Ampio Pharmaceuticals, Inc. Form S-1/A
May 23, 2011
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As filed with the Securities and Exchange Commission on May 23, 2011.

Registration No. 333-173589

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **AMENDMENT NO. 1**

TO

# FORM S-1

# **REGISTRATION STATEMENT**

UNDER

THE SECURITIES ACT OF 1933

# AMPIO PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware 2834 26-0179592 (State or other jurisdiction of (Primary Standard Industrial (I.R.S. Employer

incorporation or organization) Classification Code Number) Identification No.)

5445 DTC Parkway, P4

Greenwood Village, Colorado 80111

(303) 418-1000

(Address, including zip code, and telephone number, including area code, of the registrant s principal executive offices)

Donald B. Wingerter, Jr.

**Chief Executive Officer** 

Ampio Pharmaceuticals, Inc.

5445 DTC Parkway, P4

Greenwood Village, Colorado 80111

(303) 418-1000

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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(310) 208-1182

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. x

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer		Accelerated filer	
Non-accelerated filer	" (Do not check if a smaller reporting company)	Smaller reporting company	þ

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The selling securityholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

**SUBJECT TO COMPLETION, DATED MAY 23, 2011** 

PRELIMINARY PROSPECTUS

**6,762,609 Shares** 

**Common Stock** 

This prospectus relates to the offer for sale of 6,762,609 shares of common stock, par value \$0.0001 per share, by the existing holders of the securities named in this prospectus, whom we refer to as selling securityholders throughout this prospectus. Our common stock is listed on the NASDAQ Capital Market under the symbol AMPE. On May 19, 2011, the last reported sale price of our common stock on the NASDAQ Capital Market was \$7.95 per share. Before you invest, you should read carefully this prospectus and any prospectus supplement. For information concerning the selling securityholders and the manner in which they may offer and sell shares of our common stock, see Selling Securityholders and Plan of Distribution in this prospectus.

The distribution of securities offered hereby may be effected in one or more transactions that may take place through the NASDAQ Capital Market. These transactions may include ordinary brokers transactions, privately negotiated transactions, or sales to one or more dealers for resale of such securities as principals. The transactions may be executed at market prices prevailing at the time of sale, at prices related to such prevailing market prices, or at negotiated prices. Usual and customary or specifically negotiated brokerage fees or commissions may be paid by the selling securityholders. The selling securityholders and intermediaries through whom such securities are sold may be deemed underwriters under the Securities Act of 1933, as amended, with respect to the securities offered hereby, and any profits realized or commissions received may be deemed underwriting compensation. See Plan of Distribution.

We will not receive any of the proceeds from the sale of our common stock by the selling securityholders. We have agreed to pay expenses of registration of the offered common stock, other than transfer taxes and brokerage fees or commissions.

Investing in our common stock involves significant risks. See <u>Risk Factors</u> beginning on page 13 to read about factors you should consider before buying our common stock.

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

The date of this prospectus is , 2011.

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You should rely only on the information contained in this document. We have not authorized anyone to provide you with additional or different information from that contained in this prospectus. If anyone provides you with additional, different or inconsistent information, you should not rely on it. The selling securityholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information in this document may only be accurate on the date of this document, regardless of its time of delivery or of any sales of shares of our common stock. Our business, financial condition, results of operations or cash flows may have changed since such date.

Unless otherwise indicated or unless the context requires otherwise, all references in this prospectus to Ampio Pharmaceuticals, Inc. Ampio, the Company, we, us, our, or similar references, mean Ampio Pharmaceuticals, Inc. and its subsidiaries on a consolidated basis. References to BioSciences in this prospectus mean DMI BioSciences, Inc., now a wholly-owned subsidiary of ours. References to Life Sciences in this prospectus mean DMI Life Sciences, Inc., which is our predecessor for accounting purposes and a wholly-owned subsidiary of ours.

The registration statement containing this prospectus, including the exhibits to the registration statement, provides additional information about us and the shares of our common stock covered by this prospectus. The registration statement, including the exhibits, can be read on the SEC website or at the SEC offices mentioned under the heading Where You Can Find More Information.

This prospectus includes trademarks, such as Optina, Vasaloc, Zertane, and Ampion, which are protected under applicable intellectual property laws and are our property or the property of our subsidiaries. This prospectus also contains trademarks, service marks, copyrights and trade names of other companies which are the property of their respective owners. Solely for convenience, our trademarks and tradenames referred to

in this prospectus may appear without the <sup>®</sup> or symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames.

For investors outside the United States, we have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

#### PROSPECTUS SUMMARY

The following summary highlights selected information from this prospectus and does not contain all of the information that you should consider before investing in our common stock. This prospectus contains information regarding our business and detailed financial information. You should carefully read this entire prospectus, including the factors described under the heading Risk Factors, and the financial statements and related notes before making an investment decision.

#### **About Ampio Pharmaceuticals**

We are a development stage pharmaceutical company engaged in the discovery and development of innovative, proprietary pharmaceutical and diagnostic products to identify and treat inflammatory conditions, including metabolic disorders and diabetic complications, and male sexual dysfunction. We have a disciplined strategy and productive innovation platform that generates compounds and diagnostics with large potential value while minimizing development risk, cost, and time. Our discovery process occurs in a true clinical environment that carries low overhead costs. Each drug candidate undergoes a sophisticated business filter to identify products that can be clinically and cost-effectively developed to generate substantial value and returns while minimizing risk. Our strategy focuses on generating human safety and efficacy data in order to position our product candidates for value-creating licensing agreements with strategic partners, and is not focused on conducting FDA-directed clinical trials.

Ampio Pharmaceuticals has several characteristics that distinguish it from similar stage companies:

a range of substantive products that are the result of our innovation process, have what we believe are strong patent or patent pending positions, expected multi-billion dollar markets, and shorter regulatory paths than new molecular entities, or NMEs;

a licensing-focused strategy based on conducting safety and efficacy trials geared towards understanding a drug s potential for addressing multiple clinical indications, not by first pursuing FDA-centric clinical trials;

an innovative and proprietary drug discovery process that rapidly identifies candidates for large unmet clinical needs at considerably lower cost than NME product candidates;

access to clinical and scientific resources as a result of a contractual agreement and long-term relationship with Trauma Research LLC, or TRLLC, a related party controlled by our chief scientific officer; and

a sophisticated business filter, clinical review and intellectual property evaluation that select clinically and commercially valuable products coupled with a rapid development timeframe to reach significant value creation.

## **Our Drug Discovery Platform**

## Clinical Discovery Process

Our disciplined innovative drug discovery process begins with input from clinicians in the field, not research in the lab, and is guided primarily by patent strength, solving an unmet need, and identifying repositioned product candidates previously approved for other indications by the FDA or biologics. This process is built on clinical observations and patient data gathered under appropriate Institutional Review Board (IRB) supervision from clinicians who collaborate closely with Ampio scientists and TRLLC clinicians. As a result of these collaborative agreements and historic relationships, we obtain access to research and clinical resources at substantially lower cost than industry norms. As a result, our platform has generated lead product candidates Optina , Vasaloc , Zertane , and Ampion to address what we believe are large unmet clinical needs.

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#### Collaborations and Resources

Our chief scientific officer, Dr. David Bar-Or, collaborates with a team of biochemists, epidemiologists, molecular biologists, immunologists, computational biologists and nursing staff, and also oversees TRLLC, which provides accreditation services for two of the three Level I trauma centers in the State of Colorado. Over 120,000 emergency room consultations take place annually at these hospital facilities.

Under a sponsored research agreement, Ampio funds a variety of targeted research projects conducted by TRLLC, allowing us to further the short term clinical aims of TRLLC and to obtain intellectual property rights to any resulting product candidates. This also provides us access to clinical observations, biology and scientific information we apply to product discovery and development. In collaboration with other professional colleagues who provide advisory input such as vascular surgeons, orthopedic surgeons, neurologists, nephrologists and ER specialists, Dr. Bar-Or uses a multi-disciplinary approach to evaluate clinical interactions that direct further research. The clinical team has access to a large patient database and blood samples for testing or validating drug candidates. With over a decade of scientific research supporting many of our developments, we have built a patent portfolio of 57 granted patents and 134 patent applications.

#### Business Filter and Product Evaluation

We focus our development work on advancing product candidates that we believe offer significant therapeutic advantages over currently available treatments and which represent large potential markets. We look to advance product candidates that address multiple clinical indications, have proven safety profiles, and which can timely demonstrate clinical efficacy. We intend to continue to maintain a diversified product candidate pipeline to mitigate risks associated with pharmaceutical development and increase the likelihood of commercial success. During the development process, we review pertinent scientific literature and conduct searches of patent records in order to make a preliminary determination of patentability. As many of our product candidates are repositioned drugs, the nature and extent of potentially available patent protection is central to our development decisions.

Once identified, candidates are filtered and screened for:

indirect evidence of efficacy based on review of related publications;

market size, market acceptance and likely penetration;

patentability and other modes for protecting exclusivity; and

competitive products and manufacturing-related issues.

#### **Cost Effective Clinical Strategy**

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

#### **Product Pipeline**

Our disciplined innovation process is built on Dr. Bar-Or s research on inflammation and its role in trauma, which is an ideal platform to study inflammation. Dr. Bar-Or has completed several ground-breaking studies on the role of transition metals in inflammation and ischemia and the composition of commercially available human serum albumin products and the effect of variations in composition on trauma patient outcomes. We believe his studies are valuable because of their originality and application to patient care, and because the results are obtained from well-preserved and characterized human biosamples without the confounding influence of interspecies differences. In this context, Dr. Bar-Or s approach plays a key role in bridging the gulf between basic molecular-cellular research and human clinical research.

Three of our most advanced product candidates are repositioned drugs (Optina, Vasaloc and Zertane) for which we have secured or are seeking U.S. and international patent protection covering their unique composition or application. Strategically, repositioned drugs reduce the risk of product failure due to adverse toxicology, lead to more modest investments during development, and may achieve more rapid marketing approval. Ampion is a biologic and being developed as a NME for inflammatory diseases. Because Ampion is naturally produced in the body to fight inflammation, we believe it has a favorable safety, efficacy, and risk profile. We have also developed an Oxidation Reduction Potential (ORP) diagnostic device which has been prototyped and is now undergoing testing. The ORP device is designed for use in emergency rooms to assess stroke and chest pain stratification of patients.

We intend to demonstrate statistical proof of human efficacy of our product candidates for specific indications:

Optina and Vasaloc, repurposed danazol with patents in process for complications of diabetes;

**Zertane**, repurposed tramadol hydrochloride with granted patents to treat premature ejaculation, or PE, in men;

Ampion, an innovative biological agent with composition of matter patent coverage and efficacy in treating inflammatory disorders, including osteoarthritis, rheumatoid disease and related disorders; and

Oxidation Reduction Potential (ORP) Diagnostic Device, a diagnostic machine that measures the net oxidants and antioxidants in human blood to determine oxidative stress in the body to assess cardiovascular events and other inflammatory conditions.

Optina for Diabetic Macular Edema and Wet AMD

Optina is an orally-administered repositioned compound based on a low-dose formulation of approved drug danazol. Developed initially to treat endometriosis, danazol was first approved by the FDA in the early 1970 s and is a derivative of the synthetic steroid ethisterone. Dr. Bar-Or, our chief scientific officer, has determined that danazol in low doses has the capability to control the permeability of tissues, thus reducing vascular leakage. Vascular permeability is a key endothelial mechanism by which inflammatory cytokines and angiogenic factors affect target cells and organs to mediate the inflammatory response or cell growth. During the disease state, there is an increase in vascular permeability factors leading to vasodilation, edema formation, and disruption of intercellular membrane structure.

Optina is designed to treat diabetic macular edema, or DME, and neovascular age-related macular degeneration, or wet AMD. If untreated, diabetic macular edema leads to moderate vision loss for one out of four diabetics over a period of three years and can lead to blindness over a period of seven years. We contracted with a Canadian hospital to conduct Phase II clinical trials of Optina for \$0.97 million. Patient enrollment commenced in January 2011 and the first dose was orally administered to an enrolled patient in February 2011. We believe this study will be completed in the second or third quarter of 2011. We intend to partner or entertain licensing opportunities once we have realized significant value for Optina s application based on reported human safety

and efficacy data. According to BCC Research, the market for DME and AMD in 2009 was over \$2.4 billion in the U.S.

Approximately 14% of people with diabetes have DME. According to the American Academy of Ophthalmology, the prevalence of DME increases to 29% for people with diabetes who use insulin for more than 20 years. Existing therapies for DME and wet AMD include focal and grid laser therapy, which is the current standard of care, as well as photodynamic therapy, surgery, and intravitreal treatment for AMD using Lucentis. Lucentis is costly compared to alternative injection therapies. Avastin is currently approved only for cancer treatment, but it is being used off-label by ophthalmologists to treat DME and wet AMD. There are currently no oral medications available for treatment of DME and wet AMD. We believe Optina has the potential to effectively treat DME and wet AMD without costly laser therapy and without requiring ongoing injections of pharmaceuticals in the eye.

Vasaloc for Diabetic Nephropathy

Vasaloc, like Optina, is also based on low-dose danazol. Vasaloc is an orally-administered compound designed to treat diabetic nephropathy. Untreated diabetic nephropathy leads to kidney damage or renal failure. Approximately 20-30% of the estimated 20.8 million diabetics in the U.S. have diabetic nephropathy, according to the Cleveland Clinic. We expect to contract for Phase II clinical trials of Vasaloc to commence in the second or third quarter of 2011, and believe the trial will be completed by the first half of 2012. Our estimated cost for the trial is under \$1.2 million.

Diabetes has become the most common single cause of end-stage renal disease in the U.S. and Europe. Standard modalities for the treatment of diabetic nephropathy include controlling blood glucose levels by using a variety of hormone therapies such as insulin, by stimulating the release of insulin using sulfonylureas, or through use of insulin derivatives. As high blood pressure is known to increase the rate of decline in renal function, diabetics are generally advised to control blood pressure using one or a combination of angiotensin-converting enzyme (ACE) inhibitors, Angiotensin II receptor blockers (ARBs), calcium channel blockers, diuretics, or beta-blockers. When renal failure occurs, dialysis is often required and a kidney transplant may become the only viable treatment option. We believe Vasaloc offers an effective means to treat diabetic nephropathy by reducing vascular permeability of nephrons and glomerulus, thereby stabilizing kidney function and reducing complications from kidney damage.

## Zertane for Premature Ejaculation in Men

Zertane is a new use for tramadol hydrocloride, which was approved for marketing as a noncontrolled analgesic in 1995. Based on the results of two clinical trials BioSciences conducted, we believe Zertane can be an effective oral medication to treat premature ejaculation, or PE, in men. Premature ejaculation is the most common form of male sexual dysfunction and has a major impact on the quality of life for many men and their partners. The market opportunity is large, with an estimated 23% of males suffering from premature ejaculation (four times the number with erectile dysfunction). According to Australia s Keogh Institute of Medical Research, PE is the most common sexual complaint in males. At present no drug has been approved by the FDA for the treatment of premature ejaculation. Priligy, an orally-administered anti-depressant in the SSRI class, has been approved for the treatment of PE in two European countries, where it is marketed by Janssen-Cilag, a unit of Johnson & Johnson. National approvals and licenses in five other European countries for Priligy are expected to shortly follow. Behavioral therapy is the current standard of care for treatment of PE. We have applied for patent protection for a combination of Zertane and an erectile dysfunction, or ED, medicine to offer male patients a single oral medication that will treat both PE and ED. A combination drug would address the significant co-morbid ED and PE population. We are currently opportunistically seeking partner or licensing opportunities for the Zertane drug combination.

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#### Ampion for Inflammation

Ampion is a non-steroidal biologic, aspartyl-alanyl diketopiperazine, referred to as DA-DKP. This compound is comprised of two amino acids derived from human blood, and is designed to treat chronic inflammatory and autoimmune diseases. Because it is a naturally occurring human molecule, DA-DKP is present in the body. Like danazol, Ampion has significant effects on vascular permeability when concentrated for clinical efficacy. Dr. Bar-Or has published a number of studies and articles on the anti-inflammatory immune response of DA-DKP. We intend to conduct pilot clinical studies on the effect of DA-DKP in patients suffering from multiple sclerosis, an autoimmune disease caused by nerve damage attributable to inflammation. There is currently no cure for MS and it is unknown what triggers the body s inflammatory response. We plan to conduct four proof of concept studies of Ampion in India or Australia commencing in the second or third quarter of 2011, and expect these studies will take approximately 24 months to complete. Our estimated cost for each trial is under \$0.5 million. We intend to partner or entertain licensing opportunities once we have realized significant value for Ampion through obtaining human efficacy data.

Oxidation-Reduction Potential (ORP) Diagnostic Device for Oxidative Stress

We have also developed an Oxidation-Reduction Potential, or ORP, diagnostic machine that will measure the oxidants and antioxidants in human blood. Designed for use at a patient—s bedside or at home, the ORP device has been prototyped and is now undergoing testing. We developed a disposable electrode for use in the ORP device and have calibrated the device to measure oxidants and antioxidants while taking into account various factors that may affect oxidative stress. Oxidative stress is often a marker for inflammation, which in turn indicates the presence of disease-related processes or developing conditions. We believe that identifying patients who are experiencing oxidative stress prior to hospital discharge can serve as a predictor of readmission rates, and as a means for patients to self-detect early indicators of health-related issues.

#### Preclinical Candidate Pipeline

Ampio s development process has produced numerous product candidates with various levels of patent protection in process, and for which we have obtained *in vitro* and clinical data. These earlier stage products may be candidates for a number of potential licensees, including pharmaceutical and biotechnology companies with substantial manufacturing facilities, established sales organizations, and significant marketing resources. Dr. Bar-Or has synthesized and applied for patents covering nine compounds known as methylphenidates for anti-angiogenesis and anti-metastasis applications. These compounds are derivatives of Ritalin, but are considered NMEs. We expect to seek a special protocol assessment from the FDA under which one or more of our methylphenidate compounds can be administered under a compassionate need exception to patients suffering from advanced liver, ovarian, brain or other cancers. Methylphenidates may also have applications for macular degeneration and to Alzheimer s or other neurodegenerative disorders, as methylphenidates have strong anti-inflammatory properties. Similarly, we have conducted early research into how copper chelating peptides, also considered an NME, may be used to treat Acute Coronary Syndrome and strokes. Because of the nature and extent of clinical trials needed to obtain regulatory approval for NMEs, we plan to out-license these compounds to collaborators after we have obtained early clinical data, in the case of methylphenidates, and after toxicology studies are completed, in the case of copper chelating peptides. Our product candidate portfolio includes a number of additional compounds we are now studying, including compounds to treat gingivitis and periodontitis, to assist in the diagnosis and monitoring of skin disorders, and to test for blood-borne infectious agents.

For further information regarding our business, product candidates, and preclinical candidate pipeline, see Business.

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#### **Recent Developments**

The following developments occurred in May, April and March, 2011:

On May 16, 2011, our common stock was approved for listing on the NASDAQ Capital Market under the symbol AMPE. Trading of our common stock commenced on the NASDAQ Capital Market on May 19, 2011, at which time our common stock ceased trading on the OTC Bulletin Board.

On April 18, 2011, we held the final closing under a private placement of our common stock, which we refer to as the placement. Two prior closings of the placement occurred on March 31 and April 8, 2011. We sold in the placement an aggregate of 5,092,880 shares of our common stock at a per share price of \$2.50. We received net proceeds of \$10.9 million from the placement after placement agent commissions and a non-accountable expense allowance, as well as other offering expenses (prior to reduction of accounts payable, accrued expenses and repayment of \$100,000 in related party indebtedness). No investor warrants or investor convertible securities were issued to purchasers in the placement. We issued placement agent warrants to Fordham Financial Management, Inc., or FFM, which entitle FFM to purchase up to 463,988 shares of our common stock during the five year life of the warrants at an exercise price of \$3.125 per share.

On March 25, 2011, we acquired BioSciences. BioSciences was formerly a privately-held company and its principal asset consisted of the worldwide rights to Zertane, as to which BioSciences held 32 issued patents and 31 pending patent applications. We issued a net of 5,167,905 shares of Ampio common stock to acquire BioSciences. These shares included shares issued to holders of in-the-money BioSciences stock options and warrants, and holders of two promissory notes, outstanding immediately prior to the merger.

#### Common Stock Offered

Background:

The securityholders own or have the right to acquire an aggregate of 6,762,609 shares of common stock, of which (i) 1,281,852 shares were issued on conversion of approximately \$2.2 million in principal and accrued interest under debentures converted on February 28, 2011 by the 21 holders thereof, who included two members of our board of directors and an affiliate of one of such board members, and (ii) 4,760,380 shares issued in a private placement, or the placement (which excludes 332,500 shares sold in the placement not being registered), the final closing under which occurred on April 18, 2011 and in which 93 accredited and sophisticated investors subscribed to purchase our common stock. The shares being registered hereby also include (i) up to 463,988 shares issuable to FFM on exercise of placement agent warrants issued to FFM at the closing of the placement, and (ii) 256,389 shares of common stock issuable on exercise of outstanding warrants issued to the debenture holders. The debentures were converted at a conversion price of \$1.75 per share and the warrants issued in conjunction therewith are exercisable at \$1.75 per share. The common stock sold in the placement had a purchase price of \$2.50 per share, and the placement agent warrants issued to FFM and its designee are exercisable at \$3.125 per share, or 125% of the price of the common stock sold in the placement. There were no investor warrants or convertible instruments issued in the placement.

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Shares of Common Stock offered by the selling securityholders:

6,762,609 shares of common stock.

Use of proceeds:

Any shares of common stock offered by the selling securityholders pursuant to this prospectus will be sold by the selling securityholders for their respective accounts. We will not receive any of the proceeds from these sales. If the warrants held by the debenture holders or the placement agent warrants held by FFM are exercised for cash, the exercise price will be used for working capital and general corporate purposes. We cannot estimate how many, if any, warrants or placement agent warrants will be exercised.

Lock-up agreements:

The shares of common stock issued on conversion of the debentures and in the placement are not subject to a lock-up agreement, except to the extent such shares are held by our executive officers, directors, or employees. We and each of our executive officers, members of the board of directors, and employees have agreed, subject to certain exceptions, not to sell, transfer or dispose of any shares of our common stock through February 29, 2012. FFM and its designees have agreed not to sell, transfer or hypothecate the shares of common stock underlying the placement agent warrants, if exercised, for a period of six months from the date of this prospectus. See Plan of Distribution.

NASDAQ Capital Market symbol

**AMPE** 

#### Market and Industry Data

We obtained statistical data, market and product data, and forecasts used throughout this prospectus from market research, publicly available information and industry publications. While we believe that the statistical data, industry data and forecasts and market research are reliable, we have not independently verified the data, and we do not make any representation as to the accuracy of the information.

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

#### **Risk Factors**

Our business is subject to a number of risks of which you should be aware. These risks are described in more detail in the Risk Factors section of this prospectus. These risks include:

There is substantial doubt about our ability to continue as a going concern;

Clinical trials have not yet been completed for Optina, Vasaloc, or Ampion, and the trials may yield unfavorable results that cause us to discontinue development of these product candidates;

Collaborators may terminate licenses on short notice or discontinue clinical trials due to a change in strategic focus, as we believe occurred with respect to Zertane;

We may not secure regulatory approval to market product candidates in the U.S. or other countries;

If we do not secure collaborators with manufacturing, marketing and sales capabilities, we may not be successful in commercializing any of our product candidates that receive regulatory approvals;

Even if a product candidate is approved and reaches the market, the product may not achieve physician and patient acceptance, or may not obtain adequate reimbursement from third party payors;

We have incurred significant operating losses since inception and we expect those losses to continue for at least several years; and

We face significant competition from companies much larger than us, and our product candidates will compete with other treatments and medicines that may be more effective, or safer, than ours.

#### **Corporate Information and History**

Our executive offices are located at 5445 DTC Parkway, P4, Greenwood Village, Colorado 80111, and our telephone number is (303) 418-1000. Additional information about us is available on our website at <a href="https://www.ampiopharma.com">www.ampiopharma.com</a>. 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. You can review filings we make with the SEC at its website (<a href="https://www.sec.gov">www.sec.gov</a>), including 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. 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.

Life Sciences is our predecessor and 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. 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.

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## **Summary Selected Unaudited Quarterly Consolidated Financial Information**

The following tables set forth selected unaudited quarterly financial data for us and our subsidiaries at and for the three months ended March 31, 2011, and comparative statement of operations data for the three months ended March 31, 2010. This data should be read in conjunction with (i) the unaudited consolidated balance sheet of Ampio at March 31, 2011, and the related unaudited consolidated statements of operations, stockholders equity (deficit), and cash flows for the three months ended March 31, 2011 and 2010, and the related notes contained in this prospectus, and (ii) Management s Discussion and Analysis of Financial Condition and Results of Operations. Our interim financial information as of March 31, 2011 and 2010 includes all adjustments, consisting of normal recurring adjustments, which our management considers necessary for fair presentation of the financial position and results of operations for such periods in accordance with GAAP.

		Three Months Ended March 31,	
	2011 (unaudited)	2010 (unaudited)	
Statement of Operations Data:			
Operating Expenses			
Research and development	\$ 632,952	\$ 337,834	
General and administrative	1,604,407	1,141,173	
Total operating expenses	2,237,359	1,479,007	
Other (expense), net	(6,542,105)	(2,647)	
Net loss	\$ (8,779,464)	\$ (1,481,654)	
Basic and diluted net loss per common share	\$ (0.49)	\$ (0.11)	
Weighted average number of common shares outstanding	18,025,851	13,098,367	

	March 31, 2011 (unaudited)		
Balance Sheet Data:			
Cash, cash equivalents and investments	\$ 4,558,669		
Working capital	2,671,067		
Total assets	12,683,155		
Total liabilities	2,012,088		
Total stockholders equity	10,671,067		
Summary Selected Unaudited Pro Forma Consolidated Combined Financial Information			

The following tables set forth selected unaudited pro forma consolidated combined financial data for us and BioSciences at and for each of the years in the two-year period ended December 31 or September 30, 2010 and 2009. You should read the summary selected unaudited pro forma consolidated combined financial information presented below in conjunction with the Management s Discussion and Analysis of Financial Condition and Results of Operations, our audited financial statements for the two years ended December 31, 2010 and 2009, and BioSciences audited financial statements for the two years ended September 30, 2010 and 2009, and the related notes contained in this prospectus. Our acquisition of BioSciences required us to include financial information in this prospectus for BioSciences as a significant subsidiary that exceeds 50% significance to us using the revenue test.

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In April 2009, Life Sciences commenced operations when it purchased assets, principally intellectual property, from BioSciences. In March 2010, Life Sciences merged with a subsidiary of Chay Enterprises, a Colorado corporation. Immediately following the merger, Chay Enterprises reincorporated in Delaware and changed its name to Ampio Pharmaceuticals, Inc. For accounting and financial reporting purposes, Life Sciences was considered the acquirer and the merger was treated as a reverse acquisition. All financial information presented in this prospectus for periods prior to the Chay merger reflects only that of Life Sciences, 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.

The selected unaudited pro forma consolidated combined financial data set forth below gives retroactive effect, to the beginning of the periods presented, of the acquisition of BioSciences. We have presented the unaudited pro forma consolidated combined financial information below to provide you a better picture of what our business would have looked like had we owned BioSciences since January 1, 2009. BioSciences fiscal year ended on September 30 and Ampio s fiscal ends on December 31, so the pro forma information presented below for 2010 and 2009 represents 12-month periods for BioSciences and Ampio ending September 30 and December 31, respectively. We have also eliminated inter-company transactions from the information below.

	Pro Forma Consolidated Combined Years Ended	
	September 30, 2010 or December 31,	September 30, 2009 or December 31,
	<b>2010</b> (unaudi	2009 ited)
Statement of Operations Data:	(unada	illu)
Revenues		
License fees	\$ 625,000	\$ 875,000
Royalty fees		58,750
Milestone payments		1,500,475
Other revenues		111,943
Total revenue	625,000	2,546,168
Expenses		
Research and development	2,124,336	1,936,483
General and administrative	5,012,764	2,300,421
Amortization	37,873	37,873
Total operating expenses	7,179,943	4,274,777
Other income (expenses)		
Interest expense, net	(7,509)	(11,511)
Unrealized gain on fair value of debt instruments	37,511	
Derivative expense	(1,367,771	