Ampio Pharmaceuticals, Inc.
Form 10-K
March 18, 2019
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10 K

(Mark One)

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

For the fiscal year ended December 31, 2018

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

Commission File Number 001 35182

AMPIO PHARMACEUTICALS, INC.

(www.ampiopharma.com)

NYSE American: AMPE

Delaware	26 0179592
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

373 Inverness Parkway Suite 200 Englewood, Colorado	80112
(Address of principal executive offices)	(Zip Code)

(720) 437 6500

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value $.0001 per share	NYSE American

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "large accelerated filer", "accelerated filer" and "smaller reporting

company" in Rule 12b 2 of the Exchange Act. (check one):

Large Accelerated Filer	Accelerated Filer
Non-Accelerated Filer	Smaller reporting company
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b 2 of the Exchange Act).
Yes No

The aggregate market value of common stock held by non-affiliates of the Registrant as of June 30, 2018 was $174.5 million based on the closing price of $2.20 as of that date.

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of the latest practicable date: As of March 1, 2019, 111,127,878 shares of common stock were outstanding.

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This Report on Form 10 K refers to trademarks, such as Ampio and Ampion, which are protected under applicable intellectual property laws and are our property. This Form 10 K also contains trademarks, service marks, copyrights and trade names of other companies which are the property of their respective owners. Solely for convenience, our

trademarks and tradenames referred to in this Form 10 K may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames.

Unless otherwise indicated or unless the context otherwise requires, references in this Form 10 K to the “Company,” “Ampio,” “we,” “us,” or “our” are to Ampio Pharmaceuticals, Inc.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

Forward Looking Statements

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

We obtained statistical data, market and product data, and forecasts used throughout this Form 10 K from market research, publicly available information and industry publications. While we believe that the statistical data, industry data and forecasts and market research are reliable, we have not independently verified the data, and we do not make any representation as to the accuracy of the information.

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AMPIO PHARMACEUTICALS, INC.

PART I

Item 1.Business

Overview

Our focus is on developing Ampion, which is a compound that decreases inflammation by inhibiting specific pro-inflammatory compounds.

Ampion has advanced through late-stage clinical trials in the United States. The U.S. Food and Drug Administration, or FDA, provided guidance that we should complete a trial of Kellgren Lawrence Grade 4, or KL 4, osteoarthritis patients with concurrent controls that would be carried out under a Special Protocol Assessment, or SPA, or otherwise with FDA feedback. An SPA is a process in which sponsors reach agreement with the FDA on the design and size of a proposed clinical trial to assure a study adequately addresses scientific and regulatory requirements to support marketing approval. However, the FDA still reserves the right to make changes at a future time which could include requiring additional trials.

AMPION

Ampion for Osteoarthritis and Other Inflammatory Conditions

Ampion is the < 5 kDa ultrafiltrate of 5% Human Serum Albumin, or HSA, an FDA, approved biologic product. Ampion is a non-steroidal, low molecular weight, anti-inflammatory biologic, which has the potential to be used in a wide variety of acute and chronic inflammatory conditions, as well as immune-mediated diseases. Ampion and its known components have demonstrated anti-inflammatory activity which supports the mechanism of action.

We are currently developing Ampion as an intra-articular injection to treat the signs and symptoms of severe osteoarthritis of the knee, or OAK, which is a growing epidemic in the United States. OAK is a progressive disease characterized by gradual degradation and loss of cartilage due to inflammation of the soft tissue and bony structures of the knee joint. Progression of the most severe form of OAK leaves patients with little to no treatment options other than a total knee arthroplasty. The FDA has stated that severe OAK is an ‘unmet medical need’ with no licensed therapies for this indication. While we believe that Ampion could treat this ‘unmet medical need’, our ability to market this product is subject to FDA approval.

Market Opportunity

Osteoarthritis, or OA, is the most common form of arthritis, affecting over 30 million people in the United States. It is a progressive disorder of the joints involving degradation of the intra-articular cartilage, joint lining, ligaments, and bone. Certain risk factors in conjunction with natural wear and tear lead to the breakdown of cartilage. Osteoarthritis is caused by inflammation of the soft tissue and bony structures of the joint, which worsens over time and leads to progressive thinning of articular cartilage. Other progressive effects include narrowing of the joint space, synovial membrane thickening, osteophyte formation and increased density of the subchondral bone. The global market size for treatments that currently address moderate to moderately severe OA was valued at approximately $3.0 billion in 2016 and is expected to grow with a compound annual growth rate of 9.04% through 2025. The global demand for osteoarthritis of the knee treatment is expected to be fueled by aging demographics and increased awareness of treatment options. Despite the size and growth of the osteoarthritis of the knee market, only a few treatment options currently exist, especially in the severely diseased patient population.

Ampion Development

Since our inception, we have conducted multiple clinical trials and have advanced through late-stage clinical trials in the United States, initially under the guidance of the FDA's Office of Blood Research and Review, or OBRR, and most recently under the guidance of the FDA's Office of Tissues and Advanced Therapies, or OTAT.

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Study AP-003-A was a U.S. multicenter, randomized, double-blind trial of 329 patients who were randomized 1:1 to receive Ampion or saline control via intra-articular injection. The study showed a statistically significant reduction in pain compared to the control, with an average of greater than 40% reduction in pain from baseline at 12 weeks. Patients who received Ampion also showed a significant improvement in function and quality of life (quality of life was assessed using the Patient Global Assessment, or PGA) compared to patients who received the saline control at 12 weeks. Furthermore, the trial included severely diseased patients (defined as KL 4). From this patient population, those patients who received Ampion had a significantly greater reduction in pain than those who received the saline control. Ampion was well tolerated with minimal adverse events reported across the Ampion and saline groups in the study. There were no drug-related serious adverse events.

The trial design of AP-003-C was initiated while we were under the guidance of OBRR and modified when guidance was transferred to OTAT in 2017. The study evaluated the responder rate of Ampion-treated patients as defined by the Osteoarthritis Research Society International ("OARSI") Standing Committee for Clinical Trials Response Criteria Initiative (OMERACT), which included pain, function, and PGA in support of a label for the treatment of the signs and symptoms of severe OAK at 12 weeks.

Both OBRR and OTAT have confirmed that our successful pivotal phase III clinical trial, AP-003-A, was adequate and well-controlled and provided evidence of the effectiveness of Ampion and can contribute to the substantial evidence of effectiveness necessary for the approval of a Biologics License Application, or BLA. However, OTAT does not consider the AP-003-C trial to be an adequate and well-controlled pivotal trial and provided guidance that we should complete an additional trial of KL 4 osteoarthritis patients with concurrent controls that would be carried out under an SPA to obtain FDA concurrence on the trial design. An SPA would provide a written agreement between us and the FDA indicating concurrence by the FDA on the adequacy and acceptability of critical elements of the overall protocol design for a study intended to support a future marketing application. The existence of an SPA agreement does not guarantee that the FDA will accept a new BLA or that the trial results will be adequate to support marketing approval. Those issues are addressed during the review of a submitted application and are determined based on the adequacy of the overall submission. We do not plan to begin our clinical trial until we are awarded an SPA from the FDA. Should the FDA award the SPA, we plan to commence enrollment of patients. Even if this proposed trial is completed, the FDA may require additional clinical trials in the future. We cannot ensure that the data derived from a subsequent trial or trials will be sufficient to support marketing approval for Ampion.

Ampion Manufacturing Facility

In December 2013, we entered into a ten-year lease of a multi-purpose facility containing approximately 19,000 square feet. This facility includes a clean room to manufacture Ampion, research laboratories and our corporate offices. Ampion manufactured at our facilities is used in our clinical trials.

We moved into this manufacturing facility in the summer of 2014 and it was placed into service during the first quarter of 2016. Since then, we have implemented a quality system, validated the facility for human-use products and produced Ampion.

Optina

In 2018, we reviewed our product portfolio and made the decision to delay the development of Optina or any other product in an effort to focus available resources on the development for Ampion.

Competition

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

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If we develop a successful product, we cannot guarantee it will be clinically superior or scientifically preferable to products developed or introduced by our competitors.

Among our smaller competitors, many of these companies have established co-development and collaboration relationships with larger pharmaceutical and biotechnology firms, which may make it more difficult for us to attract strategic partners. Our current and potential competitors include major multinational pharmaceutical companies, biotechnology firms, universities and research institutions. Some of these companies and institutions, either alone or together with their collaborators, have substantially greater financial resources and larger research and development staffs than do we. In addition, many of these competitors, either alone or together with their collaborators, have significantly greater experience than us in discovering, developing, manufacturing, and marketing pharmaceutical products. If one of our competitors realizes a significant advancement in a pharmaceutical drug or biologic that addresses the disease targeted by Ampion, our product could be rendered uncompetitive or obsolete.

Our competitors may also succeed in obtaining FDA or other regulatory approvals for their product candidates more rapidly than us, which could place us at a significant competitive disadvantage or deny us marketing exclusivity rights. Market acceptance of Ampion will depend on a number of factors, including: (i) potential advantages over existing or alternative therapies, (ii) the actual or perceived safety of similar classes of products, (iii) the effectiveness of sales, marketing, and distribution capabilities and (iv) the scope of any approval provided by the FDA or foreign regulatory authorities.

Although we believe Ampion possesses attractive attributes, we cannot assure that it will achieve regulatory or market acceptance, or that we will be able to compete effectively in the pharmaceutical drug markets. If Ampion fails to gain regulatory approvals and acceptance in its intended markets, we may not generate meaningful revenues or achieve profitability.

The available treatments for osteoarthritis of the knee include:

- oral non-steroidal anti-inflammatory agents;
- opioids;
- pain patches;
- intra-articular, or IA, corticosteroids injections;
- IA hyaluronic acid, or HA, injections;
- Acetaminophen;
- Capsaicin;
- Serotonin norepinephrine reuptake inhibitors (SNRIs);
- Platelet rich plasma (PRP);
- Total knee replacement (TKR); and
- Anti-NGF antibody products such as tanezumab, fulranumab and fasinumab.

The American Academy of Orthopedic Surgeons, or AAOS, issued their second edition of clinical practice guidelines for the treatment of osteoarthritis of the knee in May 2013. The AAOS was unable to recommend for or against the use of intra-articular corticosteroid injections as studies designed to indicate efficacy are inconclusive. Further, the AAOS was also unable to recommend for or against the use of acetaminophen, opioids, or pain patches as the efficacy studies in this area are also inconclusive. Most importantly, the AAOS does not recommend (with a strong ‘strength of recommendation’) the use of hyaluronic acid injections as, in the AAOS’ assessment, the clinical evidence does not support their use. This clinical practice guideline emphasizes the ‘unmet medical need’ for osteoarthritis of the knee

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given the few accepted and available treatments. We believe Ampion is a novel treatment option that, if approved, would be the first non-steroidal, non-hyaluronic-based intra-articular treatment available for pain due to osteoarthritis of the knee.

Government Regulation

FDA Approval Process

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

Pharmaceutical and biologic product development in the United States typically involves:

- the performance of satisfactory preclinical laboratory and animal studies under the FDA's Good Laboratory Practices, or GLPs, regulation;
- the development and demonstration of manufacturing processes, which conform to the FDA mandated current Good Manufacturing Practices, or cGMP, a quality system regulating manufacturing;
- the submission and acceptance of an Investigational New Drug, or IND, application which must become effective before human clinical trials may begin in the United States;
- obtaining the approval of Institutional Review Boards, or IRBs, at each site where we plan to conduct a clinical trial to protect the welfare and rights of human subjects in clinical trials;
- adequate and well-controlled clinical trials to establish the safety and effectiveness of the biologic for each indication for which FDA approval is sought; and
- the submission to the FDA for review and approval of an NDA or a BLA.

Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease. Preclinical tests generally include laboratory evaluation of a product candidate, its chemistry, formulation, stability and toxicity, as well as certain animal studies to assess its potential safety and efficacy. Results of these preclinical tests, together with manufacturing information (in compliance with GLP and cGMP), analytical data and the clinical trial protocol (detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated), must be submitted to the FDA as part of an IND, which must become effective before human clinical trials can begin.

An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30 day time period, raises concerns or questions about the intended conduct of the trial and imposes what is referred to as a clinical hold. Preclinical studies generally take several years to complete, and there is no guarantee that an IND based on those studies will become effective, allowing clinical testing to begin. In addition to the FDA review of an IND, each medical site that desires to participate in a proposed clinical trial must have the protocol reviewed and approved by an independent IRB or Ethics Committee, or EC, for sites located outside of the United States. The IRB considers, among other things, ethical factors, and the selection and safety of human subjects. Clinical trials must be conducted in accordance with the FDA's Good Clinical Practices, or GCP, requirements. The FDA and/or IRB/EC may order the temporary, or permanent, discontinuation of a clinical trial or a specific clinical trial site to be halted at any time, or

impose other sanctions for failure to comply with requirements under the appropriate entity jurisdiction.

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Clinical trials to support NDAs or BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. Ampio is seeking a BLA for Ampion. In Phase I clinical trials, a product candidate is typically introduced either into healthy human subjects or patients with the medical condition for which the new drug is intended to be used. The main purpose of the trial is to assess a product candidate's safety and the ability of the human body to tolerate the product candidate. Phase I clinical trials generally include less than 50 subjects or patients. During Phase II trials, a product candidate is studied in an exploratory trial or trials in a limited number of patients with the disease or medical condition for which it is intended to be used in order to: (i) further identify any possible adverse side effects and safety risks, (ii) assess the preliminary or potential efficacy of the product candidate for specific target diseases or medical conditions, and (iii) assess dosage tolerance and determine the optimal dose for Phase III trials. Phase III trials are generally undertaken to demonstrate clinical efficacy and to further test for safety in an expanded patient population with the goal of evaluating the overall risk-benefit relationship of the product candidate. Phase III trials will generally be designed to reach a specific goal or endpoint, the achievement of which is intended to demonstrate the product candidate's clinical efficacy and provide adequate information for labeling of the biologic.

A drug being studied in clinical trials may be made available to individual patients in certain circumstances. Pursuant to the 21st Century Cures Act, or Cures Act, which was signed into law in December 2016, the manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug. This requirement applies on the later of 60 calendar days after the date of enactment of the Cures Act or the first initiation of a Phase II or Phase III trial of the investigational drug.

After completion of clinical testing under an IND, a BLA is prepared and submitted to the FDA. FDA approval of the BLA is required before marketing of the product may begin in the United States. The BLA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting a BLA is substantial. Under federal law, the submission of most BLAs are subject to an application user fee, currently $2.6 million. However, the FDA will waive the application user fee for the first human drug application that a small business or its affiliate submits for review. Small businesses are defined as businesses with less than 500 employees, therefore Ampio is considered a small business. The manufacturer and/or sponsor under an approved BLA are also subject to an annual program fee, currently $310,000. The annual program fee replaced the product and establishment user fees that the FDA charged in prior years. These fees typically increase annually.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the FDA's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of BLAs. Most such applications for standard biologic products are reviewed within ten months; most applications for priority biologics are reviewed in six months. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA may also refer applications for novel biologic products, or biologic products which present difficult questions of safety or efficacy, to an advisory committee, which is typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities where the biologic is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory and the BLA contains data that provide substantial evidence that the biologic is safe and effective in the indication studied.

After the FDA evaluates the BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of the BLA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the biologic outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing,

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dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

There are accelerated review processes at the FDA, including Fast Track Designation and Accelerated Approval, none of which Ampio is seeking.

Foreign Regulatory Approval

Outside of the United States, our ability to market Ampion will be contingent upon receiving marketing authorizations from the appropriate foreign regulatory authorities, whether or not FDA approval has been obtained. The foreign regulatory approval process in most industrialized countries generally encompasses risks similar to those we will encounter in the FDA approval process. The requirements governing the conduct of clinical trials and marketing authorizations, and the time required to obtain the requisite approvals, may vary widely from country to country and differ from those required for FDA approval.

Under European Union, or EU, regulatory systems, marketing authorizations may be submitted either under a centralized or decentralized procedure.

The centralized procedure provides for the grant of a single marketing authorization that is valid for all EU member states. The centralized procedure is compulsory for human medicines that are derived from biotechnology processes, such as genetic engineering, that contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the European Commission following a favorable opinion by the European Medicines Agency, or EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

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

Biosimilars and Exclusivity

The Patient Protection and Affordable Care Act, or Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, which created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. This amendment to the Public Health Services Act attempts to minimize duplicative testing. Biosimilarity, requires that there can be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, and can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the

product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times. The biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

A novel biologic is granted twelve years of exclusivity from the time of first licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitting under the abbreviated approval pathway for the

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lesser of (i) one year after the first commercial marketing, (ii) eighteen months after approval if there is no legal challenge, (iii) eighteen months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42 month period.

Post-Approval Regulation

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

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

Other Regulatory Requirements

We are also subject to regulation by other regional, national, state and local agencies, including the U.S. Department of Justice, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies. Our current and future partners are subject to many of the same requirements.

In addition, we are subject to other regulations, including regulations under the Occupational Safety and Health Act, regulations promulgated by the U.S. Drug Enforcement Administration, the Toxic Substance Control Act, the Resource Conservation and Recovery Act, and regulations under other federal, state and local laws.

Violations of any of the foregoing requirements could result in penalties being assessed against us.

Privacy

Most health care providers, including research institutions from whom we or our partners obtain patient information, are subject to privacy and security rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and the amendments to HIPAA under the Health Information Technology for Economic and Clinical Health

Act, or HITECH. Additionally, strict personal privacy laws in other countries affect pharmaceutical companies' activities in those countries. Such laws include the EU Directive 95/46/EC on the protection of individuals with regard to the processing of personal data, as well as individual EU Member States implementing additional laws. Although our clinical development efforts are not barred by these privacy regulations, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a health care provider that has not satisfied HIPAA's or the EU's disclosure standards. Failure by EU clinical trial partners to obey requirements of national laws on private personal data, including laws implementing the EU Data Protection Directive, might result in liability and/or adverse publicity.

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Information Systems

We believe that our Information Systems, or IS, capabilities are adequate to manage our core business. In addition, our internal controls related to IS are operating effectively.

Intellectual Property Summary

Ampion

In 2018, we reviewed our patent portfolio relative to Ampion. We made the decision to focus available resources by limiting the maintenance of patent protection for Ampion based on the relative importance of technologies covered by patents, the geographic jurisdiction of patents and remaining patent term. This allowed us to reduce the overall number of patents while maintaining our strategic coverage. The portfolio primarily consists of seven families filed in the United States and throughout the world.

The first family includes U.S. patents and a European patent, validated and being maintained in Germany, Great Britain and France with claims relating to methods of treating inflammatory disease and compositions of matter comprising diketopiperazine derivatives, including aspartyl-alanyl diketopiperazine, or DA-DKP. This family also includes issued patents in China, Hong Kong, and Japan. The standard 20-year expiration for patents in this family is in 2021.

The second family includes U.S. patents with claims directed to methods of treating inflammation and T-cell mediated or inflammatory diseases with compositions of matter comprising DA-DKP. This family also includes issued patents in Australia, China, New Zealand, Singapore, Hong Kong, Israel, Japan, South Africa and a European patent (validated in Germany, Great Britain, France, Italy, and the Netherlands) and pending applications in the United States, Canada, China, and Hong Kong. The standard 20-year expiration for patents in this family is in 2024.

The third family includes U.S. patents, a pending U.S. application, and issued patents in Australia, China, Eurasia (Russia), Israel, Japan, New Zealand, and Philippines and pending applications in Australia, Brazil, Canada, China, EPO, Hong Kong, Indonesia, Korea, Mexico, Malaysia, Singapore, United States, and South Africa. The claims in this family are directed to the use of DA-DKP for the treatment of degenerative joint diseases. The standard 20-year expiration for patents in this family is in 2032.

The fourth family includes a U.S. patent, a pending U.S. application and pending applications in Australia, Canada, China, EPO, Hong Kong, Japan, New Zealand with claims directed to the use of DA-DKP to mobilize, home, expand and differentiate stem cells in the treatment of subjects. The standard 20-year expiration for patents in this family is in 2034.

The fifth family includes a U.S. patent, a pending U.S. application and pending applications in Australia, Canada, China, Europe, Hong Kong, Israel, Japan, Korea and Russia with claims directed to the use of DA-DKP for the treatment of degenerative joint diseases in a multi-dose treatment regimen. The standard 20-year expiration for patents in this family is in 2035.

The sixth family includes a pending U.S. application and pending applications in Europe and Hong Kong with claims directed to the use of DA-DKP in the absence of cyclooxygenase-2, or COX-2 antagonist treatment. The standard 20-year expiration for patents in this family will be in 2036.

The seventh family includes a Patent Cooperation Treaty international application with claims directed to the use of N-acetyl-kynurenine for treatment of T-cell mediated diseases, degenerative joint disease and diseases mediated by platelet activating factor and composition of matter. The standard 20-year expiration for patents in this family will be 2037.

Optina

In 2018, we reviewed our patent portfolio relative to Optina. We made the decision to delay the development of Optina and allow existing patents and applications to lapse by non-payment of annuities and maintenance fees and non-responses to actions in the future in an effort to focus available resources on patent protection for Ampion.

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Barriers to Entry – General

We also maintain trade secrets and proprietary know-how that we seek to protect through confidentiality and nondisclosure agreements. We expect to seek U.S. and foreign patent protection for our therapeutic product. These patents may not provide meaningful protection or adequate remedies in the event of unauthorized use or disclosure of confidential and proprietary information. If we do not adequately protect our trade secrets and proprietary know-how, our competitive position and business prospects could be materially harmed.

The patent positions of companies such as ours involve complex legal and factual questions and, therefore, their enforceability cannot be predicted with any certainty. Our issued and licensed patents, and those that may be issued to us in the future, may be challenged, invalidated or circumvented, and the rights granted under the patents or licenses may not provide us with meaningful protection or competitive advantages. Our competitors may independently develop similar technologies or duplicate any technology developed by us, which could offset any advantages we might otherwise realize from our intellectual property. Furthermore, even if Ampion receives regulatory approval, the time required for development, testing, and regulatory review could mean that protection afforded to us by our patents may only remain in effect for a short period after commercialization. The expiration of patents or license rights we hold could adversely affect our ability to successfully commercialize our biologic, thus harming our operating results and financial position.

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

Our pending patent applications, or those we may file or license from third parties in the future, may not result in patents being issued. Until a patent is issued, the claims covered by an application for patent may be narrowed or removed entirely, thus depriving us of adequate protection. As a result, we may face unanticipated competition, or conclude that without patent rights the risk of bringing Ampion to market exceeds the returns we are likely to obtain. We are generally aware of the scientific research being conducted in the areas in which we focus our research and development efforts, but patent applications filed by others are maintained in secrecy for at least 18 months and, in some cases in the United States, until the patent is issued. The publication of discoveries in scientific literature often occurs substantially later than the date on which the underlying discoveries were made. As a result, it is possible that patent applications for products similar to our biologic candidate may have already been filed by others without our knowledge. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights, and it is possible that development of Ampion could be challenged by other pharmaceutical or biotechnology companies. If we become involved in litigation concerning the enforceability, scope and validity of the proprietary rights of others, we may incur significant litigation or licensing expenses, be prevented from further developing or commercializing Ampion, be required to seek licenses that may not be available from third parties on commercially acceptable terms, if at all, or subject us to compensatory or punitive damage awards. Any of these consequences could materially harm our business.

Research and Development

For the years ended December 31, 2018 and 2017, we recorded $6.8 million and $10.4 million, respectively, of research and development expenses. Research and development expenses represented 61.0% and 67.0% of total operating expenses in the years ended December 31, 2018 and 2017, respectively. More information regarding our research and development activities can be found in the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” under Item 7 of this Annual Report.

Compliance with Environmental Laws

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

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Product Liability and Insurance

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

Employees

As of March 1, 2019, we had 22 full-time employees and utilized the services of a number of consultants on a temporary basis.

Available Information

Our principal executive offices are located at 373 Inverness Parkway, Suite 200, Englewood, Colorado 80112 USA, and our phone number is (720) 437 6500.

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, electronically with the U.S. Securities and Exchange Commission, or the SEC. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is http://www.sec.gov.

You may obtain a free copy of our annual reports on Form 10-K, quarterly reports on From 10-Q, current reports on Form 8-K and amendments to those reports on our website at http://www.ampiopharma.com on the earliest practicable date following the filing with the SEC. Information found on our website is not incorporated by reference into this report.

Our Code of Conduct and Ethics and the charters of our Nominating and Governance Committee, Audit Committee, Compensation Committee and Disclosure Committee of our Board of Directors may be accessed within the Investor Relations section of our website. Amendments and waivers of the Code of Conduct and Ethics will also be disclosed within four business days of issuance on the website. Information found on our website is neither part of this annual report on Form 10 K nor any other report filed with the SEC.

Item 1A.Risk Factors

Risks Related to Our Business

Management has performed an analysis of our ability to continue as a going concern. In addition, our independent registered public accounting firm has expressed substantial doubt as to our ability to continue as a going concern.

Based on their assessment, management has raised concerns about our ability to continue as a going concern. In addition, our independent registered public accounting firm expressed substantial doubt as to our ability to continue as

a going concern in their report accompanying our audited financial statements. A “going concern” opinion could impair our ability to finance our operations through the sale of debt or equity securities or through bank financing. We have raised $139.0 million in net proceeds from equity financing in the past ten years and believe that we will be able to raise additional equity or debt financing in the future but the financing could be extremely dilutive to our current shareholders. Our ability to continue as a going concern will depend on our ability to obtain additional financing. Additional capital may not be available on reasonable terms, or at all. If adequate financing is not available, we would be required to terminate or significantly curtail our operations, or enter into arrangements with collaborative partners or others that may require us to relinquish rights to certain aspects of Ampion, or potential markets that we would not otherwise relinquish.

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If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue operations.

We have incurred significant losses since inception, expect to incur net losses for at least the next several years and may never achieve or sustain profitability.

We are a development stage biopharmaceutical company that has not generated revenues or profits and have therefore incurred significant net losses totaling $171.0 million since our inception in December 2008. We expect to generate operating losses for the foreseeable future, but intend to try to limit the extent of these losses by entering into licensing, co-development or collaboration agreements with one or more strategic partners, which may provide us with potential milestone payments and royalties. Those arrangements, if obtained, will be our primary source of revenues for the coming years. We cannot be certain that any licensing, co-development or collaboration arrangements will be obtained, or that the terms of those arrangements will result in us receiving material revenues. To obtain revenues from Ampion, we must succeed, either alone or with others, in a range of challenging activities, including completing clinical trials, obtaining marketing approval, manufacturing, marketing and selling, satisfying any post-marketing requirements and obtaining reimbursement for our product from private insurance or government payors. We, and our collaborators, may never succeed in these activities and, even if we do, or one of our collaborators does, we may never generate revenues that are significant enough to achieve profitability.

We will need substantial additional capital to fund our operations. 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 Ampion and may need to cease operations.

Developing pharmaceutical products is a very time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses could increase in connection with our ongoing activities, particularly as we initiate new clinical trials, prepare to file our Ampion BLA with the FDA and seek marketing approval for Ampion.

As of December 31, 2018, we had $7.6 million of cash which we expect can fund our operation into the second quarter of 2019. To operate as planned in fiscal 2019 and into 2020 we will need to raise at least $16.0 million through equity offerings, debt or other financing tools.

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 clinical trials and research and development;
- progress in and the costs of applying for regulatory approval for Ampion;
- the costs of sustaining our corporate overhead requirements and hiring and retaining necessary personnel;
    - 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 Ampion.

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Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through collaboration arrangements, private or public sales of our securities, including under our “at-the-market”, or ATM, equity program, debt financings, or by licensing Ampion. We cannot be certain that additional funding will be available to us on acceptable terms, if at all, or that it will be adequate to execute our business strategy. If funds are not available, we may be required to delay, reduce the scope of, or eliminate development of Ampion, or substantially curtail or close our operations altogether.

Even if we obtain additional financing, it may be on terms not favorable to us, it may be costly and it may require us to agree to covenants or other provisions that will favor new investors over existing shareholders or other restrictions that may adversely affect our business. Additional funding, if obtained, may also result in significant dilution to our stockholders. Alternatively, we may have to obtain a collaborator for Ampion at an earlier stage of development than planned, which could lower our economic value.

Our business is highly dependent on the success of Ampion. If Ampion does not receive regulatory approval or is not successfully commercialized, our business is likely to be harmed.

A substantial portion of our business and future success depends on our ability to develop, obtain regulatory approval for and successfully commercialize Ampion. We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We are devoting all of our resources to the development of Ampion. We cannot be certain that Ampion will be successful in ongoing or future clinical trials, receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

Ampion will be undergoing clinical trials that are time-consuming and expensive, the outcomes of which are unpredictable, and for which there is a high risk of failure. If clinical trials of Ampion fail to satisfactorily demonstrate safety and efficacy to the FDA and other regulators, the FDA may require additional clinical trials and we, or our collaborators, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of Ampion.

Clinical trials are long, expensive and unpredictable processes that can be subject to extensive delays. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. It may take several years to complete clinical development necessary to commercialize a biologic, and delays or failure can occur at any stage. Success in pre-clinical testing and the results of earlier clinical trials do not necessarily predict clinical success, and larger and later-stage clinical studies may not produce the same results as earlier-stage 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. 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 and we cannot be certain that we will not face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced.

We continue to work toward completion and analysis of clinical trials for Ampion. Any unfavorable outcomes of our trials for Ampion would be a major set-back for the development program 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 the product development program, which could have a material adverse effect on our business and financial condition and on the value of our common stock.

In connection with clinical testing and trials, we face a number of risks, including:

- Ampion 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 Ampion;
- the results may not confirm the positive results of earlier testing or trials;
- the results may not meet the level of statistical significance required by the FDA or other regulatory agencies to establish the safety and efficacy of Ampion; and

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- the FDA may require additional clinical testing and trials, which are costly and time consuming.

If we do not successfully complete clinical development, we will be unable to market and sell products derived from Ampion 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 BLA is submitted to the FDA. Although there are a large number of biologics in the development stage in the United States and other countries, only a small percentage result in the submission of a BLA 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 satisfactorily address the safety and effectiveness of Ampion in development, we may not receive regulatory approval of Ampion 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 or prevent our ability to generate revenues.

Human clinical trials are very expensive, time-consuming, and difficult to design, implement and complete. We currently expect clinical trials of Ampion could take from 12 to 24 months to complete, however we cannot be certain we will successfully complete current or future clinical trials within any specific time period, if at all. If we experience delay, suspensions or terminations in a clinical trial, the commercial prospects for Ampion will be harmed, our ability to generate product revenues will be delayed and our business may be jeopardized.

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

- lack of effectiveness of Ampion during clinical studies;
- adverse events, safety issues or side effects relating to Ampion or its formulation;
- not demonstrating sufficient safety and efficacy to obtain regulatory approval;
- inability to reach an agreement with the FDA on the design of a clinical trial;
- inability to reach an agreement on acceptable terms with prospective contract research organizations and clinical trial sites;
- inability to manufacture or obtain from third party materials sufficient for use in clinical studies;
- not obtaining institutional review board approval to conduct a clinical trial at a prospective clinical trial site;
- not determining dosing and making related adjustments;
- 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, 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;
- 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 Ampion;
- failure by us or our collaborators to conduct clinical trials in accordance with regulatory requirements;

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- governmental or regulatory delays and changes in regulatory requirements, interpretation, 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;
- 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 Ampion.

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

- delays in clinical trials or commercialization;
- refusal by the FDA to review pending applications or supplements to approved applications;
- product recalls or seizures;
- suspension of manufacturing;
- withdrawals of previously approved marketing applications; and
- fines, civil penalties, and criminal prosecutions.

If Ampion is not approved by the FDA, we will be unable to commercialize it in the United States.

We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing Ampion.

We rely, and will rely in the future, on medical institutions, clinical investigators, contract research organizations, contract laboratories, and collaborators to perform data collection and analysis and other aspects of our clinical trials.

Our clinical trials conducted by third parties may be delayed, suspended, or terminated if:

- the third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines;
- we replace a third party; or
- the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory requirements, or for other reasons.

Third party performance failures may increase our development costs, delay our ability to obtain regulatory approval, and delay or prevent the commercialization of Ampion. If we seek alternative sources to provide these services, we may not be able to enter into replacement arrangements without incurring delays or additional costs.

If we do not receive marketing approval for Ampion, we may not realize the investment we have made in our manufacturing facility.

In December 2013, we entered into a ten-year lease of a multi-purpose facility containing approximately 19,000 square feet. We have spent approximately $10.8 million dollars to build out this facility in anticipation of receiving approval of

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our BLA and commencing commercialization of Ampion. If the FDA does not approve our BLA for Ampion, or does not approve of our manufacturing operation, we will not be able to manufacture and commercialize Ampion in our facility and we will remain obligated to make payments under our lease, which is set to expire in 2024. Any delay or failure to receive BLA approval for Ampion could have a material adverse effect on the carrying value of the manufacturing facility as well as on our results of operations.

Relying on third-party suppliers may result in delays in our clinical trials and product introduction.

We currently obtain the Human Serum Albumin, or HSA, needed to produce Ampion for our clinical trials from one supplier in the United States. Our clinical trials and ultimately FDA approval may be delayed if we are unable to obtain a sufficient quantity of the HSA raw material needed to produce Ampion on a timely basis or if we need to establish an alternative source of supply for the raw material.

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

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

The research and development activities conducted at our facility involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials and produce hazardous waste products. Our manufacturing facility involves the controlled use of potentially hazardous substances and produces hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. If we experience a release of hazardous substances, it is possible that this release could cause personal injury or death, and require decontamination of the facility. In the event of an accident while manufacturing Ampion, we could be held liable for damages or face substantial penalties. We do not have any insurance for liabilities arising from the procurement, handling, or discharge of hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may delay our research, development and production efforts, which could harm the financial condition of our business or impair our operations.

Even if we obtain marketing approvals for Ampion, the terms of approvals and ongoing regulation of our product may limit how we, or our collaborators, manufacture and market our product, which could materially impair our ability to generate revenue.

Even if we receive regulatory approval for Ampion, 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 require a warning in the labeling and 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 Ampion effectively.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and reporting requirements. We, our contract manufacturers, our collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

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Accordingly, assuming we, or our collaborators, receive marketing approval for Ampion, we, our collaborators and contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

Ampion for which we obtain marketing approval in the future could be subject to post-marketing restrictions or withdrawal from the market and we, and our collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our product following approval.

Ampion for which we, or our collaborators, obtain marketing approval in the future, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such product, among other things, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of Ampion is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the FDA requirement to implement a Risk Evaluation and Mitigation Strategy to ensure that the benefits of a biological product outweigh its risks.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or our collaborators, do not market Ampion in accordance with the marketing approval received for the product's approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the FDCA, the Public Health Service Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.

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

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

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators, and our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA and other regulatory agencies and the timing thereof;

- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of compounds used to manufacture Ampion;
- the efforts of our collaborators with respect to the commercialization of our product; and

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· 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.

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

Even if we contract with collaborators that successfully complete clinical trials for Ampion, our product may not be commercialized for other reasons, including:

· failure to receive the regulatory clearances required to market Ampion;
· being subject to proprietary rights held by others;
· being difficult or expensive to manufacture on a commercial scale;
· having adverse side effects that make Ampion's use less desirable; or
· failing to compete effectively with products or treatments commercialized by competitors.

We might enter into agreements with collaborators to commercialize Ampion once we obtain regulatory approvals, which may affect the sales of our product and our ability to generate revenues.

We are not currently established to handle sales, marketing and distribution of pharmaceutical products and may contract with, or license, third parties to market Ampion if we receive regulatory approvals. Outsourcing sales and marketing in this manner may subject us to a variety of risks, including:

· our inability to exercise control over sales and marketing activities and personnel;
· failure or inability of contracted sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our product;
· disputes with collaborators concerning sales and marketing expenses, calculation of royalties, and sales and marketing strategies;
· unforeseen costs and expenses associated with sales and marketing;
· collaborators may 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;
· collaborators may believe our intellectual property or Ampion infringes on the intellectual property rights of others;
· collaborators may dispute their responsibility to conduct commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenues;
· collaborators may decide to pursue a competitive product developed outside of the collaboration arrangement;
· collaborators may delay the commercialization of Ampion in favor of commercializing another party's product candidate; or
· collaborators may decide to terminate or not to renew the collaboration for these or other reasons.

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

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

Our ability to succeed in the future depends on our ability to discover, develop and commercialize a pharmaceutical product that offers superior efficacy, convenience, tolerability, and safety when compared to existing treatment methodologies. We intend to do so by identifying a product candidate that is based on a modified active ingredient which previously received regulatory approval. Because our strategy is to develop a new product candidate primarily for the treatment of a disease that affects a large patient population, our product is likely to compete with a number of existing medicines or treatments, and a large number of product candidates that are being developed by others.

Many of our potential competitors have substantially greater financial, technical, personnel and marketing resources than we do. In addition, many of these competitors have significantly greater resources devoted to product development and pre-clinical research. Our ability to compete successfully will depend largely on our ability to:

· develop Ampion to be superior to other products in the market;
· attract and retain qualified personnel;
· obtain patent and/or other proprietary protection for Ampion;
· obtain required regulatory approvals; and
· obtain collaboration arrangements to commercialize Ampion.

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

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

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

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

We may be subject to legal or administrative proceedings and litigation other than product liability lawsuits which may be costly to defend and could materially harm our business, financial conditions and operations.

Although we maintain general liability and product liability insurance, this insurance may not fully cover potential liabilities. In addition, our inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to

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otherwise protect against potential product or other legal or administrative liability claims could prevent or inhibit the commercial production and sale of Ampion that receives regulatory approval, which could adversely affect our business. Product liability claims could also harm our reputation, which may adversely affect our collaborators' ability to commercialize our product successfully.

If Ampion is commercialized, this does not assure acceptance by physicians, patients, third-party payors, or the medical community in general.

We cannot be sure that Ampion, if and when approved for marketing, will be accepted by physicians, patients, third-party payors, or the medical community in general. Even if the medical community accepts a product as safe and efficacious for its indicated use, physicians may choose to restrict the use of the product if we or any collaborator are unable to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, our product is preferable to any existing medicines or treatments. We cannot predict the degree of market acceptance of Ampion once we receive marketing approval, which will depend on a number of factors, including, but not limited to:

- the clinical efficacy and safety of the product;
- the approved labeling for the product and any required warnings;
- the advantages and disadvantages of the product compared to alternative treatments;
- our and any collaborator's ability to educate the medical community about the safety and effectiveness of the product;
- the reimbursement policies of government and third-party payors pertaining to our product; and
- the market price of our product relative to competing treatments.

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

The commercial success of Ampion will depend on the reimbursement rates from health maintenance, managed care, pharmacy benefit, government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we, or our collaborators, may not be able to successfully commercialize Ampion. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or our collaborators, to establish or maintain pricing to realize a sufficient return on our or their investments.

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

- our or our collaborators' ability to set a price we believe is fair for Ampion, if approved;
- our ability to generate revenues and achieve profitability; and
- the availability of capital.

The 2010 enactments of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act are expected to significantly impact the provision of, and payment for, health care in the United States. Various provisions of these laws are designed to expand Medicaid eligibility, subsidize insurance premiums, provide incentives for businesses to provide health care benefits, prohibit denials of coverage due to pre-existing conditions, establish health insurance exchanges, and provide additional support for medical research. Additional legislative proposals to reform healthcare and government insurance programs, along with the trend toward managed healthcare in the United States, could influence the purchase of medicines and reduce demand and prices for our products, if approved. This could harm our or our collaborators' ability to market our product and generate revenues.

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Cost containment measures that health care payors and providers are instituting and the effect of further health care reform could significantly reduce potential revenues from the sale of Ampion in the future, and could cause an increase in our compliance, manufacturing, or other operating expenses. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures at the federal and state level, as well as internationally, will continue and may increase, which may make it difficult for us to sell our potential product that may be approved in the future at a price acceptable to us or any of our future collaborators.

The approval process outside the United States varies among countries and may limit our ability to develop, manufacture and sell our product internationally. Failure to obtain marketing approval in international jurisdictions would prevent Ampion from being marketed abroad.

In order to market and sell our product in the EU and many other jurisdictions, we, and our collaborators, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedures vary among countries and can involve additional testing. We may conduct clinical trials for, and seek regulatory approval to market, Ampion in countries other than the United States. Depending on the results of clinical trials and the process for obtaining regulatory approvals in other countries, we may decide to first seek regulatory approvals of Ampion in countries other than the United States, or we may simultaneously seek regulatory approvals in the United States and other countries. If we or our collaborators seek marketing approvals for Ampion outside the United States, 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 EMA, 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 United States is likely to subject us to all of the risks associated with obtaining FDA approval described above. In addition, marketing approval by the FDA does not ensure approval by the health authorities of any other country and approval by foreign health authorities does not ensure marketing approval by the FDA.

Our drug development program to date has been dependent in large part upon the services of Dr. David Bar-Or, who retired as Chief Scientific Officer in September 2018.

Our drug development program to date has been dependent in large part upon the services of Dr. David Bar-Or, who retired from his full-time role as Chief Scientific Officer effective September 30, 2018. Although Dr. Bar-Or has continued to serve as a member of our Board of Directors and our Scientific Advisory Board, the loss of his services as our full-time Chief Scientific Officer could result in delays of other product development activities, and our ability to develop and commercialize new product candidates may be diminished.

Business interruptions could limit our ability to operate our business.

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

While we are not aware of any cybersecurity incidents, the cybersecurity landscape continues to evolve and we may find it necessary to make further investments to protect our data and infrastructure.

We continuously work to install new and upgrade existing information technology systems and provide employee awareness training around phishing, malware and other cyber risks to ensure that we are protected, to the greatest extent possible, against cyber risks and security breaches. Any actual or suspected security breach or other compromise of our security measures or those of our third-party vendors, whether as a result of hacking efforts, denial-of-service attacks, viruses, malicious software, break-ins, phishing attacks or otherwise, could harm our reputation and business, require us to expend significant capital and other resources to address the breach, and result in a violation of applicable laws, regulations or other legal obligations.

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Risks Related to Our Intellectual Property

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

Our commercial success depends on obtaining and maintaining proprietary rights for Ampion including its compounds and uses. We must successfully defend these rights against third-party challenges. We will only be able to protect Ampion's proprietary compounds, and its use from unauthorized use to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them.

Our ability to obtain patent protection for Ampion and its compounds is uncertain due to a number of factors, including:

- we may not be the first to make the inventions covered by pending patent applications or issued patents;
- we may not be the first to file patent applications for Ampion or its compounds we developed or for its use;
- others may independently develop identical, similar or alternative products or compounds;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our pending patent applications may not result in issued patents;
- we may not seek or obtain patent protection in countries that may eventually provide us a significant business opportunity;
- any patents issued to us may not provide a basis for commercially viable products, may not provide any competitive advantages, or may be successfully challenged by third parties;
- our proprietary compound may not be patentable;
- others may design around our patent claims to produce competitive products which fall outside of the scope of our patents; and
- others may identify prior art which could invalidate our patents.

Even if we have or obtain patents covering Ampion or its compounds, we may still be barred from making, using and selling Ampion or technologies because of the patent rights of others. Others have or may have filed, and in the future may file, patent applications covering compounds or products that are similar or identical to ours. There are many issued U.S. and foreign patents relating to chemical compounds and therapeutic products, and some of these relate to compounds we intend to commercialize. Numerous U.S. and foreign issued patents and pending patent applications owned by others exist. These could materially affect our ability to develop Ampion or sell our product if approved. Because patent applications can take many years to issue, there may be currently pending applications unknown to us that may later result in issued patents that Ampion or its compounds may infringe. These patent applications may have priority over patent applications filed by us.

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

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

Because we operate in the highly technical field of drug discovery and development of therapies that can address inflammation and other conditions, we rely in part on trade secret protection to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential, and not disclose to third parties, all confidential information developed by the party or made known to the party by us during the party's relationship with us. These agreements also generally provide that inventions conceived by the party while rendering services for us will be our exclusive property.

However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

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

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

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

As a result, we could be prevented from commercializing Ampion.

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

The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. For example, some of our patents and patent applications cover methods of use of repositioned drugs, while

other patents and patent applications cover composition of a particular compound. The interpretation and breadth of claims allowed in some patents covering pharmaceutical compounds may be uncertain and difficult to determine, and are often affected materially by the facts and circumstances that pertain to the patented compound and the related patent claims. The standards of the United States Patent and Trademark Office, or USPTO, are sometimes uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if

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issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, and U.S. patents may be subject to reexamination proceedings by the USPTO. Foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent offices, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, reexamination and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

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

If we fail to obtain and maintain patent protection and trade secret protection for Ampion and its' proprietary compounds and their uses, we could lose our competitive advantage and the competition we face could increase, reducing any potential revenues and adversely affecting our ability to attain or maintain profitability.

Risks Related to Our Common Stock

The price of our stock has been extremely volatile and may continue to be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

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

- any actual or perceived adverse developments in clinical trials for Ampion, such as the FDA not considering the AP-003-C trial to be an adequate and well-controlled pivotal clinical trial that can support a BLA filing;
- any actual or perceived difficulties or delays in obtaining regulatory approval of Ampion in the United States or other countries once clinical trials are completed;
- any finding that Ampion is not safe or effective, or any inability to demonstrate the clinical effectiveness of Ampion when compared to existing treatments;
- any actual or perceived adverse developments in repurposed drug technologies, including any change in FDA policy or guidance on approval of repurposed drug technologies for new indications;
- any announcements of developments with, or comments by, the FDA, the EMA, or other regulatory authorities with respect to our development of Ampion;
- any announcements concerning our retention or loss of key employees, such as Dr. Bar-Or's decision to retire as our Chief Scientific Officer;
- our success or inability to obtain collaborators to conduct clinical trials, commercialize Ampion once regulatory approval is obtained, or market and sell Ampion;
- announcements of patent issuances or denials, product innovations, or introduction of new commercial products by our competitors that will compete with Ampion;

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- publicity regarding actual or potential study results or the outcome of regulatory reviews relating to the development of Ampion or our competitors;
- economic and other external factors beyond our control; and
- sales of stock by us or by our shareholders.

In addition, we believe there has been and may continue to be substantial off-market transactions in derivatives of our stock, including short selling activity or related similar activities, which are beyond our control and which may be beyond the full control of the SEC and Financial Institutions Regulatory Authority, or FINRA. While SEC and FINRA rules prohibit some forms of short selling and other activities that may result in stock price manipulation, such activity may nonetheless occur without detection or enforcement. We have held conversations with regulators concerning trading activity in our stock; however, there can be no assurance that should there be any illegal manipulation in the trading of our stock it will be detected, prosecuted or successfully eradicated. Significant short selling or other types of market manipulation could cause our stock trading price to decline, to become more volatile, or both.

The price of our stock may be vulnerable to manipulation.

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

Because our unrestricted public float has been small relative to other issuers, previous short selling efforts have impacted, and may in the future continue to impact, the value of our stock in an extreme and volatile manner to our detriment and the detriment of our shareholders. In addition, market participants with admitted short positions in our stock have published, and may in the future continue to publish, negative information regarding us and our management team on internet sites or blogs that we believe is inaccurate and misleading. We believe that the publication of this negative information has led, and may in the future continue to lead, to significant downward pressure on the price of our stock to our detriment and the further detriment of our shareholders. These and other efforts by certain market participants to manipulate the price of our common stock for their personal financial gain may cause our stockholders to lose a portion of their investment, may make it more difficult for us to raise equity capital when needed without significantly diluting existing stockholders, and may reduce demand from new investors to purchase shares of our stock.

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

Although our common stock is listed on the NYSE American, we may be unable to continue to satisfy the listing maintenance requirements and rules. If we are unable to satisfy the NYSE American criteria for maintaining our listing, our securities could be subject to delisting. To qualify for continued listing on the NYSE American, we must remain in compliance. There can be no assurances that we will be able to continue to comply with the NYSE American listing requirements.

If the NYSE American delists our securities, we could face significant consequences, including:

- a limited availability for market quotations for our securities;
- reduced liquidity with respect to our securities;
- a determination that our common stock is a “penny stock,” which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in reduced trading;

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- activity in the secondary trading market for our common stock;
- limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

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

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

As of March 1, 2019, holders of more than 5% of our common stock and our directors, executive officers and their affiliates beneficially owned 24.5% of our outstanding common stock. These shareholders may have significant effect on the outcome of actions taken by us that require shareholder approval.

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

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

- requiring supermajority shareholder voting to effect certain amendments to our certificate of incorporation and bylaws;
- restricting the ability of shareholders to call special meetings of shareholders;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by shareholders at shareholder meetings.

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

As a public company, we incur significant legal, accounting, and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC, and the NYSE American. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that have required the SEC to adopt additional rules and regulations in these areas. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, the manner in which we operate our business. Our management and other personnel devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations, and as a result of the new corporate governance and executive compensation related rules, regulations, and guidelines prompted by the Dodd-Frank Act, and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. These rules and regulations will cause us to incur significant legal and financial compliance costs and will make some activities more time-consuming and costly.

The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate,

and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or

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maintain effective controls could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting, which we may be required to include in our periodic reports that we file with the SEC under Section 404 of the Sarbanes-Oxley Act, and could harm our operating results, cause us to fail to meet our reporting obligations, or result in a restatement of our prior period financial statements. If we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal controls over financial reporting are perceived as adequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results, and the price of our common stock could decline.

We are required to comply with certain of the SEC rules that implement Section 404 of the Sarbanes-Oxley Act, which requires management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting. This assessment needs to include the disclosure of any material weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting or if we are unable to complete our evaluation, testing, and any required remediation in a timely fashion, we will be unable to assert that our internal controls over financial reporting are effective.

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

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

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

Item 1B.Unresolved Staff Comments

None.

Item 2.Properties

We maintain our headquarters in leased space in Englewood, Colorado, for monthly rental payments of approximately $27,000. The lease expires in September 2024. We anticipate that the lease can be renewed on terms similar to those now in effect.

Item 3.Legal Proceedings

On August 25, 2018 and August 31, 2018, two purported stockholders of the Company brought putative class action lawsuits in the United States District Court for the Central District of California, Shi v. Ampio Pharmaceuticals, Inc., et al., Case No. 2:18-cv-07476-SJO-RAO, and in the United States District Court for the District of Colorado, Shaffer

v. Ampio Pharmaceuticals, Inc., et al., Case No. 1:18-cv-02252-KLM, together, the “Securities Class Actions”. Plaintiffs in the Securities Class Actions allege that the Company and certain of its current officers violated federal securities laws by misrepresenting and/or omitting information regarding the AP-003 Phase III clinical trials of Ampion. Plaintiffs assert claims under Sections 10(b) and 20(a) and Rule 10b-5 under the Securities Exchange Act of 1934, on behalf of a putative class of purchasers of the Company’s common stock from December 14, 2017 through August 7, 2018. The Securities Class Actions seek unspecified damages, interest, and attorneys’ fees and costs. On October 24, 2018, certain purported stockholders filed motions to be appointed as lead plaintiff in the Shi case. On November 6, 2018, the Shaffer case was voluntarily dismissed.

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On September 10, 2018, a purported stockholder of the Company brought a derivative action in the United States District Court for the Central District of California, Cetrone v. Macaluso, et al., Case No. 2:18-cv-05970-SJO-RAO, alleging primarily that the directors and officers of Ampio breached their fiduciary duties because of their alleged misstatements and/or omissions regarding the AP-003 Phase III clinical trial of Ampion. On November 16, 2018, the case was stayed pending proceedings in the Shi case.

On October 5, 2018, a purported stockholder of the Company brought a derivative action in the United States District Court for the District of Colorado, Theise v. Macaluso, et al., Case No. 1:18-cv-02558-RBJ, which closely parallels the allegations in the Cetrone case. On November 14, 2018, a purported stockholder of the Company brought a second derivative action in the United States District Court for the District of Colorado, Lewis v. Macaluso, et al., Case No. 1:18-cv-02932-SKC, which also closely parallels the allegations in the Cetrone case. On December 19, 2018, the court consolidated the Theise and Lewis derivative actions, and the consolidated action is captioned In re Ampio Pharmaceuticals, Inc. Stockholder Derivative Litigation, Case No. 1:18-cv-02558-RBJ. On January 3, 2019, this consolidated derivative action was stayed pending proceedings in the Shi case.

The Company believes these claims are without merit and intends to defend these lawsuits vigorously. The Company currently believes the likelihood of a loss contingency related to these matters is remote and, therefore, no provision for a loss contingency is required.

Item 4.Mine Safety Disclosures.

Not applicable.

PART II

Item 5.Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Data

On June 17, 2013, our common stock began trading on the NYSE American under the ticker symbol “AMPE”. It was previously quoted on the NASDAQ Capital Market under the same ticker symbol “AMPE”.

Holders of Common Stock

As of March 1, 2019, there were approximately 11,000 holders of record of our common stock.

Dividend Policy

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

Unregistered Sales of Equity Securities and Use of Proceeds

Information regarding unregistered sales of equity securities and use of proceeds is incorporated by reference to Item 15 of Part IV, Notes to Financial Statements – Note 7 – Common Stock of this annual report on Form 10-K.

Equity Compensation Plan Information

Information regarding our Equity Compensation Plan information is contained in Note 8 to the Financial Statements.

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Item 6.Selected Financial Data

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this item.

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

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

EXECUTIVE SUMMARY

We are a development stage biopharmaceutical company focused on the development of Ampion, our product candidate, to treat prevalent inflammatory conditions for which there are limited treatment options.

The pharmaceutical market is a competitive industry with strict regulations that are time intensive and costly. However, we are committed to offer a compelling therapeutic option for the patients most in need of new treatment options, and we operate every day to advance Ampion.

Since we are in the research and development phase, we have not generated revenue to date. Our operations are funded through equity raises, which occur from time to time. To proceed with our operations, we will need to raise additional funds to support the advancement of Ampion.

Moving forward, we plan to maintain a lean and efficient operating model by streamlining our operations and continuing to allocate all our resources towards commercializing Ampion.

Discussion regarding our business is contained in Part I, Item 1. Business.

Recent Financing Activities

Information regarding our Recent Financing Activities is contained in Note 7 to the Financial Statements.

Known Trends or Future Events; Outlook

We are a clinical stage company that has not generated revenues and have therefore incurred significant net losses totaling $171.0 million since our inception in December 2008. We expect to generate operating losses for the foreseeable future as we continue the development of, and seek regulatory approval for Ampion. However, we intend to try to limit the extent of these losses by entering into co-development or collaboration agreements with one or more strategic partners. As of December 31, 2018, we had $7.6 million of cash which we expect can fund our operation into the second quarter of 2019. To operate as planned in fiscal 2019 and into 2020 we will need to raise at least $16.0

million through equity offerings, debt or other financing tools.

On September 1, 2017, we received a letter from the NYSE American stating that they had determined that we were not in compliance with Sections 1003(a)(ii) and (iii) of the NYSE American Company Guide, or the Guide, since we reported stockholders' equity of $3,734,756 as of June 30, 2017 and net losses in our five most recent fiscal years ended December 31, 2016. Prior to this, we were exempt from Section 1003(a) of the Guide since our market capitalization was above $50 million. We submitted a plan on October 2, 2017 advising the NYSE American of the actions that would be taken to regain compliance with the continued listing standards by March 19, 2019. On November 9, 2017, we received a letter from the NYSE American stating that the NYSE American had accepted our plan to regain compliance with the continued listing standards. On April 12, 2018, we received a letter from the NYSE American stating that we

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are again in compliance with all the NYSE American continued listing standards set forth in Part 10 of the Guide, specifically Sections 1003(a)(ii) and (iii). Going forward, we will be subject to continued listing monitoring.

Although we have raised net proceeds of over $139 million in the past ten years through the sale of common stock and warrants, we cannot be assured that we will be able to secure additional financing, if needed, or that it will be adequate to execute our business strategy. Even if we obtain additional financing, it may be costly and may require us to agree to covenants or other provisions that will favor new investors over existing shareholders.

Our primary focus for fiscal 2019 is raising additional capital and advancing the clinical development and BLA preparation of Ampion.

Significant Accounting Policies and Estimates

Information regarding our Significant Accounting Policies and Estimates is contained in Note 2 to the Financial Statements.

Recent Accounting Pronouncements

Information regarding recently issued accounting standards (adopted and not adopted as of December 31, 2018) is contained in Note 2 to the Financial Statements.

Stockholders' Equity – Year Ended December 31, 2018 and 2017

For the year ended December 31, 2018, we had stockholders' equity of $5.2 million. Our total net income for the year was $34.0 million. The net income is primarily attributable to the non-cash derivative gain of $45.3 million that was recognized, which is offset by the operating expenses of $11.2 million during the year ended December 31, 2018. The decrease in our stock price from $4.07 as of December 31, 2017 to $0.39 as of December 31, 2018 significantly decreased the value of our outstanding warrants, causing a derivative gain to be recognized.

For the year ended December 31, 2017, we had a deficit in stockholders' equity of $34.2 million. Our total net loss for the year was $51.9 million. The net loss was primarily attributable to the non-cash derivative loss of $36.2 million, along with $15.7 million in operating losses during the year ended December 31, 2017. The increase in our stock price from $0.90 as of December 31, 2016 to $4.07 as of December 31, 2017 significantly increased the value of our outstanding warrants, causing a derivative loss to be recognized.

Results of Operations—Year Ended December 31, 2018 and 2017

We recognized net income for the year ended December 31, 2018 of $34.0 million compared to a net loss of $51.9 million for the same period in 2017. As noted above, the net income during the 2018 period is attributable to the non-cash derivative gain of $45.3 million that was recognized, which was offset by the operating expenses of $11.2 million. The net loss during the 2017 period was attributable to the non-cash derivative loss of $36.2 million that was recognized, in addition to the operating expenses of $15.7 million. The investor warrant exercises and decrease in our stock price from $4.07 as of December 31, 2017 to $0.39 as of December 31, 2018 caused the valuation of the warrant liability to decrease resulting in a derivative gain during the 2018 period. The increase in our stock price from $0.90 as of December 31, 2016 to $4.07 as of December 31, 2017 caused the valuation of the warrant liability to increase resulting in a derivative loss during the 2017 period. The operating expenses decreased $4.5 million from the 2017 period to the 2018 period primarily due to a $3.6 million decrease in research and development costs and a $900,000

decrease in general and administrative costs, which is further explained below.

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Research and Development

Research and development costs consist of clinical trials and sponsored research, labor, stock-based compensation, consultants and sponsored research – related party. These costs relate solely to research and development without an allocation of general and administrative expenses and are summarized as follows:

	Years Ended December 31,	
	2018	2017
Clinical trials and sponsored research	$ 2,699,000	$ 5,529,000
Consultants and other	2,114,000	1,950,000
Labor	1,825,000	2,320,000
Stock-based compensation	191,000	298,000
Sponsored research - related party	—	324,000
	$ 6,829,000	$ 10,421,000

Comparison of Years Ended December 31, 2018 and 2017

Research and development costs decreased $3.6 million, or 34.5%, for the year ended December 31, 2018 compared to the same period in 2017. The decrease is primarily attributable to lower costs related to clinical trials and sponsored research expense, labor costs and stock-based compensation, as well as the sponsored research-related party. Our clinical trial costs decreased from the 2017 period to the 2018 period. During the 2017 period, we incurred initial costs and clinical trial development expenses related to the AP-003-C study. During the 2018 period, we only incurred clinical trial development expenses related to the OLE study, which was considered an extension of the AP-003-C study. Due to the OLE study being an extension study, we did not incur initial costs during the 2018 period. In addition, the number of patients enrolled in the OLE study was less than the AP-003-C study, causing the expenses for the OLE study to be lower. The OLE study was terminated during August 2018, with close-out costs being incurred through the beginning of fiscal 2019. Labor costs for the 2018 period decreased from the 2017 period primarily due to the elimination of the bonus accrual because of a one-time option repricing, which is further discussed in Notes 2 and 8 of our financial statements. The elimination of the PTO carryover also decreased the 2018 period labor costs. In addition, Dr. Bar-Or retired from his full-time role as our Chief Scientific Officer, effective September 30, 2018. Therefore, we only incurred nine months of his salary during the 2018 period compared to twelve months during the 2017 period. The decrease in stock-based compensation is a result of fewer options being granted at lower stock prices and previously awarded high priced options becoming fully vested during 2018. With high priced options becoming fully vested during 2018, we did not recognize a full year of stock-based compensation expense for those options during the 2018 period, whereas we did recognize a full year of stock-based compensation expense for those options during the 2017 period. In addition, the sponsored research – related party expense also contributed to the decrease in the research and development costs due to the termination of the Trauma Research Agreement during the 2017 period with no costs incurred during the 2018 period. Consultants and other costs increased as we incurred costs related to discussions with the FDA surrounding our clinical trials.

General and Administrative

General and administrative expenses consist of labor, director fees, stock-based compensation, patents and intellectual property, professional fees which include legal, auditing and accounting, occupancy, travel and other which includes rent, insurance, investor/public relations and professional subscriptions. These costs are summarized as follows:

	Years Ended December 31,	
	2018	2017
Occupancy, travel and other	$ 1,828,000	$ 2,167,000
Professional fees	928,000	763,000
Labor	534,000	956,000
Patent costs	523,000	568,000
Stock-based compensation	313,000	507,000
Directors fees	229,000	294,000
	$ 4,355,000	$ 5,255,000

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Comparison of Years Ended December 31, 2018 and 2017

General and administrative costs decreased $900,000, or 17.1%, for the year ended December 31, 2018 compared to the same period in 2017. The decrease is primarily attributable to lower occupancy, travel and other expenses, labor and stock-based compensation. Occupancy, travel and other expense decreased due to the termination of a contractual agreement that was intended to assist us with potential partnerships, as well as a decrease in insurance premiums from the 2018 period compared to the 2017 period. Occupancy, travel and other expense also decreased as we did not incur costs related to media outreach during the 2018 period compared to the 2017 period. In addition, we incurred less travel costs during the 2018 period compared to the 2017 period. As noted in the Research and Development section above, labor costs decreased for the 2018 period compared to the 2017 period primarily due to the elimination of the bonus accrual related to the option repricing, further discussed in Notes 2 and 8 of our financial statements. The elimination of the PTO carryover also decreased the 2018 period labor costs. The decrease in stock-based compensation is a result of fewer options being granted at lower stock prices and previously awarded high priced options becoming fully vested during 2018. With high priced options becoming fully vested during 2018, we did not recognized a full year of stock-based compensation expense for those options during the 2018 period, whereas we did recognize a full year of stock-based compensation expense for those options during the 2017 period. Director fees also decreased as there were fewer board meetings during the 2018 period. There was an increase in professional fees due to an increase in legal fees related to litigation and an increase in accounting fees, as well as the amortization of a retainer related to a debt financing deal that did not occur.

Net Cash Used in Operating Activities

During 2018, our operating activities from continuing operations used $12.1 million in cash, which was less than the net income of $34.0 million primarily due to the $45.3 million non-cash gain from the warrant derivative, a decrease of $2.5 million in accounts payable and accrued compensation and $180,000 increase in prepaid expenses. These amounts were offset by stock-based compensation, depreciation and amortization, loss from disposal of fixed assets and common stock issued for services.

During 2017, our operating activities from continuing operations used $11.4 million in cash, which was less than the net loss of $51.9 million primarily due to the $36.2 million non-cash loss from the warrant derivative, as well as the stock-based compensation, depreciation and amortization and amortization of the prepaid research and development. Cash used in operating activities also included a $332,000 decrease in accrued compensation, which was offset by a $2.1 million increase in accounts payable and accrued expenses and a decrease in prepaid expenses.

Net Cash Used in Investing Activities

During 2018, cash was used to purchase $564,000 of equipment.

During 2017, cash was used to purchase $72,000 of equipment.

Net Cash from Financing Activities

During 2018, we received $4.9 million from option and warrant exercises. We also received gross proceeds from the sale of common stock in a confidentially marketed public offering of $8.0 million, which was offset by offering costs of $844,000.

During 2017, we received gross proceeds from the sale of common stock in registered direct offerings of $13.3 million, which was offset by offering costs of $1.3 million. We also received $2.8 million from option and warrant exercises.

Contractual Obligations and Commitments

Information regarding Contractual Obligations and Commitments is contained in Note 6 to the Financial Statements.

Liquidity and Capital Resources

We have not generated revenue or profits. Our primary activities are focused on research and development, advancing Ampion and raising capital. As of December 31, 2018, we had $7.6 million of cash which we expect will fund our

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operation into the second quarter of 2019. To operate as planned in fiscal 2019 and into 2020 we will need to raise at least $16.0 million through equity offerings, debt or other financing tools. This projection is based on many assumptions that may prove to be wrong, and we could exhaust our available cash and cash equivalents earlier than presently anticipated. We will be required to seek additional capital to expand our clinical and commercial development activities for Ampion. We intend to evaluate the capital markets from time to time to determine whether to raise additional capital in the form of equity, convertible debt or otherwise, depending on market conditions relative to our need for funds at such time.

We have prepared a budget for 2019 which reflects cash requirements for fixed, on-going expenses such as payroll, legal and accounting, patents and overhead at an average cash burn rate of approximately $700,000 per month. Additional funds are planned for regulatory approvals, clinical trials, outsourced research and development and commercialization consulting. Accordingly, it will be necessary to raise additional capital and/or enter into licensing or collaboration agreements. At this time, we expect to satisfy our future cash needs through private or public sales of our securities, debt financings or our Controlled Equity Offering Sales Agreement that we agreed to in February 2016 with respect to our ATM. We cannot be certain that financing will be available to us on acceptable terms, or at all. Volatility in the financial markets has adversely affected the market capitalizations of many pharmaceutical companies, particularly small capitalization companies, and generally made equity and debt financing more difficult to obtain. This volatility, coupled with other factors, may limit our access to additional financing.

If we cannot raise adequate additional capital in the future when we require it, we will be required to delay, reduce the scope of, or eliminate the development program for Ampion or our future commercialization efforts or suspend operations for a period until we are able to raise additional capital. We also may be required to relinquish greater or all rights to Ampion, at an earlier stage of development or on less favorable terms than we would otherwise choose. This may lead to impairment or other charges, which could materially affect our balance sheet and operating results.

Off Balance Sheet Arrangements

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

Impact of Inflation

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

Item 7A. Quantitative and Qualitative Disclosures about Market Risks

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data

The Financial Statements and Supplementary Data required by this item are in Item 15 of Part IV, “Index to Financial Statements” at page F 1 of this annual report on Form 10 K and are incorporated herein by reference.

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

Effective October 1, 2018, EKS&H LLLP (“EKS&H”), the independent registered public accounting firm for Ampio Pharmaceuticals, Inc. (the “Company”), combined with Plante & Moran PLLC (“Plante Moran”). As a result of this transaction, on October 1, 2018, EKS&H resigned as the independent registered public accounting firm for the Company. Concurrent with such resignation, the Company’s Audit Committee approved the engagement of Plante Moran as the new independent registered public accounting firm for the Company.

The audit reports of EKS&H on the Company’s financial statements for the years ended December 31, 2017 and 2016 did not contain an adverse opinion or a disclaimer of opinion, and were not qualified or modified as to uncertainty, audit scope or accounting principles except, the audit report of EKS&H on the Company’s financial statements for the years ended

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December 31, 2017 and 2016 contained an explanatory paragraph indicating that there was substantial doubt about the ability of the Company to continue as a going concern.

During the two most recent fiscal years ended December 31, 2017 and 2016 and through the subsequent interim period preceding EKS&H's resignation, there were no disagreements between the Company and EKS&H on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreements, if not resolved to the satisfaction of EKS&H would have caused them to make reference thereto in their reports on the Company's financial statements for such years.

During the two most recent fiscal years ended December 31, 2017 and 2016 and through the subsequent interim period preceding EKS&H's resignation, there were no reportable events within the meaning set forth in Item 304(a)(1)(v) of Regulation S-K.

During the two most recent fiscal years ended December 31, 2017 and 2016 and through the subsequent interim period preceding Plante Moran's engagement, the Company did not consult with Plante Moran on either (1) the application of accounting principles to a specified transaction, either completed or proposed; or the type of audit opinion that may be rendered on the Company's financial statements, and Plante Moran did not provide either a written report or oral advise to the Company that Plante Moran concluded was an important factor considered by the Company in reaching a decision as to the accounting, auditing or financial reporting issue; or (2) any matter that was either the subject of a disagreement, as defined in Item 304(a)(1)(iv) of Regulation S-K, or a reportable event, as defined in Item 304(a)(1)(v) of Regulation S-K.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

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

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting (as such term is defined in Rules 13a 15(f) under the Exchange Act). Our management assessed the effectiveness of our internal controls over financial reporting as of December 31, 2018. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013). Our management has concluded that, as of December 31, 2018, our internal controls over financial reporting are effective based on these criteria.

Plante Moran PLLC, the independent registered public accounting firm that audited our financial statements included in this Annual Report on Form 10-K, has issued an attestation report on our internal control over financial reporting, which is included herein at F-2.

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Changes in Internal Control over Financial Reporting

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

Item 9B. Other Information

None.

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PART III

Item 10. Directors and Executive Officers, and Corporate Governance

The following table sets forth the names, ages and positions of our directors and executive officers as of March 10, 2019.

Name	Age	Position With Ampio	Principal Occupation and Areas of Relevant Experience For Directors	Director/Officer Since
Michael Macaluso (4)	67	Chief Executive Officer and Chairman of the Board	Mr. Macaluso founded Life Sciences and has been a member of the Board of Directors of Life Sciences, our predecessor, since its inception. Mr. Macaluso has also been a member of our Board of Directors since the merger with Chay Enterprises in March 2010 and our Chief Executive Officer, or CEO, since January 2012. Mr. Macaluso was appointed president of Isolagen, Inc. (AMEX: ILE) and served in that position from June 2001 to August 2001, when he was appointed Chief Executive Officer. In June 2003, Mr. Macaluso was re-appointed as President of Isolagen and served as both Chief Executive Officer and President until September 2004. Mr. Macaluso also served on the Board of Directors of Isolagen from June 2001 until April 2005. From October 1998 until June 2001, Mr. Macaluso was the owner of Page International Communications, a manufacturing business. Mr. Macaluso was a founder and Principal of International Printing and Publishing, a position Mr. Macaluso held from 1989 until 1997, when he sold that business to a private equity firm. Mr. Macaluso’s experience in executive management and marketing within the pharmaceutical industry, monetizing company opportunities and corporate finance led to the conclusion of our Board of Directors that he should serve as a director of our company considering our business and structure.	March 2010

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Name	Age	Position With Ampio	Principal Occupation and Areas of Relevant Experience For Directors	Director/Officer Since
David Bar-Or, MD	70	Director and Former Chief Scientific Officer	Dr. Bar-Or served as our Chief Scientific Officer from March 2010 until September 2018. Dr. Bar-Or also served as our chairman of the Board from March 2010 until May 2010. From April 2009 until March 2010, he served as chairman of the Board and Chief Scientific Officer of Life Sciences. Dr. Bar-Or is currently the director of Trauma Research at Swedish Medical Center, Englewood, Colorado, St. Anthony's Hospital, Lakewood, Colorado and The Medical Center of Plano, Plano, Texas. Dr. Bar-Or is the founder of Ampio Pharmaceuticals, Inc. Dr. Bar-Or was principally responsible for all patented and proprietary technologies acquired by us from BioSciences in April 2009. He was also responsible for all patents issued and applied for since then, having been issued over 270 patents and having filed or co-filed almost 120 patent applications. Dr. Bar-Or has authored or co-authored over 160 peer-reviewed journal articles and several book chapters. Dr. Bar-Or is a reviewer for over 45 peer reviewed scientific and clinical journals. He is the recipient of the Gustav Levi Award from the Mount Sinai Hospital, New York, New York, the Kornfeld Award for an outstanding MD Thesis, the Outstanding Resident Research Award from the Denver General Hospital, and the Outstanding Clinician Award for the Denver General Medical Emergency Resident Program. Dr. Bar-Or received his medical degree from The Hebrew University, Hadassah Medical School, Jerusalem, Israel, following which he completed a biochemistry fellowship at Hadassah Hospital under Professor Alisa Gutman and undertook post-graduate residency training at Denver Health Medical Center, specializing in emergency medicine, a discipline in which he is board certified. He completed the first research fellowship in Emergency Medicine at Denver Health	March 2010

Medical Center under the direction of Professor Peter Rosen.

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

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Name	Age	Position With Ampio	Principal Occupation and Areas of Relevant Experience For Directors	Director/Officer Since
Philip H. Coelho (1)(2)(3)(4)	75	Director	Mr. Coelho has served as a member of our Board of Directors since April 2010. Mr. Coelho has been in the senior management of high technology consumer electronic or medical device companies for over 30 years. Mr. Coelho is the Chief Technology Officer and Co-Founder of SynGen Inc., a firm inventing and commercializing products that harvest stem and progenitor cells derived from a donor or the patient's own body to treat human disease. Prior to founding SynGen Inc. in October 2009, Mr. Coelho was the President and CEO of PHC Medical, Inc., a consulting firm, from August 2008 through October 2009. From August 2007 through May 2008, Mr. Coelho served as the Chief Technology Architect of ThermoGenesis Corp., a medical products company he founded in 1986 that focused on the regenerative medicine market. From 1989 through July 2007, he was Chairman and CEO of ThermoGenesis Corp. Mr. Coelho served as Vice President of Research & Development of ThermoGenesis from 1986 through 1989. He was President of Castleton Inc. from 1982 to 1986, and President of ESS Inc. from 1971 to 1982. Mr. Coelho also serves as a member of the board of directors of NASDAQ-listed company, Catalyst Pharmaceuticals Partners, Inc. (CPRX) (since October 2002), and served as a member of the Board of Directors of NASDAQ-listed Mediware Information Systems, Inc. (MEDW) (from December 2001 until July 2006, and commencing again in May 2008 until it was sold in December 2012). Mr. Coelho received a B.S. degree in thermodynamic and mechanical engineering from the University of California, Davis and has been awarded	April 2010

more than 50 U.S. patents in the areas of cell cryopreservation, cryogenic robotics, cell selection, blood protein harvesting and surgical homeostasis.

Mr. Coelho's long tenure as a CEO of a public medical device company, as director of a public pharmaceutical company, prior and current public company board experience, and knowledge of corporate finance and governance as an executive and director, as well as his demonstrated success in developing patented technologies, led to the conclusion of our Board of Directors that he should serve as a director of our company considering our business and structure.

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Name	Age	Position With Ampio	Principal Occupation and Areas of Relevant Experience For Directors	Director/Officer Since
Richard B. Giles (1)(2)(3)(4)	69	Director	Mr. Giles, CPA, has served as a member of our Board of Directors since August 2010. Mr. Giles is the Chief Financial Officer, or CFO, of Ludvik Electric Co., an electrical contractor headquartered in Lakewood, Colorado, a position he has held since 1985. Ludvik Electric is a private electrical contractor that has completed electrical contracting projects throughout the United States, South Africa and Germany. As CFO and Treasurer of Ludvik Electric, Mr. Giles oversees accounting, risk management, financial planning and analysis, financial reporting, regulatory compliance, and tax-related accounting functions. He serves also as the trustee of Ludvik Electric Co.'s 401(k) plan. Prior to joining Ludvik Electric, Mr. Giles was an Audit Partner for three years with Higgins Meritt & Company, then a Denver, Colorado CPA firm, and during the preceding nine years he was an Audit Manager and a member of the audit staff of Price Waterhouse, one of the legacy firms which now comprises PricewaterhouseCoopers. While with Price Waterhouse, Mr. Giles participated in a number of public company audits, including one for a leading computer manufacturer. Mr. Giles received a B.S. degree in accounting from the University of Northern Colorado. He is a member of the American Institute of Certified Public Accountants, Colorado Society of Certified Public Accountants, Construction Financial Management Association and Financial Executives International. Mr. Giles' experience in executive financial management, accounting and financial reporting, corporate accounting and internal controls led to	August 2010

the conclusion of our Board of Directors that he should serve as a director of our company considering our business and structure.

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Name	Age	Position With Ampio	Principal Occupation and Areas of Relevant Experience For Directors	Director/Officer Since
David R. Stevens, Ph.D. (1)(2)(3)(4)	69	Director	Dr. Stevens has served as a member of our Board of Directors since June 2011. Dr. Stevens has worked in the FDA regulated life science industries since 1978. He has been a board member of Cetya, Inc. since November 2013. He has served on the boards of several other public and private life science companies, including Micro-Imaging Solutions, LLC (2007-2018), Poniard Pharmaceuticals, Inc. (2006 2012), Aqua Bounty Technologies, Inc. (2002 2012), and Smart Drug Systems, Inc. (1999 2006), and was an advisor to Bay City Capital from 1999 to 2006. Dr. Stevens was previously President and CEO of Deprenyl Animal Health, Inc., a public veterinary pharmaceutical company, from 1990 to 1998, and Vice President, Research and Development, of Agrion Corp., a private biotechnology company, from 1986 to 1988. He began his career in pharmaceutical research and development at the former Upjohn Company, where he contributed to the preclinical evaluation of Xanax and Halcion. Dr. Stevens received B.S. and D.V.M. degrees from Washington State University, and a Ph.D. in Comparative Pathology from the University of California, Davis. He is a Diplomate of the American College of Veterinary Pathologists. Dr. Stevens' experience in executive management in the pharmaceutical industry and knowledge of the medical device industry led to the conclusion of our Board of Directors that he should serve as a director of our company considering our business and structure.	June 2011

Thomas E. Chilcott III (4)	Chief Financial Officer, Treasurer and Secretary	Prior to taking his current role, Mr. Chilcott served as our Controller. Mr. Chilcott was the President and Chief Financial Officer of Chilcott Consulting Group from September 2006 to December 2016. Mr. Chilcott began his career as an auditor with KPMG Peat Marwick. He graduated from Villanova University with a BS of Administration in Accountancy and is a Certified Public Accountant in good standing. Mr. Chilcott is a member of the Colorado Society of Certified Public Accountants.

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Name	Age	Position With Ampio	Principal Occupation and Areas of Relevant Experience For Directors	Director/Officer Since
Holli Cherevka (4)	35	Chief Operating Officer	Prior to taking her current role, Ms. Cherevka served as our Vice President of Operations and oversaw the clinical, regulatory and manufacturing operations. She has held roles of increasing responsibility throughout her career at Ampio including site leadership, strategic planning, contractor management and product portfolio leadership. Previously, Ms. Cherevka was the Director of Business Development at the American College of Radiology (ACR) Image Metrix. Ms. Cherevka earned a Bachelor of Arts from California State University, Chico, and holds a Master of Science in Biomedical and Molecular Sciences Research from King's College, London. Ms. Cherevka is a member of the Parenteral Drug Association, Colorado Bioscience Association and the International Society of Pharmaceutical Engineers. She has represented Ampio Pharmaceuticals at conferences for the International Society of Pharmaceutical Engineers as well as at Global Investment Conferences.	September 2017

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

Family Relationships

There are no family relationships between any of our directors. Raphael Bar-Or, a non-executive officer, is the son of David Bar-Or, our former Chief Scientific Officer and a Director.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our executive officers, directors and persons who beneficially own greater than 10% of our Common Stock to file certain reports, Forms 3, 4 and 5, with the SEC with respect to ownership and changes in ownership of our Common Stock. To our knowledge, we have one shareholder who beneficially owns more than 10% of our Common Stock. See Item 12 for further information on beneficial ownership. Based solely on our review of the copies of such forms received by us, or written representations from certain reporting persons, we

believe during the period from January 1, 2018 to December 31, 2018, all filing requirements applicable to our officers, directors and 10% beneficial owners were complied with.

Code of Business Conduct and Ethics

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

Meetings

During the year ended December 31, 2018, there were (i) eight meetings of the Board of Directors, (ii) four meetings of the Audit Committee, (iii) seven meetings of the Compensation Committee, (iv) one meeting of the Nominating and Governance Committee, and (v) no meetings of the Disclosure Committee insofar as the committee was not formally established until late 2018. No incumbent director attended fewer than seventy-five percent (75%) of the aggregate of

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(1) the total number of meetings of the Board, and (2) the total number of meetings held by all committees of the Board during the period that such director served.

Annual Meeting Attendance, Executive Sessions and Shareholder Communications

Since 2011, our policy has been that our directors attend the annual meeting of stockholders. We previously did not have a policy concerning director attendance at annual meetings. Commencing in 2011, our policy has also been that our non-employee directors are required to meet in separate sessions without management on a regularly scheduled basis four times a year. Generally, these meetings are expected to take place in conjunction with regularly scheduled meetings of the Board throughout the year. Our 2018 annual meeting was attended by four of the five directors serving on our Board.

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

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

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

Involvement in Certain Legal Proceedings

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

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

Leadership Structure of the Board

The Board of Directors does not currently have a policy on whether the same person should serve as both the Chief Executive Officer and Chairman of the Board or, if the roles are separate, whether the chairman should be selected from the non-employee directors or should be an employee. The Board believes that it should have the flexibility to

make these determinations in a way that it believes provides the best leadership for the Company. Our current chairman, Michael Macaluso, was appointed our Chief Executive Officer effective January 2012. Mr. Macaluso has served as a member of our Board since March 2010 and had been a member of the Board of Directors of Life Sciences from December 2009.

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Risk Oversight

The Board oversees risk management directly and through its committees associated with their respective subject matter areas. Generally, the Board oversees risks that may affect our business, including operational matters. The Audit Committee is responsible for oversight of our accounting and financial reporting processes and discusses with management our financial statements, internal controls and other accounting and auditing matters. The Compensation Committee oversees certain risks related to compensation programs and the Nominating and Governance Committee oversees certain corporate governance risks. The Disclosure Committee assists in establishing, implementing, maintaining and evaluating controls or other procedures to ensure that the information required to be disclosed in the Company's reports furnished or filed under the Securities Exchange Act of 1934 is properly communicated to the chief executive officer and the chief financial officer. As part of their roles in overseeing risk management, these committees periodically report to the Board regarding briefings provided by management and advisors as well as the committees' own analysis and conclusions regarding certain risks faced by us. Management is responsible for implementing the risk management strategy and developing policies, controls, processes and procedures to identify and manage risks.

Committees of the Board

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

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

- selecting and hiring our independent auditors;
- appointing, compensating and overseeing the work of our independent auditors;
- approving engagements of the independent auditors to render any audit or permissible non-audit services;
- reviewing the qualifications and independence of the independent auditors;
- monitoring the rotation of partners of the independent auditors on our engagement team as required by law;
- reviewing our financial statements and reviewing our critical accounting policies and estimates;
- reviewing the adequacy and effectiveness of our internal controls over financial reporting;
- reviewing and discussing with management and the independent auditors the results of our annual audit, our quarterly financial statements and our publicly filed reports; and
- reviewing related party transactions.

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

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

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

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

Our Compensation Committee and the Board of Directors have not yet established a succession plan for our Chief Executive Officer. Mr. Macaluso is in excellent health and is performing to the satisfaction of the Board of Directors. Therefore, the Compensation Committee does not believe there is a pressing need to have a succession plan for the CEO position.

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

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

- evaluating and making recommendations regarding the organization and governance of the Board of Directors and its committees;
- assessing the performance of members of the Board of Directors and making recommendations regarding committee and chair assignments;
- recommending desired qualifications for Board of Directors membership and conducting searches for potential members of the Board of Directors; and
- reviewing and making recommendations for our corporate governance guidelines.

The members of our Nominating and Governance Committee are currently Messrs. Giles, Stevens and Coelho. Mr. Coelho is the chairman of our Nominating and Governance Committee. Our Board of Directors has determined that

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each member of our Nominating and Governance Committee is independent within the meaning of the independent director guidelines of the NYSE American.

Disclosure Committee. Our Disclosure Committee provides assistance to the CEO and the CFO, or the Senior Officers, in fulfilling their responsibilities regarding the identification and disclosure of material information about us and the accuracy, completeness and timeliness of such disclosures. The Disclosure Committee is responsible for, among other things:

- designing, adopting and maintaining appropriate procedures and standards that are designed to ensure that: (i) information that we are required to disclose to the SEC, and other written information that we will disclose to the public is recorded, processed, summarized and reported accurately and on a timely basis; (ii) risks and risk factors are adequately disclosed; and (iii) such information is accumulated and communicated to our management, including our Senior Officers, as appropriate, to allow timely decisions regarding required disclosure (the “Disclosure Controls”);
- monitoring the integrity and evaluating the effectiveness of the Disclosure Controls;
- reviewing our: (i) Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, proxy statement, material registration statements, and any other information filed with the SEC; (ii) press releases containing financial information, earnings guidance, information about material developments, or other information material to our security holders; and (iii) correspondence broadly disseminated to shareholders and all presentations to analysts and the investment community (collectively, the “Covered Reports”);
- discussing with the Senior Officers all relevant information relative to the Disclosure Committees responsibilities and proceedings, including: (i) the preparation of our disclosures in the Covered Reports; (ii) the evaluation of the effectiveness of the Disclosure Controls; and (iii) any false statement or omission of material fact discovered upon review of a Covered Report; and
- providing or overseeing an annual mandatory training session to our Board of Directors and employees, which shall include coverage of the following topics: (i) risk assessment and compliance, (ii) our Code of Ethics, (iii) any and all manuals or policies established by us concerning legal or ethical standards of conduct to be observed in connection with work performed for the Company, and (iv) the obligations of the Disclosure Committee and the rules, regulations and other factors that impact disclosures contained in the Covered Reports.

The members of our Disclosure Committee are currently Messrs. Macaluso, Chilcott, Giles, Coelho and Dr. Stevens, as well as Ms. Cherevka. Dr. Stevens is the chairman of our Disclosure Committee.

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

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Non-Employee Director Compensation

Our Compensation Committee established the following fees for payment to members of our Board of Directors or committees, for the fiscal year ended December 31, 2018:

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

The Non-Employee Director Compensation for fiscal 2018 included a grant to each Director of options to purchase 30,000 shares of our common stock on the date of our annual shareholder meeting of stockholders, vesting monthly over the succeeding twelve months. The 2018 annual meeting occurred on December 15, 2018.

Director Compensation for 2018

The table below summarizes the compensation paid by us to non-employee directors for the year ended December 31, 2018. Our employee directors do not receive additional compensation for their services as a member of our Board of Directors.

Name	Fees Earned or Paid in Cash	Stock Option Awards (1)	Stock Awards (2)	All Other Compensation	Total
Philip H. Coelho (3)	$ 86,500	$ 10,337	$ 20,000	$ —	$ 116,837
Richard B. Giles (4)	$ 77,000	$ 10,337	$ 20,000	$ —	$ 107,337

David Stevens, Ph.D. (5)	$ 65,000	$ 10,337	$ 20,000	$ —	$ 95,337

(1) On December 15, 2018, the date of the 2018 annual meeting, each of Messrs. Coelho, Giles and Dr. Stevens was granted options to purchase 30,000 shares of common stock. These options have an exercise price of $0.40 per share. These options vest over 12 months and have a term of 10 years from the grant date. The amounts reported under “Stock Option Awards” in the above table reflect the grant date fair value of these awards as determined in accordance with the Financial Accounting Standards Board’s Accounting Standards Codification Topic 718, Compensation – Stock Compensation. The value of stock option awards was estimated using the Black-Scholes option pricing model. The valuation assumptions used in the valuation of options granted may be found in Note 8 to our financial statements included in this annual report on Form 10-K for the year ended December 31, 2018.

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(2) On January 2, 2018, each of Messrs. Coelho, Giles and Dr. Stevens was awarded 5,747 shares of common stock under the 2010 Plan, at a price of $3.48 which was the closing price of our common stock on the date of grant per share, equivalent to $20,000. Since fiscal 2012, the aggregate number of stock awards to each Messrs. Coelho, Giles and Dr. Stevens totaled 41,536 shares of common stock with a value of $100,000.
(3) The aggregate number of shares issuable upon exercise of option awards outstanding at December 31, 2018 for Mr. Coelho was 685,554, of which 655,554 were fully vested.
(4) The aggregate number of shares issuable upon exercise of option awards outstanding at December 31, 2018 for Mr. Giles was 770,000, of which 740,000 were fully vested.
(5) The aggregate number of shares issuable upon exercise of option awards outstanding at December 31, 2018 for Dr. Stevens was 345,000, or which 315,000 were fully vested.

Item 11.Executive Compensation

Executive Compensation

Named Executive Officers

For our fiscal year ended December 31, 2018, our Named Executive Officers were: (i) Michael Macaluso, our Chief Executive Officer, who has served as our Chief Executive Officer since January 2012, (ii) Thomas E. Chilcott, our Chief Financial Officer, who has served as our Chief Financial Officer, Secretary and Treasurer since June 2017, (iii) David Bar-Or, M.D., our former Chief Scientific Officer, who served as our Chief Scientific Officer from March 2010 to September 2018, and (iv) Holli Cherevka, our current Chief Operating Officer, who has served as our Chief Operating Officer since September 2017. We had no other executive officers serving during the year ended December 31, 2018.

The following table shows for the fiscal years ended December 31, 2018 and December 31, 2017, compensation awarded to, paid to, or earned by our Name Executive Officers.

Summary Compensation of Named Executive Officers

Name and Principal Position (a)	Year (b)	Salary ($) (c)	Bonus ($) (d)	Stock Award ($) (e)	Option Awards ($)(1) (f)	Total ($) (j)
Named Executive Officers						
Michael Macaluso						
Chief Executive Officer	2018	300,000	5,000	—	—	305,000
effective January 2012	2017	300,000	5,000	—	268,016	573,016
David Bar-Or, M.D.						
Former Chief Scientific Officer and	2018	228,218	—	—	—	228,218
Chairman	2017	300,000	5,000	—	46,728	351,728
Thomas E. Chilcott						
Chief Financial Officer	2018	225,000	30,000 (2)	—	34,472 (3), (4)	289,472
effective June 2017	2017	166,458 (5)	55,000 (6)	—	170,386	391,844
Holli Cherevka						

Chief Operating Officer	2018	200,000		5,000		—	22,383	(4)	227,383
effective September 2017	2017	187,195	(7)	45,000	(8)	—	91,887		324,082

(1) The amounts reported under "Option Awards" in the above table reflect the grant date fair value of these awards as determined in accordance with the Financial Accounting Standards Board's Accounting Standards Codification Topic 718, Compensation – Stock Compensation, rather than amounts paid to or realized by the named individual. The value of the option awards was estimated using the Black-Scholes option pricing model. The valuation assumptions used in the valuation of options granted may be found in Note 8 to our financial statements included in this annual report on Form 10-K for the year ended December 31, 2018.

(2) Mr. Chilcott received a $25,000 bonus based on his employment agreement for his involvement in raising non-dilutive funds through warrant exercises.

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(3) Mr. Chilcott was granted 75,000 options due to his performance in fiscal year 2018 and the value of the option award totaled $33,000, which was recognized in the period ended September 30, 2018.
(4) The Compensation Committee approved a one-time option repricing where the exercise price of each relevant option was amended to reduce such exercise price to $0.75. "Relevant Options" are all outstanding stock options as of October 1, 2018 (vested or unvested) to acquire shares of our common stock that have exercise prices above $0.75; provided, however, that the maximum dollar value of the repricing for any individual will not exceed $500,000 (with such value calculated by multiplying (i) the difference between the initial exercise price and $0.75 by (ii) the number of options being repriced (see further information in Note 8 of the financial statements and within the Outstanding Equity Awards table contained in this section). The value of repricing the options for Mr. Chilcott and Ms. Cherevka totaled $1,400 and $22,400, respectively, and these amounts were recognized in the period ended December 31, 2018.
(5) Mr. Chilcott was appointed interim Chief Financial Officer, effective June 2017 and Chief Financial Officer, effective August 2017.
(6) Mr. Chilcott received a $50,000 bonus based on his employment agreement for the October 2017 Securities Purchase Agreement.
(7) Ms. Cherevka was appointed Chief Operating Officer, effective September 2017.
(8) Ms. Cherevka received a $40,000 bonus related to her performance during 2016, which was paid out during 2017.

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

Employment Agreements

We entered into an employment agreement with Mr. Michael Macaluso, our Chief Executive Officer, effective January 9, 2012. This agreement provided for an annual salary of $195,000, with an initial term ending January 9, 2015. On October 1, 2013, we increased Mr. Macaluso's annual salary from $195,000 to $300,000. On December 20, 2014, we extended the employment agreement of Mr. Macaluso for three additional years, expiring January 9, 2017. On March 9, 2017, we extended his employment agreement for another three years until January 9, 2020. In connection with his 2017 Amendment, Mr. Macaluso was awarded 400,000 options to purchase our common stock at an exercise price of $0.81 vesting annually over three years beginning on March 9, 2018.

In August 2010, we entered into an employment agreement with Dr. David Bar-Or, our former Chief Scientific Officer, or CSO. The employment agreement with Dr. Bar-Or superseded his prior agreement with Life Sciences. The agreement had an initial term ending July 31, 2013. The agreement provided for an annual salary of $300,000. On July 15, 2013, we extended the employment agreement of Dr. David Bar-Or for one additional year, expiring July 31, 2014. In connection with this amendment, Dr. Bar-Or was awarded 300,000 options to purchase our common stock at an exercise price of $6.15 with 50% vesting upon grant and 50% after one year. On August 11, 2014, we extended the employment agreement of Dr. Bar-Or for one additional year, expiring July 31, 2015. In connection with this amendment, Dr. Bar-Or was awarded 300,000 options to purchase our common stock at an exercise price of $6.48 with 50% vesting upon grant and 50% after one year. On August 3, 2015, we extended the employment agreement of Dr. Bar-Or for one additional year, expiring July 31, 2016. In connection with this amendment, Dr. Bar-Or was awarded 300,000 options to purchase our common stock at an exercise price of $2.60 with such options vesting on the date that we meet all endpoints in connection with the Ampion clinical trial as determined in the sole discretion of our Compensation Committee. We did not meet the primary end point on the Ampion trial, so the options granted to Dr. Bar-Or in July 2015 expired unvested on June 30, 2016. On August 1, 2016, we extended the employment agreement of Dr. Bar-Or for one additional year, which expired on July 31, 2017. On June 30, 2017, we extended the Employment Agreement of Dr. Bar-Or for one additional year, expiring July 1, 2018. In connection with this agreement, Dr. Bar-Or was awarded 133,000 options to purchase our common stock at an exercise price of $0.50 with

100% vesting immediately. In July 2018, we extended the employment agreement of Dr. Bar-Or for an additional month. On August 29, 2018, Dr. Bar-Or notified us of his decision to retire from his role as CSO, effective September 30, 2018. Dr. Bar-Or will continue to serve as a member of the Board of Directors and the Scientific Advisory Board.

We entered into an employment agreement with Mr. Thomas Chilcott, our Chief Financial Officer, on August 23, 2017, which provided for an annual salary of $200,000 and a term ending August 16, 2019. In connection with this employment agreement, Mr. Chilcott was awarded 200,000 options to purchase common stock at an exercise price of

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$0.48, with 50% vesting upon grant and 50% after one year. On December 29, 2017, the Compensation Committee approved a salary increase for Mr. Chilcott of $25,000, effective January 1, 2018.

We entered into an employment agreement with Ms. Holli Cherevka, our Chief Operating Officer, on September 19, 2017, which provided for an annual salary of $200,000 and a term ending September 19, 2019. In connection with this employment agreement, Ms. Cherevka was awarded 200,000 options to purchase common stock at an exercise price of $0.55, with 50% vesting upon grant and 50% after one year.

Each officer is eligible to receive a discretionary annual bonus each year that will be determined by the Compensation Committee of the Board of Directors based on individual achievement and Company performance objectives established by the Compensation Committee. Included in those objectives, as applicable for the responsible officer, are (i) obtaining successful clinical trial results, (ii) preparation and compliance with a fiscal budget, (iii) the sale of intellectual property not selected for clinical trials by us at prices, and times, approved by the Board of Directors and (iv) making significant scientific discoveries acceptable to the Board of Directors. The targeted amount of the annual bonus for Mr. Macaluso, Mr. Chilcott and Ms. Cherevka is 50% of the applicable base salary, although the actual bonus may be higher or lower.

Outstanding Equity Awards

The following table provides a summary of equity awards outstanding for each of the Named Executive Officers as of December 31, 2018:

wards					Stock Awards		
f g ed xercisable	Number of Securities Underlying Unexercised Options Unexercisable (#) (c)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) (d)	Option Exercise Price ($) (e)	Option Expiration Date (f)	Number of Shares or Units of Stock That Have Not Vested (#) (g)	Market Value of Shares or Units of Stock That Have Not Vested ($) (h)	Equity Incentive Awards: Number o Unearned Shares, U or Other Rights Th Have Not Vested (# (i)
	266,667	(1) —	0.81	3/9/2027	—	—	—
(2)	—	—	3.46	12/20/2024	—	—	—
	—	—	2.76	5/7/2022	—	—	—

—		—	1.70	8/27/2020	—	—	—
—		—	1.03	8/12/2020	—	—	—
—		—	—	12/29/2018			
—		—	—	12/29/2018	—	—	—
—		—	—	12/29/2018	—	—	—
—		—	—	12/29/2018	—	—	—
—		—	—	12/29/2018	—	—	—
—		—	0.51	9/20/2028			
—		—	0.48	8/23/2027	—	—	—
33,334	(3)	—	0.60	6/15/2027	—	—	—
25,000	(4)	—	0.75	(5) 1/18/2027	—	—	—
—		—	0.55	9/19/2027	—	—	—
—		—	0.51	8/8/2027	—	—	—
—		—	0.75	(5) 7/15/2026	—	—	—
—		—	0.75	(5) 10/6/2024	—	—	—
—		—	0.75	(5) 11/8/2023	—	—	—
—		—	8.62	11/8/2023			
—		—	0.75	(5) 4/2/2023	—	—	—
—		—	0.75	(5) 1/14/2023	—	—	—

(1) The unexercisable options vest annually starting on the first anniversary of the grant date and become fully vested on March 9, 2020. The option awards remain exercisable until they expire ten years from the date of grant subject to earlier expiration following termination of employment.

(2) A total of 220,000 vested options were forfeited as of August 8, 2017.

(3)

The unexercisable options vest annually starting on the grant date and become fully vested on June 15, 2019. The option awards remain exercisable until they expire ten years from the date of grant subject to earlier expiration following termination of employment.

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(4) The unexercisable options vest annually starting on the grant date and become fully vested on January 18, 2019. The option awards remain exercisable until they expire ten years from the date of grant subject to earlier expiration following termination of employment.
(5) These options were included in the one-time option repricing on October 1, 2018 (see further information in Note 8 in the financial statements).

Potential Payments upon Termination or Change in Control

If the employment of Mr. Chilcott or Ms. Cherevka is terminated at our election at any time, for reasons other than death, disability, cause (as defined in the agreement) or a voluntary resignation, or if the officer terminates their employment for good reason, the officer in question shall be entitled to receive a lump sum severance payment equal to one and a half times or one half times their base salary, respectively and of the continued payment of premiums for continuation of the officer's health and welfare benefits pursuant to COBRA or otherwise, for a period of two years from the date of termination, subject to earlier discontinuation if the officer is eligible for comparable coverage from a subsequent employer. Mr. Macaluso is not entitled to any such termination payments pursuant to the terms of his employment agreement. All severance payments, less applicable withholding, are subject to the officer's execution and delivery of a general release of us and our affiliates and each of their officers, directors, employees, agents, successors and assigns in a form acceptable to us, and a reaffirmation of the officer's continuing obligation under the propriety information and inventions agreement (or an agreement without that title, but which pertains to the officer's obligations generally, without limitation, to maintain and keep confidential all of our proprietary and confidential information, and to assign all inventions made by the officer to us, which inventions are made or conceived during the officer's employment). If the employment is terminated for cause, no severance shall be payable by us.

"Good Reason" means:

· a material reduction in the officer's overall responsibilities or authority or scope of duties;
· a material reduction of the officer's compensation; or
· relocation of the officer to a facility or location not within 40 miles of the state capitol building in Denver, Colorado.

"Cause" means:

· willful malfeasance or willful misconduct in connection with employment;
· conviction of, or entry of a plea of guilty or nolo contendere to, any crime other than a traffic violation or misdemeanor;
· willful and deliberate violation of a company policy;
· unintended but material breach of any written policy applicable to all employees which is not cured within 30 business days;
· unauthorized use or disclosure of any proprietary information or trade secrets of the company;
· willful and deliberate breach of the employment agreement;
· any other material breach of the employment agreement which is not cured within 30 business days; or
· gross negligence in the performance of duties.

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

- The acquisition by an individual, entity, or group, other than us or any of our subsidiaries, of beneficial ownership of 50% or more of the combined voting power or economic interests of our then outstanding voting securities entitled to vote generally in the election of directors (excluding any issuance of securities by us in a transaction or series of transactions made principally for bona fide equity financing purposes);
- The acquisition of us by another entity by means of any transaction or series of related transactions to which we are a party (including, without limitation, any stock acquisition, reorganization, merger or consolidation but excluding any issuance of securities by us in a transaction or series of related transactions made principally for bona fide equity financing purposes) other than a transaction or series of related transactions in which the holders of our voting securities outstanding immediately prior to such transaction or series of related transactions retain, immediately after such transaction or series of related transactions, as a result of our shares held by such holders prior to such transaction or series of related transactions, at least a majority of the total voting power represented by our outstanding voting securities or such other surviving or resulting entity (or if we are or such other surviving or resulting entity is a wholly-owned subsidiary immediately following such acquisition, its parent); or
- The sale or other disposition of all or substantially all our assets in one transaction or series of related transactions.

In the event of a Change of Control, all outstanding stock options, restricted stock and other stock-based grants held by Mr. Macaluso, Mr. Chilcott and Ms. Cherevka become fully vested and exercisable, and all such stock options remain exercisable from the date of the Change in Control until the expiration of the term of such stock options.

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

The employment agreements do not provide for the payment of a "gross-up" payment under Section 280G of the Code. The following table provides estimates of the potential severance and other post-termination benefits that each of Mr. Macaluso, Mr. Chilcott and Ms. Cherevka would have been entitled to receive assuming their respective employment was terminated as of December 31, 2018 for the reason set forth in each of the columns.

Recipient and Benefit	Cause; Without good reason;	Without Cause; Good reason	Death; Disability	Change in Control
Michael Macaluso				
Stock Options (1)	$ —	$ —	$ —	$ —
Total	$ —	$ —	$ —	$ —
Thomas Chilcott				
Salary	$ —	$ 337,500	$ —	$ —
Stock Options (1)	—	—	—	—
Value of health benefits provided after termination (2)	—	81,512	—	—
Total	$ —	$ 419,012	$ —	$ —
Holli Cherevka				
Salary	$ —	$ 100,000	$ —	$ —
Stock Options (1)	—	—	—	—

Value of health benefits provided after termination (2)		—	54,896		—	—
Total	$	—	$ 154,896	$	—	$ —

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(1) Amounts represent the intrinsic value (that is, the value based upon the company's stock price on December 31, 2018 of $0.39 per share), minus the exercise price of the equity awards that would have become exercisable as of December 31, 2018. These stock options had no intrinsic value as of December 31, 2018 due to the stock price being below the exercise price as of this date.
(2) The value of such benefits is determined based on the estimated cost of providing health benefits to the Named Executive Officer for a period of two years.

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

The following table sets forth information regarding beneficial ownership of our common stock as of March 1, 2019 by:

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

We have determined beneficial ownership in accordance with SEC rules. The information does not necessarily indicate beneficial ownership for any other purpose. Under these rules, the number of shares of common stock deemed outstanding includes shares issuable upon exercise of options and warrants held by the respective person or group which may be exercised or converted within 60 days after March 1, 2019.

For purposes of calculating each person's or group's percentage ownership, stock options and warrants exercisable within 60 days after March 1, 2019 are included for that person or group but not the stock options or warrants of any other person or group. Ownership is based on 111,127,878 shares of common stock outstanding at March 1, 2019.

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Unless otherwise indicated and subject to any applicable community property laws, to our knowledge, each stockholder named in the following table possesses sole voting and investment power over the shares listed. Unless otherwise noted below, the address of each stockholder listed on the table is c/o Ampio Pharmaceuticals, Inc., 373 Inverness Parkway, Suite 200, Englewood, Colorado 80112.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned (1)
5% Stockholders		
CVI Investments Inc. (2)		
C/O Heights Capital Management, Inc.		
101 California Street, Suite 3250		
San Francisco, CA 94111	12,104,835	10.3 %
Bruce Terker (3)		
950 W. Valley Road, Suite 2900		
Wayne, PA 19087	9,553,331	8.6 %
Directors and Name Executive Officers		
Michael Macaluso (4)	2,883,418	2.6 %
David Bar-Or (5)	—	— %
Richard B. Giles (6)	1,069,549	1.0 %
Philip H. Coelho (7)	821,482	0.7 %
Holli Cherevka (8)	590,000	0.5 %
Thomas Chilcott (9)	416,666	0.4 %
David R. Stevens (10)	411,990	0.4 %
Directors and executive officers as a group (seven people)	6,193,105	5.6 %

(1) Based on shares issued and outstanding as the most recent practicable date, March 1, 2019.
(2) Based solely on a Schedule 13G filed on February 12, 2019 by CVI Investments, Inc. reporting beneficial ownership as of December 31, 2018.
(3) Based solely on a Schedule 13G filed on January 31, 2019 by Bruce Terker, reporting beneficial ownership as of December 31, 2018.
(4) Includes options to purchase 1,096,666 shares that are exercisable within 60 days of March 1, 2019.
(5) Dr. Bar-Or stock options expired on December 29, 2018, therefore his beneficial ownership is 0.0% as of March 1, 2019.
(6) Includes options to purchase 750,000 shares that are exercisable within 60 days of March 1, 2019.
(7) Includes options to purchase 665,554 shares that are exercisable within 60 days of March 1, 2019.
(8) Includes options to purchase 590,000 shares that are exercisable within 60 days of March 1, 2019.
(9) Includes options to purchase 416,666 shares that are exercisable within 60 days of March 1, 2019.
(10) Includes options to purchase 325,000 shares that are exercisable within 60 days of March 1, 2019.

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

Related Party Transactions

Other than the director and executive compensation arrangements discussed above in Item 11 “Executive Compensation”, we have not been a party to any transactions since January 1, 2018 in which the amount involved exceeded or will exceed $120,000, and in which any director, executive officer or holder of more than 5% of any class of our voting stock, or any member of the immediate family of or entities affiliated with any of them, had or will have a material interest.

Policies and Procedures for Related Party Transactions

We have adopted a formal written policy that our executive officers, directors, nominees for election as directors, beneficial owners of more than 5% of any class of our common stock and any member of the immediate family of any of the foregoing persons, are not permitted to enter into a related party transaction with us without the prior consent of our Audit Committee, subject to the pre-approval exceptions described below. If advance approval is not feasible then the

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related party transaction will be considered at the Audit Committee's next regularly scheduled meeting. In approving or rejecting any such proposal, our Audit Committee is to consider the relevant facts and circumstances available and deemed relevant by our Audit Committee, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related party's interest in the transaction. Our Board of Directors has delegated to the chair of our Audit Committee the authority to pre-approve or ratify any request for us to enter into a transaction with a related party, in which the amount involved is less than $120,000 and where the chair is not the related party. Our Audit Committee will also review certain types of related party transactions that it has deemed pre-approved even if the aggregate amount involved will not exceed $120,000 including, employment of executive officers, director compensation, certain transactions with other organizations, transactions where all stockholders receive proportional benefits, transactions involving competitive bids, regulated transactions and certain banking-related services.

Director Independence

Our common stock is listed on the NYSE American. The listing rules of the NYSE American require that a majority of the members of the board of directors be independent. The rules of the NYSE American require that, subject to specified exceptions, each member of our Audit, Compensation and Nominating and Governance Committees be independent. Audit Committee members must also satisfy the independence criteria set forth in Rule 10A 3 under the Securities Exchange Act of 1934. Under the rules of the NYSE American, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

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

Based upon information provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board of Directors has determined that none of Messrs. Coelho and Giles and Dr. Stevens, representing three of our five directors, has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined by the NYSE American. Our Board of Directors also determined that Messrs. Giles, Coelho and Stevens, who comprise our Audit Committee, our Compensation Committee, our Nominating and Governance Committee, and our Disclosure Committee, satisfy the independence standards for those committees established by applicable SEC rules and the NYSE American rules. In making this determination, our Board of Directors considered the relationships that each non-employee director has with our Company and all other facts and circumstances our Board of Directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. The Board of Directors also has determined that Mr. Giles qualifies as an "audit committee financial expert," as defined in Item 401(h) of Regulation S-K promulgated under the Exchange Act.

Item 14.Principal Accountant Fees and Services

Plante Moran, PLLC, or Plante Moran, (formerly known as EKS&H LLLP) has served as our independent auditors since January 2010 and has been appointed by the Audit Committee of the Board of Directors to continue as our independent auditors for the fiscal year ended December 31, 2018.

The following table presents aggregate fees for professional services rendered by our independent registered public accounting firm, Plante Moran for the respective periods.

	Year Ended December 31,	
	2018	2017
Audit fees (1)	$ 141,000	$ 153,000
Audit-related fees (2)	47,000	34,000
Tax fees (3)	16,000	22,000
Total fees	$ 204,000	$ 209,000

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(1) Audit fees are comprised of annual audit fees and quarterly review fees.
(2) Audit-related fees for fiscal years 2018 and 2017 are comprised of fees related to reviewing the prospectus supplement, proxy statement and registration statements.
(3) Tax fees are comprised of tax compliance and preparation.

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

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

Audit services include audit work performed in the audit of the annual financial statements, review of quarterly financial statements, reading of annual, quarterly and current reports, as well as work that generally only the independent auditor can reasonably be expected to provide.

Audit-related services are for assurance and related services that are traditionally performed by the independent auditor, including the provisions of consents and comfort letters in connection with the filing of registration statements, due diligence related to mergers and acquisitions and special procedures required to meet certain regulatory requirements.

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

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

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

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

PART IV

Item 15.Exhibits and Financial Statement Schedules

(a)(1) Financial Statements

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

- Report of Independent Registered Public Accounting Firm
- Balance Sheets as of December 31, 2018 and 2017
- Statements of Operations for the years ended December 31, 2018 and 2017
- Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2018 and 2017

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· Statements of Cash Flows for the years ended December 31, 2018 and 2017
· Notes to Financial Statements

(a)(2) Financial Statement Schedules

Not Applicable.

(a)(3) Exhibits

Exhibit number	Exhibit title
2.1	Agreement and Plan of Merger, dated March 2, 2010. (1)
2.2	Securities Put and Guarantee Agreement dated March 2, 2010. (1)
2.3	Agreement and Plan of Merger, dated September 4, 2010. (2)
2.4	Amendment to Agreement and Plan of Merger, effective December 31, 2010. (3)
2.5	Amendment to Agreement and Plan of Merger, dated March 22, 2011. (7)
3.1	Certificate of Incorporation of the Registrant, as currently in effect. (4)
3.2	Certificate of Amendment to Certificate of Incorporation. (4)
3.3	Plan of Conversion of Chay Enterprises, Inc. to a Delaware corporation. (4)
3.4	Amended and Restated Bylaws of the Registrant, as currently in effect. (33)
4.1	Specimen Common Stock Certificate of the Registrant. (6)
4.2	Form of Underwriter Warrant. (9)
4.3	Form of Warrant to Purchase Common Stock. (23)
4.4	Form of Warrant to Purchase Common Stock. (23)
4.5	Form of Warrant. (31)
10.1	Form of Director and Executive Officer Indemnification Agreement. (5)
10.2**	2010 Stock Incentive Plan and forms of option agreements. (5)
10.3***	Sponsored Research Agreement dated September 1, 2009. (5)
10.4**	Employment Agreement, effective January 9, 2012, by and between Ampio Pharmaceuticals, Inc. and Michael Macaluso. (10)
10.5**	Amendment to Employment Agreement between Ampio Pharmaceuticals, Inc. and David Bar-Or, M.D., dated July 15, 2013. (11)
10.6	Securities Purchase Agreement by and among Ampio Pharmaceuticals, Inc. and the Purchasers (as defined therein), dated September 25, 2013. (12)
10.7**	Amendment to Employment Agreement between Ampio Pharmaceuticals, Inc. and Michael Macaluso, dated October 4, 2013. (13)
10.8	Lease Agreement by and between Ampio Pharmaceuticals, Inc. and NCWP – Inverness Business Park, LLC, dated December 13, 2013. (35)
10.9**	Amendment of 2010 Stock and Incentive Plan. (14)
10.10***	Human Serum Albumin Ingredient Purchase and Sale Agreement by and between Ampio Pharmaceuticals, Inc. and Supplier, dated October 10, 2013. (15)
10.11**	Employment Agreement between Ampio Pharmaceuticals, Inc. and Gregory A. Gould, executed June 4, 2014 and effective June 10, 2014. (16)
10.12**	Amendment to Employment Agreement between Ampio Pharmaceuticals, Inc. and David Bar-Or, M.D., dated August 11, 2014. (17)
10.13**	Amendment to Employment Agreement between Ampio Pharmaceuticals, Inc. and Michael Macaluso, dated December 20, 2014. (18)
10.14**	Amendment to Employment Agreement between Ampio Pharmaceuticals, Inc. and David Bar-Or, M.D., dated August 3, 2015. (19)

10.15	Amendment to Human Serum Albumin Ingredient Purchase and Sale Agreement among Ampio Pharmaceuticals, Inc., Octapharma USA, Inc. and Nova Biologics, Inc., effective as of October 8, 2015. (20)
10.16	Controlled Equity Offering SM Sales Agreement, dated February 10, 2016, by and between Ampio Pharmaceuticals, Inc. and Cantor Fitzgerald Co. (21)
10.17	Amendment to Employment Agreement between Ampio Pharmaceuticals, Inc. and David Bar-Or, M.D., dated July 28, 2016. (22)

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Exhibit number	Exhibit title
10.18	Purchase Agreement between Ampio Pharmaceuticals, Inc. and the investor named therein, dated August 29, 2016. (23)
10.19**	Amendment to Employment Agreement between Ampio Pharmaceuticals, Inc. and Michael Macaluso, dated March 9, 2017. (24)
10.20	Waiver and Consent Agreement, dated March 27, 2017, by and between Ampio Pharmaceuticals, Inc. and CVI Investments, Inc. (25)
10.21	Securities Purchase Agreement, dated June 2, 2017, by and among Ampio Pharmaceuticals, Inc. and the investors named therein. (26)
10.22	Addendum No. 7, dated June 30, 2017, to the Sponsored Research Agreement, dated September 1, 2009, by and between Ampio Pharmaceuticals, Inc. and Trauma Research LLC. (27)
10.23**	Amendment to Employment Agreement between Ampio Pharmaceuticals, Inc. and David Bar-Or, M.D., dated June 30, 2017. (27)
10.24**	Employment Agreement, dated August 23, 2017, by and between Ampio Pharmaceuticals, Inc. and Thomas E. Chilcott, III. (28)
10.25**	Employment Agreement, dated September 19, 2017, by and between Ampio Pharmaceuticals, Inc. and Holli Cherevka. (29)
10.26	Securities Purchase Agreement, dated as of October 15, 2017, by and among Ampio Pharmaceuticals, Inc. and the investors named therein. (30)
10.27	Underwriting Agreement, dated August 9, 2018, by and between Ampio Pharmaceuticals, Inc. and Canaccord Genuity LLC. (31)
10.28	Amendment No. 1, dated August 10, 2018, to the Underwriting Agreement by and between Ampio Pharmaceuticals, Inc. and Canaccord Genuity LLC . (31)
10.29	Form of Warrant Exercise Agreement. (34)
16.1	Letter Regarding Change in Certifying Accountant, dated March 16, 2010. (5)
16.2	Letter from EKS&H LLLP to the SEC dated October 4, 2018. (32)
21.1	List of subsidiaries of the Registrant. (8)
23.1*	Consent of Plante & Moran PLLC.
23.2*	Consent of EKS&H LLLP.
31.1*	Certificate of the Chief Executive Officer of Ampio Pharmaceuticals, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certificate of the Chief Financial Officer of Ampio Pharmaceuticals, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certificate of the Chief Executive Officer and the Chief Financial Officer of Ampio Pharmaceuticals, Inc. pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	XBRL (extensible Business Reporting Language). The following materials from Ampio Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2018 formatted in XBRL: (i) the Balance Sheets, (ii) the Statements of Operations, (iii) the Statements of Stockholders' Equity (Deficit), (iv) the Statements of Cash Flows, and (v) the Notes to the Financial Statements.

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(1)	Incorporated by reference from Registrant's Form 8-K filed March 8, 2010.
(2)	Incorporated by reference from Registrant's Amendment No. 1 to Form 8-K filed January 7, 2011.

(3)	Incorporated by reference from Registrant's Amendment No. 2 to Form 8-K filed January 7, 2011.
(4)	Incorporated by reference from Registrant's Form 8-K filed March 30, 2010.
(5)	Incorporated by reference from Registrant's Form 8-K/A filed March 17, 2010.
(6)	Incorporated by reference from Registrant's Registration Statement on Form S-4 filed January 7, 2011.
(7)	Incorporated by reference from Registrant's Form 8-K filed March 25, 2011.
(8)	Incorporated by reference from Registrant's Registration Statement on Form S-1 filed November 12, 2010.
(9)	Incorporated by reference from Registrant's Form 8-K filed July 13, 2012.
(10)	Incorporated by reference from Registrant's Form 8-K filed September 13, 2012.
(11)	Incorporated by reference from Registrant's Form 8-K filed July 19, 2013.
(12)	Incorporated by reference from Registrant's Form 8-K filed September 26, 2013.
(13)	Incorporated by reference from Registrant's Form 8-K filed October 4, 2013.
(14)	Incorporated by reference from Registrant's Proxy Statement on Form 14A filed November 1, 2013.
(15)	Incorporated by reference from Registrant's Form 10-K/A filed May 23, 2014.

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(16) Incorporated by reference from Registrant's Form 8-K filed June 10, 2014.
(17) Incorporated by reference from Registrant's Form 8-K filed August 15, 2014.
(18) Incorporated by reference from Registrant's Form 8-K filed December 29, 2014.
(19) Incorporated by reference from Registrant's Form 8-K filed August 6, 2015.
(20) Incorporated by reference from Registrant's Form 8-K filed October 20, 2015.
(21) Incorporated by reference from Registrant's Form 8-K filed on February 10, 2016.
(22) Incorporated by reference from Registrant's

Form 10-Q filed August 2, 2016.

(23) Incorporated by reference from Registrant's Form 8-K filed on August 29, 2016.

(24) Incorporated by reference from Registrant's Form 8-K filed on March 13, 2017.

(25) Incorporated by reference from Registrant's Form 8-K filed on March 28, 2017.

(26) Incorporated by reference from Registrant's Form 8-K filed on June 6, 2017.

(27) Incorporated by reference from Registrant's Form 8-K filed on July 7, 2017.

(28) Incorporated by reference from Registrant's Form 8-K filed on August 29, 2017.

(29) Incorporated by reference from Registrant's

Form 8-K filed on September 22, 2017.

(30) Incorporated by reference from Registrant's Form 8-K filed on October 16, 2017.

(31) Incorporated by reference from Registrant's Form 8-K filed on August 13, 2018.

(32) Incorporated by reference from Registrant's Form 8-K filed October 4, 2013.

(33) Incorporated by reference from Registrant's Form 10-Q filed November 14, 2018.

(34) Incorporated by reference from Registrant's Form 8-K filed on December 10, 2018.

(35) Incorporated by reference from Registrant's Form 8-K filed December 19,

2013.

* Filed herewith.

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

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

Item 16.None

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SIGNATURES

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

AMPIO PHARMACEUTICALS, INC.

Date: March 18, 2019 By: /s/ Michael Macaluso
Michael Macaluso
Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant in the capacities indicated, on March 18, 2019.

Signature	Title
/s/ Michael Macaluso Michael Macaluso	Chairman of the Board and Chief Executive Officer
/s/ Thomas E. Chilcott Thomas E. Chilcott	Chief Financial Officer (Principal Financial and Accounting Officer), Secretary and Treasurer
/s/ David Bar-Or David Bar-Or	Director
/s/ Philip H. Coelho Philip H. Coelho	Director
/s/ Richard B. Giles Richard B. Giles	Director
/s/ David R. Stevens David R. Stevens	Director

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AMPIO PHARMACEUTICALS, INC.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of Ampio Pharmaceuticals

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying balance sheet of Ampio Pharmaceuticals (the “Company”) as of December 31, 2018, the related statement of operations, stockholders' equity, and cash flows for year ended December 31, 2018, and the related notes (collectively referred to as the “financial statements”). We also have audited the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the “COSO framework”).

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flows for the year ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in the COSO framework.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company’s financial statements and an opinion on the Company's internal

control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audit of the financial statements included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provide a reasonable basis for our opinions.

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Definition and Limitations of Internal Control over Financial Reporting

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

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

/s/ Plante & Moran, PLLC

We have served as the Company’s auditor since 2010.

Denver, Colorado

March 18, 2019

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Report of Independent Public Accounting Firm

To the Shareholders and Board of Directors of

Ampio Pharmaceuticals, Inc.

Englewood, Colorado

OPINIONS ON THE CONSOLIDATED FINANCIAL STATEMENTS

We have audited the accompanying balance sheet of Ampio Pharmaceuticals (the “Company”) as of December 31, 2017, and the related statement of operations, stockholders’ equity, and cash flows, for the year ended December 31, 2017, and the related notes (collectively referred to as the “financial statements”).

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2017, and the results of its operations and its cash flows for the year ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

GOING CONCERN UNCERTAINTY

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

BASIS FOR OPINIONS

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

/s/ EKS&H LLLP

March 6, 2018

Denver, Colorado

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AMPIO PHARMACEUTICALS, INC.

Balance Sheets

	December 31, 2018	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 7,585,392	$ 8,209,071
Prepaid expenses and other	413,280	233,815
Total current assets	7,998,672	8,442,886
Fixed assets, net (Note 2)	5,997,582	6,837,861
Deposits	33,856	33,856
Total assets	$ 14,030,110	$ 15,314,603
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued expenses	$ 1,324,651	$ 2,785,529
Accrued compensation	—	1,033,261
Deferred rent - current portion	59,579	59,579
Total current liabilities	1,384,230	3,878,369
Long-term deferred rent	476,753	537,364
Warrant derivative liability	6,933,031	45,075,755
Total liabilities	8,794,014	49,491,488
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred Stock, par value $0.0001; 10,000,000 shares authorized; none issued	—	—
Common Stock, par value $0.0001; 200,000,000 shares authorized; shares issued and outstanding - 110,941,516 in 2018 and 80,060,345 in 2017	11,094	8,006
Additional paid-in capital	176,227,510	170,803,783
Accumulated deficit	(171,002,508)	(204,988,674)
Total stockholders' equity	5,236,096	(34,176,885)
Total liabilities and stockholders' equity	$ 14,030,110	$ 15,314,603

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

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AMPIO PHARMACEUTICALS, INC.

Statements of Operations

	Years Ended December 31,	
	2018	2017
Operating expenses		
Research and development	$ 6,828,612	$ 10,097,178
Research and development - related party (Note 9)	—	323,554
General and administrative	4,355,350	5,255,467
Total operating expenses	11,183,962	15,676,199
Other income (expense)		
Interest (expense) income	(5,012)	3,086
Derivative gain (loss)	45,298,316	(36,218,832)
Loss from disposal of fixed assets	(123,176)	—
Total other income (expense)	45,170,128	(36,215,746)
Net income (loss)	$ 33,986,166	$ (51,891,945)
Basic and diluted net income (loss) per common share	$ 0.46	$ (0.79)
Weighted average number of common shares outstanding	73,358,034	65,297,348

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

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AMPIO PHARMACEUTICALS, INC.

Statements of Stockholders' Equity

	Common Stock Shares	Amount	Additional Paid-in Capital	Advance to Stockholder	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2016	57,179,686	$ 5,718	$ 159,732,194	$ (25,160)	$ (153,078,441)	$ 6,634,311
Common stock issued for services	62,478	6	59,994	—	—	60,000
Common stock issued, net of offering costs of $1,721,173	18,699,645	1,870	6,998,512		—	7,000,382
Warrants issued in connection with the registered direct offering to the placement agent	—	—	369,465		—	369,465
Cumulative effect of ASU 2016-09, net	—	—	18,288		(18,288)	—
Options exercised, net	66,667	7	33,994	—	—	34,001
Warrants exercised, net	4,051,869	405	2,771,939	—	—	2,772,344
Warrant modification	—	—	74,527			74,527
Stock-based compensation, net	—	—	744,870	—	—	744,870
Write-off of advance to stockholder	—	—	—	25,160	—	25,160
Net loss	—	—	—	—	(51,891,945)	(51,891,945)
Balance at December 31, 2017	80,060,345	8,006	170,803,783	—	(204,988,674)	(34,176,885)
Common stock issued for services	17,241	2	59,998	—	—	60,000
Common stock issued in connection with the confidentially marketed public offering, net of	20,000,000	2,000	(2,000)			—

offering costs of $844,409						
Options exercised, net	348,783	35	636,375	—	—	636,410
Warrants exercised, net	10,515,147	1,051	4,285,568	—	—	4,286,619
Stock-based compensation, net	—	—	443,786	—	—	443,786
Net income	—	—	—	—	33,986,166	33,986,166
Balance at December 31, 2018	110,941,516	$ 11,094	$ 176,227,510	$ —	$ (171,002,508)	$ 5,236,096

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

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AMPIO PHARMACEUTICALS, INC.

Statements of Cash Flows

	Years Ended December 31,	
	2018	2017
Cash flows from operating activities		
Net income (loss)	$ 33,986,166	$ (51,891,945)
Adjustments to reconcile net income (loss) to net cash used in operating activities		
Stock-based compensation	443,786	744,870
Warrant modification expense	—	74,527
Depreciation and amortization	1,281,379	1,214,474
Loss from disposal of fixed assets	123,176	—
Write-off of advance to stockholder	—	25,160
Amortization of prepaid research and development - related party (Note 9)	—	323,555
Common stock issued for services	60,000	60,000
Derivative (gain) loss	(45,298,316)	36,218,832
Changes in operating assets and liabilities		
(Increase) decrease in prepaid expenses and other	(179,465)	129,716
(Decrease) increase in accounts payable and accrued expenses	(1,460,877)	2,076,235
Decrease in deferred rent	(60,611)	(50,939)
Decrease in accrued compensation	(1,033,261)	(332,432)
Net cash used in operating activities	(12,138,023)	(11,407,947)
Cash flows used in investing activities		
Purchase of fixed assets	(564,276)	(72,325)
Net cash used in investing activities	(564,276)	(72,325)
Cash flows from financing activities		
Proceeds from sale of common stock related to the confidentially marketed public offering	8,000,000	—
Costs related to sale of common stock related to the confidentially marketed public offering	(844,409)	—
Proceeds from sale of common stock related to the registered direct offering	—	13,339,873
Costs related to sale of common stock related to the registered direct offering	—	(1,351,708)
Proceeds from option and warrant exercise	4,923,029	2,806,344
Net cash provided by financing activities	12,078,620	14,794,509
Net change in cash and cash equivalents	(623,679)	3,314,237
Cash and cash equivalents at beginning of period	8,209,071	4,894,834
Cash and cash equivalents at end of period	$ 7,585,392	$ 8,209,071
Non-cash transactions:		
Warrant derivative liability in connection with the confidentially marketed public offering	$ 8,008,500	$ —

Warrant derivative liability in connection with the registered direct offering	—	4,618,318
Warrants issued to placement agent in connection with the registered direct offering	—	369,465
Placement agent warrant exercises, net	—	17

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

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AMPIO PHARMACEUTICALS, INC.

Notes to Financial Statements

Note 1 – Basis of Presentation

The accompanying financial statements have been prepared in conformity with U.S. Generally Accepted Accounting Principles ("GAAP"). Ampio Pharmaceuticals, Inc. ("Ampio" or "the Company") is a biopharmaceutical company focused primarily on developing Ampion, which is a compound that decrease inflammation by inhibiting specific pro-inflammatory compounds.

The Company's activities have been primarily related to research and development and raising capital. The Company has not generated revenue to date.

Note 2 – Summary of Significant Accounting Policies

Cash and Cash Equivalents

The Company considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. The Company's investment policy is to preserve principal and maintain liquidity. The Company periodically monitors its positions with, and the credit quality of, the financial institutions with which it invests. During the year ended as of December 31, 2018, Ampio has maintained balances in excess of federally insured limits.

Fixed Assets

Fixed assets are recorded at cost and once placed in service are depreciated using the straight-line method over their estimated useful lives. Leasehold improvements are amortized over the shorter of the estimated economic life or related lease terms. Fixed assets consist of the following:

	Estimated Useful Lives in Years	December 31, 2018	2017
Manufacturing facility/clean room	3 - 8	$ 3,076,000	$ 2,773,000
Leasehold improvements	10	6,075,000	6,075,000
Office furniture and equipment	5 - 10	511,000	557,000
Lab equipment	5 - 8	1,128,000	1,059,000
Less accumulated depreciation and amortization		(4,793,000)	(3,626,000)
Fixed assets, net		$ 5,997,000	$ 6,838,000

The Company recorded depreciation and amortization expense in the respective periods as follows:

	Years Ended December 31, 2018	2017
Depreciation and Amortization Expense	$ 1,281,000	$ 1,214,000

Accrued Compensation

Accrued compensation consisted of earned paid time off (PTO) and the employee bonus accrual. As of October 1, 2018, the Compensation Committee amended the PTO policy to eliminate the year end carryover. In addition, on October 1,

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2018, the Compensation Committee also approved a one-time option repricing where the exercise price of certain employee options was reduced to an exercise price of $0.75. The amended stock options provide an additional incentive to retain and motivate key contributors of the Company. In conjunction with the repricing, the Compensation Committee eliminated all outstanding accrued bonuses, which amounted to approximately $813,000. Therefore, the accrued compensation balance is $0 for the year ended December 31, 2018. See Note 8 for additional information on the option repricing.

Use of Estimates

The preparation of financial statements in accordance with GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant items subject to such estimates and assumptions include the fair value of the warrant derivative liability, stock-based compensation, the useful lives of fixed assets, impairment of fixed assets, valuation allowance and the going concern. Actual results could differ from these estimates.

Derivatives

In connection with the August 2018 confidentially marketed public offering, the Company issued to investors warrants to purchase an aggregate of 20.0 million shares of common stock at an exercise price of $0.40 with a term of five years. Due to certain derivative features, these investor warrants are accounted for under liability accounting and are recorded at fair value each reporting period. See Notes 4 and 8 for additional information on derivatives.

In connection with the June 2017 registered direct offering, the Company issued to investors warrants to purchase an aggregate of approximately 11.0 million shares of common stock at an exercise price of $0.76 with a term of five years. Due to certain derivative features, these investor warrants are accounted for under liability accounting and are recorded at fair value each reporting period. See Notes 4 and 8 for additional information on derivatives.

Income Taxes

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that includes the enactment date. The overall change in deferred tax assets and liabilities for the period measures the deferred tax expense or benefit for the period. The measurement of deferred tax assets may be reduced by a valuation allowance based on judgmental assessment of available evidence if deemed more likely than not that some or all of the deferred tax assets will not be realized. The Company has recorded a valuation allowance against all of its deferred tax assets, as management has concluded that it is more likely than not that the net deferred tax asset will not be realized through future taxable income, based primarily on the Company’s history of operating losses.

Net Income or Loss per Common Share

Basic net income or loss per share is computed by dividing the net income or loss available to common stockholders by the weighted-average number of shares outstanding during the period. Diluted income or loss per share is computed by dividing net income or loss by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of additional common shares that would have been outstanding if the potential common shares had been issued. The Company’s potential dilutive shares include stock options and warrants for shares of common stock. The Company recognized net income as of December 31, 2018, or the 2018

period, which is primarily attributable to the non-cash derivative gain. The non-cash derivative gain is considered an unusual item and as a result, diluted income or loss per share is computed in the same manner as the basic net income or loss per share. If the Company did not have the non-cash derivative gain, a net loss would have been recognized. Therefore, all potentially dilutive shares of common stock have been excluded from the computation of the dilutive net loss per share for the 2018 period, as they would have been anti-dilutive. The Company recognized a net loss as of December 31, 2017, therefore all

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potentially dilutive shares of common stock have been excluded from the computation of the dilutive net loss per share as they would have been anti-dilutive. The potential dilutive shares of common stock consist of the following:

	Years Ended December 31,	
	2018	2017
Potentially dilutive securities, excluded:		
Outstanding stock options	5,426,165	7,247,165
Warrants to purchase shares of common stock	22,283,191	13,332,243
	27,709,356	20,579,408

Stock-Based Compensation

The Company accounts for share based payments by recognizing compensation expense based upon the estimated fair value of the awards on the date of grant. The Company determines the estimated grant fair value using the Black-Scholes option pricing model and recognizes compensation costs ratably over the requisite service period which approximates the vesting period using the graded method.

Research and Development

Research and development costs are expensed as incurred in the respective periods.

Fair Value of Financial Instruments

The Company’s financial instruments include cash and cash equivalents, accounts payable and accrued expenses, and warrant derivative liability. The carrying amounts of cash and cash equivalents and accounts payable and accrued expenses are carried at cost which approximates fair value due to the short maturity of these instruments. Warrants are recorded at estimated fair value based on a Black-Scholes warrant pricing model. The valuation policies are determined by the Chief Financial Officer and approved by the Company’s Board of Directors. See Note 4 for additional information on the fair value of financial instruments.

Impairment of Long-Lived Assets

The Company performs an annual evaluation of the recoverability of the carrying value of its long-lived assets to determine if facts and circumstances indicate that the carrying value of assets may be impaired and if any adjustment is warranted. Based on the Company’s evaluation as of December 31, 2018 and 2017, no impairment existed for long-lived assets.

Adoption of Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-09, “Compensation -Stock Compensation (Topic 718): Improvements to Employee Share Based Payment Accounting”. The standard includes multiple provisions intended to simplify various aspects of the accounting for share based payments. The amendments are expected to significantly impact net income, earnings per share, and the

statement of cash flows. Implementation and administration may present challenges to companies with significant share based payment activities. These amendments were effective for public entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted in any interim or annual period, with any adjustments reflected as of the beginning of the fiscal year of adoption. The Company adopted ASU 2016-09 in the first quarter of 2017. The Company elected to recognize forfeitures as they occur rather than estimating the forfeiture rate on the option grant date. The cumulative-effect of the change was $18,000 which was charged to retained earnings during the first quarter of 2017.

In May 2017, the FASB issued ASU 2017-09, “Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting”. The amendments provide guidance on determining which changes to the terms and conditions of share-

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based payment awards require an entity to apply modification accounting under Topic 718. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award changes as a result of the change in terms or conditions. For all entities, this standard is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company adopted ASU 2017-09 during the first quarter of 2018 and the adoption of this guidance did not have a material impact on the Company's financial statements.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, "Leases (Topic 842)". The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. Lessees are required to use a modified retrospective transition approach for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. In July 2018, the FASB issued ASU 2018-10, "Codification Improvements to Topic 842, Leases," to clarify how to apply certain aspects of the new lease standard. In July 2018, the FASB also issued ASU 2018-11, "Leases (Topic 842): Targeted Improvements," to give entities another option for transition. The additional option for transition allows an entity to apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption or apply a practical expedient. The new standards are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years.

The Company expects that this standard will have a material effect on the financial statements. While the Company continues to assess all of the effects of the adoption, it currently believes that the most significant effects relate to (1) the recognition of a new ROU asset and lease liability on its balance sheet for the office operating lease; (2) the derecognition of the existing deferred rent balances; and (3) providing new disclosure regarding its leasing activities. The Company does not expect significant change in its leasing activities between now and adoption. On adoption, the Company currently expects to recognize an additional operating lease liability of approximately $1.7 million, which represents the present value of the remaining minimum lease payments. The Company will also derecognize the deferred rent balance, which includes deferred tenant improvements, of approximately $540,000 and recognized an ROU asset of $1.2 million.

In June 2018, the FASB issued ASU 2018-07, "Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting". The amendment expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. Companies should apply the requirements of Topic 718 to nonemployee awards except for certain exemptions specified in the amendment. The guidance is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within those fiscal years. Early adoption is permitted, but no earlier than the Company's adoption date of ASU 2014-09 "Revenue from Contracts with Customers (Topic 606)". The Company does not expect the adoption of this ASU will have a significant impact on its financial statements.

In July 2018, the FASB issued ASU 2018-09, “Codification Improvements”, which facilitates amendments to a variety of topics to clarify, correct errors in, or make minor improvements to the accounting standards codification. The effective date of the standard is dependent on the facts and circumstances of each amendment. Some amendments do not require transition guidance and will be effective upon the issuance of this standard. A majority of the amendments in ASU 2018-09 will be effective for fiscal years beginning after December 15, 2018. The Company does not expect the adoption of this ASU will have a significant impact on its financial statements.

In August 2018, the FASB issued ASU 2018-13, “Fair Value Measurement - Disclosure Framework (Topic 820)”. The updated guidance improves the disclosure requirements on fair value measurements. The updated guidance is effective for fiscal years beginning after December 15, 2019, including interim reporting periods within those fiscal years. Early adoption is permitted for any removed or modified disclosures. The Company does not expect the adoption of this ASU will have a significant impact on its financial statements.

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The Company does not discuss recent pronouncements that are not anticipated to have an impact on or are unrelated to its financial condition, results of operations, cash flows or disclosures.

Note 3 – Going Concern

As reflected in the accompanying financial statements, the Company had cash of $7.6 million with net income of $34.0 million for the year ended December 31, 2018. The net income is primarily attributable to the non-cash derivative gain of $45.3 million that was recognized, which was offset by the operating expenses of $11.2 million during the year ended December 31, 2018. The Company used net cash in operations of $12.1 million for the year ended December 31, 2018. The Company ended the year with an accumulated deficit of $171.0 million and stockholders' equity of $5.2 million. In addition, the Company is a clinical stage biopharmaceutical company and has not generated any revenues or profits to date. These factors raise substantial doubt about the Company's ability to continue as a going concern.

For the year ended December 31, 2018, the Company received a total of $4.9 million from investor warrants and stock options being exercised. See additional information in Note 8 regarding warrant and stock option exercises. In addition, the Company raised gross proceeds of $8.0 million in a confidentially marketed public offering. See additional information in Note 7 regarding the confidentially marketed public offering. The Company expects that current cash resources and operating cash flows will be sufficient to sustain operations into the second quarter of 2019. The ability of the Company to continue its operations is dependent on management's plans, which includes continuing to raise equity-based and debt financing, as well as encouraging additional warrant exercises. However, there is no assurance that the Company will be successful in raising sufficient capital.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. These financial statements do not include any adjustments relating to the recovery of the recorded assets or the classification of the liabilities that might be necessary should the Company be unable to continue as a going concern.

Note 4 – Fair Value Considerations

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

Level 1:Inputs that reflect unadjusted quoted prices in active markets that are accessible to the Company for identical assets or liabilities;

Level 2:Inputs include quoted prices for similar assets and liabilities in active or inactive markets or that are observable for the asset or liability either directly or indirectly; and

Level 3:Unobservable inputs that are supported by little or no market activity.

The Company’s assets and liabilities which are measured at fair value are classified in their entirety based on the lowest level of input that is significant to their fair value measurement. The Company’s policy is to recognize transfers in and/or out of fair value hierarchy as of the date in which the event or change in circumstances caused the transfer. The Company has consistently applied the valuation techniques discussed below in all periods presented.

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The following table presents Ampio's financial assets and liabilities that were accounted for at fair value on a recurring basis as of December 31, 2018 and 2017, by level within the fair value hierarchy:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
December 31, 2018				
LIABILITIES				
Warrant derivative liability	$ —	$ —	$ 6,933,000	$ 6,933,000
December 31, 2017				
LIABILITIES				
Warrant derivative liability	$ —	$ —	$ 45,076,000	$ 45,076,000

The warrant derivative liability was valued using the Black-Scholes valuation methodology because that model embodies all the relevant assumptions that address the features underlying these instruments. The significant assumptions in valuing the warrant derivative liability as of December 31, 2018, December 31, 2017 and at issuance are disclosed in Note 8.

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

	Derivative Instruments
Balance as of December 31, 2017	$ 45,076,000
Warrant issuances	8,008,000
Warrant exercises	(13,281,000)
Modified warrant exercises	(1,972,000)
Change in fair value	(30,898,000)
Balance as of December 31, 2018	$ 6,933,000

Note 5 – Income Taxes

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

	Years Ended December 31,	
	2018	2017
Expense (benefit) at federal statutory rate	21.0 %	(34.0) %

State, net of federal income tax impact	(0.8)	%	(0.9)	%
Change in federal tax rate	0.0	%	35.8	%
Stock-based compensation	2.3	%	0.0	%
Registered offering loss / warrant expense	(28.1)	%	23.7	%
Aytu change from subsidiary to investee	0.0	%	0.0	%
Change in valuation allowance	5.6	%	(24.6)	%
Effective tax rate	0.0	%	0.0	%

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

	Years Ended December 31,	
	2018	2017
Long-term deferred income tax assets (liabilities):		
Accrued liabilities	$ —	$ 247,000
Interest expense carryforward	1,000	—
Deferred rent	132,000	147,000
Net operating loss carryforward	35,868,000	32,766,000
Share-based compensation	2,255,000	3,192,000
Unrealized loss on trading security	774,000	771,000
Property and equipment	(210,000)	(236,000)
Warrants	67,000	82,000
Less: Valuation allowance	(38,887,000)	(36,969,000)
Total long-term deferred income tax assets (liabilities)	$ —	$ —

As of December 31, 2018, Ampio has approximately $145.4 million in net operating loss (“NOL”) carryforwards that, subject to limitation, may be available in future tax years to offset taxable income. The majority of these net operating loss carryforwards expire from 2019 through 2037. Approximately $12.6 million of the NOL carryforward carries forward indefinitely. Under the provisions of the Internal Revenue Code, substantial changes in the Company’s ownership may result in limitations on the amount of NOL carryforwards that can be utilized in future years.

Ampio has provided a full valuation allowance against its deferred tax assets as it has determined that it is not more likely than not that recognition of such deferred tax assets will be utilized in the foreseeable future. The amount of income taxes and related income tax positions taken are subject to audits by federal and state tax authorities. Ampio has adopted accounting guidance for uncertain tax positions which provides that in order to recognize an uncertain tax benefit, the taxpayer must be more likely than not of sustaining the position, and the measurement of the benefit is calculated as the largest amount that is more than 50% likely to be realized upon recognition of the benefit. Ampio believes that it has no material uncertain tax positions and has fully reserved against Ampio’s future tax benefit with a valuation allowance and does not expect significant changes in the amount of unrecognized tax benefits to occur within the next twelve months. Ampio’s policy is to record a liability for the difference between benefits that are both recognized and measured pursuant to GAAP and tax positions taken or expected to be taken on the tax return. Then, to the extent that the assessment of such tax positions changes, the change in estimate is recorded in the period in which the determination is made. Ampio reports tax-related interest and penalties as a component of income tax expense. During the periods reported, management of Ampio has concluded that no significant tax position requires recognition. Ampio files income tax returns in the United States federal and various state jurisdictions. The Company is no longer subject to income tax examinations for federal income taxes before 2015 or for Colorado before 2014. Net operating loss carryforwards are subject to examination in the year they are utilized regardless of whether the tax year in which they are generated has been closed by statute. The amount subject to disallowance is limited to the NOL utilized. Accordingly, the Company may be subject to examination for prior NOL’s generated as such NOL’s are utilized.

In December 2017, the Tax Cuts and Jobs Act (the "2017 Tax Act") was enacted. The 2017 Tax Act significantly revised the U.S. corporate income tax regime by, among other things, lowering the U.S. corporate tax rate from 35% to 21% effective January 1, 2018. In accordance with Staff Accounting Bulletin No. 118, which provides SEC staff

guidance for the application of ASC Topic 740, the Company recognized the income tax effects of the 2017 Tax Act in its financial statements in the year the 2017 Tax Act was signed into law. As such, the Company's 2017 financial statements reflect the income tax effects of the 2017 Tax Act for which the accounting is complete and provisional amounts for those specific income tax effects for which the accounting is incomplete but a reasonable estimate could be determined. The Company did not identify items for which the income tax effects of the 2017 Tax Act have not been completed and a reasonable estimate could not be determined as of December 31, 2017.

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As a result of the 2017 Tax Act, the Company recorded a provisional tax expense of $18.6 million for the year ended December 31, 2017 related to the remeasurement of deferred tax assets and liabilities to reflect the reduction in the U.S. corporate income tax rate from 35% to 21%. The Company recognized a corresponding $18.6 million decrease in net deferred tax assets as of December 31, 2017. The $18.6 million tax expense recognized was fully offset by a reduction in valuation allowance, resulting in zero net tax expense for the year ended December 31, 2017 related to the reduction in tax rates and zero net decrease in the net deferred tax assets as of December 31, 2017.

Note 6 – Commitments and Contingencies

The following table summarizes the commitments and contingencies as of December 31, 2018 which are described below:

	Total	2019	2020	2021	2022	2023	Thereafter
Clinical research and trial obligations	50,000	50,000	—	—	—	—	—
Biologics License Application (BLA) consulting services	1,161,000	1,161,000	—	—	—	—	—
Facility lease	2,005,000	326,000	335,000	345,000	355,000	364,000	280,000
	$ 3,216,000	$ 1,537,000	$ 335,000	$ 345,000	$ 355,000	$ 364,000	$ 280,000

Clinical Research and Trial Obligations

In November 2017, Ampio entered into an Open Label Extension (OLE) study agreement. In August 2018, the Company terminated the OLE study. The Company will continue to incur close-out costs for the study through the beginning of fiscal 2019. As of December 31, 2018, there is an outstanding commitment of $50,000.

Biologics License Application (BLA) Consulting Services

In March 2018, Ampio entered into a BLA consulting services agreement, which has an outstanding commitment of $1.2 million. This contract is an open-ended contract and the Company incurs costs as sections of the BLA are completed. The Company has incurred $51,000 against the contract as of December 31, 2018.

Facility Lease

In December 2013, Ampio began a 125 month non-cancellable operating lease for office space and the manufacturing facility effective May 1, 2014. The lease had initial base rent of $23,000 per month, with the total base rent over the term of the lease of approximately $3.3 million, which includes rent abatements and leasehold incentives. The Company recognizes rent expense on a straight-line basis over the term of the lease. The Company recognizes deferred rent when the straight-line rent expense exceeds the actual lease payments and reduces deferred rent when the actual lease payments exceed the straight-line rent expense. Deferred rent is classified between current and long-term on the balance sheet.

The Company recorded rent expense in the respective periods is as follows:

	Years Ended December 31,	
	2018	2017
Rent expense	$ 260,000	$ 260,000

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Note 7 – Common Stock

Capital Stock

At December 31, 2018 and 2017, Ampio had 200.0 million shares of common stock authorized with a par value of $0.0001 per share, and 10.0 million shares of preferred stock authorized with a par value of $0.0001 per share.

At December 31, 2018 and 2017, Ampio had 110,941,516 and 80,060,345 common shares outstanding, respectively. As of these same dates, Ampio had no preferred shares outstanding.

Shelf Registration

In March 2017, Ampio filed a shelf registration statement on Form S 3 with the Securities and Exchange Commission ("SEC") to register Ampio common stock and warrants in an aggregate amount of up to $100.0 million for offerings from time to time, as well as 5.0 million shares of common stock available for sale by selling shareholders. The shelf registration was declared effective in April 2017 by the SEC. As a result of equity raises, approximately $78.7 million remained available under the Form S 3 as of December 31, 2018. This shelf registration statement on Form S 3 expires in March of 2020.

Confidentially Marketed Public Offering

In August 2018, the Company completed a confidentially marketed public offering. In this offering, the Company issued 20.0 million shares of its common stock and warrants to purchase up to 20.0 million shares of common stock. The common stock and warrants were sold in units, with each unit consisting of one share of common stock and a warrant to purchase one share of common stock. Each unit was sold to the investors in this offering at a negotiated price of $0.40 per unit generating gross proceeds of $8.0 million. In connection with the offering, the underwriter received a 7% commission totaling $560,000. The Company also incurred expenses related to legal, accounting, and other registration costs of $284,000. The shares and the warrants were offered and sold pursuant to the Company's shelf registration statement on Form S-3, which was declared effective by the SEC in April 2017.

The warrants have an exercise price of $0.40 per share and are exercisable immediately with a term of five years from issuance. The warrants include a provision where the warrant holder has the contractual right to request a cash exercise if the effectiveness of the registration statement is not maintained, but securities law would prevent the Company from issuing registered shares in a cash exercise. Therefore, the Company could be forced to cash settle the warrants. Based on this derivative feature, these warrants must be accounted for as a liability at fair value under Accounting Standards Codification ("ASC") 815 "Derivatives and Hedging". On the date of issuance, these warrants were valued at $8.0 million.

The Company's net cash proceeds from the confidentially marketed public offering totaled $7.2 million. When the additional non-cash charges of $8.0 million related to the 20.0 million warrants are offset against the net cash transaction proceeds, the non-cash charges exceeded 100% of the proceeds. Therefore, the Company is required to take the additional cost above the transaction proceeds and recognize a loss on the day it entered into the transaction. The loss on the transaction was $853,000 and this amount is included in the derivative gain on the statement of

operations.

Registered Direct Offerings

In October 2017, the Company entered into a Securities Purchase Agreement, with certain investors, pursuant to which the Company sold approximately 7.7 million shares of common stock at a price per share of $0.875. The gross proceeds from the offering were approximately $6.7 million. The costs associated with the offering were approximately $490,000. The shares were offered and sold pursuant to the Company's shelf registration statement on Form S-3, which was declared effective by the SEC in April 2017.

In June 2017, the Company completed a registered direct offering. In this offering, Ampio issued directly to multiple investors approximately 11.0 million shares of its common stock and approximately 11.0 million warrants to purchase

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shares of common stock. The common stock and warrants were sold in units, with each unit consisting of one share of common stock and a warrant to purchase one share of common stock. Each unit was sold to the investors in this offering at a negotiated price of $0.60 per unit generating gross proceeds of $6.6 million. In connection with the offering, the placement agent received an 8% commission totaling $533,000 and approximately 879,000 warrants with an exercise price of $0.76. The expiration date of these warrants is June 1, 2022. At issuance, these warrants had a value of $369,000 and were accounted for as equity-based warrants. The placement agent warrants provide for cashless exercise, which the placement agents may elect if there is no effective registration statement. The Company also incurred expenses related to legal, accounting, and other registration costs of $292,000.

The investor warrants have an exercise price of $0.76 per share and were exercisable starting on December 7, 2017 with a term of five years from issuance. The investor warrants include a provision where the warrant holder has the contractual right to request a cash exercise if the effectiveness of the registration statement is not maintained, but securities law would prevent the Company from issuing registered shares in a cash exercise. Therefore, the Company could be forced to cash settle the warrant. Based on this derivative feature, these warrants must be accounted for as a liability at fair value under ASC 815 “Derivatives and Hedging”. On the date of issuance, these warrants were valued at $4.6 million. The shares and the warrants were offered and sold pursuant to the Company’s shelf registration statement on Form S-3, which was declared effective by the SEC in April 2017.

The June 2017 registered direct offering included participation rights of 35% for any proposed or intended issuance or sale or exchange of securities being offered until the second anniversary of the closing date, which would have expired on June 2, 2019. However, in July 2018, the Company obtained the required number of waivers necessary to eliminate these participation rights.

In September 2016, the Company completed a registered direct offering. In this offering, the Company issued directly to an institutional investor 5.0 million shares of its common stock and warrants to purchase up to 5.0 million shares of common stock. The common stock and warrants were sold in units, with each unit consisting of one share of common stock and a warrant to purchase one share of common stock. Each unit was sold to the investor in this offering at a negotiated price of $0.75 per unit generating gross proceeds of $3.75 million. In connection with the offering, the placement agent received a 6% commission totaling $225,000 and 150,000 warrants with an exercise price of $0.9375. The expiration date of these warrants is September 1, 2021. At issuance, these warrants had a value of $89,000 and were accounted for as equity-based warrants. The placement agent warrants provide for cashless exercise, which the placement agents may elect if there is no effective registration statement. The Company also incurred expenses related to legal, accounting, and other registration costs of $113,000.

The investor warrants had an exercise price of $1.00 per share and were immediately exercisable with a term of five years from issuance. In addition, the investor warrants included a provision for an adjustment to the exercise price upon subsequent issuances of common stock by the Company at a price less than the warrant exercise price and the investor was entitled to purchase additional shares, such that the aggregate purchase price of $5.0 million for the warrant shares remained unchanged. The investor warrants also included a provision for redemption at the Black-Scholes value at the request of the holder upon a change of control. Based on these derivative features, these warrants were accounted for as a liability at fair value under ASC 480 “Distinguishing Liabilities from Equity”. On the

date of issuance, these warrants were valued at $4.1 million. The shares and the warrants were offered and sold pursuant to the Company's shelf registration statement on Form S-3 which was declared effective by the SEC in January 2014. The Form S-3 expired in January of 2017 and the Company filed a new Form S-3 in April 2017.

There was a participation right of 30% for any proposed or intended issuance or sale or exchange of securities being offered until the first anniversary of the closing date, which expired on September 1, 2017.

The Company's net cash proceeds from the registered direct offering were $3.4 million. When the additional non-cash charges of $4.2 million related to the 5.0 million investor warrants and the 150,000 placement agent warrants were offset against the net cash transaction proceeds, this exceeded 100% of the proceeds so the Company was required to take the additional cost above the transaction proceeds and recognize a loss on the day of the transaction. The loss on the transaction was $804,000 and was included in derivative loss on the statement of operations.

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On March 27, 2017, the Company entered into a Waiver and Consent Letter Agreement with the investor from the September 2016 registered direct offering, amending the terms of the warrants previously issued. Under the Waiver and Consent Agreement, the investor waived the right to have the warrant exercise price reduced and the number of shares of common stock underlying the warrant increased in the event the Company secures any financing, including debt, which includes issuing or selling shares of common stock for a price per share less than the warrant exercise price. The investor also waived the prohibition on the Company's ability to issue or sell shares of its common stock, options or convertible securities at a price which varies or may vary with the market price of the common stock or pursuant to an equity credit line or similar "at-the-market" offering. The waivers are permanent. In return, the Company agreed to reduce the exercise price of the warrants from $1.00 to $0.40 and to not issue or sell any shares of its capital stock for a period of 10 trading days following the execution of the Waiver and Consent Agreement. All other terms of the warrants remained the same. Based upon the amendment to this warrant agreement, the Company recognized a non-cash derivative gain of $1.1 million during the quarter ended March 31, 2017.

Controlled Equity Offering

In February 2016, Ampio entered into a Controlled Equity Offering SM Sales Agreement (the "Agreement") with a placement agent to implement an "at-the-market" equity program under which Ampio, from time to time may offer and sell shares of its common stock having an aggregate offering price of up to $25.0 million through the placement agent. The Company has no obligation to sell any of the shares and may at any time suspend sales under the Agreement or terminate the Agreement in accordance with its terms. The Company has provided the placement agent with customary indemnification rights. The placement agent will be entitled to a fixed commission of 3.0% of the gross proceeds from shares sold.

No shares were sold under the Agreement during fiscal 2018 or fiscal 2017.

Common Stock Issued for Services

The Company issued 17,241 and 62,478 shares of common stock valued at $60,000 for non-employee directors as part of their director fees for fiscal years 2018 and 2017, respectively.

Note 8 – Equity Instruments

Options

In 2010, the Company's shareholders approved the adoption of a stock and option award plan (the "2010 Plan"), under which shares were reserved for future issuance under restricted stock awards, options, and other equity awards. The 2010 Plan permits grants of equity awards to employees, directors and consultants. The shareholders have approved a total of 11.7 million shares reserved for issuance under the 2010 Plan.

During 2018, the Company granted 285,333 options at a weighted average exercise price of $0.48 to officers, employees and directors. Of the options granted, 195,333 options vested immediately while 90,000 options vest monthly over the succeeding twelve months. Former employees exercised a total of 409,666 options with a weighted average exercise price of $2.06. The Company received $636,400 as of December 31, 2018 related to these option

exercises. A total of 3,334 options were forfeited and 1,693,333 options expired as of December 31, 2018.

During 2017, the Company granted 1,581,334 options at a weighted average exercise price of $0.66 to officers, employees and directors. Of the options granted, 638,000 options vested immediately while 943,334 options vest over a one to three-year period. A total of 66,667 options were exercised at a weighted average exercise price of $0.51 by employees. The Company received $34,000 as of December 31, 2017 related to these option exercises. During 2017, the Company had 1,443,334 options that were forfeited.

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The following table summarizes the Company's stock option activity:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding December 31, 2016	7,175,832	$ 3.64	4.99	$ —
Granted	1,581,334	$ 0.66		
Exercised	(66,667)	$ 0.51		
Forfeited	(1,443,334)	$ 4.01		
Expired or Cancelled	—	—		
Outstanding at December 31, 2017	7,247,165	$ 2.87	5.16	$ 12,739,512
Granted	285,333	$ 0.48		
Exercised	(409,666)	$ 2.06		
Forfeited	(3,334)	$ 1.02		
Expired or Cancelled	(1,693,333)	$ 3.92		
Outstanding at December 31, 2018	5,426,165	$ 1.99	4.89	$ —
Exercisable at December 31, 2018	4,984,497	$ 2.11	4.57	$ —
Available for grant at December 31, 2018	4,366,145			

Stock options outstanding at December 31, 2018 are summarized in the table below:

Range of Exercise Prices	Number of Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Lives
$0.48 - $2.00	3,293,423	$ 0.82	5.86
$2.01 - $5.00	1,750,000	$ 3.07	3.24
$5.01 - $8.93	382,742	$ 7.13	4.22
	5,426,165	$ 1.99	4.89

The Company computes the fair value for all options granted or modified using the Black-Scholes option pricing model. To calculate the fair value of the options, certain assumptions are made regarding components of the model, including the estimated fair value of the underlying common stock, risk-free interest rate, volatility, expected dividend yield and expected option life. Changes to the assumptions could cause significant adjustments to the valuation. The Company calculates its volatility assumption using the actual changes in the market value of its stock. The Company adopted ASU 2016-09 in fiscal 2017 and no longer estimates a forfeiture rate. Instead, forfeitures are recognized as they occur. The Company's historical option exercises do not provide a reasonable basis to estimate an expected term due to the lack of sufficient data. Therefore, the Company estimates the expected term by using the simplified method. The simplified method calculates the expected term as the average time to vest and the contractual life of the options. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for treasury securities of similar maturity. The Company has computed the fair value for the options granted and modified, which totaled $347,000 for the period ended December 31, 2018, using the following assumptions:

Years Ended December 31,

	2018		2017	
Expected volatility	101% - 201	%	34% - 113	%
Risk free interest rate	1.86% - 2.96	%	1.16% - 2.13	%
Expected term (years)	0.3 - 5.5		0.5 - 6.5	
Dividend yield	0.0	%	0.00	%

On October 1, 2018, the Compensation Committee approved a one-time option repricing where the exercise of each relevant option (as defined below) was amended to reduce such exercise price to $0.75 per share. “Relevant Options” are certain outstanding stock options as of October 1, 2018 (vested or unvested) to acquire shares of the Company’s Common Stock that have exercise prices above $0.75 per share; provided, however, that the maximum dollar value of the repricing for any individual will not exceed $500,000 (with such value calculated by multiplying (i) the difference

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between the initial exercise price and $0.75 by (ii) the number of options being repriced). The Company has computed the fair value for the one-time option repricing, which totaled $97,000 for the period ended December 31, 2018, using the following assumptions:

Assumptions for one-time option repricing	At Date of Repricing
Expected volatility	215.48 %
Risk free interest rate	2.60 %
Expected term (years)	1.0
Dividend yield	0.0 %

Stock-based compensation expense related to the fair value of stock options was included in the statements of operations as research and development expenses and general and administrative expenses as set forth in the table below. The Company determined the fair value as of the date of grant using the Black-Scholes option pricing model and expenses the fair value ratably over the vesting period. The following table summarizes stock-based compensation for the years ended 2018 and 2017:

	Years Ended December 31, 2018	2017
Research and development expenses		
Stock-based compensation	$ 191,000	$ 298,000
General and administrative expenses		
Common stock issued for services	60,000	60,000
Stock-based compensation	253,000	447,000
	$ 504,000	$ 805,000
Unrecognized expense at December 31, 2018	$ 68,341	
Weighted average remaining years to vest	1.00	

Warrants

In connection with the August 2018 confidentially marketed public offering, the Company issued warrants to purchase an aggregate of 20.0 million shares of common stock at an exercise price of $0.40 with a term of five years. Due to certain derivative features, these warrants are accounted for under liability accounting and are recorded at fair value each reporting period. As of December 31, 2018, these warrants had a fair value of $5.2 million. Significant assumptions as of December 31, 2018 and at issuance were as follows:

Assumptions for warrants issued August 13, 2018:	December 31, 2018		At Issuance	
Exercise Price	$ 0.40		$ 0.40	
Volatility	129.8	%	121.8	%
Equivalent term (years)	4.62		5.00	
Risk-free interest rate	2.50	%	2.75	%
Number of shares	15,600,000		20,000,000	

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In connection with the June 2017 registered direct offering, the Company issued investor warrants to purchase an aggregate of approximately 11.0 million shares of common stock at an exercise price of $0.76 with a term of five years. Due to certain derivative features, these warrants are accounted for under liability accounting and are recorded at fair value each reporting period. As of December 31, 2018, these warrants had a fair value of $1.7 million. Significant assumptions as of December 31, 2018, December 31, 2017 and at issuance were as follows:

Assumptions for warrants issued June 2, 2017:	December 31, 2018	December 31, 2017	At Issuance
Exercise Price	$ 0.76	$ 0.76	$ 0.76
Volatility	134.1 %	102.4 %	94.6 %
Equivalent term (years)	3.42	4.40	5.00
Risk-free interest rate	2.47 %	2.14 %	1.71 %
Number of shares	6,093,582	7,605,851	10,990,245

In connection with the 2016 registered direct offering, the Company issued to an investor warrants to purchase an aggregate of 5.0 million shares of common stock at an exercise price of $1.00 with a term of five years. In March 2017, the exercise price of these warrants was reduced from $1.00 to $0.40. Due to certain derivative features, these warrants were accounted for under liability accounting and were recorded at fair value each reporting period. As of December 31, 2018, no fair value was recorded as these warrants were exercised in full during the first quarter of 2018.

The combined value for the warrant liability at December 31, 2018 is $6,933,000. See Note 4 for additional information regarding the warrant derivative liability.

During the 2017 registered direct offering, the Company issued to the placement agent warrants to purchase an aggregate of 879,000 shares of common stock at an exercise price of $0.76 with a term of five years. These warrants were accounted for as equity-based awards. See Note 7 for additional information. These placement agent warrants were valued using the Black-Scholes methodology. The significant assumptions at issuance were as follows:

Expected volatility	94.6 %
Risk free interest rate	1.71 %
Expected term (years)	5.0
Dividend yield	0.0 %

The following table summarizes the Company’s warrant activity:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding at December 31, 2016	5,648,576	$ 1.20	4.28
	11,869,464	$ 0.76	4.42

Warrants issued in connection with the registered direct offering				
Warrants exercised	(4,185,797)	$	0.72	
Outstanding at December 31, 2017	13,332,243	$	0.73	4.01
Warrants issued in connection with the confidentially marketed public offering	20,000,000	$	0.40	4.62
Warrants exercised	(10,550,476)	$	0.42	
Warrants expired	(498,576)	$	3.24	
Outstanding at December 31, 2018	22,283,191	$	0.51	4.25

During December 2018, the Company entered into a Warrant Exercise Agreement (the “Exercise Agreement”) with certain holders of the warrants (the “Exercising Holders”) from the August 2018 confidentially marketed public offering, which the Exercising Holders owned warrants exercisable for 5,950,000 shares of common stock. Pursuant to the Exercise Agreement, the Exercising Holders and the Company agreed that the Exercising Holders would exercise their warrants with respect to 4,225,000 shares of common stock underlying such warrants for a reduced exercise price equal

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to $0.30 per share. The Company received proceeds totaling approximately $1.3 million as of December 31, 2018 from the exercise of the warrants by these Exercising Holders.

In addition to the warrants exercised above, the Company had several other warrant exercises. The Company issued 175,000 shares of common stock from the exercise of investor warrants with an exercise price of $0.40 from the 2018 confidentially marketed public offering. The Company also issued 1,511,999 shares of common stock from the exercise of investor warrants with an exercise price of $0.76 from the 2017 registered direct offering. In addition, the Company issued 4,500,000 shares of common stock from the exercise of investor warrants at an exercise price of $0.40 from the 2016 registered direct offering. After this warrant exercise, the Company no longer has outstanding $0.40 warrants from the 2016 registered direct offering. The Company received proceeds totaling approximately $3.0 million as of December 31, 2018 related to these investor warrant exercises.

The combined proceeds for the investor warrant exercises at December 31, 2018 is approximately $4.3 million.

In July 2018, 138,477 of the placement agent warrants from the 2017 direct offering were cashlessly exercised, which resulted in the issuance of 103,148 shares of common stock.

In March 2017, the Company modified 498,576 of its outstanding warrants which extended the expiration until June 30, 2018. The $75,000 additional expense related to this modification was recognized in the quarter ended March 31, 2017. These warrants all expired as of June 30, 2018.

In March 2017, the Company modified the 5.0 million warrants issued in conjunction with the Company's September 2016 registered direct offering with an original strike price of $1.00 down to $0.40. The $1.1 million gain related to this modification was recognized in the quarter ended March 31, 2017. See Note 7 for additional information. As noted above, these warrants were exercised in full during the first quarter of 2018.

Note 9 – Related Party Transactions

Sponsored Research Agreement

The Company entered into a sponsored research agreement with Trauma Research LLC, an entity controlled by one of the Company's Directors and former Chief Scientific Officer ("CSO"), Dr. Bar-Or, in September 2009, which was amended seven times with the last amendment occurring in June 2017. Under the amended terms, the agreement was terminated effective July 5, 2017. The remaining prepaid of $252,000 was expensed during the quarter ended June 30, 2017. In conjunction with terminating this agreement, the Company extended the contract for Dr. Bar-Or until July 2018. In July 2018, the Company extended Dr. Bar-Or's employment agreement for an additional month. On August 29, 2018, Dr. Bar-Or notified the Company of his decision to retire from his role as CSO, effective September 30, 2018. Dr. Bar-Or will continue to serve as a member of the Board of Directors and the Scientific Advisory Board of the Company.

Note 10 – Litigation

On August 25, 2018 and August 31, 2018, two purported stockholders of the Company brought putative class action lawsuits in the United States District Court for the Central District of California, Shi v. Ampio Pharmaceuticals, Inc., et al., Case No. 2:18-cv-07476-SJO-RAO, and in the United States District Court for the District of Colorado, Shaffer v. Ampio Pharmaceuticals, Inc., et al., Case No. 1:18-cv-02252-KLM, together, the "Securities Class Actions". Plaintiffs in the Securities Class Actions allege that the Company and certain of its current officers violated federal securities laws by misrepresenting and/or omitting information regarding the AP-003 Phase III clinical trials of Ampion. Plaintiffs assert claims under Sections 10(b) and 20(a) and Rule 10b-5 under the Securities Exchange Act of 1934, on behalf of a putative class of purchasers of the Company's common stock from December 14, 2017 through August 7, 2018. The Securities Class Actions seek unspecified damages, interest, and attorneys' fees and costs. On October 24, 2018, certain purported stockholders filed motions to be appointed as lead plaintiff in the Shi case. On November 6, 2018, the Shaffer case was voluntarily dismissed.

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On September 10, 2018, a purported stockholder of the Company brought a derivative action in the United States District Court for the Central District of California, Cetrone v. Macaluso, et al., Case No. 2:18-cv-05970-SJO-RAO, alleging primarily that the directors and officers of Ampio breached their fiduciary duties because of their alleged misstatements and/or omissions regarding the AP-003 Phase III clinical trials of Ampion. On November 16, 2018, the case was stayed pending proceedings in the Shi case.

On October 5, 2018, a purported stockholder of the Company brought a derivative action in the United States District Court for the District of Colorado, Theise v. Macaluso, et al., Case No. 1:18-cv-02558-RBJ, which closely parallels the allegations in the Cetrone case. On November 14, 2018, a purported stockholder of the Company brought a second derivative action in the United States District Court for the District of Colorado, Lewis v. Macaluso, et al., Case No. 1:18-cv-02932-SKC, which also closely parallels the allegations in the Cetrone case. On December 19, 2018, the court consolidated the Theise and Lewis derivative actions, and the consolidated action is captioned In re Ampio Pharmaceuticals, Inc. Stockholder Derivative Litigation, Case No. 1:18-cv-02558-RBJ. On January 3, 2019, this consolidated derivative action was stayed pending proceedings in the Shi case.

The Company believes these claims are without merit and intends to defend these lawsuits vigorously. The Company currently believes the likelihood of a loss contingency related to these matters is remote and, therefore, no provision for a loss contingency is required.

Note 11 – Employee Benefit Plan

Ampio has a 401(k) plan that allows participants to contribute a portion of their salary, subject to eligibility requirements and annual IRS limits. The Company does not match employee contributions.

Note 12 – Subsequent Events

In the first quarter of 2019, the Company issued 50,000 shares of common stock from the exercise of investor warrants with an exercise price of $0.40. The Company received $20,000 during the first quarter of 2019 related to investor warrant exercises.

On January 2, 2019, the Company awarded 45,454 shares of common stock to each independent director at a price of $0.44 per share equivalent to $20,000, which was the closing price of our common stock on the date of grant.