Ampio Pharmaceuticals, Inc.
Form 424B5
July 16, 2012
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Filed Pursuant to Rule 424(b)(5)
Registration No. 333-177116

PROSPECTUS SUPPLEMENT

(To the Prospectus dated October 28, 2011)

4,615,400 Shares

Common Stock

Ampio Pharmaceuticals, Inc. is offering 4,615,400 shares of our common stock pursuant to this prospectus supplement and the accompanying prospectus.

Our common stock is listed on the NASDAQ Capital Market under the symbol AMPE . On July 11, 2012, the last reported sale price of our common stock on the NASDAQ Capital Market was $4.281 per share.

Our business and an investment in our common stock involves a high degree of risk. See Risk Factors beginning on page S-5 of this prospectus supplement, on page 5 of the accompanying prospectus and in the documents incorporated by reference into this prospectus supplement and the accompanying prospectus.

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

	Per Share	Total
Public offering price	$ 3.2500	$ 15,000,050

Underwriting discount (1)	$ 0.2275	$ 1,050,004
Proceeds, before expenses, to us	$ 3.0225	$ 13,950,046

(1) See Underwriting beginning on page S-27 for a detailed description of the compensation payable to the underwriters.

The underwriters may purchase up to an additional 692,310 shares from us and the selling stockholders identified in this prospectus supplement at the public offering price, less the underwriting discount, within 45 days from the date of this prospectus supplement to cover over-allotments, if any. We will not receive any of the proceeds from the sale of shares of common stock being sold by the selling stockholders.

The underwriters expect to deliver the shares against payment on or about July 18, 2012.

Aegis Capital Corp **Fordham Financial Management, Inc.**

July 12, 2012

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PROSPECTUS SUPPLEMENT

PROSPECTUS

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ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part, the accompanying prospectus, gives more general information about securities we may offer from time to time, some of which does not apply to this offering. Generally, when we refer to this prospectus, we are referring to both parts of this document combined together with all documents incorporated by reference. If the description of the offering varies between this prospectus supplement and the accompanying prospectus, you should rely on the information contained in this prospectus supplement. However, if any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference into this prospectus supplement or the accompanying prospectus the statement in the document having the later date modifies or supersedes the earlier statement. You should rely only on the information contained in or incorporated by reference into this prospectus supplement or contained in or incorporated by reference into the accompanying prospectus to which we have referred you. We have not authorized anyone to provide you with information that is different. If anyone provides you with different or inconsistent information, you should not rely on it. The information contained in, or incorporated by reference into, this prospectus supplement and contained in, or incorporated by reference into, the accompanying prospectus is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of securities. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference herein and therein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you under the captions Where You Can Find More Information and Incorporation of Documents by Reference in this prospectus supplement.

We are offering to sell, and are seeking offers to buy, the shares only in jurisdictions where such offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the shares in certain jurisdictions or to certain persons within such jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about and observe any restrictions relating to the offering of the shares and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Unless the context otherwise requires, we use the terms Ampio Pharmaceuticals, Ampio, we, us, the Company and our in this prospectus supplement to refer to Ampio Pharmaceuticals, Inc. and its subsidiaries on a consolidated basis. References to BioSciences in this prospectus supplement mean DMI BioSciences, Inc., now a wholly-owned subsidiary of ours. References to Life Sciences in this prospectus supplement mean DMI Life Sciences, Inc., which is our predecessor for accounting purposes and a wholly-owned subsidiary of ours. Life Sciences was formed in December 2008 and commenced operations when it acquired certain assets of BioSciences in April 2009. In March 2010, Life Sciences merged with a subsidiary of Chay Enterprises, Inc., a publicly traded Colorado corporation, which we refer to in this prospectus supplement as Chay Enterprises. Immediately after the merger, Chay Enterprises changed its name to Ampio Pharmaceuticals, Inc., and reincorporated in Delaware. We acquired BioSciences, now a wholly-owned subsidiary of ours, in March 2011.

All references in this prospectus supplement to our consolidated financial statements include, unless the context indicates otherwise, the related notes.

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

The industry and market data and other statistical information contained in the documents we incorporate by reference are based on management s own estimates, independent publications, government publications, reports by market research firms or other published independent sources, and, in each case, are believed by management to be reasonable estimates. Although we believe these sources are reliable, we have not independently verified the information.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

- our expectations related to the use of proceeds, if any, from this offering;
- the results and timing of our clinical trials, particularly the results of our Optina, Ampion and Zertane 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;
- our plans to develop other product candidates; and

other factors discussed elsewhere in this prospectus or any prospectus supplement.

You should not place undue reliance on our forward-looking statements because the matters they describe are subject to known and unknown risks, uncertainties and other unpredictable factors, many of which are beyond our control. Our forward-looking statements are based on the information currently available to us and speak only as of the date on the cover of this prospectus. New risks and uncertainties arise from time to time, and it is impossible for us to predict these matters or how they may affect us. Over time, our actual results, performance or achievements will likely differ from the anticipated results, performance or achievements that are expressed or implied by our forward-looking statements, and such differences might be significant and materially adverse to our investors. We have no duty to, and do not intend to, update or revise the forward-looking statements in this prospectus after the date of this prospectus except to the extent required by the federal securities laws. You should consider all risks and uncertainties disclosed in our filings with the Securities and Exchange Commission, or the SEC, described in the sections of this prospectus supplement entitled Where You Can Find More Information and Incorporation of Documents by Reference and the sections of the accompanying prospectus entitled Incorporation of Certain Information by Reference and Where You Can Find Additional Information, all of which are accessible on the SEC s website at www.sec.gov.

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PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights information contained elsewhere or incorporated by reference into this prospectus supplement and the accompanying prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our securities. You should read this entire prospectus supplement and the accompanying prospectus carefully, including the Risk Factors section contained in this prospectus supplement and our consolidated financial statements and the related notes and the other documents incorporated by reference into this prospectus supplement and in the accompanying prospectus.

Business Overview

We are a development stage 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 diseases 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: (i) new uses for FDA-approved drugs, referred to as repositioned drugs, (ii) new molecular entities, or NMEs, and (iii) rapid point-of-care tests for diagnosis, monitoring and screening.

Our Product Pipeline

Ampion for Inflammation

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 the plasma. Dr. Bar-Or has published a number of studies and articles on the anti-inflammatory immune response of DA-DKP. 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). In October 2011, we released a preliminary analysis of a 60 patient Ampion trial for patients with osteoarthritis of the knee in Australia. These results permitted expansion of the trial to 42 patients with an addition of two arms comparing Ampion as a mono-therapy versus normal saline, which we believe will demonstrate efficacy as an anti-inflammatory. The clinical trial has been completed and the preliminary results have been evaluated. We had a pre-IND meeting with the Center for Biological Evaluation and Research division of the FDA on May 10, 2012 to obtain clarity for a Phase III pivotal trial. Osteoarthritis, or 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 United States, 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 injectables, but depending on the ultimate safety and efficacy of the product, it might also replace some of the other forms of treatment.

Optina for Diabetic Macular Edema

Optina is an orally-administered compound in development for the treatment of diabetic macular edema, or 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. David Bar-Or, our chief scientific officer, discovered that low doses of danazol reverse

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inflammation induced increases in the permeability of blood vessels, thus reducing vascular leakage. Optina is designed to treat DME, which is a swelling of the retina in diabetic patients due to the leaking of fluid from blood vessels within the macula. 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. We previously entered into a contract with St. Michael s Hospital in Toronto, Canada to conduct a Phase II clinical trial of Optina. Patient enrollment for this trial began in January 2011. The clinical trial was discontinued after the planned interim review indicated encouraging results. We have requested and received confirmation of a pre-IND meeting with the FDA on Optina for DME, which is scheduled to take place in late July 2012. The International Diabetes Federation estimates that 285 million people around the world have diabetes and approximately 14% of people with diabetes have DME. Existing therapies for DME and the wet form of Age Related Macula Degeneration, or AMD, include focal and grid laser therapy, which is the current standard of care, as well as photodynamic therapy, surgery, and intravitreal treatment 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 resulting 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. Additionally, a proof of concept trial for allergic rhinitis utilizing a low dose of danazol, the active compound in Optina, was completed and shown to support the mechanism of action.

Zertane for Premature Ejaculation in Men

Zertane is a new use for tramadol hydrochloride, which was approved by the FDA for marketing as a noncontrolled 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, or 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 between 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. Behavioral therapy is the current standard of care for treatment of PE. Our Phase III clinical trial 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 in 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 and a Premature Ejaculation Profile. We reached agreement with the Australian Therapeutic Goods Administration on a plan for preparation of manufacturing and common technical documents to obtain regulatory approval for Zertane in Australia. The submission is expected to be made early fourth quarter of 2012 and we hope to obtain approval in Australia as early as 2013. We also had a pre-IND meeting with the CDER Urology and Reproductive group division of the FDA on June 20, 2012. We are actively seeking partners to help commercialize Zertane in the United States and worldwide. For example, in September 2011, we entered into a license, development and commercialization agreement with a major Korean pharmaceutical company, which agreement grants the pharmaceutical company exclusive rights to market Zertane in South Korea for the treatment of PE and for a combination drug to be developed, utilizing Zertane and an erectile dysfunction drug. We also entered into a license and distribution agreement with a Brazilian pharmaceutical company for exclusive rights to market Zertane in Brazil. We are also in discussions with other parties about other potential licensing and distribution opportunities.

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Pre-Clinical Product Pipeline

Methylphenidates

As part of our ongoing pre-clinical research efforts, we have identified methylphenidate (ritalin) derivatives/analogues as potential product candidates to further evaluate and develop. Methylphenidates are strong anti-angiogenic, anti-inflammatory and anti-proliferative compounds. The lead compound has shown strong activity in vitro for glioblastoma multiforme, renal cell carcinoma and inflammatory breast cancer. We have recently received composition of matter patent protection worldwide for this compound. The mechanism of action was identified and mediated through the activation of a specific phosphatase.

Recent Developments

On July 3, 2012, Dr. David Bar-Or, our Founder and Chief Scientific Officer, and Michael Macaluso, our Chief Executive Officer and Chairman, agreed to extend lock-up restrictions regarding their sale or other disposition of approximately 4,743,373 shares of common stock to January 1, 2013, subject to certain exceptions, including limited sales (up to 429,400 shares of common stock collectively) in connection with publicly registered offerings.

For information relating to the lock-up restrictions covering an aggregate of approximately 4,000,000 shares of our common stock which expired on June 30, 2012 and the lock-up restrictions covering an aggregate of approximately 5,225,000 shares of our common stock which will expire on July 15, 2012, please see Risk Factors Risks Related to Our Common Stock and this Offering *Future sales of shares by existing stockholders could cause our stock price to decline* beginning on page S-22 of this prospectus supplement.

Corporate Information

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 stockholders became the controlling stockholders 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.

On March 23, 2011, Ampio acquired all of the outstanding stock of BioSciences. Its principal asset consisted of the worldwide rights to Zertane, as to which BioSciences held 32 issued patents and 31 pending patent applications. Zertane is a repurposed drug to treat male sexual dysfunction pertaining to premature ejaculation (PE) in men.

In May 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.

Our principal executive offices are located at 5445 DTC Parkway, Suite 925, Greenwood Village, Colorado 80111, and our telephone number is (720) 437-6500. Additional information about us is available on our website at www.ampiopharma.com. The information contained on or that may be obtained from our website is not, and shall not be deemed to be, a part of this prospectus.

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The Offering

Securities offered by us	4,615,400 shares of common stock
Common stock to be outstanding after this offering	36,376,569 shares of common stock
Over-allotment option	407,210 shares of common stock offered by us and 285,100 shares of common stock offered by the selling stockholders
Use of proceeds	We intend to use the net proceeds from this offering for general corporate purposes, including conducting pivotal trials for Ampion and Zertane, Phase II and III trials for Optina, pre-IND development for methylphenidates and general working capital. We will not receive any of the proceeds from the sale of shares of common stock that may be sold by the selling stockholders pursuant to the exercise of the underwriters over-allotment option. See Use of Proceeds on page S-23.
Risk factors	See Risk Factors beginning on page S-5 of this prospectus supplement, on page 4 of the accompanying prospectus and in the documents incorporated by reference into this prospectus supplement and the accompanying prospectus, for a discussion of factors you should carefully consider before investing in our securities.
NASDAQ Capital Market trading symbol	AMPE

The number of shares of common stock to be outstanding after this offering is based on 31,761,169 shares outstanding on June 30, 2012 and excludes as of that date:

- options representing the right to purchase a total of 4,577,074 shares of common stock at a weighted average exercise price of $2.12 per share; and
- warrants representing the right to purchase a total of 649,979 shares of common stock at a weighted-average exercise price of $2.77 per share.

Except as otherwise indicated, all information in this prospectus supplement assumes no exercise by the underwriters of their over-allotment option.

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RISK FACTORS

You should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks we are not presently aware of or that we currently believe are immaterial may also impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained or incorporated by reference into this prospectus supplement and the accompanying prospectus, including our financial statements and related notes.

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 March 31, 2012, we had an accumulated deficit of approximately $31.0 million. We expect our annual net losses to continue over the next several years as we advance development programs and incur significant clinical development costs.

We have not received, and do not expect to receive for several years, any revenues from the commercialization of our product candidates. We 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 fee 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;

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cannot obtain, or believe they cannot obtain, the necessary regulatory approvals;

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

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

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

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

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

We 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, a handheld device for use at home or in healthcare facilities that will measure the oxidants/antioxidant balances in human blood and plasma;

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 fee 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.

Zertane, 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

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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 our primary products.

An unfavorable outcome in one or more trials for Zertane, 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;

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

determining dosing and making related adjustments; and

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

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

lack of effectiveness of product candidates during clinical studies;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The FDA must approve any new medicine before it can be marketed and sold in the United States. We must provide the FDA with data from preclinical and clinical studies that demonstrate that our product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. We will not obtain this approval for a product candidate unless and until the FDA approves a NDA. The processes by which regulatory approvals are obtained from the FDA to market and sell a new or repositioned product are complex,

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

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

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

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addition, marketing approval by the FDA does not ensure approval by the health authorities of any other country, and approval by foreign health authorities does not ensure marketing approval by the FDA.

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

Even if we receive regulatory approval for a product candidate, this approval may carry conditions that limit the market for the product or put the product at a competitive disadvantage relative to alternative therapies. For instance, a regulatory approval may limit the indicated uses for which we can market a product or the patient population that may utilize the product, or may be required to carry a warning on its packaging. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings. These restrictions could make it more difficult to market any product candidate effectively. Once a product candidate is approved, we remain subject to continuing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of promotion and marketing. In addition, the labeling, packaging, adverse event reporting, advertising, promotion and recordkeeping for an approved product remain subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with an approved product in the U.S. or overseas or at any contract manufacturers facilities, a regulatory agency may impose restrictions on the product, any contract manufacturers or on us, including requiring us to reformulate the product, conduct additional clinical studies, change the labeling of the product, withdraw the product from the market or require a contract manufacturer to implement changes to its facilities. In addition, we may experience a significant drop in the sales and royalties related to the product, its reputation in the marketplace may suffer, and we could face lawsuits.

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

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

We sometimes estimate for planning purposes the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of 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;

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our receipt of approvals by the FDA and other regulatory agencies and the timing thereof;

other actions, decisions or rules issued by regulators;

our ability to access sufficient, reliable and affordable supplies of compounds used in the manufacture of our product candidates;

the efforts of our collaborators with respect to the commercialization of our products; and

the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

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

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

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

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

The development of pharmaceutical products is capital-intensive. At March 31, 2012, we had cash of approximately $8.3 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.

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Until we can generate significant continuing revenues, we expect to satisfy our future cash needs