Ampio Pharmaceuticals, Inc.
Form 10-K
February 09, 2012
**Table of Contents**

# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-K

**(Mark One)**

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the fiscal year ended December 31, 2011**

¨ **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** | **26-0179592** |
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification Number)** |
| **5445 DTC Parkway** | **80111** |

**Suite 925**

**Greenwood Village, Colorado**
**(Address of principal executive offices)** **(Zip Code)**

**(720) 437-6500**

**(Registrant s telephone number, including area code)**

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

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

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

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 x

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 x 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 x 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 x |
| 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 x

The aggregate market value of common stock held by non-affiliates of the Registrant as of June 30, 2011 was $177,637,356.

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 9, 2012, 31,113,921 shares of common stock were outstanding.

**Table of Contents**

**TABLE OF CONTENTS**


| | | Page |
|---|---|---|
| | **PART I** | |
| Item 1 | BUSINESS | 5 |
| Item 1A | RISK FACTORS | 21 |
| Item 1B | UNRESOLVED STAFF COMMENTS | 37 |
| Item 2 | PROPERTIES | 37 |
| Item 3 | LEGAL PROCEEDINGS | 37 |
| Item 4 | [REMOVED AND RESERVED] | 37 |
| | **PART II** | |
| Item 5 | MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES | 38 |
| Item 6 | [REMOVED AND RESERVED] | 38 |
| Item 7 | MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS | 39 |
| Item 7A | QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK | 45 |
| Item 8 | FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA | 45 |
| Item 9 | CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE | 45 |
| Item 9A | CONTROLS AND PROCEDURES | 45 |
| Item 9B | OTHER INFORMATION | 46 |
| | **PART III** | |
| Item 10 | DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE | 47 |
| Item 11 | EXECUTIVE COMPENSATION | 55 |
| Item 12 | SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS | 58 |
| Item 13 | CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE | 59 |
| Item 14 | PRINCIPAL ACCOUNTANT FEES AND SERVICES | 61 |
| | **PART IV** | |
| Item 15 | EXHIBITS AND FINANCIAL STATEMENT SCHEDULES | 63 |
| SIGNATURES | | 66 |

Exhibit 10.24
Exhibit 31.1
Exhibit 31.2
Exhibit 32.1


This Report on Form 10-K refers to trademarks, such as Optina, Ampion, Zertane and Vasaloc, which are protected under applicable intellectual property laws and are our property or the property of our subsidiaries. This Form 10-K also contains trademarks, service marks, copyrights and trade names of other companies which are the property of their respective owners. Solely for convenience, our trademarks and tradenames referred to in this Form 10-K may appear without the ® or symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames.

**Table of Contents**

*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.*

EXPLANATORY NOTE

The Registrant was a smaller reporting company under applicable SEC rules and regulations for the year ended December 31, 2011. The Registrant has determined that it will be an accelerated filer under applicable SEC rules and regulations for the year ending December 31, 2012. In accordance with the transition rules established by the SEC, the Registrant is permitted to use the scaled disclosure requirements applicable to smaller reporting companies in this Annual Report on Form 10-K. The Registrant will be transitioning to the disclosure requirements applicable to accelerated filers beginning with the Registrant s Quarterly Report on Form 10-Q for the quarterly period ending March 31, 2012.

**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 sim 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 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:

- the results and timing of our clinical trials, particularly the Optina and Ampion trials;
- the regulatory review process and any regulatory approvals that are issued or denied by the FDA, the EMEA, or other regulatory agencies;
- our need to secure collaborators to license, manufacture, market and sell any products for which we receive regulatory approval in the future;
- the results of our internal research and development efforts;
- the commercial success and market acceptance of any of our product candidates that are approved for marketing in the United States or other countries;
- the safety and efficacy of medicines or treatments introduced by competitors that are targeted to indications which our product candidates have been developed to treat;
- acceptance and approval of regulatory filings;

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

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

our plans to develop other product candidates.

You should not place undue reliance on our forward-looking statements 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.

**Table of Contents**

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.

Table of Contents

**AMPIO PHARMACEUTICALS, INC.**

**PART I**

**Item 1.** ***Business***

**Overview and General Discussion of the Business**

We are a development stage biopharmaceutical company engaged in discovering and developing innovative, proprietary pharmaceutical drugs and diagnostic products to identify, treat, and prevent a broad range of human diseases including metabolic disorders, eye disease, kidney disease, acute and chronic inflammation, and male sexual dysfunction. Our predecessor, DMI Life Sciences, Inc. ( Life Sciences ), was formed by Michael Macaluso, our chief executive officer and chairman of our Board of Directors, and incorporated in Delaware in December 2008. Life Sciences did not conduct any business activity until April 16, 2009, at which time Life Sciences purchased certain assigned intellectual property (including 107 patents and pending patent applications, business products and tangible property) from DMI BioSciences, Inc. ( BioSciences ), a scientific discovery, privately-held Colorado corporation formed in May 1990 by Dr. David Bar-Or. Life Sciences issued 3,500,000 shares of our common stock to BioSciences, and assumed certain liabilities, as consideration for the assets purchased from BioSciences.

In March 2010, Life Sciences merged with a subsidiary of Chay Enterprises, Inc. ( Chay ), a publicly-traded company incorporated in Colorado. Simultaneous with the merger, we changed our name to Ampio Pharmaceuticals, Inc. ( Ampio ), and reincorporated in Delaware. As a result of the Chay merger, we became a publicly-traded company and the outstanding Series A preferred stock of Life Sciences was converted into Life Sciences common stock, in accordance with Life Sciences amended and restated certificate of incorporation. For accounting and financial reporting purposes, Life Sciences was considered the acquirer and the Chay merger was treated as a reverse acquisition. All financial information presented in this Form 10-K for periods prior to the Chay merger reflects only that of Life Sciences, and does not reflect the pre-merger Chay assets, liabilities, or operating results. In addition, all share, per share and related Life Sciences information has been adjusted to take into account the Chay merger.

**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. The final consent agreement was approved by both parties January 5, 2011 and the merger closed on March 23, 2011. BioSciences owned the rights to one product, Zertane™, and held 32 issued patents and 31 pending patent applications related to the product. Zertane™ is a new use for tramadol hydrochloride, and was approved for marketing as a non-controlled analgesic in 1995. As of December 31, 2011, there are 32 issued patents and 34 pending applications, 3 of which are allowed related to the product. The purpose of the BioSciences acquisition was to unify our management team and ownership as (i) BioSciences owned and donated back to Ampio, 3,500,000 shares of Ampio common stock, or approximately 20% of the outstanding Ampio shares of common stock, (ii) Ampio s Zertane™ Product Manager, Bruce G. Miller, was also the president, a director and a principal Class B shareholder of BioSciences, (iii) Ampio s chief scientific officer and director, Dr. David Bar-Or, was a former executive officer and director, and a principal Class B shareholder of BioSciences, (iv) Richard B. Giles, a shareholder of BioSciences, is a member of the Board of Directors and shareholder of Ampio, and (v) several other Ampio investors were also shareholders of BioSciences.

The aggregate consideration paid by Ampio to BioSciences shareholders in the merger was 8,473,789 shares of Ampio common stock which is net of shares exchanged for options in settlement of a dispute with three option holders of BioSciences. This consideration includes the shares payable to holders of in-the-money BioSciences stock options and warrants, and holders of two BioSciences promissory notes, outstanding immediately prior to the effective time of the merger. 435,717 out-of-the-money options to purchase Ampio shares at an average price of $1.54 were also issued as consideration.

**Acquisition of Product Technology License**

In December 2011, Ampio acquired all rights, title and interest in and to the manufacturing rights and know-how relating to an oral disintegrating tablet ( ODT ) for Zertane™ for $2,000,000 plus potential future consideration based on net sales of the product. We believe that this purchase will aid in the regulatory approval and commercialization of Zertane™.

**Business Model**

We are focused on developing proprietary drugs and diagnostic products which capitalize on our own internal discoveries and our intellectual property. This intellectual property includes owned and assigned patents, filed patent applications, exclusive licenses, and trade secrets and

know-how, some of which may be the subject of future patent applications. Our intellectual property is strategically focused on three primary areas: new indications for previously approved drugs, New Molecular Entities ( NMEs ), and rapid point-of-care tests for diagnosis, monitoring and screening. Promising discoveries are evaluated, with a particular emphasis on candidates for which we believe there is a relatively quick path to commercialization. This path could be through identifying new applications, indications, dosing, or chemical combinations for compounds previously approved as safe and effective by the Federal

Table of Contents

Drug Administration ( FDA ) or other established governmental regulatory agencies. Known as drug repositioning, we believe this strategy reduces the risk of product failure due to adverse toxicology, leads to more modest investments during development, and may achieve more rapid marketing approval. With our focus on discovery and development, we will likely seek partners to help us ultimately commercialize our discoveries in the United States, Europe, and additional international markets.

We are currently in the clinical stage of development on three product candidates that were discovered by Dr. Bar-Or and chosen from our pre-clinical pipeline based upon ultimate market potential and our belief that these candidates had a relatively shorter pathway to commercialization. Two of these product candidates, Zertane™, in development for premature ejaculation ( PE ) and Optina™, in development for diabetic macular edema (DME), are repositioned drugs for which we have secured or are securing U.S. and international patent protection covering their unique formulation, application, or newly discovered formulas. Our third clinical stage product, Ampion™, is in development for treatment of osteoarthritis of the knee and is covered by a pharmaceutical composition of matter patent. However, Ampion™ is derived from human serum albumin, an already approved human blood product. As such, we believe Ampion™ will be regulated by the Center for Biologics Evaluation and Research ( CBER ) division of the FDA. Biologics are controlled by separate legislation from drugs and may have relatively fewer safety concerns in some instances as they are derived from the human body. Given the depth of our pre-clinical pipeline, we may choose to collaborate, license, or sell discoveries that we choose not to develop internally.

*New Molecular Entities*

While our products furthest along in clinical development are primarily repositioned drugs, we have several new molecular entities in our pre-clinical pipeline. As announced in our press release on November 16, 2011, we have received PTO notification of the allowance of two U.S. patents on new chemical entities that have been developed internally. The first patent is directed to a unique class of compounds that combine elements of diketopiperazines (same class as Ampion ) and methylphenidate derivatives. The second patent is directed to novel derivatives of methylphenidate (Ritalin). Both patents contain not only use claims for these novel compounds, and pharmaceutical compositions containing them, but also composition of matter claims. We believe that these compounds could have specific application to brain tumors as well as other malignancies. We could either continue to develop these products internally, or seek another pharmaceutical company partner to do so.

Our Product Pipeline

The following table summarizes the status of our products in clinical development.

**Table of Contents**

*Ampion™: 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 derived from two amino acids 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. Early in the discovery of DA-DKP by us, it became apparent that it is the natural by-product of commercially available human serum albumin ( HSA ). In the manufacture of HSA, an FDA approved human biologic, DA-DKP is the result of cleavage and cyclization from the end (N-terminus aspartate and alanine) of albumin just as we believe occurs inside the human body. Many referenced publications now mention the pharmacological, including anti-inflammatory, properties, of HSA. HSA has been used topically in the eye to decrease irritation and is now the subject of a large clinical trial, ClinicalTrials.gov Identifier NCT00796419, to decrease inflammation in the lung after trauma. It is our belief that one of the active anti-inflammatory ingredients in HSA is the DA-DKP compound.

Ampion™ was shown in vitro to have 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. There are numerous clinical areas in need of improved anti-inflammatory medications. The figure below shows a group of disease states that we believe Ampion™ could be used to treat.

Early in vitro and animal studies conducted by us and our predecessors using Ampion™ showed indications of efficacy in treating autoimmune diseases such as Multiple Sclerosis ( MS ). However, we believe that clinical trials in Multiple Sclerosis would require substantial financial and time commitments not considered viable at this time. Other clinical indications, such as Osteoarthritis, have the advantage of high prevalence within the population and well defined outcomes. Therefore, we have decided to pursue these indications as a first step to ascertain the safety and efficacy of the Ampion™ compound. Assuming a successful outcome of these initial clinical trials and proof of concept studies, we intend to actively pursue other indications such as inflammatory conditions of the eye, perioperative inflammation, and autoimmune diseases such as Crohn s disease, rheumatoid arthritis, Sjogren s syndrome, and Multiple Sclerosis. We will evaluate the potential and may choose to develop Ampion™ for these additional indications with or without collaboration with a partner.

We control a patent for pharmaceutical compositions that include DA-DKP and a patent for a method for the production of DA-DKP as a synthetic (small molecule component).

If we were to produce the molecule synthetically, we believe that most regulatory authorities would consider it an NME and, as such, would require detailed animal toxicology studies as well as extensive Phase I, II and III human studies to demonstrate safety. We believe that these studies would take 5 to 7 years and cost several hundred million dollars to complete. Alternatively, the presence of Ampion™ in the already FDA approved HSA, presents a unique option to expedite this process. As such, we have moved forward with a filtrate of HSA as an injectable for our osteoarthritis trials and commenced human efficacy studies in 2011.

**Table of Contents**

In October 2011, we released a preliminary analysis of a 60 patient Ampion™ trial for patients with osteoarthritis of the knee in Australia. Sixty patients were injected with a steroid (standard of care) with or without Ampion™. Initial results showed Ampion™ well tolerated with no additional difference in adverse events and further demonstrated synergistic efficacy in combination with the steroid. These results permitted expansion of the trial to 42 patients with an addition of two arms comparing Ampion™ as a mono-therapy versus vehicle (normal saline) which we believe will demonstrate its efficacy as an anti-inflammatory. Preliminary analysis of the pain scores portion of the trial demonstrated positive results, suggesting that Ampion may be a therapeutic alternative to steroids for osteoarthritis with a very favorable safety profile. One simple way to analyze the data is to determine the overall change in pain scores at different time points after the knee injections with Ampion or vehicle control. Pain trials are notorious for involving a significant placebo effect which usually tends to fade with passage of time. The overall difference in pain score was 41% for Ampion at 30 days post injection compared to baseline. The placebo vehicle control (saline) showed a difference of 28% over the same time period and was not statistically significant. With Ampion , 64% of patients had a clinically meaningful improvement (2 or more on the 1-10 pain scale) and 18% did not benefit. With the vehicle control/placebo, no clear difference was seen as 40% showed improvement and 40% did not benefit (Chi square=0.125).

This human data, along with our extensive in-vitro data elucidating the mechanisms of action for Ampion™, will be the basis of discussions with the FDA for definitive clinical trials. We have filed our pre IND meeting request with the FDA and we hope to rapidly gain clarity and initiate the definitive trial(s) in the second half of 2012.

Osteoarthritis ( OA ) is a degeneration of the joints, including articular cartilage, subchondrial bone, and periarticular muscles. The disease is progressive and symptoms include joint pain and inflammation, stiffness, crepitus, and limitation of movement. OA is one of the major causes of pain in the world and there are estimated to be over 80 million sufferers worldwide. In the US, there are over 29 million OA patients, of which roughly 10 million have OA of the knee. There are a variety of pharmacological treatments for the symptoms of OA, including oral NSAIDs and COX-2 inhibitors, as well as topical NSAIDs, injectable steroids and injectable hyaluronic acids. We believe that Ampion™ will compete directly with the injectables, but depending upon the ultimate safety and efficacy of the product, it might also replace some of the other forms of treatment. There are over 3 million OA patients in the US that receive some form of injection as a treatment per year. One of the market leader hyaluronic acids, Genzyme s Synvisc, reported over $300,000,000 in revenues in 2011, and clinical studies have shown modest efficacy relative to control. Steroid injections are generic, effectively off-label, and concerns have been expressed that chronic steroid injections could lead to joint destruction and tissue atrophy.

*Optina™: Repositioned Drug to Treat Diabetic Macular Edema (DME)*

Optina™ is an orally-administered compound in development for the treatment of diabetic macular edema (DME). Optina™, a low-dose danazol, is based on a derivative of the synthetic steroid ethisterone. Danazol was approved by the FDA in the 1970 s for endometriosis and, more recently, for other chronic indications such as hereditary angioedema. Dr. Bar-Or discovered an unexpected activity: low doses of danazol reverse inflammation induced increases in the permeability of blood vessels, thus reducing vascular leakage. This effect may reduce the vasogenic edema produced from multiple diseases, including diabetes. The effect of danazol is systemic , meaning that it works throughout the whole body not just in isolated regions. This oral therapy works inside the vessel and may be beneficial to multiple organs simultaneously (e.g. both the eyes and kidneys of diabetic patients).

The specific dosage is proprietary and subject to present patent filings. However, the dose is below any approved dosage tablet on the market. The existing indications of Danazol all appear to require a dosage that Dr. Bar-Or has established has no beneficial vascular effect and may, in fact, worsen vascular permeability. We believe that published literature already shows that doses lower than what is currently approved are ineffective in treatment of these existing indications. Therefore, we believe that generic approval of Danazol based on existing indications will not be possible at doses effective for treating DME. This unexpected finding that use of Danazol at low doses inhibits vascular hyperpermeability will support patentability of current patent claims. Further, since existing approved uses of Danazol are at higher doses than what can be effectively used to treat vascular hyperpermeability, we believe that completion for treatment of DME from off-label use of Danazol for existing approved uses will not be significant.

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-masked, Placebo-Controlled, Parallel Treatment Group, Dose-Ranging, Efficacy and Safety Study of Oral (Optina™) Capsules in Subjects with Diabetic Macular Edema. This ongoing trial is still in the patient recruitment stage. Patients either receive a placebo or Optina™ with the primary end point being a direct physical measurement of the edema at the back of the eye, measured with optical coherence tomography. The secondary endpoint of visual acuity is measured with lines on an eye chart. We anticipate the results of this trial will be available in mid-2012 and will provide the basis for discussion of pivotal trials to be conducted in the United States. The greater purpose of the secondary endpoint is to accurately calculate the size of study required to demonstrate efficacy using visual acuity, the current FDA guidance. Our current hypothesis is that our trials will be shorter than those for alternative treatments for this indication based on our assertion that this daily oral therapy is only effective during administration. Early indications also suggest that low dose danazol may also be efficacious in decreasing vascular permeability in the kidneys of diabetic patients

and, therefore, potentially delaying the onset of diabetic nephropathy. Development of Vasaloc™, another of our product candidates, as a separate indication is pending supportive data from the Optina trial and discussion with regulators.

Table of Contents

In 2011, we supported an FDA exempted, investigator directed trial using commercially available danazol recompounded into a low dose danazol spray for the reduction of symptoms of allergic rhinitis. We believe that this study, though small (N=20), demonstrated the ability of danazol to reduce the edema (stuffiness) in the nasal mucosa. This study added to the experience of safety and efficacy in the treatment of edema in another tissue of the human body.

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. We plan to go to the FDA to discuss the regulatory pathway and structure of the clinical trials needed for approval in the second half of 2012.

The market size for DME is difficult to measure but the demographics suggest a 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

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 the wet form of Age Related Macula Degeneration ( 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 diabetic eye disease. 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 and composition patent applications for Optina™ in a variety of ocular and other indications in the U.S. and internationally. The patent portfolio strategy is to pursue protection for both the market areas we are pursuing and the clinical data being generated.

*Zertane ™*

Zertane ™ is a new use for tramadol hydrochloride, which was approved by the FDA for marketing as a non-controlled analgesic in 1995. Based on the results of our Phase III clinical trial, which were announced in June 2011, we believe Zertane ™ can be an effective oral medication to treat premature ejaculation (PE ) in men. PE is the most common form of male sexual dysfunction and has a major impact on the quality of life for many men and their partners. The market opportunity may be large and, depending on the definition used (less than one minute or less than two minutes), the incidence is estimated to be 3 to 23% of males suffering from PE. According to Australia s Keogh Institute of Medical Research, PE is the most common sexual complaint in males. At present, no drug has been approved by the FDA for the treatment of PE. Only one product has been formally approved anywhere in the world for PE; Johnson & Johnson s Priligy, an orally administered anti-depressant in the SSRI class, which has been approved in 25 countries outside of the US and is actively promoted in 14 of these countries.

We believe that our unique formulation has numerous advantages over uncontrolled use of the generic tramadol. First, we have obtained the rights to a patented orally disintegrating tablet ( ODT ) formulation which is under license from the manufacturer. The ODT formulation is convenient and has the potential to speed absorption. In addition, based on the extensive clinical trials conducted to date, we have identified the concentration we believe has maximum beneficial effect and the least side effects: 62 mg. Decreasing the dosage to 50 mg creates a small but significant increase in therapeutic failure. Increasing the dosage to 100 mg has no

9

Table of Contents

significant effect on preventing PE but significantly increases side effects such as erectile dysfunction. We also believe that the proposed packaging of an F1 rated triple tablet blister pack significantly limits the risk of abuse and misuse as compared to the tramadol 30 tablet bottle. We believe that regulatory approval of Zertane™ would greatly alleviate concerns of physicians or pharmacists who would like to provide tramadol for this condition. Not only does it create a regulated drug supply with accurate dosage, impurity and stability testing in an ODT format, it provides indication specific product insert sheets for patient information of how best to use it to get the greatest effect with the least risk.

Our Phase III clinical trial for Zertane™ was a randomized, double-blind, placebo-controlled, multi-center study to evaluate the efficacy and safety of two doses of Zertane™ for the treatment of PE. The study was conducted at 62 sites in 11 countries in Eastern and Western Europe and included 604 intent-to-treat patients. The clinical study demonstrated statistically significant efficacy and safety for Zertane in treating PE, utilizing co-primary endpoints of Intravaginal Ejaculatory Latency Time (IELT) and a Premature Ejaculation Profile (PEP). We are in the process of preparing our regulatory dossier for Zertane and expect to submit the dossier to the Australian regulatory authority, the TGA, in 2012. Assuming that we receive regulatory approval promptly thereafter, we would expect to begin generating revenues for Zertane beginning in mid to late 2013. In the second quarter of 2012 we also expect to request a pre IND meeting with the FDA.

We are actively seeking partners to help commercialize Zertane™ in the US and worldwide. For example, in September 2011, we entered into a license, development and commercialization agreement with Daewoong Pharmaceuticals Co., Ltd., in South Korea, which grants the pharmaceutical company exclusive rights to market Zertane™ in South Korea for the treatment of PE and for a combination drug to be developed, utilizing Zertane™ and an erectile dysfunction drug. We are in discussions with other parties about other potential licensing and distribution opportunities

*Pre-Clinical Pipeline*

It has been widely reported that the average cost of developing a NME from discovery to launch is more the $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 test through rapid, low-cost preclinical proof-of-concept ( POC ) studies. Preclinical POC studies involve 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, 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. The methylphenidate derivatives are being considered for the treatment of Glioblastoma multiforme (a fatal brain cancer), inflammatory breast cancer and for autoimmune/inflammatory conditions, including ophthalmic disorders. We have also conducted early research into how copper chelating peptides, which would also be NME compounds, 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 will likely out-license these compounds to collaborators at an early stage in development.

*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 payers and quality assurance organizations that use diagnostic performance to measure and improve health care quality.

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

stroke, and pneumonia.

Table of Contents

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

We are developing a handheld Oxidation-Reduction Potential ( ORP ) diagnostic device for use at home or in healthcare facilities that will measure the oxidants/antioxidant balances in human blood and plasma. The ORP device is intended to provide 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 (or plasma) exposed to disposable electrode strips to provide a rapid test result that will measure the redox balance in human blood.

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

The pivotal clinical trials will use already available full patient samples of blood plasma to confirm efficacy with certain clinical indications and provide data for a 510(k) submission to the FDA. To obtain 510(k) clearance, we must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a device legally marketed in the U.S. for which a premarket approval application ( PMA ) was not required. We believe that there is a predicate device for ORP that was used to test the viability of organs for transplant. The FDA s goal is to review and act on each 510(k) within 90 days of submission, but it may take longer based on requests for additional information by the FDA. Most 510(k)s do not require supporting data from clinical trials, but the FDA may request such data. We have several other research initiatives underway at this time. However, these initiatives are early-stage and are not yet capable of being assessed for commercialization.

**Business Strategy**

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

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

During the discovery process, we review pertinent scientific literature and conduct searches of patent records in order to make a preliminary determination of patentability. As some 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 also target discovery and development of new uses for approved drugs because these drugs are based on compounds or medicines already approved by the FDA and/or the EMEA. We believe these 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 expedite regulatory approval and commercialization of our currently identified primary drug candidates, we are seeking clarity with the FDA and have filed or are preparing to file pre IND meeting requests. We plan also to outsource manufacturing, and, when deemed appropriate, to out-license to collaborators the rights to sell and market 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 such 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.

11

Table of Contents

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. If a product candidate receives regulatory approval and may have the potential to be successfully commercialized, we would evaluate our business model based on the current business and regulatory environments, with the possibility of shifting 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.

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
- fines, civil penalties, and criminal prosecutions.

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

Table of Contents

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

*Regulatory Approval Process for NMEs*

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

- the performance of satisfactory preclinical laboratory and animal studies under the FDA s Good Laboratory Practices regulation;
- the development and demonstration of manufacturing processes which conform to FDA-mandated cGMP;
- the submission and acceptance of an Investigational New Drug ( IND ) application which must become effective before human clinical trials may begin in the United States;
- obtaining the approval of Institutional Review Boards ( IRBs ), at each site where we plan to conduct a clinical trial to protect the welfare and rights of human subjects in clinical trials;
- the successful completion of a series of adequate and well-controlled human clinical trials to establish the safety, purity, potency and efficacy of any product candidate for its intended use; and
- 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 no 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:

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

Table of Contents

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 an 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.

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

14

Table of Contents

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, 2011, we owned or were the exclusive licensee under thirteen issued United States patents, 47 U.S. pending patent applications, 86 issued international patents, and 140 pending international patent applications. The following tabulates the U.S. and international patents owned or licensed by us, 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 |
|---|---|---|
| 5,470,750 | 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 |
| 6,974,839 | March 15, 2022 | Zertane (method of use) |
| 7,575,929 | July 5, 2025 | Diagnostic for multiple sclerosis (method claims) |
| 7,592,304 | May 25, 2022 | Metal-binding peptides that bind CuI/II metal ions (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) |
| 7,973,008 | September 29, 2020 | Metal-binding peptides that bind CuI/II metal ions (method of use) |
| 7,982,008 | July 31, 2024 | Treatment of diseases and conditions mediated by increased phosphorylation (composition of matter) |
| 8,017,728 | September 29, 2020 | Metal-binding peptides that bind CuI/II metal ions (method of use) |
| 8,076,485 | March 1, 2027 | Methylphenidate derivatives (composition of matter) |

Table of Contents

**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 |
| New Zealand | 576931 | 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 | 2252361 | March 15, 2022 | Zertane |
| China | 02809928.1 | March 15, 2022 | Zertane |
| Europe | 1397126 | March 15, 2022 | Zertane (validated in Austria, Belgium, Cyprus,Denmark, Finland, France, Germany, Greece, Ireland, Italy, Lichtenstein, Luxembourg, Monaco, Netherlands, Portugal, Spain, Sweden, Switzerland and United Kingdom, for a total of 20 issued patents) |
| Hong Kong | 1068549 | March 15, 2022 | Zertane |
| Japan | 4377585 | March 15, 2022 | Zertane |
| Mexico | 244522 | March 15, 2022 | Zertane |
| New Zealand | 528935 | March 15, 2022 | Zertane |
| Philippines | 1-2003-500893 | March 15, 2022 | Zertane |
| Singapore | 98942 | March 15, 2022 | Zertane |
| South Korea | 10-0908350 | March 15, 2022 | Zertane |
| South Africa | 2003/8067 | March 15, 2022 | Zertane |
| Europe | 1845780 | January 20, 2026 | Methylphenidate derivatives (validated in Belgium, Croatia, Czech Republic, France, Germany, Hungary, Ireland, Italy, Netherlands, Poland, Romania, Slovenia, Spain, Sweden, Turkey and United Kingdom, for a total of 16 issued patents) |
| New Zealand | 556456 | January 20, 2026 | Methylphenidate derivatives |
| Australia | 770999 | September 29, 2020 | Metal binding peptides |

Table of Contents

| Country or Region | Patent No. | Expiration Date | Description |
|---|---|---|---|
| India | 233058 | September 29, 2020 | Metal binding peptides |
| Israel | 148797 | September 29, 2014 (can be renewed for six more years | Metal binding peptides |
| New Zealand | 518266 | September 29, 2020 | Metal binding peptides |
| South Korea | 10-1062041 | September 29, 2020 | Metal binding peptides |
| Australia | 2003299568 | November 25, 2023 | Treatment of diseases and conditions mediated by increased phosphorylation |
| India | 241239 | November 25, 2023 | Treatment of diseases and conditions mediated by increased phosphorylation |
| New Zealand | 540767 | November 25, 2023 | Treatment of diseases and conditions mediated by increased phosphorylation |
| Australia | 2003279761 | October 2, 2023 | Diagnosis of diseases using diketopiperazines and truncated proteins |
| Europe | 1571970 | October 2, 2023 | Diagnosis of diseases using diketopiperazines and truncated proteins (validated in Belgium, Croatia, Denmark, Finland, France, Germany, Iceland, Ireland, Italy, Netherlands, Norway, Poland, Spain, Switzerland, Sweden and United Kingdom, for a total of 17 issued patents) |
| Japan | 4674317 | 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 |
| Australia | 2003 299933 | October 2, 2023 | Diagnosis of inflammation and ischemia using post-translationally modified proteins and peptides |
| New Zealand | 539734 | October 2, 2023 | Diagnosis of inflammation and ischemia using post-translationally modified proteins and peptides |

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

The patent positions of companies such as ours involve complex legal and factual questions and, therefore, their enforceability cannot be predicted with any certainty. Our issued and licensed patents, and those that may be issued to us in the future, may be challenged, invalidated or circumvented, and the rights granted under the patents or licenses may not provide us with meaningful protection or competitive advantages. Our competitors may independently develop similar technologies or duplicate any technology developed by us, which could offset any advantages we might otherwise realize from our intellectual property. Furthermore, even if

Table of Contents

our product candidates receive regulatory approval, the time required for development, testing, and regulatory review could mean that protection afforded us by our patents may only remain in effect for a short period after commercialization. The expiration of patents or license rights we hold could adversely affect our ability to successfully commercialize our pharmaceutical drugs or diagnostics, thus harming our operating results and financial position.

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

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

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

**Competition**

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

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

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.

Table of Contents

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.

Research and development costs were $6.6 million and $2.0 million in 2011 and 2010, 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. See Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations Results of Operations Year Ended December 31, 2011 and 2010 .

**Compliance with Environmental Laws**

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

**Product Liability and Insurance**

The development, manufacture and sale of pharmaceutical products involve inherent risks of adverse side effects or reactions that can cause bodily injury or even death. Product candidates we succeed in commercializing could adversely affect consumers even after obtaining regulatory approval and, if so, we could be required to withdraw a product from the market or be subject to administrative or other proceedings. As we are not now manufacturing, marketing or distributing pharmaceutical products or diagnostics, we have elected not to obtain product liability insurance at the current time. We expect to obtain clinical trial liability coverage for human clinical trials, and appropriate product liability insurance coverage for products we manufacture and sell for human consumption. The amount, nature and pricing of such insurance coverage will likely vary due to a number of factors such as the product candidate s clinical profile, efficacy and safety record, and other characteristics. We may not be able to obtain sufficient insurance coverage to address our exposure to product recall or liability actions, or the cost of that coverage may be such that we will be limited in the types or amount of coverage we can obtain. Any uninsured loss we suffer could materially and adversely affect our business and financial position.

**Employees**

As of February 9, 2012, we had 12 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, Suite 925, Greenwood Village, Colorado 80111 USA, and our phone number is (720) 437-6500.

We maintain a website on the internet at *www.ampiopharma.com*. 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)*, 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.

Table of Contents

**Item 1A.** ***Risk Factors***

**Risks Related to Our Business**

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

We have experienced significant net losses since inception. As of December 31, 2011, we had an accumulated deficit of approximately $28.2 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 plan to seek licensing and collaboration arrangements, which may provide us with potential milestone payments and royalties and those arrangements, if obtained, will be our primary source of revenues for the next several years. For example, in September 2011, we entered into a license, development and commercialization agreement with a major Korean pharmaceutical company with respect to Zertane in South Korea, which provided for a $500,000 upfront payment and future milestone payments that are contingent upon achievement of regulatory approvals and cumulative net sales targets. We cannot be certain that this or other licensing or collaboration arrangements will be concluded, or that the terms of those arrangements will result in our receiving material revenues. To obtain revenues from product candidates, we must succeed, either alone or with others, in developing, obtaining regulatory approval for, and manufacturing and marketing drugs with significant market potential. We may never succeed in these activities, and may never generate revenues that are significant enough to achieve profitability.

***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, as well as to commercialize and manufacture product candidates. We currently have only one collaboration agreement in effect, which relates to Zertane in South Korea. Collaboration agreements typically call for milestone payments that depend on successful demonstration of efficacy and safety, obtaining regulatory approvals, and clinical trial results. Collaboration revenues are not guaranteed, even when efficacy and safety are demonstrated. The current economic environment may result in potential collaborators electing to reduce their external spending, which may prevent us from developing our product candidates.

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

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

delay the development or commercialization of our product candidates in favor of developing or commercializing another party s product candidate; or

decide to terminate or not to renew the collaboration for these or other reasons.

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

Table of Contents

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

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

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

- continue to fund, or initiate funding for, clinical trials of Ampion and Optina;
- prepare for and apply for regulatory approval for our product candidates;
- commercialize Zertane, including regulatory and contract manufacturing;
- further develop and assess the clinical utility of the oxidation reduction potential (ORP) diagnostic device, or 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 currently have only one collaboration agreement in effect, which relates to Zertane in South Korea.

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

***Ampion, Optina and the ORP Device are currently undergoing, or are expected to undergo, clinical trials that are time-consuming and expensive, the outcomes of which are unpredictable, and for which there is a high risk of failure.***

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

Our product development programs are at various stages of development. We continue to work toward completion and analysis of clinical trials for three primary products: Ampion, Optina and the ORP device. On October 13, 2011, we announced the completion of the treatment phase of our 60 patient Ampion trial for patients with moderate to severe osteoarthritis of the knee. On October 26, 2011, we released a preliminary summary analysis of the results. Based on these results, the Australian regulators have approved Ampion to be tested as a stand-alone therapy and the trial has been expanded to include two additional arms of the study: Ampion alone versus saline alone. On January 31, 2012 we announced the preliminary analysis of this trial which demonstrated positive results and suggested that Ampion may be a therapeutic alternative to steroids for osteoarthritis with a very favorable safety profile. We have filed a pre IND meeting request with the FDA to gain clarity and initiate definitive trial(s) in the second half of 2012. With respect to Optina, we previously 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. In January 2011, St. Michael s began enrolling patients in the trial and in February 2011, the first dose was administered to an enrolled patient. The Optina patient enrollment is continuing, and the results are expected to be available in the second quarter of

Table of Contents

2012. Additionally, a proof of concept trial for allergic rhinitis utilizing a low dose of danazol, the main formulation of Optina, was completed and shown to support the mechanism of action. We also are now testing the prototype ORP device to measure oxidation and antioxidation levels in the blood. The ORP development project is ongoing and may be completed during the second quarter of 2012. Our Vasaloc drug candidate for diabetic nephropathy, which (like Optina) contains danazol, will be evaluated for clinical trial after completion and evaluation of the Optina trial.

An unfavorable outcome in one or more trials for Ampion, Optina or the ORP Device would be a major set-back for the development programs for these product candidates and for us. Due to our limited financial resources, an unfavorable outcome in one or more of these trials may require us to delay, reduce the scope of, or eliminate one of these product development programs, which could have a material adverse effect on us and the value of our common stock.

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

- a product candidate is ineffective, inferior to existing approved medicines, unacceptably toxic, or has unacceptable side effects;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- the results may not confirm the positive results of earlier testing or trials; and
- the results may not meet the level of statistical significance required by the U.S. Food and Drug Administration, or FDA, or other regulatory agencies.

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

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

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

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

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;

manufacturing sufficient quantities of a product candidate;

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

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

determining dosing and making related adjustments; and

Table of Contents

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;

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.

Table of Contents

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

Assuming successful completion of clinical trials, we expect to submit NDAs to the FDA at various times in the future under §505(b)(2) of the Food, Drug and Cosmetic Act, as amended, or the FDCA. NDAs submitted under this section are eligible to receive FDA new drug approval by relying in part on the FDA s findings for a previously approved drug. The FDA s 1999 guidance on §505(b)(2) applications states that new indications for a previously approved drug, a new combination product, a modified active ingredient, or 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.

***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 trial for Ampion is being conducted in Australia, the clinical trial for Optina is being conducted in Canada and the Zertane clinical trials were conducted in Europe. 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.

Table of Contents

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

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

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

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

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

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

Our success is dependent in large part upon the continued services of our Chief Scientific Officer, Dr. David Bar-Or. We have an employment agreement with Dr. Bar-Or and a research agreement with Trauma Research, LLC, an entity owned by Dr. Bar-Or that conducts research and development activities on our behalf. These agreements are terminable on short notice for cause by us or Dr. Bar-Or and may also be terminated

without cause under certain circumstances. We do not maintain key-man life insurance on Dr. Bar-Or, although we may elect to obtain such coverage in the future. If we lost the services of Dr. Bar-Or for any reason, our clinical testing and other product development activities may experience significant delays, and our ability to develop and commercialize new product candidates may be diminished.

Table of Contents

***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, 2011, we had cash of approximately $11.4 million. We have not received, and do not expect to receive for several years, any revenues from the commercialization of our product candidates. In March and April 2011, we obtained a total of $10.9 million in net proceeds from the sale of common stock in a private placement, and in December 2011, we obtained a total of approximately $8.5 million in net proceeds from the sale of common stock in a registered direct offering. 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 our research and development programs;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we obtain;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory clearances to market our product candidates.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through 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 contracted collaborator 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.

Table of Contents

***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.

Once regulatory approval is obtained, a marketed product and its manufacturer are subject to continual review. The discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer or manufacturing facility, including withdrawal of the product from the market. Any manufacturers with which we contract are required to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs. A failure of any of our contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in the launch of products based on our product candidates into the market. Failure by third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, revocation or suspension of marketing approval for any products granted pre-market approvals, seizures or recalls of products, operating restrictions, and criminal prosecutions.

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

We do not 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.

Table of Contents

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;
- obtain patent and/or other proprietary protection for our product candidates;
- obtain required regulatory approvals; and
- obtain collaboration arrangements to commercialize our product candidates.

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

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

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

The risk that we may be sued on product liability claims is inherent in the development and commercialization of pharmaceutical products. Side effects of, or manufacturing defects in, products that we develop which are commercialized by any collaborators could result in the deterioration of a patient s condition, injury or even death. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits increases. Claims may be brought by individuals seeking relief for themselves or by individuals or groups seeking to represent a class. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of the affected products.

Although we maintain general liability and product liability insurance, this insurance may not fully cover potential liabilities. In addition, inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercial production and sale of any of our product candidates that receive regulatory approval, which could

adversely affect our business. Product liability claims could also harm our reputation, which may adversely affect our collaborators ability to commercialize our products successfully.

Table of Contents

***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 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

Table of Contents

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, 2011, we owned or were the exclusive licensee under 13 issued United States patents, 47 U.S. pending patent applications, 86 issued international patents, and 140 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;
- 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

Table of Contents

metabolic disorders, cancer, inflammatory responses, and the other fields in which we are developing products. These could materially affect our ability to develop our product candidates or sell our products if approved. Because patent applications can take many years to issue, there may be currently pending applications unknown to us that may later result in issued patents that our product candidates or compounds may infringe. These patent applications may have priority over patent applications filed by us.

We periodically conduct searches to identify patents or patent applications that may prevent us from obtaining patent protection for our compounds or that could limit the rights we have claimed in our patents and patent applications. Disputes may arise regarding the source or ownership of our inventions. It is difficult to determine if and how such disputes would be resolved. Others may challenge the validity of our patents. If our patents are found to be invalid, we will lose the ability to exclude others from making, using or selling the compounds or products addressed in those patents. In addition, compounds or products we may license may become important to some aspects of our business. We generally will not control the prosecution, maintenance or enforcement of patents covering licensed compounds or products.

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

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

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

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

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

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

32

Table of Contents

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

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

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

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

**Risks Related to Our Common Stock**

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

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

- any actual or perceived adverse developments in clinical trials for Ampion, Optina or the ORP device;
- any licensee s termination of a license, such as that experienced with Zertane in 2010;
- any actual or perceived difficulties or delays in obtaining regulatory approval of any of our product candidates in the United States or other countries once clinical trials are completed;
- any finding that our product candidates are not safe or effective, or any inability to demonstrate clinical effectiveness of our product candidates when compared to existing treatments;
- any actual or perceived adverse developments in repurposed drug technologies, including any change in FDA policy or guidance on approval of repurposed drug technologies for new indications;

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

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

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

Table of Contents

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

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

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

economic and other external factors beyond our control; and

sales of stock by us or by our shareholders.

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

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

a limited availability for market quotations for our securities;

reduced liquidity with respect to our securities;

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

activity in the secondary trading market for our common stock;

limited amount of news and analyst coverage; and

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

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

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

As of December 31, 2011, our directors, executive officers and their affiliates beneficially owned approximately **25.4**% of our outstanding common stock. These shareholders may control effectively the outcome of actions taken by us that require shareholder approval.

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

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

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

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

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

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

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

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

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

Table of Contents

***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.***

We have no plans to pay dividends on our common stock. We generally intend to invest future earnings, if any, to fund our growth. Any payment of future dividends will be at the discretion of our Board of Directors and will depend on, among other things, our earnings, financial condition, capital requirements, level of indebtedness, statutory and contractual restrictions applying to the payment of dividends and other considerations our Board of Directors deem relevant. Any future credit facilities or preferred stock financing we obtain may further limit our ability to pay dividends on our common stock.

***Future sales of shares by existing stockholders could cause our stock price to decline.***

As of February 9, 2012, we had 31,113,921 shares of our common stock outstanding. Of these shares, 8,667,905 shares of common stock were issued to former BioSciences shareholders in connection with the acquisition of BioSciences in March 2011. Subsequently, 194,116 of these shares were cancelled as a result of a settlement with three shareholders, resulting in 8,473,789 net shares outstanding. The net shares issued are free-trading, subject to the provisions of lock-up agreements under which such shareholders were prohibited from selling, pledging or hypothecating our common stock until December 31, 2011. On October 5, 2011, the Board of Directors of Ampio approved the commencement of a program under which certain of such former BioSciences shareholders voluntarily agreed to a six-month extension, from December 31, 2011 to June 30, 2012, of these lock-up restrictions. In consideration for agreeing to such extension, the former BioSciences shareholders who signed modified lock-up agreements have been permitted to sell up to 5% of their shares per month beginning September 15, 2011 and, effective immediately upon their establishing trading accounts that are approved by Ampio in order to permit administration and enforcement of the modified lock-up restrictions. The holders of approximately 54% of the net shares of Ampio common stock issued to former BioSciences shareholders signed modified lock-up agreements.

Another former BioSciences shareholder, holding the largest number of shares of Ampio common stock of all former BioSciences shareholders (approximately 18% of the 8,473,789 shares), has also signed a modified lock-up agreement extending restrictions on most (but not all) of such shareholder s shares through June 30, 2012, with exceptions for certain third party transfers and/or pledges of the shares as collateral for a loan, where the lender has the right to recover the collateral and sell a portion of the shares in certain circumstances, including in the event that our stock price changes.

In the aggregate, approximately 72% of the 8,473,789 shares of Ampio common stock issued to former BioSciences shareholders are subject to modified lock-up agreements, with the remaining 28% of the 8,473,789 shares (approximately 2.4 million shares) being freely tradable.

Executive and non-executive officers of BioSciences who received stock as a result of the BioSciences acquisition, and executive and non-executive officers and employees of Ampio at the time of the acquisition, have signed lock-up agreements covering the shares of our common stock owned by such persons for a period through February 28, 2012. Of these individuals, each holder who currently owns more than 85,000 shares of Ampio common stock has agreed to extend these lock-up restrictions to July 15, 2012, subject to certain exceptions. In connection with his departure from the Company on January 9, 2012, the lock-up restrictions with respect to Don Wingerter Jr., our former Chief Executive Officer, will expire 90 days after the date of Mr. Wingerter s departure, on April 8, 2012.

Sales of a substantial number of shares of our common stock in the public market by existing stockholders whether upon the expiration of the above described lock-up agreements or otherwise, could cause the market price of our common stock to decline. If there are more shares of common stock offered for sale than buyers are willing to purchase, then the market price of our common stock may decline to a market price at which buyers are willing to purchase shares.

Table of Contents

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

None.

**Item 2.** ***Properties***

We maintain our headquarters in leased space in Greenwood Village, Colorado, for a monthly rental of approximately $8,500. The lease expires in July 2014. We anticipate that the lease can be renewed on terms similar to those now in effect.

**Item 3.** ***Legal Proceedings***

We are currently not a party to any material legal or administrative proceedings and are not aware of any 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**

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

| | Common Stock | |
|---|---|---|
| | High | Low |
| First quarter 2010 | $ 1.50 | $ 1.50 |
| Second quarter 2010 | $ 4.50 | $ 0.75 |
| Third quarter 2010 | $ 3.50 | $ 1.00 |
| Fourth quarter 2010 | $ 3.00 | $ 2.01 |
| First quarter 2011 | $ 8.75 | $ 2.20 |
| Second quarter 2011 | $ 8.61 | $ 2.80 |
| Third quarter 2011 | $ 9.19 | $ 4.32 |
| Fourth quarter 2011 | $ 8.26 | $ 3.77 |

As of February 2, 2012, there were of record approximately 1,650 holders of our common stock.

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

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

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

**Equity Compensation Plan Information**

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

| Plan Category | Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (a) | Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b) | Number of Securities Remaining available for Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c) |
|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| Equity compensation plans approved by security holders | 3,832,874 | $ | 1.74 | 1,551,887 |
| Equity compensation plans not approved by security holders | | | | |
| Total | 3,832,874 | $ | 1.74 | 1,551,887 |

**Item 6.** ***(Removed and Reserved)***

Table of Contents

**Item 7.** ***Management s Discussion and Analysis of Financial Condition Results of Operations***

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing elsewhere in this report. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the Risk Factors section of this Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

**Overview**

We are a development stage biopharmaceutical company engaged in discovering and developing innovative, proprietary pharmaceutical drugs and diagnostic products to identify, treat and prevent a broad range of human diseases including metabolic disorders, eye disease, kidney disease, acute and chronic inflammation and male sexual dysfunction. 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.

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. On May 19, 2011, our common stock commenced trading on the NASDAQ Capital Market under the symbol AMPE , at which time our common stock ceased trading on the OTC Bulletin Board.

On March 23, 2011, Ampio acquired all of the outstanding stock of BioSciences for 8,667,905 shares of Ampio common stock (the merger stock ). Ampio acquired BioSciences in order to obtain all rights to Zertane, BioSciences male sexual dysfunction drug for PE. The business combination occurred following the satisfaction or waiver of all conditions to closing. As called for in the merger agreement, Ampio issued 405,066 shares of merger stock to holders of BioSciences in-the-money stock options and warrants, 500,000 shares of merger stock to holders of two BioSciences promissory notes in extinguishment of the notes, and placed 250,000 shares of merger stock in an indemnification escrow until December 31, 2011. The remaining 7,512,839 shares of merger stock were issued to the holders of BioSciences common stock on a pro rata basis. All shares were subject to receipt from each such stockholder of a signed lock-up agreement under which each agreed not to sell, pledge or hypothecate the merger stock until on or after December 31, 2011. Certain of these lock-up agreements were modified after September 30, 2011. As required by the merger agreement, at the closing BioSciences donated back to Ampio s capital 3,500,000 shares of Ampio common stock formerly owned by BioSciences. Ampio separately issued 212,693 options in replacement of 250,850 Biosciences options that were out-of-the-money as of the date of execution of the merger agreement. On June 17, 2011, an additional 223,024 options were issued in exchange for 98,416 previously issued shares of Ampio stock pursuant to an agreement with three former BioSciences option holders. During 2011, we filed a claim on the indemnification escrow and were awarded 95,700 shares of Ampio stock to reflect the full value of the 223,024 options issued in exchange for the shares relinquished. On December 31, 2011 the remaining 154,300 indemnification escrow shares were allocated to the appropriate shareholders. All shares donated back, relinquished and escrow shares awarded to Ampio have been cancelled.

Table of Contents

**Business Update/Financing Activities**

On February 28, 2011, we issued an aggregate of 1,281,852 shares of our common stock in retirement of the convertible debentures issued to 21 holders of such debentures. The convertible debentures were previously issued in three tranches. The first tranche consisted of $430,000 in principal amount issued in August 2010 to two directors and an affiliate of one of those directors. The second tranche consisted of $1.38 million in principal amount issued in October, November and December 2010 to 19 unaffiliated holders (seven of whom were already our shareholders), and the third tranche in January 2011 was an increase of $382,000 in principal amount of debentures purchased by five holders who originally purchased debentures in November 2010. The principal amount of the debentures and accrued interest were converted into our common stock at $1.75 per share. Debentures held by two directors and an affiliate of one director were converted on the same terms as debentures held by unaffiliated parties. The debenture holders were collectively issued warrants to purchase 256,389 shares of our common stock as additional consideration for the purchase of the debentures. Those warrants are exercisable at $1.75 per share.

On March 31, April 8 and April 18, 2011, Ampio closed private placements of its common stock (the 2011 Private Placement ). A total of 5,092,880 shares of common stock were issued resulting in gross proceeds of $12,732,200, of which the Company received net proceeds of $10,916,538, after placement agent commissions, non-accountable expenses and other offering costs. The placement agent also received 509,288 warrants valued at $888,664 in connection with the closing. We applied a portion of the private placement proceeds in March and April 2011 to pay accrued expenses, to pay accrued salaries owed to certain of our officers, to reduce accounts payable, and to repay a $100,000 promissory note to Michael Macaluso, our chief executive officer and chairman of the board.

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

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

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

On December 27, 2011, Ampio completed a registered direct offering of its common stock A total of 2,220,255 shares were issued at a price of $4.25 per share resulting in gross proceeds of $9,436,084 of which Ampio received net proceeds of $8,454,001, after placement agent commissions, non-accountable expenses and other offering costs. No warrants were issued.

The net proceeds of the 2011 offerings have been or will be used for general corporate purposes and working capital, including completion of the Ampion and Optina clinical trials and costs related to the regulatory approval and commercialization of Zertane.

Table of Contents

**Management Update**

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

***Lockups***

On October 5, 2011, the Ampio Board of Directors approved a modified lock-up program under which certain former BioSciences stockholders who voluntarily agreed to a six-month extension of existing lock-up restrictions to June 30, 2012, would be permitted to sell up to 5% of their shares per month effective September 15, 2011 and immediately upon their establishing trading accounts that are approved by Ampio. The holders of approximately 54% of the total 8,473,789 net merger shares agreed to these terms. In addition, a group holding approximately 18% of the merger stock, have agreed to a lock-up that allows them to collateralize a loan provided that shares cannot be sold unless the share price falls below a defined floor or, if not used as collateral, allows the monthly sale of 5% of the holdings beginning January 15, 2012 through June 30, 2012.

In addition, executive officers and directors of BioSciences and Ampio agreed to lock-up restrictions expiring on February 28, 2012. In October 2011, Ampio management and employees holding an aggregate of 8,250,000 shares agreed to extend their existing lock-up restrictions until July 15, 2012, but they will not be prohibited from selling a pro rata portion of their holdings of a total of up to 1,000,000 shares for all selling stockholders should Ampio decide to sell stock in a future public offering

**Known Trends or Future Events; Outlook**

We have not generated any significant revenues and have therefore incurred significant net losses totaling $28.2 million since our inception in December 2008. The assets we purchased from BioSciences in April 2009 generated minimal revenues prior to their acquisition. Unless we secure a collaborator for one or more of our product candidates and generate substantial license revenues, we will need additional capital in order to continue to implement our business strategy. Although we have raised capital in the past and raised net proceeds of $19.4 million through the sale of common stock in 2011, we cannot assure you that we will be able to secure such additional financing, if needed, or that it will be adequate to execute our business strategy. Even if we obtain additional financing, it may be costly and may require us to agree to covenants or other provisions that will favor new investors over existing shareholders. 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 try to limit the extent of these losses by entering into co-development or collaboration agreements with one or more strategic partners, such as the license agreement entered into in September 2011 with a major Korean pharmaceutical company.

At this time, due to the risks inherent in the clinical trials and the stage of development of our product candidates, we are unable to estimate with any certainty the costs we will incur for the continued development of our product candidates for commercialization as clinical development timelines, probability of success, and development costs vary widely. While our current focus is primarily on obtaining regulatory approval for Zertane and advancing the clinical trials of Ampion and Optina, and the development of the ORP device, we anticipate that we will make determinations on an ongoing basis as to which product candidates to pursue and how much funding to direct to each product candidate in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment of each product candidate s commercial potential and our financial position. Our current trial for Optina, which contains repurposed danazol, is primarily focused on diabetic macula edema. Our Vasaloc drug candidate, which also contains danazol, for diabetic nephropathy will be evaluated for clinical trial after completion and evaluation of the Optina trial. The Ampion trial is currently focused on osteoarthritis in the knee. The treatment phase of this first Ampion trial is completed and we are proceeding with an expanded stand-alone therapy with Ampion alone versus saline alone. On January 31, 2012 we announced the preliminary analysis of this trial which demonstrated positive results, suggesting that Ampion may be a therapeutic alternative to steroids for osteoarthritis with a very favorable safety profile. We cannot forecast with any degree of certainty which product candidates will be subject to future collaborative or licensing arrangements, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our product candidate plans and capital requirements.

**Significant Accounting Policies and Estimates**

Our 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-

41

Table of Contents

lived assets, fair value of our derivative instruments, allowances and contingencies. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The methods, estimates, and judgments used by us in applying these most critical accounting policies have a significant impact on the results we report in our financial statements.

***Patents***

Costs of establishing patents consisting of legal fees paid to third parties and related costs are currently expensed as incurred. We will continue this practice unless we can demonstrate that such costs add economic value to our business, in which case we will capitalize such costs as part of intangible assets. The primary consideration in making this determination is whether or not we can demonstrate that such costs have, in fact, increased the economic value of our intellectual property. Legal and related costs which do not meet the above criteria will be expensed as incurred. The $500,000 fair value of the Zertane patents acquired in connection with the March 2011 acquisition of BioSciences is being amortized over the remaining U.S. patent lives of approximately 11 years.

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

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

***Product Technology License***

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

***Research and Development***

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.

***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.

***Derivatives***

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

***Income Taxes***

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

Table of Contents

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

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

***Revenue***

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

***Expenses***

***Research and Development***

Research and development costs are summarized as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2011 | 2010 |
| Labor | $ 1,364,000 | $ 889,000 |
| Patent costs | 962,000 | 399,000 |
| Stock-based compensation | 316,000 | 381,000 |
| Clinical trials and sponsored research | 1,694,000 | 239,000 |
| Technology license | 2,000,000 | |
| Consultants | 312,000 | 64,000 |
| | $ 6,648,000 | $ 1,972,000 |

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 2011 relates to our primary product candidates as we began Ampion and Optina clinical trials early in 2011and acquired a $2,000,000 product technology license related to our Zertane product. We also continued to maintain and strengthen our patent portfolio on our primary product candidates. Labor costs increased as a result of several employees having job responsibilities change from administrative to research and development.

***General and Administrative***

General and administrative costs are summarized as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2011 | 2010 |
| Labor | $ 888,000 | $ 775,000 |
| Stock-based compensation | 1,641,000 | 2,715,000 |
| Professional fees | 656,000 | 863,000 |
| Occupancy, travel and other | 932,000 | 225,000 |
| Directors fees | 387,000 | 154,000 |
| | $ 4,504,000 | $ 4,732,000 |

Professional fees consist primarily of legal, audit and accounting costs, 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

decrease in expenses in 2011 relates primarily to decreased stock-based compensation offset principally by increases in outside directors fees and occupancy, travel and other resulting from expansion of operations. The director fees resulted from the adoption of a compensation plan for independent directors in August 2010. With the acceleration of research and development, job responsibilities of several existing employees changed from administrative functions so that the costs associated with those employees were more appropriately allocated to research and development beginning April 1, 2011.

***Derivative Expense***

We recorded $1.6 million and $1.4 million in non-cash derivative expense in 2011 and 2010, respectively, in connection with our hybrid financial instruments consisting of debentures and related warrants. The expense relates to the fair value at inception and

Table of Contents

subsequent changes in fair value of the debentures issued in 2011 and 2010 stemming from the embedded derivative features (conversion options, down-round protection and mandatory conversion provisions) and the changes in fair value of warrants issued in conjunction with the debentures.

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

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

***Foreign income tax expense***

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

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

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

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

***Net Cash from Financing Activities***

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

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

**Liquidity and Capital Resources**

At December 31, 2011, Ampio had cash of $11,362,000 and payables of $631,000.

As a development stage biopharmaceutical company, we have not generated significant revenue as our primary activities are focused on research and development, advancing our primary product candidates, and raising capital. In the years ended December 31, 2011, we used net cash in operating activities of $9.1 million and inception to date of $13.1 million. During 2011, we funded our operations through sales of common stock and debt securities. The net proceeds of these activities in 2011 were $19.8 million. Cash on hand at December 31, 2011 was $11.4 million.

We have prepared a budget for 2012 which reflects cash requirements for fixed, on-going expenses such as payroll, legal and accounting, patents and overhead at an average cash burn rate of between $450,000 and $500,000 per month. Additional funds in the range of $150,000 per month are planned for regulatory approvals, completion of clinical trials, and planning for commercialization of Zertane. We expect our cash reserves

to last into the third or fourth quarter of 2013. To the extent we decide to further expand our clinical trials, it will be necessary to raise additional capital and/or enter into licensing or collaboration agreements. At this time, we expect to satisfy our future cash needs through private or public sales of our securities or debt financings. We cannot be certain that financing will be available to us on acceptable terms, or at all. Over the last two years, volatility in the financial markets has adversely affected the market capitalizations of many pharmaceutical companies and generally made equity and debt financing more difficult to obtain. This volatility, coupled with other factors, may limit our access to additional financing.

Table of Contents

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

**Off Balance Sheet Arrangements**

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

**Recently Issued Accounting Pronouncements**

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

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

**Impact of Inflation**

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

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

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

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

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

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

**None**

**Item 9A.** ***Controls and Procedures***

**Evaluation of Disclosure Controls and Procedures**

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

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

Table of Contents

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Rules 13a-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2011. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ( COSO ) in *Internal Control-Integrated Framework*. Our management has concluded that, as of December 31, 2011, our internal control over financial reporting is effective based on these criteria.

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

**Changes in Internal Control over Financial Reporting**

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

**Item 9B.** ***Other Information***

None.

Table of Contents

## PART III

**Item 10.** ***Directors and Executive Officers, and Corporate Governance***

The following table sets forth the names, ages and positions of our executive officers and directors as of February 9, 2012.

| Name | Age | Position With Ampio | Principal Occupation and Areas of Relevant Experience For Directors | Director Since |
|---|---|---|---|---|
| Michael Macaluso | 60 | Chief Executive Officer and Chairman of the Board | Mr. Macaluso founded Life Sciences and has been a member of board of directors of Life Sciences, our predecessor, since its inception. Mr. Macaluso has also been a member of our Board of Directors since the merger with Chay Enterprises in March 2010 and our Chief Executive Officer since January 9, 2012. Mr. Macaluso was appointed president of Isolagen, Inc. (AMEX: ILE) and served in that position from June 2001 to August 2001, when he was appointed chief executive officer. In June 2003, Mr. Macaluso was re-appointed as president of Isolagen and served as both chief executive officer and president until September 2004. Mr. Macaluso also served on the board of directors of Isolagen from June 2001 until April 2005. From October 1998 until June 2001, Mr. Macaluso was the owner of Page International Communications, a manufacturing business. Mr. Macaluso was a founder and principal of International Printing and Publishing, a position Mr. Macaluso held from 1989 until 1997, when he sold that business to a private equity firm.<br><br>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. | March 2010 |
| David Bar-Or, M.D. | 63 | Chief Scientific Officer and Director | Dr. Bar-Or has served as our chief scientific officer since March 2010. Dr. Bar-Or also served as our chairman of the board from March 2010 until May 2010. From April 2009 until March 2010, he served as chairman of the board and chief scientific officer of Life Sciences. Dr. Bar-Or is currently the director of Trauma Research at Swedish Medical Center, Englewood, Colorado, and St. Anthony s Hospital, Denver, Colorado. Dr. Bar-Or is principally responsible for the patented and proprietary technologies acquired by us from BioSciences in April 2009, having been issued over 50 patents and having filed or co-filed almost 120 patent applications. Dr. Bar-Or has authored or co-authored over 80 peer-reviewed journal articles and is the recipient of the Gustav Levi Award from the Hadassah/Mount Sinai Hospital, New York, New York, the Kornfield Award for an outstanding MD Thesis, the Outstanding Resident Research Award from the Denver General Hospital, and the Outstanding Clinician Award for the Denver General Medical Emergency Resident Program. Dr. Bar-Or received his medical degree from 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. | March 2010 |

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.

Table of Contents

| Name | Age | Position With Ampio | Principal Occupation and Areas of Relevant Experience For Directors | Director Since |
|---|---|---|---|---|
| Dr. Vaughan L. Clift | 50 | Chief Regulatory Affairs Officer | Dr. Clift has been employed by us since March 2010 and was employed by Life Sciences from May 2009 until March 2010. From 2005 to 2009, Dr. Clift was the chief executive officer of Detectachem LLC, a Houston, Texas-based manufacturer of a hand-held explosive and narcotics detection device. Dr. Clift was the Vice President of Operations for Isolagen from 2002 until 2005. From January 2001 to May 2002, Dr. Clift researched home oxygen therapy systems while developing an oxygen system for NASA. From July 1997 to January 2001, he was Chief Scientist of DBCD, Inc., a medical device company that manufacturers 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[(1)(2)(3)] | 68 | 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., a medical products company he founded in 1986 that focused on the regenerative medicine market. From 1989 through July 2007, he was Chairman and Chief Executive Officer of ThermoGenesis Corp. Mr. Coelho served as Vice President of Research & 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.<br><br>Mr. Coelho s long tenure as a chief executive officer of a public medical device company, as director of a public pharmaceutical company, prior and current public company board experience, and knowledge of corporate finance and governance as an executive and director, as well as his demonstrated success in developing patented technologies, led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure. | April 2010 |

Table of Contents

| Name | Age | Position With Ampio | Principal Occupation and Areas of Relevant Experience For Directors | Director Since |
|---|---|---|---|---|
| Richard B. Giles[1][2][3] | 62 | Director | 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 & 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.<br><br>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. | August 2010 |
| David R. Stevens, Ph.D.[1][2] | 62 | Director | Dr. Stevens has served as a member of our Board of Directors since June 2011. Dr. Stevens is currently Executive Chairman of Cedus, Inc., a privately-held biopharmaceutical company. In addition, Dr. Stevens serves as a director of Poniard Pharmaceuticals, Inc., a NASDAQ-listed biopharmaceutical company focused on the development and commercialization of cancer therapeutics, where he has been a member of the board of directors since May 2004. Dr. Stevens is a member of the nominating and corporate governance committee, and the audit committee, of Poniard Pharmaceuticals. Dr. Stevens is also a board member of Micro-Imaging Solutions, LLC, a privately-held medical device company, and Aqua Bounty Technologies, Inc., a biotechnology firm listed on the AIM market of the London Stock Exchange. He formerly served as a board member of Advanced Cosmetic Intervention, Inc., a privately-held medical device company, from August 2006 through April 2008, at which time ACI was sold. Following the sale and through May 2011, Dr. Stevens served as the trustee of the ACI Liquidating Trust. He was an advisor to Bay City Capital LLC, a life sciences venture capital fund, from 1999 to 2006. Dr. Stevens was previously president and chief executive officer of Deprenyl Animal Health, Inc., a public veterinary pharmaceutical company, from 1990 to 1998, and Vice President, Research and Development, of Agrion Corp., a private biotechnology company, from 1985 to 1988. He began his career in pharmaceutical research and development at the former Upjohn Company, where he | June 2011 |

contributed to the preclinical evaluation of Xanax and Halcion. Dr. Stevens received B.S. and D.V.M. degrees from Washington State University, and a Ph.D. in comparative pathology from the University of California, Davis. He is a Diplomate of the American College of Veterinary Pathologists.

Dr. Stevens has worked in the pharmaceutical and biotechnology industries since 1978. Dr. Stevens experience in executive management in the pharmaceutical industry, prior and current public company board experience, and knowledge of the medical device industry led to the conclusion of our Board that he should serve as a director of our company in light of our business structure.

Table of Contents

| Name | Age | Position With Ampio | Principal Occupation and Areas of Relevant Experience For Directors | Director Since |
|---|---|---|---|---|
| Mark D. McGregor | 70 | Chief Financial Officer | Mark D. McGregor has been employed by us since April 2011. Mr. McGregor is a certified public accountant with over 30 years financial experience in a variety of industries. Mr. McGregor served in various financial capacities with Louisville, Colorado-based Storage Technology Corporation, or StorageTek, from February 1985 until October 2005. During this period, Mr. McGregor held three positions with StorageTek, including director of revenue management (1985-1987), assistant corporate controller (1987-1993), and vice president, corporate treasurer and corporate development (1993-2005). In these positions, Mr. McGregor s responsibilities included treasury and risk management, developing financial strategic plans, cash management and investments, managing foreign currency and interest rate exposures, credit provider and credit rating agency relations, and insurance risk management. His responsibilities also included corporate and international consolidation and reporting, SEC and management reporting, financial integration, disbursements operations, evaluating potential acquisitions, conducting financial due diligence, negotiating credit line provisions to promote operating flexibility, optimizing capital structures, and implementing stock buy-back programs to enhance stockholder value. Mr. McGregor was directly involved in two divestitures and four acquisitions while with StorageTek, in addition to leading the deal team in connection with the sale of StorageTek to Sun Microsystems in 2005. After leaving StorageTek, Mr. McGregor served as the chief financial officer of Integrated Management Information, Inc., or IMI, from February 2006 to November 2007. IMI is a publicly-traded provider of identification, verification and communications solutions for the agriculture, livestock, and food industries based in Castle Rock, Colorado. Since retiring as chief financial officer of IMI in November 2007, Mr. McGregor has been engaged part-time in the real estate business as an agent with Keller Williams Realty in Castle Rock, Colorado. He began his career with Price Waterhouse, now PricewaterhouseCoopers LLP, where he spent 13 years with the Audit Department. Mr. McGregor holds a BBA degree in accounting from Texas A&M University and served in the United States Army from 1964 to 1966, where he attained the rank of First Lieutenant. | |

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

**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**

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

50

Table of Contents

On September 27, 2011, each of our executive officers and directors filed Form 3 s pursuant to Section 16(a) of the Exchange Act. These reports were not timely filed. Except in the case of Dr. Stevens, the reports were due on the effective date of the Company s registration statement on Form 8-A registering the Company s common stock under Section 12 of the Exchange Act, which effective date was May 18, 2011. Because Dr. Stevens was appointed to the Board on June 8, 2011, his initial Form 3 was due on June 20, 2011. On September 27, 2011, Dr. Stevens also filed a Form 4 pursuant to Section 16(a) of the Exchange Act with respect to the grant to Dr. Stevens by the Company of (i) an option to purchase 100,000 shares on July 25, 2011 and (ii) an option to purchase 25,000 shares on August 29, 2011. These reports were not timely filed. The reports were due on the second business day following the date of grant of the respective stock option.

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

**Code of Business Conduct and Ethics**

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

**Meetings**

During the year ended December 31, 2011, there were held (i) thirteen meetings of the Board of Directors, (ii) nine meetings of the Audit Committee, (iii) eight meetings of the Compensation Committee, and (iv) three meetings of the Nominating and Governance Committee. No incumbent director attended fewer than seventy-five percent (75%) of the aggregate of (1) the total number of meetings of the Board, and (2) the total number of meetings held by all committees of the Board during the period that such director served.

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

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

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

- junk mail and mass mailings
- resumes and other forms of job inquiries
- surveys
- solicitations or advertisements.

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

**Involvement in Certain Legal Proceedings**

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

Table of Contents

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

**Leadership Structure of the Board**

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

**Risk Oversight**

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

**Board Committees**

Our Board of Directors has an Audit Committee, a Compensation Committee and a Nominating and Governance Committee, each of which has the composition and the responsibilities described below. The Audit Committee, Compensation Committee and Nominating and Governance Committee all operate under charters approved by our Board of Directors, which charters are available on our website.

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

- selecting and hiring our independent auditors;
- appointing, compensating and overseeing the work of our independent auditors;
- approving engagements of the independent auditors to render any audit or permissible non-audit services;
- reviewing the qualifications and independence of the independent auditors;
- monitoring the rotation of partners of the independent auditors on our engagement team as required by law;
- reviewing our financial statements and reviewing our critical accounting policies and estimates;
- reviewing the adequacy and effectiveness of our internal controls over financial reporting; and

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

The members of our Audit Committee are Messrs. Giles, Coelho and Stevens. Mr. Giles is our Audit Committee chairman and was appointed to our Audit Committee on August 10, 2010. Our Board of Directors has determined that each member of the Audit Committee meets the financial literacy requirements of the national securities exchanges and the SEC, and Mr. Giles qualifies as our Audit Committee financial expert as defined under SEC rules and regulations. Our Board of Directors has concluded that the composition of our Audit Committee meets the requirements for independence under the current requirements of the NASDAQ Capital Market and SEC rules and regulations. We believe that the functioning of our Audit Committee complies with the applicable requirements of SEC rules and regulations, and applicable requirements of the NASDAQ Capital Market.

Table of Contents

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

- reviewing and recommending policies, plans and programs relating to compensation and benefits of our directors, officers and employees;
- reviewing and recommending compensation and the corporate goals and objectives relevant to compensation of our chief executive officer;
- reviewing and approving compensation and corporate goals and objectives relevant to compensation for executive officers other than our chief executive officer;
- evaluating the performance of our executive officers in light of established goals and objectives;
- developing in consultation with our Board of Directors and periodically reviewing a succession plan for our chief executive officer; and
- administering our equity compensations plans for our employees and directors.

The members of our Compensation Committee are Messrs. Coelho, Giles and Stevens. Mr. Coelho is the chairman of our Compensation Committee. Each member of our Compensation Committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended, is an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, or the IRC, and satisfies the independence requirements of the NASDAQ Capital Market. We believe that the composition of our Compensation Committee meets the requirements for independence under, and the functioning of our Compensation Committee complies with, any applicable requirements of the NASDAQ Capital Market and SEC rules and regulations.

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

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

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

- evaluating and making recommendations regarding the organization and governance of the Board of Directors and its committees;
- assessing the performance of members of the Board of Directors and making recommendations regarding committee and chair assignments;

recommending desired qualifications for Board of Directors membership and conducting searches for potential members of the Board of Directors; and

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

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

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

**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:

Table of Contents

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

**Director Compensation for 2011**

The table below summarizes the compensation paid by us to non-employee directors for the year ended December 31, 2011.

| Name | Fees Earned or Paid in Cash | Stock Option Awards (1)(2) | All Other Compensation | Total |
|---|---|---|---|---|
| Michael Macaluso | | | | |
| 2011 | $ 151,500(3) | $ | $ | $ 151,500 |
| Philip H. Coelho | | | | |
| 2011 | 173,800(4) | 271,884 | | 445,684 |
| Richard B. Giles | | | | |
| 2011 | 143,333(5) | 271,884 | | 415,217 |
| David R. Stevens, Ph.D. | | | | |
| 2011 | 72,200 | 429,444 | | 501,644 |

(1) The amounts in this column reflect the grant date fair values of the stock awards based on the last reported sale price of the common stock at the dates of grant. Please see Item 15 of Part IV, Notes to Consolidated Financial Statements Note 12 Stock-Based Compensation.

(2) At December 31, 2011, Messrs. Macaluso, Coelho, Giles Stevens held options to acquire 550,000, 340,554, 400,000 and 125,000 shares of common stock, respectively. 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. Dr. Stevens joined the Board in June, 2011. Mr. Coelho exercised 34,446 of his options in 2011.

(3) Includes $61,500 earned in 2010 but paid in 2011.

(4) Includes $58,000 earned in 2010 but paid in 2011.

(5) Includes $34,333 earned in 2010 but paid in 2011.

Table of Contents

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

**Executive Compensation**

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

**Summary Compensation of Named Executive Officers**

| Name and Principal Position | Year | Salary | | Bonus | Stock Award | Option Award (1) | Non-Equity Incentive Plan Compensation | Change in Pension Value and Nonqualified Deferred Compensation Earnings | All Other Compensation | Total |
|---|---|---|---|---|---|---|---|---|---|---|
| Donald B. Wingerter, Jr., former Chief Executive Officer(6) | 2011 | $ 242,500 | | $ 71,250 | $ | $ | $ | $ | $ | $ 313,750 |
| | 2010 | 145,333 | | 29,000 | | 385,179 | | | | 559,512 |
| David Bar-Or, M.D. Chief Scientic Officer and Former Chairman | 2011 | 281,875 | (2) | 5,000 | | | | | | 286,875 |
| | 2010 | 227,500 | (3) | | | 451,968 | | | | 679,468 |
| Vaughan Clift, M.D. Chief Regulatory Affairs Officer | 2011 | 228,003 | (4) | 5,000 | | | | | | 233,003 |
| | 2010 | 198,000 | (5) | 29,500 | | 235,669 | | | | 463,169 |
| Mark D. McGregor Chief Financial Officer since April, 2011 | 2011 | 111,932 | | 5,000 | | 155,420 | | | | 272,352 |

(1) Option awards are reported at fair value at the date of grant. See Item 15 of Part IV, Notes to Consolidated Financial Statements Note 12 Stock-Based Compensation.
(2) Excludes $85,313 in salary deferred by Dr. Bar-Or in prior years paid in 2011.
(3) Includes $68,250 in salary deferred by Dr. Bar-Or at December 31, 2010.
(4) Excludes $42,333 in salary deferred by Dr. Clift at December 31, 2010 paid in 2011.
(5) Includes $42,333 in salary deferred by Dr. Clift at December 31, 2010.
(6) Mr. Wingerter departed the Company on January 9, 2012.

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

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

**Table of Contents**

The following table provides a summary of equity awards outstanding for each of the Named Executive Officers as of December 31, 2011:

| | | Option Awards | | | | | Stock Awards | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Name | | Number of Securities Underlying Unexercised Options Exercisable (#) | Number of Securities Underlying Unexercised Options Unexercisable (#) (1) | Equity Incentive Plan Awards: Numer of Securities underlying Unexercised Unearned Options (#) | Option Exercise Price ($) | Option Expiration Date | Number of Shares or Units of Stock That Have Not Vested (#) | Market Value of Shares or Units of Stock That Have Not Vested ($) | Eqauity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#) | Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($) |
| (a) | | (b) | (c) | (d) | (e) | (f) | (g) | (h) | (i) | (j) |
| *Named Executive Officers* | | | | | | | | | | |
| David Bar-Or, M.D. | (1) | 466,667 | 233,333 | | $ 1.03 | 8/12/2020 | | | | |
| Mark D. McGregor | (2) | 50,000 | 50,000 | | 2.50 | 4/4/2021 | | | | |
| Vaughan Clift, M.D. | (3) | 243,333 | 121,667 | | 1.03 | 8/12/2020 | | | | |
| Donald B. Wingerter, Jr., former chief executive officer | (3) | 400,000 | 200,000 | | 1.03 | 8/12/2020 | | | | |

(1) Unexercisable option becomes exercisable by its terms on August 12, 2012.
(2) Unexercisable option becomes exercisable by its terms on April 4, 2012
(3) Unexercisable option become exercisable by its terms pm August 12, 2012 or, pursuant to an amendment of employment terms effective May 31, 2011, upon termination if without Cause or for Good Reason.

**Employment Agreements**

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

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

The employment agreements provide for an initial grant of stock options to Mr. Wingerter, Dr. Bar-Or, and Dr. Clift in the amount of 675,000, 700,000 and 365,000 options, respectively. Each option is exercisable for a period of ten years at an exercise price per share equal to the quoted closing price of our common stock on August 11, 2010. The options vest approximately 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 the employment agreements). Mr. Wingerter and Dr. Clift s unvested options immediately vest in the event of termination without cause or for good reason (as such terms are defined in the employment agreements).

**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, for reasons other than death, disability or cause (as defined in the employment agreements), or if an officer terminates his employment for good reason(as defined in the employment agreements), the officer in question shall be entitled to receive a lump sum severance payment equal to two times

Table of Contents

his base salary and of the continued payment of premiums for continuation of the officer s health and welfare benefits pursuant to COBRA or otherwise, for a period of two years from the date of termination, subject to earlier discontinuation if the officer is eligible for comparable coverage from a subsequent employer. All severance payments, less applicable withholding, are subject to the officer s execution and delivery of a general release of us and our subsidiaries and affiliates and each of their officers, directors, employees, agents, successors and assigns in a form acceptable to us, and a reaffirmation of the officer s continuing obligation under the propriety information and inventions agreement (or an agreement without that title, but which pertains to the officer s obligations generally, without limitation, to maintain and keep confidential all of our proprietary and confidential information, and to assign all inventions made by the officer to us, which inventions are made or conceived during the officer s employment). 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 material reduction of the officer s then-current base salary; or

relocation of the officer to a facility or location more than 40 miles from Denver, Colorado.

Cause means:

willful malfeasance or willful misconduct;

gross negligence or willful misconduct in the performance of duties;

conviction of a felony or a crime other than a misdemeanor;

willful and deliberate violation of Company policy or an unintended but material breach of any written employment policy that is not cured;

unauthorized use or disclosure of the Company s proprietary information; or

willful breach of employment obligations.

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

i. the acquisition by any individual, entity, or group, other than the Company of beneficial ownership of 50% or more of the combined voting power or economic interests of the then outstanding voting securities of the Company in a transaction made principally for bona fide equity financing purposes;

ii the acquisition of the Company by another entity by means of any transaction to which the Company is party (including, without limitation, any stock acquisition, reorganization, merger or consolidation but excluding any issuance of securities by the Company in

a transaction made principally for bona fide equity financing purposes) other than a transaction in which the holders of the voting securities of the Company outstanding immediately prior to such transaction retain, immediately after such transaction, at least a majority of the total voting power represented by the outstanding voting securities of the Company or such other surviving or resulting entity; or

iii the sale or other disposition of all or substantially all of the assets of the Company.

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. Effective May 31, 2011, an amendment of the employment terms for Mr. Wingerter or Dr. Clift clarified that if the employee is terminated without cause or if the employee terminates his employment with good reason, all unvested stock options then held by the employee shall be accelerated, deemed vested, and immediately exercisable.

Table of Contents

**Chief Executive Officer Departure**

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

**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, 2011 by:

- each person or group of affiliated persons known by us to be the beneficial owner of more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all executive officers and directors as a group.

We have determined beneficial ownership in accordance with SEC rules. The information does not necessarily indicate beneficial ownership for any other purpose. Under these rules, the number of shares of common stock deemed outstanding includes shares issuable upon exercise of options and warrants held by the respective person or group which may be exercised or converted within 60 days after December 31, 2011. 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, 2011 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 31,081,434 shares of common stock outstanding at December 31, 2011.

Unless otherwise indicated and subject to any applicable community property laws, to our knowledge, each stockholder named in the following table possesses sole voting and investment power over the shares listed. Unless otherwise noted below, the address of each stockholder listed on the table is c/o Ampio Pharmaceuticals, Inc., 5445 DTC Parkway, Suite 925, Greenwood Village, Colorado 80111.

| Name of Beneficial Owner | Number of Shares Beneficially Owned | Percentage of Shares Beneficially Owned |
|---|---|---|
| Michael Macaluso (1) | 2,618,484 | 7.8% |
| David Bar-Or (2) | 3,166,667 | 9.2% |
| Donald B. Wingerter, Jr. (3) | 725,000 | 2.3% |

| | | |
|---|---|---|
| Vaughn Clift (4) | 818,333 | 2.6% |
| Philip H. Coelho (5) | 375,099 | 1.2% |
| Richard B. Giles (6) | 622,142 | 2.0% |
| David R. Stevens (7) | 58,333 | 0.2% |
| Mark D. McGregor(8) | 70,000 | 0.2% |
| Bruce G. Miller (9) | 1,500,000 | 4.6% |
| Wannell Crook (9) | 1,100,000 | 3.4% |
| Raphael Bar-Or (9) | 1,025,000 | 3.2% |
| James Winkler (9) | 1,025,000 | 3.2% |
| All executive officers and directors (eight persons) | 8,454,058 | 25.4% |

(1) Includes an aggregate of 577,379 shares of common stock issuable to Mr. Macaluso by virtue of (i) exercise of currently exercisable stock options, (ii) exercise of warrants, , and (iii) his service as a non-management director.

Table of Contents

(2) Includes 466,667 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 400,000 shares of common stock issuable to Mr. Wingerter on exercise of currently exercisable stock options. Mr. Wingerter departed the Company as of January 9, 2012.
(4) Includes (i) 243,333 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 340,554 shares of common stock issuable to Mr. Coelho on exercise of currently exercisable stock options.
(6) Includes 451,918 shares of common stock issuable to Mr. Giles by virtue of (i) exercise of currently exercisable stock options, and (ii) 40,000 shares of common stock issuable to Barbara Giles, Mr. Giles spouse, on exercise of currently exercisable options.
(7) Includes 58,333 shares of common stock issuable to Dr. Stevens on exercise of currently exercisable stock options.
(8) Includes 50,000 shares of common stock issuable to Mr. McGregor on exercise of currently exercisable stock options.
(9) Such persons are non-executive officers of Ampio.

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

**Related Party Transactions**

In addition to the director and executive compensation arrangements discussed above in Item 11. Executive Compensation Executive Compensation and Employment Agreements, we or Life Sciences have been a party to the following transactions since January 1, 2009 in which the amount involved exceeded or will exceed $120,000, and in which any director, executive officer or holder of more than 5% of any class of our voting stock, or any member of the immediate family of or entities affiliated with any of them, had or will have a material interest.

In April 2009, Life Sciences issued 3,500,000 shares of its common stock to BioSciences 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 Mr. Macaluso, Life Science s founder, and $100,000 payable to BioSciences. The related party notes payable were unsecured, bore interest at 6% and initially were scheduled 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. In October and November 2010, we borrowed an additional $215,971 from BioSciences. The notes evidencing the foregoing borrowings were extended to become due at the earlier of April 30, 2011, or closing of a financing exceeding $5 million. On closing of the BioSciences acquisition, our borrowings from BioSciences were extinguished. The note to Mr. Macaluso was paid in full from the proceeds of the 2011 Private Placement.

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 $8,312 to Life Sciences and $1,527 in short-term non-interest bearing advances at December 31, 2010. In October and November 2010, we borrowed $215,971 from BioSciences in non-interest bearing advances. That amount was extinguished on closing of the BioSciences acquisition.

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 were scheduled to vest on a monthly basis between the second and fourth anniversaries of the date of grant. Vesting was subject to acceleration upon achieving certain milestones and such milestones were achieved in April 2011.

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 lease payments of $7,236 on behalf of TRLLC. Lease commitments expired as of January 2011. In exchange, TRLLC will assign any intellectual property rights it develops on our behalf under the research agreement. The research agreement expires in 2014 and may be terminated by either party on six months notice or immediately if either party determines that the other is not fulfilling its obligations under the

agreement. Life Sciences was current in its financial obligations under the research agreement at December 31, 2010 and June 30, 2011.

Table of Contents

Life Sciences has license agreements with the Institute for Molecular Medicine, Inc. a nonprofit research organization founded by Dr. Bar-Or, who also serves as its executive director. The license agreements were assigned to Life Sciences as a part of the asset purchase from BioSciences. Under the license agreements, Life Sciences pays the costs associated with obtaining and maintaining intellectual property subject to the license agreements. In the license covering certain Methylphenidate derivatives, Life Sciences is entitled to deduct twice the amounts it has paid to maintain the intellectual property from any amounts that may become due to the Institute for Molecular Medicine, Inc. under the license agreement, if and when the intellectual property becomes commercially viable and generates revenue. We paid $122,599 during 2011 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 former chief executive officer, purchased 325,000 of such shares for a purchase price of approximately $36,800 which was advanced on his behalf by Life Sciences. Dr. Clift s spouse purchased 575,000 shares for a purchase price of approximately $65,000 which was likewise advanced by Life Sciences. Life Sciences made advances to the other four non-executive officers and employees in the additional amount of approximately $48,000 to facilitate these share purchases. $22,600 was repaid in 2011. These shares were issued immediately before the closing of the Chay merger but after the shareholders of Chay had approved the merger. Life Sciences was not a public company at the time such advances were made.

In August 2010, Michael Macaluso and Richard B. Giles, both members of our Board of Directors, together with an affiliate of Mr. Giles, purchased convertible debentures from us for $430,000. The debentures were issued in principal amounts of $230,000, $100,000 and $100,000, respectively, to Mr. Macaluso, Mr. Giles, and James A. Ludvik. Mr. Ludvik is the sole owner of Ludvik Electric Co., for which Mr. Giles serves as the chief financial officer. The debentures accrued interest at the rate of 8% per annum. The principal and accrued interest of the debentures were converted into our common stock at a conversion price of $1.75 per share on February 28, 2011, on the same terms under which convertible debentures issued to non-affiliates were converted. In conjunction with the issuance of the debentures, we issued warrants to Messrs. Macaluso, Giles and Ludvik representing the right to purchase an aggregate of 21,500 shares of our common stock. We paid no commission in connection with the sale of the debentures and the warrants, and did not engage a placement agent to assist it in the sale of these unregistered securities. Upon closing of our bridge financing in November 2010, we reserved an additional 27,643 shares for issuance to Messrs. Macaluso, Giles and Ludvik for most favored nation adjustments to the warrants previously issued to these persons.

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

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

Upon the formation of Life Sciences, shares of common stock issued to Bruce Miller, James Winkler, M.D., Raphael Bar-Or and Wannell Crook were subject to vesting requirements under which one-third of the shares vested immediately, one-third vested monthly from April 16, 2010 to April16, 2011, and the remainder vesting monthly through April 16, 2012. The second and third tranches were subject to accelerated vesting based on development milestones being achieved by Life Sciences. In April 2011, the Board of Directors determined that the milestones for accelerated vesting had been met and that the portion of the shares that was unvested would vest immediately. All vested shares remain subject to contractual lockup agreements entered into in connection with the acquisition of BioSciences in March 2011.

**Policies and Procedures for Related Party Transactions**

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

banking-related services.

Table of Contents

**Director Independence**

Our common stock is listed on the NASDAQ Capital Market. The listing rules of the NASDAQ Capital Market require that a majority of the members of the board of directors be independent. The rules of the NASDAQ Capital Market require that, subject to specified exceptions, each member of our Audit, Compensation and Nominating and Governance Committees be independent. Audit Committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as ame