</b>
Cash and cash equivalents at beginning of period	71,983		
<b>Cash and cash equivalents at end of period</b>	<b>\$ 671,279</b>	<b>\$ 71,983</b>	<b>\$ 671,279</b>
<b>Supplementary cash flow information:</b>			
Interest paid	\$	\$	\$
Income taxes paid	\$	\$	\$
<b>Non cash transactions:</b>			
Note payable assumed in asset purchase, recorded as a distribution	\$	\$ 200,000	\$ 200,000
Accounts payable assumed in asset purchase, recorded as a distribution	\$	\$ 48,515	\$ 48,515
Conversion of notes payable to Series A preferred stock	\$	\$ 200,000	\$ 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

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



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**AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**(A Development Stage Company)**

**Notes to Consolidated Financial Statements**

**(unaudited)**

**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) and DMI Acquisition Corp. 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, cancer, and acute and chronic inflammation diseases.

Life Sciences was incorporated in the state of Delaware on December 18, 2008. 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 10 - 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. As a result, the business and financial information included in the 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.

As Ampio's activities to date have been primarily research and development and raising capital, and Ampio does not yet have revenue, Ampio is considered to be in the development stage.

***Financial Condition***

Ampio has no revenue to date, has incurred significant losses and negative cash flows from operations since its inception, and is expected to continue to incur losses and negative cash for the foreseeable future. Ampio's ability to execute on its business plan and continue as a going concern is contingent upon its ability to raise additional financing. Although the Company has plans to raise capital, no assurance can be given that the Company will receive additional financing.

These factors (continuing negative cash flows and uncertain financing), raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

**Note 2 Summary of Significant Accounting Policies**

***Principals of Consolidation***

These 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 investments. Ampio maintains balances from time to time in excess of the federally insured limits.

*Patents*

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

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

The preparation of financial statements in accordance with Generally Accepted Accounting Principles in the United States ( GAAP ) requires management to make estimates and assumptions that affect the reported amounts assets and liabilities, disclosures of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. 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 and stock-based compensation. 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 warrants was calculated using a bi-nomial-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 3 Short Term Debt.

### ***Income Taxes***

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

### ***Net Loss per Common Share***

GAAP provides for the calculation of Basic and Diluted earnings per share. Basic earnings per share includes no dilution and are computed by dividing income available to common stockholders by the weighted-average number of shares outstanding during the period. Diluted earnings per share reflect the potential of securities that could share in the earnings of the Company, similar to fully diluted earnings per share. Basic and diluted loss per share was the same in 2010 and 2009. Although there were common stock equivalents of 3,136,969 and 1,077,864 shares outstanding at December 31, 2010 and 2009, respectively, consisting of stock options and warrants in 2010 and convertible Series A Preferred Stock in 2009; 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 and totaled \$1,972,134 and \$1,070,370 for 2010 and 2009, respectively.

### ***Newly Issued Accounting Pronouncements***

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

ASU No. 2010-05 Compensation Stock Compensation (Topic 718): *Escrowed Share Arrangements and the Presumption of Compensation*. This update simply codifies EITF Topic D-110, Escrowed Share Arrangements and the Presumption of Compensation issued on June 18,

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2009. In EITF Topic No. D-110, SEC staff clarified that entities should consider the substance of the transaction in evaluating whether the presumption of compensation may be overcome, including whether the transaction was entered into for a reason unrelated to employment, such as to facilitate a financing transaction. In that situation, the staff generally believes that the escrowed shares should be reflected as a discount in the allocation of proceeds.

ASU No. 2010-06 Fair Value Measurements and Disclosures (Topic 820): *Improving Disclosures about Fair Value Measurements*. This update amends Subtopic 820-10 that requires new disclosures about transfers in and out of Levels 1 and 2 and activity in Level 3 fair value measurements. This update also amends Subtopic 820-10 to 43 clarify certain

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existing disclosures. The new disclosures and clarifications of existing disclosures are effective for interim and annual reporting periods beginning after December 15, 2009, except for the disclosures about purchases, sales, issuances, and settlements in the roll forward of activity in Level 3 fair value measurements, which are effective for fiscal year beginning after December 15, 2010.

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

In December 2010, the FASB issued ASU 2010-29, Business Combinations (ASC Topic 805) *Disclosure of Supplementary Pro Forma Information for Business Combinations*. This amendment expands the supplemental pro forma disclosures to include a description of the nature and amount of material, nonrecurring pro forma adjustments directly attributable to the business combination included in the reported pro forma revenue and earnings. This amendment is effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010. Early adoption is permitted. We intend to adopt this guidance in 2011. Other than requiring additional disclosures with respect to the BioSciences acquisition, the adoption of this new guidance will not have a material impact on Ampio's consolidated financial statements.

**Note 3 Short Term Debt**

Ampio incurred a weighted average face interest rate of 7.3% and 6.0% on average short term debt of \$649,011 and \$23,562 outstanding during 2010 and 2009, respectively. The weighted average face interest rate was 7.6% and 6.0% on short term debt outstanding at December 31, 2010 and 2009, respectively.

***Related Party Notes Payable***

As of December 31, 2010, Ampio had \$400,000 in related party notes payable to shareholders and directors, of which \$200,000 was advanced in November and December, 2009 and \$200,000 was advanced in June, 2010. The Notes Payable are unsecured, bear interest at 6%, are subordinate to the debenture issues described below and mature on the earlier of April 30, 2011 or completion of an offering of at least \$5 million.

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

On August 8, 2010, Ampio issued \$430,000 face value Senior Convertible Unsecured Debentures with related parties (the 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 accrue interest at 8% per annum. Both the principal and interest are payable upon the earlier of (i) one business day after the closing of the Public Offering or (ii) April 30, 2011. The principal amount of the Related Party Debentures is convertible into common stock at the lower of (i) \$1.75 per share or (ii) the per-share price at which Ampio common stock is sold in an underwritten public offering that is the subject of a registration statement on Form S-1 to be filed with the SEC. Accordingly, using the \$1.75 as the conversion price, the Related Party Debentures are indexed to 245,714 shares of Ampio common stock. Each of the principal and debt conversion rates are subject to adjustment for recapitalization events or sales of equity or equity-linked contracts with a price or conversion price less than the contractual conversion price. The Related Party Debentures are subject to a default interest rate, at the creditor's option, if Ampio defaults on the debentures. The significant events that could trigger a default include Ampio's failure to service the debentures, failure to deliver conversion stock, bankruptcy and the filing of significant judgments against Ampio.

The warrants issued in connection with the Related Party Debentures have an expiration date of December 31, 2013. The exercise price of the warrants is the per-share price equal to the per-share price of the common stock sold in the Public Offering. If the Public Offering is not completed on or prior to March 31, 2011, then the exercise price will equal to the lowest closing price of Ampio common stock in the period commencing between April 1, 2011 and ending May 31, 2011. The warrants are subject to adjustment for recapitalization events. The warrants are described more fully in Note 8 Common Stock.



**Table of Contents****Senior Unsecured Mandatorily Redeemable Debentures**

Between October 22, 2010 and December 29, 2010, Ampio issued three tranches of Senior Unsecured Mandatorily Redeemable Debentures (the Redeemable Debentures) with an aggregate face value of \$1,381,000. Additionally, 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 accrue interest at 8% per annum. Both the principal and interest is mandatory convertible at the earlier of (i) one business day after the closing of a public or private offering, exceeding 10 million, or (ii) March 31, 2011. The holder has the option, at any time prior to the mandatory conversion date, to convert the debentures into common stock at the lower of (i) \$1.75 per share or (ii) the per-share price at which Ampio common stock is sold in the offering. Accordingly, using the \$1.75 as the conversion price, the Redeemable Debentures are indexed to 789,143 shares of Ampio common stock. Each of the principal and debt conversion rates are subject to adjustment for recapitalization events or sales of equity or equity-linked contracts with a price or conversion price less than the contractual conversion price. The Redeemable Debentures are subject to a default interest rate, at the creditor's option, if Ampio defaults on the debentures. The significant events that could trigger a default include Ampio's failure to service the debentures, failure to deliver conversion stock, bankruptcy and the filing of significant judgments against Ampio.

The warrants issued in connection with the Redeemable Debentures have an expiration date of December 31, 2013. The exercise price of the warrants is the per-share price equal to the per-share price of the common stock sold in the Public Offering. If the Public Offering is not completed on or prior to March 31, 2011, then the exercise price will be \$1.75. The warrants are subject to adjustment for recapitalization events. The warrants are described more fully in Note 8 – 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 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 have recorded the Senior Convertible Debentures at fair value.

Ampio also concluded that the Warrants 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 on the financing dates:

<b>Purchase price allocation:</b>	<b>Tranche 1 (a)</b>	<b>Tranche 2 (b)</b>	<b>Tranche 3 (c)</b>	<b>Tranche 4 (d)</b>
Hybrid debt instruments	\$ 598,575	\$ 407,202	\$ 1,605,248	\$ 169,073
Warrants	21,332	59,191	237,036	22,517
Derivative loss, included in derivative expense	(189,907)	(256,393)	(789,284)	(73,590)
	\$ 430,000	\$ 210,000	\$ 1,053,000	\$ 118,000

Notes:

- (a) Tranche 1 issuance date was August 10, 2010
- (b) Tranche 2 issuance dates were between October 22, 2010 and October 29, 2010
- (c) Tranche 3 issuance dates were between November 12, 2010 and November 29, 2010
- (d) Tranche 4 issuance dates were between December 13, 2010 and December 29, 2010

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**Table of Contents****Note 4 - Derivative Financial Instruments**

The components of warrant derivative liability as reflected in the balance sheet as of December 31, 2010:

Ampio's financings giving rise to derivative financial instruments:	Indexed Shares	Fair Values
<b>Warrants (dates correspond to financing):</b>		
Issued with August 10, 2010 \$430,000 face value financing	21,500	\$ 48,757
Issued with October 22, 2010 October 29, 2010 \$210,000 face value financing	24,000	53,985
Issued with November 12, 2010 November 29, 2010 \$1,053,000 face value financing	120,343	271,349
Issued with December 13, 2010 December 29, 2010 \$118,000 face value financing	13,486	24,580
	179,329	\$ 398,671

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 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.

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 year ended December 31, 2010:

	Derivative Income (Expense)
<b>Warrants (dates correspond to financing):</b>	
Issued with August 10, 2010 \$430,000 face value financing	\$ (27,425)
Issued with October 22, 2010 October 29, 2010 \$210,000 face value financing	5,206
Issued with November 12, 2010 November 29, 2010 \$1,053,000 face value financing	(34,313)
Issued with December 13, 2010 December 29, 2010 \$118,000 face value financing	(2,065)
	(58,597)
<b>Day-one derivative losses:</b>	
Issued with August 10, 2010 \$430,000 face value financing	(189,907)
Issued with October 22, 2010 October 29, 2010 \$210,000 face value financing	(256,393)
Issued with November 12, 2010 November 29, 2010 \$1,053,000 face value financing	(789,287)
Issued with December 13, 2010 December 29, 2010 \$118,000 face value financing	(73,587)
	\$ (1,367,771)

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The following table summarizes the effects on Ampio's unrealized gain (loss) associated with hybrid debt instruments recorded at fair value by type of financing for the year ended December 31, 2010:

	Unrealized Gain	Unrealized Loss	Net Unrealized Gain (Loss)
\$430,000 face value senior convertible debentures due April 30, 2011	\$	\$ (10,271)	\$ (10,271)
\$210,000 face value senior mandatorily convertible debentures due March 31, 2011	81,008		81,008
\$1,053,000 face value senior mandatorily convertible debentures due March 31, 2011		(25,955)	(25,955)
\$118,000 face value senior mandatorily convertible debentures due March 31, 2011		(7,271)	(7,271)
	\$ 81,008	\$ (43,497)	\$ 37,511

**Note 5 Fair Value Considerations**

Ampio's financial instruments include cash and cash equivalents, prepaid expenses, 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 liability. 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 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, the Company 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. See Note 4 Derivative Financial Instruments for additional information about derivative financial instruments.

Authoritative guidance defines fair value as the price that would be received to sell an asset paid to 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 the Company. Unobservable inputs are inputs that reflect the Company's 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 us for identical assets or liabilities;
- Level 2: Inputs include quoted prices for similar assets and liabilities in active or inactive markets or that are observable for the asset or liability either directly or indirectly; and
- Level 3: Unobservable inputs that are supported by little or no market activity.

The Company'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. The Company'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.



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The following table presents the Company's financial assets and liabilities that were accounted for at fair value on a recurring basis as of December 31, 2010 and 2009, by level within the fair value hierarchy:

	Level 1	Fair Value Measurements Using		Total
		Level 2	Level 3	
<b>December 31, 2010</b>				
<b>ASSETS</b>				
Money market fund (included in cash and cash equivalents)	\$ 168,876	\$	\$	\$ 168,876
<b>LIABILITIES</b>				
Hybrid debt instruments			2,133,743	2,133,743
Warrant derivative liabilities			398,671	398,671
<b>December 31, 2009</b>				
<b>ASSETS</b>				
Money market fund (included in cash and cash equivalents)	\$ 69,357	\$	\$	\$ 69,357

The warrant derivative liability was 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 December 31, 2010:

Warrants:	Tranche 1(a)	Tranche 2 (b)	Tranche 3 (c)	Tranche 4 (d)
Exercise price	\$ 1.75	\$ 1.75	\$ 1.75	\$ 1.75
Volatility	212.48%	212.48%	212.48%	212.48%
Equivalent term (years)	3.00	2.82	2.88	2.96
Risk-free interest rate	1.02%	1.02%	1.02%	1.02%

Notes:

- (a) Tranche 1 issuance date was August 10, 2010
- (b) Tranche 2 issuance dates were between October 22, 2010 and October 29, 2010
- (c) Tranche 3 issuance dates were between November 12, 2010 and November 29, 2010
- (d) Tranche 4 issuance dates were between December 13, 2010 and December 29, 2010

The warrant derivative liability was 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:

Warrants:	Tranche 1(a)	Tranche 2 (b)	Tranche 3 (c)	Tranche 4 (d)
Exercise price	\$ 1.40	\$ 1.75	\$ 1.75	\$ 1.75
Volatility	212.48%	212.48%	212.48%	212.48%
Equivalent term (years)	3.47	3.08	3.08	3.08
Risk-free interest rate	0.78%	0.53%	0.75%	1.02%

Notes:

- (a) Tranche 1 issuance date was August 10, 2010
- (b) Tranche 2 issuance dates were between October 22, 2010 and October 29, 2010
- (c) Tranche 3 issuance dates were between November 12, 2010 and November 29, 2010
- (d) Tranche 4 issuance dates were between December 13, 2010 and December 29, 2010

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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. Significant assumptions were as follows as of December 31, 2010:

<b>Hybrid Debt Instruments:</b>	<b>Tranche 1(a)</b>	<b>Tranche 2 (b)</b>	<b>Tranche 3 (c)</b>	<b>Tranche 4 (d)</b>
Exercise price	\$ 1.75	\$ 1.75	\$ 1.75	\$ 1.75
Volatility	89.69%	140.73%	140.73%	140.73%
Equivalent term (years)	0.087	0.253	0.253	0.253
Risk-free interest rate	0.19%	0.19%	0.19%	0.19%

Notes:

- (a) Tranche 1 issuance date was August 10, 2010
- (b) Tranche 2 issuance dates were between October 22, 2010 and October 29, 2010
- (c) Tranche 3 issuance dates were between November 12, 2010 and November 29, 2010
- (d) Tranche 4 issuance dates were between December 13, 2010 and December 29, 2010

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:</b>	<b>Tranche 1(a)</b>	<b>Tranche 2 (b)</b>	<b>Tranche 3 (c)</b>	<b>Tranche 4 (d)</b>
Exercise price	\$ 1.40	\$ 1.75	\$ 1.75	\$ 1.75
Volatility	262.40%	241.87%	169.50%	155.58%
Equivalent term (years)	0.483	0.440	0.374	0.296
Risk-free interest rate	0.19%	0.19%	0.19%	0.19%

Notes:

- (a) Tranche 1 issuance date was August 10, 2010
- (b) Tranche 2 issuance dates were between October 22, 2010 and October 29, 2010
- (c) Tranche 3 issuance dates were between November 12, 2010 and November 29, 2010
- (d) Tranche 4 issuance dates were between December 13, 2010 and December 29, 2010

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>Derivatives and hybrid debt instruments</b>	
	<b>2010</b>	<b>2009</b>
Balance as of January 1	\$	\$
Total losses (realized or unrealized):		
Included in earnings:	(1,330,260)	
Purchases, issuances and settlements	(1,811,000)	
<b>Balance as of December 31</b>	<b>\$ (3,141,260)</b>	<b>\$</b>
Change in unrealized losses included in earnings relating to derivatives and hybrid debt instruments held as of December 31	\$ (1,330,260)	\$

**Table of Contents****Note 6 Income Taxes**

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

	<b>Year Ended December 31,</b>	
	<b>2010</b>	<b>2009</b>
Statutory rate	(34.0)%	(34.0)%
State income taxes, net of federal income tax impact	(3.1)%	(3.3)%
Share based compensation	6.0%	0.0%
Research and development credits	(0.3)%	4.5%
Increase in valuation allowance	31.4%	32.8%
Effective tax rate	0.0%	0.0%

As of December 31, 2010 and 2009, Ampio provided a full valuation allowance against the deferred tax asset based on the weight of available evidence, both positive and negative, including the Ampio's operating loss, which indicated that it is more likely than not that such benefits will not be realized. Deferred tax assets comprised of the following:

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Deferred tax assets		
Net operating loss and credit carry forwards	\$ 2,381,000	\$ 494,000
Derivative expense	506,838	
Research and development credits		67,748
Accrued liabilities	188,547	22,000
Total deferred tax asset	3,076,385	583,748
Deferred tax liabilities		
Unrealized gain on fair value of debt instruments	(24,108)	
Total deferred tax liabilities	(24,108)	
Net deferred tax asset before valuation allowance	3,052,277	583,748
Valuation allowance	(3,052,277)	(583,748)
Net deferred tax asset	\$	\$

As of December 31, 2010, Ampio had an available net operating loss (NOL) carry forward of approximately \$6,400,000 for federal and state purposes, expiring beginning in 2029. Under the provisions of the Internal Revenue Code, substantial changes in the Company's ownership may result in limitations on the amount of the NOL carryforwards which can be utilized in future years.

The Company uses of a two-step approach for recognizing and measuring tax benefits taken or expected to be taken in a tax return and disclosures regarding uncertainties in income tax positions. Only positions that meet the more likely than not threshold are recognized for financial reporting purposes. Unrecognized tax benefits are reflected as a reduction in the Company's total deferred tax asset. A reconciliation of the beginning and ending amount of unreconciled tax benefit follows:

	<b>Unrecognized Tax Benefit</b>
Balance December 31, 2009 and 2008	\$



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Additions based on tax positions for the current year	121,133
Balance, December 31, 2010	\$ 121,133

The additions based on tax positions for the current year relates to tax credits.

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

The Company files tax returns in the United States and in the state of Colorado. The tax years since inception remain open to examinations by the major taxing jurisdictions to which the Company is subject. The Company has not filed tax returns prior to 2009.

### **Note 7 Commitments and Contingencies**

Ampio entered into a clinical research agreement with a hospital and a physician investigator, (collectively, the Parties) effective April 1, 2010. Under the terms of the clinical research agreement, Ampio agreed to fund and support a clinical trial to a minimum of \$600,000, based up on a budget to be agreed upon by the Parties. Ampio has made payments to the hospital of \$75,000 in 2010. The clinical research agreement will remain in full force until the clinical trial is completed or until terminated by one of the Parties. In conjunction with the clinical trial, Ampio entered into a master services agreement with a pharmaceutical contract research organization to provide data management and statistical services for a total of \$134,415, of which Ampio paid \$12,500 in 2010.

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During August 2010, Ampio entered into employment agreements with three of its officers. Under the employment agreements, the officers are collectively entitled to receive \$571,000 in annual salaries. Upon completion of a financing of \$10,000,000 or more, the annual salaries will collectively increase to \$825,000. The employment agreements have terms of three years.

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 days notice. Obligations under the Sponsored Research Agreement are as follows:

2011	\$ 270,537
2012	263,750
2013	263,750
2014	175,833
	\$ 973,870

Ampio leases its offices under a non-cancellable operating lease expiring in 2011. Rent expense totaled \$62,975 and \$32,433 in 2010 and 2009, respectively. The obligation under a non-cancellable operating lease is \$31,423 for 2011.

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

During November 2010, Ampio entered into a definitive merger agreement with BioSciences, Inc. (BioSciences) to exchange all of BioSciences' s outstanding shares in exchange for 7,762,839 shares of Ampio common stock. BioSciences will contribute to Ampio the previously owned 3,500,000 shares of Ampio stock at consummation of the definitive merger. In connection with the definitive merger, BioSciences has negotiated satisfaction of its notes payable to a stockholder in exchange for 500,000 shares of Ampio common stock and will satisfy BioScience' s in-the-money stock options in exchange for 405,066 shares of Ampio common stock. Per the definitive merger agreement, the merger closes at the time the 8,667,905 shares issued for considerations are registered.

**Note 8 Common Stock****Capital Stock**

Prior to the Merger, Life Sciences had 15,000,000 shares of common stock with a par value of \$0.001 and 2,000,000 share of Series A Preferred Stock authorized with a par value of \$0.001. At December 31, 2010, 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 per share.

**Capital Transactions**

Life Sciences issued 1,080,000 shares of Common Stock to its founder in December 2008 at a value of \$.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 Company valued those assets in excess of \$300,000, for financial reporting purposes the assets and liabilities have been recorded at predecessor cost. In conjunction with the asset purchase, 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 has therefore recorded the proceeds as a liability. The shares were issued in

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 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.

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Ampio 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 9 Stock Based Compensation. The remaining \$3,281 is reflected as a deferred charge in stockholders equity, and will be recognized into expense as the services are provided.

**Restricted Common Stock**

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

**Equity Incentive Plan**

Ampio adopted a stock plan in March 2010. During August of 2010, the number of shares of common stock for reserved issuance to officers, directors, employees and consultants through various means, including incentive stock options, non-qualified stock options, restricted stock grants, and other forms of equity equivalents was increased from 2,500,000 to 4,500,000. The Company granted options to purchase 2,930,000 shares in August of 2010, of which 1,820,000 vested immediately, and the remaining 1,110,000 options vest annually over two years.

The Company 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. The Company estimated a volatility factor utilizing a weighted average of comparable published volatilities of peer companies. Due to the small number option holders, the Company has estimated a forfeiture rate of zero. The Company 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, the Company has computed the fair value of all options granted during 2010 using the following assumptions:

Expected volatility	72%
Risk free interest rate	1.48%
Expected term (years)	5.5 -5.75
Dividend yield	0%

Stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding at December 31, 2009 and 2008		\$	
Granted	2,930,000	\$ 1.13	
Outstanding at December 31, 2010	2,930,000	\$ 1.13	9.63
Exercisable at December 31, 2010	1,820,000	\$ 1.19	9.63

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The weighted average grant date fair value of options was \$1.13. The Company recognized stock based compensation expense of \$1,297,083 related to stock options during the year ended December 31, 2010 and from Inception to December 31, 2010. As of December 31, 2010, the Company had \$578,452 of unrecognized compensation costs from options granted under the plan to be recognized over a weighted average remaining period of 1.62 years.

**Warrants**

Ampio issued warrants in 2010 in conjunction with its 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		\$	
Warrants issued	206,973	\$ 1.75	
Outstanding December 31, 2010	206,973	\$ 1.75	2.99

Ampio issued warrants to purchase 21,500 shares of common stock to the holders of the Related Party Debentures in August 2010. Under the most-favored-nations clause of the Related Party Debentures, those number of shares entitled to be purchased was later increased to 49,144 based on an exercise price of \$1.75 per share. The number of shares and the exercise price are subject to down round protection as follows. The exercise price will be the lesser of \$1.75 or the price of common stock to be set forth in the Offering, as defined in the agreement. In the event that an Offering has not been completed by March 31, 2011, the exercise price will be 1.75 per share. The number of shares applicable to the warrants will be the principal balance, divided by the exercise price multiplied by 20%. The warrants expire on December 31, 2103.

Ampio issued warrants to purchase 157,825 shares of common stock to the holders of the Redeemable Debentures in October through December of 2010. The number of shares and the exercise price are subject to down round protection as follows. The exercise price will be the lesser of \$1.75 or the price of common stock to be set forth in the Offering. In the event that an Offering has not been completed by March 31, 2011, the exercise price will be 1.75 per share. The number of shares applicable to the warrants will be the principal balance, divided by the exercise price multiplied by 20%. The warrants expire on December 31, 2103.

**Note 9 Stock-Based Compensation**

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

	2010	2009
Research and development expenses		
Stock options	\$ 381,093	\$
General and administrative expenses		
Common stock issued to third parties for services	1,799,219	
Stock options	915,990	
Total stock-based compensation expense	\$ 3,096,302	\$



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**Note 10 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, Michael Macaluso.

As of December 31, 2009, Life Sciences had \$100,000 in notes payable to Mike Macaluso, Life Sciences' founder, and \$100,000 payable to BioSciences. The related party notes payable are unsecured, bear interest at 6% and 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 June 30, 2010, bringing the total amount owed by us to BioSciences to \$300,000. The notes evidencing the foregoing borrowings have been extended to become due at the earlier of March 2, 2011, or closing of a financing exceeding \$5 million.

BioSciences paid operating expenses on behalf of Life Sciences, and funds were advanced and repaid between Life Sciences and BioSciences, during 2009. Disbursements to BioSciences during 2009, including prepayment of liabilities assumed under the asset purchase agreement, totaled \$111,943. BioSciences owed \$7,236 us in short-term non-interest bearing advances at December 31, 2009. 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.

Ampio 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, Ampio pays the costs associated with maintaining intellectual property subject to the license agreements. In return, Ampio is entitled to deduct twice the amounts it has paid to maintain the intellectual property from any amounts that may become due to the Institute for Molecular Medicine, Inc. under the license agreements, if and when the intellectual property becomes commercially viable and generates revenue. Ampio may cease funding the intellectual property costs and abandon the license agreements at any time. Life Sciences incurred \$61,000 and \$53,000 during 2010 and 2009, respectively, in legal and patent fees to maintain the intellectual property of the Institute for Molecular Medicine, Inc.

Immediately prior to the Merger, Chay accepted subscriptions for an aggregate of 1,325,000 shares of common stock from six officers and employees of Life Sciences, for a purchase price of \$150,183. These shares were issued immediately before 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.

Related party receivable at December 31, 2010 consisted of \$5,711 due from the Chay Control Shareholders.

**Note 11 Subsequent Events**

During January, 2011, the Company issued \$382,000 in Redeemable Debentures and warrants to purchase 43,657 share of common stock (subject to adjustment) on the same terms as the Redeemable Debentures and related warrants issued in 2010, in exchange for \$382,000 in cash.

Subsequent to December 31, 2010, under the terms of an employment agreement, the Company agreed to issue options to purchase 40,000 shares of common stock at an exercise price of \$2.20 per share. In addition, the Company's board of directors resolved to issue options to purchase 335,000 shares of stock to two of its directors and one outside consultant, issuable at fair market value of the Company's stock on the date of the closing of a public offering, provided that the offerings' gross proceeds exceed \$5 million and is completed by April 30, 2011.

The Company became obligated to grant 13,635 shares or restricted common stock to three non-employee directors on January 1, 2011 at a collective value of \$30,000 for services to be rendered in 2011, based upon the terms of their directors' compensation agreements.