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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, 2019

☐ **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 **(State or other jurisdiction of incorporation or organization)**	**26-0179592** **(I.R.S. Employer Identification Number)**
373 Inverness Parkway **Suite 200** **Englewood, Colorado** **(Address of principal executive offices)**	**80112** **(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	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $.0001 per share	**AMPE**	**NYSE American**

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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 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 28, 2019, the last business day of the registrant's most recently completed second fiscal quarter, was $54.2 million based on the closing price of $0.39 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 February 14, 2020, 158,780,993 shares of common stock were outstanding.

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This Annual Report on Form 10-K ("Annual Report") 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 such 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" relate to Ampio Pharmaceuticals, Inc.

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 the Private Securities Litigation Reform Act of 1995. 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 intended as 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 negatives of such 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 data and other industry data, and forecasts used in this Form 10-K from market research, publicly available information and industry publications. Industry publications generally state that they obtain their information from sources that they believe to be reliable, but they do not guarantee the accuracy and completeness of the information. Similarly, while we believe that the statistical data, market data and other industry data and forecasts used herein are reliable, we have not independently verified the data, and we do not make any representation as to the accuracy of the information.

AMPIO PHARMACEUTICALS, INC.

PART I

Item 1. ***Business***

Overview

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

Ampion has advanced through late-stage clinical trials in the United States. The U.S. Food and Drug Administration ("FDA") provided guidance that we should complete a trial of severe osteoarthritis of the knee ("OAK") patients with concurrent controls that would be carried out under an Special Protocol Assessment ("SPA").

In June 2019, we received an SPA agreement from the FDA for our Phase III clinical trial titled, "A Randomized, Controlled, Double-Blind Study to Evaluate the Efficacy and Safety of an Intra-Articular Injection of Ampion in Adults with Pain Due to Severe Osteoarthritis of the Knee" (the "AP-013 study"). An SPA is a process in which sponsors may ask to meet with the FDA to reach agreement with the FDA on the design and size of certain clinical trials to determine if they adequately address scientific and regulatory requirements for a study that could support regulatory submission. An SPA agreement indicates concurrence by the FDA with the adequacy and acceptability of specific critical elements of overall protocol design (e.g. entry criteria, dose selection, endpoints and planned analyses) for a study intended to support a future marketing application. These elements are critical to ensuring that the trial conducted under the protocol can be considered an adequate and well-controlled study that can support marketing approval. Feedback on these issues provides the greatest benefit to sponsors in planning late-phase development strategy. The existence of our SPA agreement does not guarantee that the FDA will accept our biologics license application ("BLA") for Ampion when submitted, or that the results of the trials we have conducted on Ampion will be adequate to support approval. Those issues are addressed during the review of a submitted application and are determined based on the adequacy of the overall submission.

Corporate History

Our predecessor, DMI Life Sciences, Inc. ("Life Sciences"), was incorporated in Delaware in December 2008. In March 2010, Life Sciences was merged with a subsidiary of Chay Enterprises, Inc. As a result of this merger, Life Sciences stockholders became the controlling stockholders of Chay Enterprises, Inc. Following the merger, we reincorporated in Delaware as Ampio Pharmaceuticals, Inc. in March 2010.

AMPION

Ampion for Osteoarthritis and Other Inflammatory Conditions

We have developed a novel biologic drug, Ampion, containing blood-derived cyclized peptide and small molecules that target multiple pathways in the innate immune response and other pathways that are characteristic of OAK disease. Ampion targets the cellular pathways in the innate immune response correlated with pain, inflammation, and joint damage in osteoarthritis. *In vitro* studies have shown that Ampion represses the transcription of proteins responsible for inflammation, while activating anti-inflammatory proteins. Ampion has also been shown *in vitro* to regulate the cellular pathways responsible for tissue growth and healing. We believe that this mechanism of action interrupts the disease process responsible for the pain and disability associated with OAK and provides market expansion potential as a disease modifying biologic and may provide a treatment option for other inflammatory and degenerative indications.

We are currently developing Ampion as an intra-articular injection to treat the signs and symptoms of severe 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 and incurable disease 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 intra-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 OAK was valued at approximately $3.6 billion in 2018 and is expected to grow with a compound annual growth rate of 9.11% through 2026. The global demand for OAK treatment is expected to be fueled by aging demographics and increased awareness of treatment options. Despite the size and growth of the OAK market, only a few treatment options currently exist, with none labeled specifically for 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.

Study AP-003-A was a 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 with Ampion treatment. Patients who received Ampion also showed a significant improvement in function and quality of life compared to patients who received the saline control at 12 weeks. Quality of life was assessed using Patient Global Assessment ("PGA"). Furthermore, the trial included severely diseased patients, defined radiographically as Kellgren Lawrence Grade 4 ("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.

In 2018, the FDA reiterated and confirmed that our successful pivotal Phase III clinical trial, AP-003-A, was adequate and well-controlled, provided evidence of the effectiveness of Ampion and can contribute to the substantial evidence of effectiveness necessary for the approval of a BLA. The FDA provided guidance that we should complete an additional trial of KL 4 severe OAK patients with concurrent controls that would be carried out under an SPA to obtain FDA concurrence on the trial design.

As noted above, we received an SPA agreement in June 2019 from the FDA for a clinical protocol for the AP-013 study. The SPA agreement for the AP-013 study finalized patient enrollment at 1,034 patients, with a sample size assessment at an interim analysis of 724 patients to allow an adjustment up to 1,551 patients if deemed necessary. In the SPA agreement, the FDA agreed that the design and planned analysis of the AP-013 study adequately addressed the objectives necessary to support a regulatory submission. According to the FDA's guidance for industry regarding SPAs (published in April 2018), an SPA documents the FDA's agreement that the design and planned analysis of a study can address objectives in support of a regulatory submission; however, final determinations for marketing application approval are made after a complete review of the marketing application and are based on the entire data in the application. Following the receipt of the SPA agreement, we initiated the AP-013 study, identified and engaged clinical sites for the trial, and initiated dosing of patients at those sites. As of December 31, 2019, we completed the enrollment and dosing of 724 patients required for the interim analysis sample size assessment, which we expect to occur in late March 2020. As of February 14, 2020, we had dosed 875 patients.

Ampion Manufacturing Facility

In May 2014, we commenced a 125-month lease of a multi-purpose facility containing approximately 19,000 square feet. This facility includes quality control and research laboratories, our corporate offices and approximately 3,000 square feet of modular clean rooms to manufacture Ampion.

Since the manufacturing site has been operational, we have implemented a quality system for both U.S. and European Union ("EU") regulatory compliance, validated the facility for human-use products, produced Ampion and placebo for

use in the inception-to-date clinical trials, and produced approximately 200,000 vials of Ampion without a sterility failure.

The manufacturing facility utilizes automated equipment with single use line sets and modular clean rooms designed to maximize flexibility and scalability while meeting international quality standards to fulfill potential future global demand. We believe that the Ampion manufacturing process delivers a competitive cost of goods that is significantly lower than the industry benchmark. Additionally, we estimate that the maximum capacity for this turnkey facility is approximately 8.0 million vials per year. During fiscal 2019, we engaged an independent third-party to conduct a quality audit of the Ampion manufacturing facility, which confirmed that our facility is expected to meet the requirements of an FDA inspection for the CMC section of a BLA filing.

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 all available resources on the development for Ampion. We have not changed that decision.

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.

Market acceptance of Ampion will depend on a number of factors, including: (i) its potential advantages over existing or alternative therapies; (ii) the actual or perceived safety of similar classes of products; (iii) the effectiveness of our 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 approval 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 severe OAK have not included publicly available demonstrations of efficacy in severely diseased patients and may include:

- oral non-steroidal anti-inflammatory agents;
- opioids;
- pain patches;
- intra-articular ("IA") corticosteroids injections;
- IA hyaluronic acid injections;
- acetaminophen;
- capsaicin;
- serotonin norepinephrine reuptake inhibitors;
- platelet rich plasma; and

- total knee replacement.

The American Academy of Orthopedic Surgeons (“AAOS”), issued their second edition of clinical practice guidelines for the treatment of OAK in May 2013, which is the latest edition of such guidelines. 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. 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 OAK 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 severe osteoarthritis of the knee.

Government Regulation

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act (“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 BLA, adverse facility inspection reports (Form 483), 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 (“GLPs”), regulation;
- the development and demonstration of manufacturing processes, which conform to the FDA mandated current Good Manufacturing Practices (“cGMP”), including a quality system regulating manufacturing;
- the submission and acceptance of an Investigational New Drug (“IND”) application which must become effective before human clinical trials may begin;
- obtaining the approval of Institutional Review Boards (“IRBs”), at each clinical trial site 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 a BLA, depending on the product’s components, intended effect, and claims.

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 safety. 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 ("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 ("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.

Clinical trials to support BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. Ampio is seeking a BLA for Ampion's treatment of severe OAK. 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.

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 application 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 of these applications are subject to an application user fee, currently $2.9 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 believes that it will be considered a small business and intends to submit a small business waiver for waiver of the BLA application user fee. The manufacturer and/or sponsor under an approved BLA are also subject to an annual program fee, currently $325,000. 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. Applications for standard biologic products are typically reviewed within ten months; most applications for priority or accelerated biologics are reviewed in six months. There are accelerated review processes at the FDA, including Fast Track Designation and Accelerated Approval, none of which Ampio is currently seeking.

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 will issue 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 product with specific prescribing information for specific indications. As a condition of the BLA approval, the FDA may require a risk evaluation and mitigation strategy ("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 ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, 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.

We have advanced through late-stage clinical trials on Ampion in the United States. Nevertheless, our current regulatory strategy may not secure the final regulatory approval of Ampion for the chosen product indications. In addition, the approval(s) 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, if approved, will be successfully commercialized.

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 Common Technical Document ("CTD") used to assemble the Quality, Safety, and Efficacy information for submission of an Ampion BLA in the United States is currently recognized throughout Europe, Canada and Japan. 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 may differ from those required for FDA approval.

Under 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 ("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 Ampion for 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, if approved, will be successfully commercialized.

Biosimilars and Exclusivity

The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2020 (collectively referred to as the "Affordable Care Act"), signed into law on March and May 2010, includes a subtitle called the Biologics Price Competition and Innovation Act ("BPCIA") of 2009. The BPCIA grants a novel biologic, or reference product, 12 years of market exclusivity. It also 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, which 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, including 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.

We believe that Ampion is a novel biologic product and, as such, we expect it will be granted 12 years of market exclusivity as measured from the FDA approval date.

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 will be 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 our BLA for Ampion's treatment of severe OAK, we and the 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 ("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, as amended ("HIPAA"). 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.

Information Systems

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

Intellectual Property Summary

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. 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 inflammatory diseases with compositions of matter. This family 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 and Canada. 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, Russia, Israel, Japan, Korea, Mexico, Malaysia, New Zealand, Philippines, and South Africa, and pending applications in Brazil, Canada, EPO, Hong Kong, Indonesia, Singapore, and United States. The claims in this family are directed to the use 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, issued patents in Australia and Japan, and pending applications in Canada, China, EPO, Hong Kong, and New Zealand with claims directed to the use to mobilize, attract, 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 two U.S. patents, 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 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 Ampion in the absence of cyclooxygenase-2 ("COX-2") inhibition. The standard 20-year expiration for patents in this family will be in 2036.

The seventh family includes a pending U.S. application with composition of matter 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 in 2037.

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. We have not changed that decision.

Barriers to Entry – General

We also maintain trade secrets and proprietary know-how that we seek to protect through confidentiality and nondisclosure agreements and other controls over confidential information. We have sought 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 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 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 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 after filing and, in some cases in the U.S., 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, 2019 and 2018, we recorded $12.6 million and $6.8 million, respectively, of research and development expenses. Research and development expenses represented 67.9% and 61.0% of total operating

expenses in the years ended December 31, 2019 and 2018, 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.

Raw Materials and Principal Suppliers

We currently obtain the raw material needed to produce Ampion for our clinical trials from one supplier in the United States.

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, if we obtain regulatory approval of Ampion, we will obtain appropriate product liability insurance coverage for Ampion that we manufacture and sell for human use. 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 February 14, 2020, we had 23 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.

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 U.S. Securities and Exchange Commission (“SEC”). Information found on our website is not incorporated by reference into this report.

Our Code of Business Conduct and Ethics and the charters of the Nominating and Governance Committee, Audit, Compensation, and Disclosure Committees of our Board of Directors (our “Board”) may be accessed within the Investor Relations section of our website. Amendments and waivers of the Code of Business 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 and issuance of debt or equity securities or through bank financing. We believe that we will be able to raise additional equity or debt financing in the future; however, any future financing could be dilutive to our current stockholders. 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. 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 the foreseeable future and may never achieve or sustain profitability.

We are a pre-revenue development stage biopharmaceutical company that has not generated operating revenues or profits and have therefore incurred an accumulated deficit totaling $184.6 million as of December 31, 2019. We expect to continue generating operating losses for the foreseeable future but intend to limit the extent of these losses by entering into licensing, collaboration or similar type of agreements with one or more strategic partners, which may provide us with potential fixed or contingent licensing fees and/or milestone/royalty payments. We cannot be certain that any licensing 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 successful completion of all requisite clinical trials, filing of the BLA with the FDA, obtaining marketing approval, manufacturing and commercialization, satisfying any post-marketing requirements and obtaining appropriate level of reimbursement from both private insurance and government payors. We, and/or 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 additional capital to fund our future 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 and commercializing biopharmaceutical 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 finalize our current clinical trial, prepare to file our Ampion BLA with the FDA and seek marketing approval for Ampion.

As of December 31, 2019, we had $6.5 million of cash and cash equivalents which we expect can fund our operation into the second quarter of 2020.

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;
- incremental costs should we be required to or determine to increase patient sample size beyond 1,034 patients;
- 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;

- the costs of defending lawsuits and other claims by third parties or responding to various government agencies that we are required to report to or respond to inquiries from;

- the costs associated with obtaining Directors and Officers ("D&O") insurance, which may be higher due to our industry and due to our current shareholder litigation and government investigation concerning trading in our publicly listed securities; and

- the likely increase in the future level of D&O policy retention amounts given the industry trend and our current experience with increased legal costs associated with our current litigation and government investigation.

Until we can generate ongoing operating profit on an ongoing and reliable basis, we expect to satisfy our future ongoing cash and liquidity needs through one or more of the following: (i) third-party collaboration arrangements, (ii) private or public sales of our securities, which we expect will include an "at-the-market" ("ATM") equity program, or (iii) debt financings. We cannot be certain that additional funding and incremental working capital will be available to us on acceptable terms, if at all, or that it will exist in a timely and/or adequate manner to allow for the proper execution of our near and long-term business strategy. In addition, we are subject to certain restrictions under our agreement with an investment banker that we entered into in June 2019, which may prevent us from conducting an ATM or continuous equity financing in the near term until June 2021. The investment banker may also exercise a right of first refusal to act as the investment banker or placement agent on certain future transactions. Therefore, it is possible funds may not be available on terms and conditions acceptable to management and stockholders of the Company due to these limitations or otherwise and we may be required to delay, reduce the scope of, or eliminate further development of Ampion and the planned filing of the BLA and/or substantially curtail or close our operations altogether.

Even if we obtain requisite 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 stockholders or other restrictions that may adversely affect our business. Additional funding, if obtained, may also result in significant dilution to our stockholders.

We may be limited in our ability to access sufficient funding through a public or private equity offering or convertible debt offering.

NYSE American rules impose restrictions on our ability to raise funds through a private offering of our common stock, convertible debt or similar instruments without obtaining stockholder approval. Under NYSE American rules, an offering of more than 20% of our total shares outstanding at a price per share less than the greater of book or market value of the stock requires stockholder approval unless the offering qualifies as a "public offering" for purposes of the NYSE American rules. In June 2019, we sold 30.0 million shares of our common stock in a public offering, which was more than 20% of our total shares outstanding at that time at a price per share less than the greater of book or market value of the stock at that time, and if we had not been able to sell through a public offering at that time, such offering would have required stockholder approval. Under current SEC regulations, if immediately following the filing of this Annual Report, our public float is less than $75 million, and for so long as our non-affiliated public float is less than $75 million, the amount we will be able to raise through primary public offerings of securities in the twelve-month period using our current shelf registration statement on Form S-3, which was declared effective by the SEC in April 2017, or a newly filed shelf registration statement on Form S-3 will be limited to an aggregate of one-third of our non-affiliated public float, which is referred to as the baby shelf rules.

As of February 14, 2020, our non-affiliated public float was approximately $107.4 million, based on 156,250,310 shares of outstanding common stock held by non-affiliates at a price of $0.69 per share, which was the last reported sale price of the Company's common stock on the NYSE American Market on February 14, 2020. While we do not anticipate that we will be subject to the baby shelf rules immediately after filing our Annual Report, we have been subject to the baby shelf rules in the past and it is possible that we will be subject to the baby shelf rules in the future. In such event, the amount of financing the Company could raise may be limited.

We received an SPA agreement from the FDA relating to our product candidate. This SPA agreement does not guarantee approval of Ampion or any other particular outcome from regulatory review.

We requested agreement from the FDA under an SPA for our AP-013 study of Ampion, which we received in writing from the FDA in June 2019. The FDA's SPA process is designed to facilitate the FDA's review and approval of biologics by allowing the FDA to evaluate the proposed design and size of certain clinical trials that are intended to form the primary basis for determining a biologic's efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial conduct and data analysis. The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the product candidate with respect to the effectiveness of the indication studied. Based on their review, the FDA will then issue a SPA Agreement letter, or a SPA No Agreement letter.

As stated in the FDA's guidance for industry regarding SPAs (published in April 2018), a SPA agreement does not guarantee approval of a product candidate, even if the trial is conducted in accordance with the protocol. Moreover, the FDA may revoke or alter our SPA agreement in certain circumstances. In particular, a SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, we fail to comply with the agreed upon trial protocols, or the relevant data, assumptions, or information provided by us in our request for the SPA change or are found to be false or omit relevant facts. In addition, even after an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement.

Even though we obtained an agreement on our SPA, we cannot assure you that our AP-013 study of Ampion will succeed or will result in any FDA approval for Ampion. Moreover, if the FDA revokes or alters its agreement under our SPA, or interprets the data collected from the AP-013 Study differently than we do, the FDA may not deem the data sufficient to support an application for regulatory approval, or the FDA may require additional clinical trials to support a BLA for Ampion's treatment of severe OAK, both of which could materially impact our business, financial condition, and results of operations.

Our business is 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 solely 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.

If clinical trials of Ampion fail to satisfactorily demonstrate safety and efficacy to the FDA and other regulators, the FDA or other regulators 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 for a desired indication 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's treatment of severe OAK. Any unfavorable outcome of our current AP-013 Study of Ampion, which we anticipate will be the last clinical trial that we conduct prior to BLA submission, would be a major set-back for the development program and for us. Due to our limited financial resources, an unfavorable outcome in the AP-013 Study may require us to delay, reduce the scope of, or eliminate our only active product development program, which we expect would 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, but not limited to the following:

- Ampion is ineffective, or is considered inferior to existing approved medicines;
- 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;
- the FDA may require additional clinical testing and trials, which are costly and time consuming; and
- as a result of the interim review of 724 patients achieving the 12-week endpoint, we may determine to increase the size of the patient sample size beyond 1,034 patients, which would result in a delay of concluding the current AP-013 study and could result in additional costs.

If we do not successfully complete clinical development, file our BLA and receive marketing approval from the FDA, we will be unable to market and sell products derived from Ampion and generate revenues. Even if we do successfully complete the AP-013 study, the results may not be sufficient for FDA approval of our BLA for Ampion's treatment of severe OAK, the FDA may not deem the data sufficient to support an application for regulatory approval, or if the FDA required additional clinical trials to support a BLA, the results may not necessarily be 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 current clinical study is substantially delayed or fails 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.

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 currently 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.

Relying on third-party suppliers may result in delays in our ongoing clinical trial and introduction of our product to the market.

We currently obtain the raw material needed to produce Ampion for our clinical trials from one supplier in the United States. Our current agreement with this supplier expires in December 2020 and we are in the process of securing a long-term supply agreement. Future clinical trials, if required, and FDA approval may be delayed if we are unable to obtain a sufficient quantity of the 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 and manufacturers are subject to continual review. The discovery of previously unknown problems with a product or supplier and manufacturers may result in restrictions on the product, supplier, or manufacturing facility, including withdrawal of the product from the market. Our raw material supplier is required to operate in accordance with 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.

We currently, and from time to time in the future may, outsource portions of our internal business functions to third-party providers. Outsourcing these functions has significant risks, and our failure to manage these risks successfully could materially adversely affect our business, results of operations, and financial condition.

We currently, and from time to time in the future may, outsource portions of our internal business functions to third-party providers including information technology, human resources, internal audit testing, legal services and certain calculations and other information that support our accounting and financial reporting, among other things. Third-party providers may not comply on a timely basis with all of our requirements or may not provide us with an acceptable level of service. In addition, our reliance on third-party providers could have significant negative consequences, including significant disruptions in our operations and significantly increased costs to undertake our operations. For example, any failure by the third-party providers that assist us with financial reporting to provide us with accurate information or implement and maintain effective controls may cause us to be unable to meet our reporting obligations as a publicly traded company and we could experience deficiencies in our operations that could have an adverse effect on the effectiveness of our internal control over financial reporting. As a result of our outsourcing activities, it may be more difficult for us to recruit and retain qualified employees for our business needs at any time and if we have a failure in our outsourced financial reporting activities, our independent registered public accounting firm may not be able to provide us with an unqualified report regarding the effectiveness of our internal control over financial reporting, which may cause investors to lose confidence in the reliability of our financial statements and could result in a decrease in the value of our common stock. Our failure to successfully outsource any material portion of our business functions could materially adversely affect our business, results of operations, and financial condition.

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

In May 2014, we commenced a 125- month lease of a multi-purpose facility containing approximately 19,000 square feet. We have built out this facility in anticipation of receiving approval of our BLA and commencing commercialization of Ampion for treatment of severe OAK. If the submission of our BLA for Ampion is significantly delayed, the FDA does not approve our BLA for Ampion, and/or does not approve of our manufacturing operation, we will not be able to manufacture Ampion for commercial sale 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.

While the likelihood of the use hazardous materials is deemed minimal, in the unlikely instance we use hazardous and/or biological materials in a manner that causes injury or violates applicable law, we may be liable for damages or fines.

The use of hazardous and biological materials is deemed unlikely. However, the activities conducted at our facility (i.e. research and development and manufacturing) may, from time to time, involve the controlled use of potentially hazardous substances, including, but not limited to, chemical and biological materials and 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 unlikely 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, in the event of an accident, 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, or our collaborators, 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 treatment of severe OAK. For instance, the indicated use for Ampion that we have negotiated with the FDA is “treatment of the signs and symptoms of severe OAK”, which will mean that our product will not be marketed to persons having less than severe OAK, a regulatory approval may further limit the indicated uses for which we can market a product or the patient population that may utilize the product. These restrictions could make it more difficult to market Ampion effectively.

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. The expenses and costs we will incur to comply with FDA post approval requirements could limit our financial resources for other development activities.

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 use for which the product may be marketed and there may be conditions of approval.

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.

Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. The costs and expenses we may incur to comply with FDA post approval requirements could limit our financial resources for other development activities.

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, submission of a BLA application, 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 the compound used to manufacture Ampion;
- the efforts of our collaborators with respect to the commercialization of our product; and
- 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 currently contract with or may contract with in the future successfully complete clinical trials of Ampion, our product may not be commercialized successfully for other reasons.

Even if the contractors that we currently contract with for the AP-013 study, or contractors that we may contract with in the future, 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, 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.

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.

Ampion is regulated by the FDA, and as such, may subject it to competition sooner than anticipated.

With the enactment of the BPCIA an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway established legal authority for the FDA to review and approve biosimilars, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. The BPCIA provides a period of exclusivity for product granted "reference product exclusivity," under which an application for a biosimilar product referencing such products cannot be approved by the FDA until 12 years after the original branded product is approved under a BLA.

This period of regulatory exclusivity does not apply to companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Therefore, if Ampion were to receive reference product exclusivity, a competitor may seek approval of a product candidate under a full BLA. In such a case, although the competitor would not enjoy the benefits of the abbreviated pathway for biosimilar approval created under the BPCIA, the FDA would not be precluded from making effective an approval of the competitor product pursuant to a BLA prior to the expiration of our 12-year period of market exclusivity.

We could 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.

If we develop an approved product, we cannot provide assurance it will be first to market, clinically superior or scientifically preferable to existing or future products and/or treatments developed or introduced by our competitors. 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, or a lack of demonstrated, treatment methodologies. 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.

Lawsuits or investigations could divert our resources, result in substantial liabilities and reduce the commercial potential of Ampion.

We are currently and may be additionally in the future subject to legal or administrative proceedings and litigation which may be costly to defend and could materially harm our business, financial conditions and operations. While we do not anticipate that the current legal and administrative proceedings and litigation that we are currently subject to are likely to result in liability for the Company, the cost of responding to and defending ourselves in such proceedings was approximately $600,000 in 2019 and $84,000 in 2018, which was material, and, as of December 31, 2019, had not met our retention levels under our insurance.

Additionally, 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 us, or our 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.

Although we maintain general liability and product liability and directors and officers 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 otherwise protect against potential legal or administrative liability claims could prevent or inhibit the commercial production and sale of Ampion, if and when it receives regulatory approval, which could in turn adversely affect our business. Lawsuits and investigations, or threats thereof, could also harm our reputation, which may adversely affect our collaborators' ability to commercialize our product successfully.

We may have difficulties obtaining and maintaining sufficient insurance coverage.

As a result of a number of factors, such as ongoing litigation, certain of the insurance products that we purchase have become less available and their cost has increased significantly in 2019. Although we maintain directors and officers insurance as well as general liability and product liability insurance, these insurance coverages only cover potential liabilities after our retention has been met and only to the extent of the insurance coverage, therefore, our insurance coverages may not fully cover potential liabilities. In addition, our inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product or other legal or administrative liability claims could prevent or inhibit the manufacture and sale of Ampion if it receives regulatory approval, which could adversely affect our business.

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 at 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 enactment of the Affordable Care Act is 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. 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 outside the United States, we, or our collaborators, may need to obtain separate marketing approvals and comply with numerous and varying regulatory requirements in global markets which do not recognize the FDA approval process. The approval procedures in these jurisdictions vary among countries and can require separate clinical trials and approval submission/approval process involve additional testing. 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 ("MAA") to the EMA which conducts a validation and scientific approval process in evaluating a product for safety and efficacy. As further noted above, 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.

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain, and motivate qualified personnel.

We are highly dependent on our executive officers; the loss of whose services may adversely impact the achievement of our objectives. Recruiting and retaining other qualified employees, consultants, and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives and scientific personnel in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, our current financial needs and potential benefit packages at other pharmaceutical and biotechnology companies may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive, key employee, consultant, or advisor may impede the progress of our research, development and commercialization objectives.

In order to induce valuable employees to remain employed at Ampio, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies.

Despite our efforts to retain valuable employees, members of our management, scientific, and development teams have in the past and may in the future terminate their employment with us. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, prospects, financial condition or results of operations. We do not maintain "key man" insurance policies on the lives of these individuals or any of our other employees. Our success also depends on our ability to continue to attract, retain, and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel.

Many of the other biotechnology and pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They may also provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we can offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can discover, develop and commercialize product candidates will be limited.

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 continues to serve as a member of our Board and our Scientific Advisory Board, the loss of his services as our full-time Chief Scientific Officer could diminish when, and if, we have the financial resources to do so, our ability to develop and commercialize new product candidates.

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.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities.

We are exposed to the risk that our employees, contract research organizations, principal investigators, consultants, and commercial partners may engage in fraudulent conduct or other illegal activity or may fail to disclosure unauthorized activities to us. Misconduct by these parties could include intentional, reckless and/or negligent failures to comply with:

- the laws and regulations of the FDA and non-U.S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulatory bodies;
- manufacturing standards we have established;

- healthcare fraud and abuse laws and regulations in the United States and similar foreign laws; or
- laws requiring the accurate reporting of financial information or data or the disclosure of unauthorized activities to us.

In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Our ability to use our net operating loss carryforwards may be subject to limitation.

Under Section 382 of the Internal Revenue Code of 1986, as amended, substantial changes in our ownership may limit the amount of net operating loss carryforwards that could be utilized annually in the future to offset our taxable income. Specifically, this limitation may arise in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such annual limitation may significantly reduce the utilization of our net operating loss carryforwards before they expire. We believe it is likely that transactions that have occurred in the past and other transactions that may occur in the future, could trigger an ownership change pursuant to Section 382, which could limit the amount of net operating loss carryforwards that could be utilized annually in the future to offset our taxable income, if any.

Further, the Tax Act changed the federal rules governing net operating loss carryforwards. For net operating loss carryforwards arising in tax years beginning after December 31, 2017, the Tax Act limits a taxpayer's ability to utilize such carryforwards to 80% of taxable income. In addition, net operating loss carryforwards arising in tax years ending after December 31, 2017 can be carried forward indefinitely, but carryback is generally prohibited. Net operating loss carryforwards generated before January 1, 2018 will not be subject to the Tax Act's taxable income limitation and will continue to have a twenty-year carryforward period. Nevertheless, our net operating loss carryforwards and other tax assets could expire before utilization and could be subject to limitations, which could harm our business, revenue, and financial results.

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 composition and uses. We must successfully defend these rights against third-party challenges. We will only be able to protect Ampion's proprietary composition and its uses 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 composition 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 for its uses;
- others may independently develop identical, similar, or alternative products or compositions;
- 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 compositions may not be patentable;
- others may design around our patent claims to produce competitive products which fall outside of the scope of our patents;
- others may identify prior art which could invalidate our patents; and
- the availability and length of patent term extension (PTE) under the Hatch-Waxman Act for approved products are subject to a number of factors and PTE could be unavailable or less than the maximum 5 years for PTE for Ampion.

Even if we have or obtain patents covering Ampion or its uses, we may still be barred from making, using and selling Ampion because of the patent rights of others. Others have or may have filed, and in the future may file, patent applications covering compositions or products that are similar or identical to ours. There are many issued U.S. and foreign patents and pending patent applications relating to chemical compounds, biological compositions and therapeutic products, and some of these may relate to compositions we intend to commercialize. 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 uses may infringe. These patent applications may have priority over patent applications filed by us.

We have conducted searches in the past to identify patents or patent applications that may prevent us from obtaining patent protection for our compositions or that could limit the rights we have claimed in our patents and patent applications, however, currently there are no ongoing searching efforts. 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 compositions or uses addressed in those patents.

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, methods of making Ampion and/or methods of using Ampion infringe the intellectual property rights of others. There are many patents relating to pharmaceuticals used to treat inflammation. Some of these may encompass Ampion or components of 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 pharmaceuticals encompassed by their claims. 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 Ampion, while other patents and patent applications cover the composition of Ampion. The interpretation and breadth of claims allowed in some patents covering pharmaceutical compositions may be uncertain and difficult to determine and are often affected materially by the facts and circumstances that pertain to the patented composition and the related patent claims. The standards of the United States Patent and Trademark Office ("USPTO") are sometimes uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated, or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, and U.S. patents may be subject to reexamination or other post-grant 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 rejection 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, its proprietary composition and its 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;
- any actual or perceived difficulties or delays in obtaining regulatory approval of Ampion in the United States or other countries;
- 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;
- our success or inability to obtain collaborators to conduct clinical trials, or commercialize Ampion once regulatory approval is obtained;
- announcements of patent issuances or denials, product innovations, or introduction of new commercial products by our competitors that will compete with Ampion;
- publicity regarding actual or potential study results or the outcome of regulatory reviews relating to the development of Ampion or our competitors' products;
- economic and other external factors beyond our control; and
- sales of stock by us or by our stockholders.

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 ("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. 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.

We believe that 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 stockholders. 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 stockholders. 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;
- 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 stockholders to influence corporate matters.

As of February 14, 2020, holders of more than 5% of our common stock and our directors, executive officers and their affiliates beneficially owned 27.4% of our outstanding common stock. These stockholders may have significant effect on the outcome of actions taken by us that require stockholder 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 stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions include:

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

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

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 ("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 continuously 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 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, qualified executive officers and/or qualified internal and independent auditors. 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 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 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, research laboratories, and manufacturing facilities in leased space located in Englewood, Colorado, for monthly lease 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***

Information regarding Legal Proceedings is contained in *Note 14* to the Financial Statements.

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 February 14, 2020, there were approximately 11,600 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 current and future available resources to develop Ampion. If we issue any preferred stock and/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

None.

Equity Compensation Plans Information

Information regarding our equity compensation plans is contained in Item 12 under "Securities Authorized for Issuance Under Equity Compensation Plans" and *Note 11* to the Financial Statements. The Company's 2010 Stock and Incentive Plan (the "2010 Plan") was terminated by the Board in December 2019 following approval by the Company's stockholders of the new 2019 Stock and Incentive Plan (the "2019 Plan").

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 pre-revenue development stage biopharmaceutical company focused entirely on the development of Ampion, our lead product candidate, to treat prevalent inflammatory conditions for which there are limited treatment options.

The pharmaceutical market is a highly 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 for OAK.

Since we are in the research and development phase, we have not generated revenue to date. Our operations have been funded solely through equity raises, which have occurred from time to time since inception.

Moving forward, we plan to maintain a lean and efficient operating model by streamlining our operations and continuing to allocate all our resources towards achieving regulatory approval for the FDA marketing approval and subsequent commercialization of 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 10* to the Financial Statements.

Known Trends or Future Events; Outlook

We are a pre-revenue development stage company that has not generated revenues and therefore, we have incurred an accumulated deficit of $184.6 million as of December 31, 2019. We expect to generate continued operating losses for the foreseeable future as we continue development of Ampion toward filing a BLA for regulatory approval of Ampion's treatment of severe OAK. In addition, we are exploring collaboration agreements with multiple strategic partners with the goal to try to limit the extent of these losses. As of December 31, 2019, we had $6.5 million of cash and cash equivalents which we expect will fund our operation into the second quarter of 2020. These existing and on-going

factors continue to raise substantial doubt about our ability to continue as a going concern (see *Note 3* to the Financial Statements).

As of December 31, 2019, we have approximately $66.7 million available under the shelf registration statement with 118,382,387 authorized shares remaining. However, we cannot be certain that we will be able to secure additional financing or that funding, if secured, will be adequate to execute our business strategy. Even if we are able to obtain additional financing, such additional financing may be costly and may require us to agree to covenants or other provisions that favor new investors over existing shareholders.

Our primary focus for fiscal year 2020 is completion of the AP-013 clinical study and the filing of a BLA with the FDA for Ampion to treat the signs and symptoms of severe OAK.

Significant Accounting Policies and Estimates

Our financial statements were prepared in accordance with GAAP. The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses incurred during the reporting period. On an on-going basis, management evaluates its estimates and judgments, including those related to recoverability of long-lived assets, valuation allowance(s), useful lives of assets and remaining useful lives, stock compensation, warrant derivative liability, right-of-use asset, lease liability, clinical trial accrual and the ability for the Company to continue as a going concern. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable and appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The methods, estimates, and judgments used by us in applying these most critical accounting policies have a significant impact on the results we report in our financial statements. Additional information regarding our Significant Accounting Policies and Estimates is contained in *Note 2, 3 and 7* to the Financial Statements.

Recent Accounting Pronouncements

Information regarding recently issued and relevant accounting standards (adopted and not adopted as of December 31, 2019) is contained in *Note 2* to the Financial Statements.

Results of Operations—Year Ended December 31, 2019 Compared to December 31, 2018

We recognized a net loss for the year ended December 31, 2019 (the “2019 period”) of $13.6 million compared to net income recognized of $34.0 million for the year ended December 31, 2018 (the “2018 period”). The net loss during fiscal 2019 was attributable to operating expenses of $18.6 million, offset by the recognition of a non-cash derivative gain of $4.9 million. The 17.3 million warrant exercises during fiscal 2019 caused the valuation of the warrant liability to decrease, resulting in a non-cash derivative gain. This non-cash derivative gain was slightly offset by the increase in our stock price from $0.39 as of December 31, 2018 to $0.58 as of December 31, 2019, which caused the valuation of the warrant liability to increase. The net income during fiscal 2018 was primarily attributable to the non-cash derivative gain of $45.3 million, which was partially offset by operating expenses of $11.2 million. The 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 fiscal 2018. The operating expenses increased $7.4 million from the 2018 period to the 2019 period primarily due to a $5.8 million increase in research and development costs and a $1.6 million increase in general and administrative costs, which are both further explained below.

Research and Development

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

	Years Ended December 31,	
	2019	2018
Clinical trial	$ 7,149,000	$1,754,000
Salaries and benefits	2,743,000	1,828,000
Depreciation	1,216,000	1,189,000
QC and R&D labs	507,000	771,000
Operations / manufacturing	326,000	379,000
Regulatory / FDA	294,000	453,000
Professional fees	184,000	192,000
Equipment rental and repair	114,000	72,000
Stock-based compensation	89,000	191,000
Total research and development	$12,622,000	$6,829,000

Comparison of Years Ended December 31, 2019 and 2018

Research and development costs increased $5.8 million, or 84.8%, for the 2019 period compared to the 2018 period. Clinical trials expense increased $5.4 million for the 2019 period compared to the 2018 period due to the commencement of the AP-013 Phase III clinical study (“AP-013 study”) in June 2019. Salaries and benefits also increased $915,000 for the 2019 period compared with the 2018 period, primarily due to the favorable accrual adjustment resulting from the elimination of the 2018 annual incentive compensation accrual as a result of the repricing of employee stock options in October 2018, which resulted in an adjustment totaling $488,000 for the 2018 period. This 2018 favorable adjustment was partially offset by a de minimis stock-based compensation expense from the repricing of employee stock options. In addition, during the 2019 period, we added three new positions to assist with the direct management and oversight of the AP-013 study and certain of our employees received merit increases effective at the commencement of 2019. These three new positions and merit increases were partially offset by the reduction of the CSO position, which occurred during the end of the 2018 period. The increases in the clinical trial expenses and salaries and benefits were partially offset by a decrease in laboratory, regulatory/FDA, and stock-based compensation expenses. Laboratory expenses decreased for the 2019 period compared to the 2018 period as we finalized a quality control project related to the manufacturing of Ampion. Regulatory/FDA expenses decreased for the 2019 period compared to the 2018 period as we finalized our discussions with the FDA regarding our prior clinical trials. Stock-based compensation decreased for the 2019 period compared with the 2018 period as previously awarded high-priced options became fully vested during the 2019 period.

General and Administrative

General and administrative expenses consist of direct labor, director fees, stock-based compensation, patent costs, professional fees (for example: legal, auditing, and accounting) and occupancy, travel and other (for example: rent, insurance, investor/public relations, and professional subscriptions). These costs are summarized as follows:

	Years Ended December 31,	
	2019	2018
Professional fees	$2,474,000	$1,979,000
Salaries and benefits	1,062,000	493,000
Insurance	826,000	529,000
Facilities	502,000	474,000
Stock-based compensation	397,000	313,000
Director fees	335,000	229,000
Other	163,000	171,000
Travel and meetings	139,000	75,000
Depreciation	56,000	92,000
Total general and administrative	$5,954,000	$4,355,000

Comparison of Years Ended December 31, 2019 and 2018

General and administrative costs increased $1.6 million, or 36.7 %, for the 2019 period compared to the 2018 period. Professional fees increased primarily due to an increase in legal fees related to ongoing current litigation and government investigation matters. The increase in professional fees was partially offset by a one-time cost related to a strategic assessment of the osteoarthritis environment report that occurred during the 2018 period. Labor costs for the 2019 period increased compared to the 2018 period due to the favorable adjustment totaling $325,000 during the 2018 period resulting from an accrual adjustment resulting from the elimination of the annual discretionary corporate bonus accrual. In addition, there was a separation agreement that was executed with our former Chief Financial Officer (“CFO”) during the 2019 period resulting in an increase of $160,000 in labor costs. Insurance expense increased from the 2019 period compared to the 2018 period primarily due to an increase of $500,000 in our D&O insurance premiums covering our new policy period as a result of the current litigation and government investigation matters. Stock-based compensation increased due to the issuance of stock options related to the employment agreement for our new CFO, along with the cancellation and reissuance of previously awarded stock options for certain non-employee directors, which was partially offset by previously awarded high-priced options becoming fully vested during 2019. Directors fees increased as more board meetings were held during the 2019 period as compared to the 2018 period. Travel and meetings expenses increased from the 2019 period compared to the 2018 period as our clinical team performed site visits, increased frequency of non-deal roadshows and incremental travel and relocation related expenses consistent with our employment agreement with our new CFO.

Net Cash Used in Operating Activities

During 2019, our operating activities used approximately $15.4 million in cash, which was more than our net loss of $13.6 million primarily as a result of the non-cash gain from the warrant derivative totaling $4.9 million, non-cash charges related to depreciation and amortization, and stock-based compensation totaling $1.7 million; partially offset by changes in operating assets and liabilities totaling $1.4 million.

During 2018, our operating activities used approximately $12.1 million in cash, which was less than the net income of $34.0 million primarily as a result of the non-cash gain from warrant derivative totaling $45.3 million, non-cash charges related to depreciation and amortization, stock-based compensation and loss from disposal of fixed assets totaling $1.9 million; partially offset by change in operating assets and liabilities totaling $2.7 million.

Net Cash Used in Investing Activities

During 2019, cash used to acquire manufacturing machinery and equipment totaled $22,000.

During 2018, cash used to acquire manufacturing machinery and equipment totaled $564,000.

Net Cash from Financing Activities

During the 2019, we received gross proceeds from the sale of common stock in a public offering of $12.0 million, which was offset by offering related costs of $1.2 million. In addition, we also received gross proceeds from warrant exercises of $3.9 million, which was offset by related costs of $277,000.

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

Contractual Obligations and Commitments

Information regarding Contractual Obligations and Commitments is contained in *Note 7* to the Financial Statements.

Liquidity and Capital Resources

We have not generated operating revenue or profits. Our primary activities since inception have been focused on research and development activities for advancement of Ampion towards BLA submission, which has required raising capital. As of December 31, 2019, we do not have sufficient liquidity to meet our obligations for the next twelve months. Specifically, we had $6.5 million of cash and cash equivalents which we expect will fund our operations into April 2020. 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. In addition, we anticipate that we will seek additional capital investments in both the near and long-term to enable us to primarily support (i) our existing AP-013 study, (ii) BLA preparation and submission, (iii) existing base business operations and (iv) commercial development activities for Ampion. We intend to evaluate the capital markets on an ongoing basis to determine the appropriate timing for such capital raise and which will depend on existing market conditions relative to our need for funds at such time.

The audit reports on our financial statements for the fiscal year ended December 31, 2019 and 2018 contained an explanatory paragraph indicating that there was substantial doubt about our ability continue as a going concern. In order to address the going concern, we have prepared a projection through March 31, 2021. This projection 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 $900,000 per month. The projection also reflects costs related to regulatory approvals, clinical trials and outsourced research and development costs of approximately $900,000 per month through the second quarter of 2020, which then decreases to $300,000 per month from the third quarter of 2020 through the fourth quarter of 2020. Accordingly, we believe that it will be necessary to raise additional capital and/or enter into licensing or collaboration agreements to fund the further development and regulatory activities that we plan to conduct. As of December 31, 2019, we have approximately $66.7 million available under the shelf registration statement with 118,382,387 authorized shares remaining. At this time, we expect to satisfy our future cash needs through private or public sales of our securities, option/warrant exercises, debt financings and/or partnering/licensing transaction. In February 2020, the Company entered into a Sales Agreement with two agents to implement an “at-the-market” equity offering program under which the Company may issue and sell from time to time shares of its common stock (see *Note 16* to the Financial Statements). Volatility in the financial markets has adversely affected the market capitalizations of many pre-revenue stage biopharmaceutical companies, particularly small capitalization companies such as Ampio, and has generally made equity and debt financing very difficult to obtain without significant dilution to existing shareholders. This volatility, coupled with other factors, may limit our access to additional financing.

If we cannot obtain funding through capital raises and/or partnering/licensing transactions in the future when we require it, we will be required to delay, reduce the scope of, or eliminate our development, manufacturing, and/or regulatory programs for Ampion and/or our future commercialization efforts and/or suspend operations for a period until we are able to secure additional funding. If we are not successful in raising sufficient funds to pay for further development and licensing of Ampion, we may choose to license or otherwise relinquish greater, or all rights to Ampion, at an earlier stage of development or on less favorable terms than we would otherwise choose. This would 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***

The Audit Committee (the "Audit Committee") of the Board of Directors conducted a comprehensive process to determine the Company's independent registered public accounting firm for the fiscal year ending December 31, 2019. On July 10, 2019, the Audit Committee approved the engagement of Moss Adams LLP as the Company's independent registered public accounting firm for the Company's fiscal year ending December 31, 2019. The Company's stockholders also approved of the engagement of Moss Adams LLP during the Company's annual meeting on December 14, 2019.

During the fiscal years ended December 31, 2018, and 2017, and the subsequent interim periods through July 10, 2019, neither the Company nor anyone on its behalf has consulted with Moss Adams LLP regarding: (i) the application of accounting principles to a specific transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, and neither a written report or oral advice was provided to the Company that Moss Adams LLP concluded was an important factor considered by the Company in reaching a decision as to any accounting, auditing, or financial reporting issue, (ii) any matter that was the subject of a disagreement within the meaning of Item 304(a)(1)(iv) of Regulation S-K, or (iii) any reportable event within the meaning of Item 304(a)(1)(v) of Regulation S-K.

In conjunction with the appointment of Moss Adams LLP as described herein, on July 10, 2019, Plante & Moran PLLC ("Plante Moran") notified the Company of its resignation as the Company's independent registered public accounting firm effective July 10, 2019.

As previously reported, on October 1, 2018, EKS&H LLLP ("EKS&H"), the Company's prior independent registered public accounting firm, resigned in connection with EKS&H's combination with Plante Moran. Plante Moran had served as the Company's registered public accounting firm since that time.

The audit report of Plante Moran on the Company's financial statements for the fiscal year ended December 31, 2018 did not contain an adverse opinion or disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope or accounting principles except the audit report of Plante Moran on the Company's financial statements for the year ended December 31, 2018 contained an explanatory paragraph indicating that there was substantial doubt about the ability of the Company to continue as a going concern. EKS&H's audit report on the Company's financial statements for the year ended December 31, 2017 contained a similar explanatory paragraph regarding the ability of the Company to continue as a going concern.

During the Company's two most recent fiscal years and through July 10, 2019, there were no disagreements within the meaning of Item 304(a)(1)(iv) of Regulation S-K with Plante Moran (or its predecessor EKS&H) on any matters of accounting principles or practices, financial statement disclosure or auditing scope and procedure which, if not resolved to the satisfaction of Plante Moran (or EKS&H), would have caused Plante Moran (or EKS&H) to make reference to the

subject matter in connection with its reports, and there were no reportable events 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 and the remediation efforts relating to the identified material weakness (as discussed further below), 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, 2019. 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, 2019, our internal controls over financial reporting are effective based on these criteria.

Moss Adams LLP, 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 as of December 31, 2019, which is included herein at F-2.

Remediation of Previously Reported Material Weakness

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

In May 2019, we identified a material weakness relating to identification of information for determining appropriate disclosure. The material weakness related to a deficiency in the procedures in place to ensure the timely and complete disclosure of certain information to our Disclosure Committee. While the material weakness did not result in a misstatement, we recognize the material weakness impacted the timeliness and completeness of certain disclosures and the subsequent determination of proper disclosure in the financial statements.

Management implemented the following procedures to remediate the material misstatement and, after further evaluation, concluded that the material weakness was remediated as of December 31, 2019:

- The management team provides the Disclosure Committee with finalized drafts of each of the periodic reports that the Company files with the SEC, press releases and other public statements planned to be made by the Company in advance of the Company's filing of such items. Where appropriate, as in the a case of the Form 10-K and Form 10-Q filings, the draft periodic reports provided to the Disclosure Committee have been reviewed by the Company's legal team. Drafts of each of the proposed periodic reports, press releases and other public statements are provided sufficiently in advance of the planned filing, or release, date so as to provide the Disclosure Committee members sufficient time to review, comment and ask questions regarding each of such periodic reports, press releases and other public filings prior to filing, or release.

- Disclosure Committee members provide either a physical or e-mail certification to the Senior Officers of the Company prior to the filing of each public filing as to the Committee's conclusions regarding their evaluation of the effectiveness of the Company's disclosure controls.

Changes in Internal Control over Financial Reporting

As noted above, the Company implemented remedial procedures to address the material weakness disclosed in our quarterly reports on Form 10-Q for the last three quarters of fiscal 2019 related to our disclosure controls and procedures, which has been fully remediated as of this Annual Report. Other than these remedial procedures, there has been no changes in our internal controls over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the fourth quarter of 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

None.

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 February 1, 2020.

Name	Age	Position With Ampio	Principal Occupation and Areas of Relevant Experience For Directors	Director/Officer Since
Michael Macaluso [4]	68	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 since the merger with Chay Enterprises in March 2010, our Chief Executive Officer ("CEO") since January 9, 2012 and the Chairman of our Board since May 2010. In addition, Mr. Macaluso has served as the Chairman of Aytu BioScience's (AYTU) Compensation Committee since 2019. Mr. Macaluso was appointed President of Isolagen, Inc. (ILE) and served in that position from June 2001 to August 2001, when he was appointed CEO. In June 2003, Mr. Macaluso was re-appointed as President of Isolagen and served as both CEO 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 that he should serve as a director of our company considering our business and structure.	March 2010

Name	Age	Position With Ampio	Principal Occupation and Areas of Relevant Experience For Directors	Director/Officer Since
David Bar-Or, MD	71	Director and Former Chief Scientific Officer	Dr. Bar-Or served as our Chief Scientific Officer ("CSO") 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 CSO of DMI Life Sciences, Inc. Dr. Bar-Or is currently the owner of Trauma Research, LLC and the director of Trauma Research at Swedish Medical Center, Englewood, Colorado, St. Anthony's Hospital, Lakewood, Colorado, Penrose Hospital, Colorado Springs, Colorado, Research Medical Center, Kansas City, Missouri, Wesley Medical Center, Wichita, Kansas 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 DMI BioSciences, Inc. in April 2009. He was also responsible for all patents issued and applied for since then, having been awarded over 500 patents and having been an inventor on almost 120 patent applications. Dr. Bar-Or has authored or co-authored over 180 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 Medical Center under the direction of Professor Peter Rosen.	March 2010

Name	Age	Position With Ampio	Principal Occupation and Areas of Relevant Experience For Directors	Director/Officer Since
			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 that he should serve as a director of our company considering our business and structure.	
Philip H. Coelho [1][2][3][4]	75	Director	Mr. Coelho has served as a member of our Board since April 2010. Mr. Coelho is the Chief Technology Officer of ThermoGenesis Corp., a firm he founded in 1986 and retired from in 2007, which invents and commercializes products that isolate, purify and cryopreserve stem, progenitor and immune cells derived from a donor or the patient's own body to treat human disease. Prior to rejoining ThermoGenesis Corp., Mr. Coelho founded SynGen Inc. in October 2009, and merged that company with ThermoGenesis Corp. in 2017. Mr. Coelho was the President and CEO of PHC Medical, Inc., a consulting firm, from August 2008 through October 2009. From August 2007 through May 2008, Mr. Coelho served as the Chief Technology Architect of ThermoGenesis Corp. From 1989 through July 2007, he was Chairman and CEO of ThermoGenesis Corp. Mr. Coelho served as Vice President of Research & Development of ThermoGenesis from 1986 through 1989. Mr. Coelho has been in the senior management of high technology consumer electronic or medical device companies for over 30 years. He was President of Castleton Inc. from 1982 to 1986, and President of ESS Inc. from 1971 to 1982. Mr. Coelho 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 more than 50 U.S. patents in the areas of cell cryopreservation, cryogenic robotics, cell selection, blood protein harvesting, and surgical homeostasis.	April 2010

Name	Age	Position With Ampio	Principal Occupation and Areas of Relevant Experience For Directors	Director/Officer Since
			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 that he should serve as a director of our company considering our business and structure.	
Richard B. Giles [1][2][3][4]	70	Director	Mr. Giles, CPA, has served as a member of our Board since August 2010. Mr. Giles is the Chief Financial Officer ("CFO") and Treasurer 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, and Construction Financial Management Association. Mr. Giles' experience in executive financial management, accounting and financial reporting, corporate accounting and internal controls led to the conclusion of our Board that he should serve as a director of our company considering our business and structure.	August 2010

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]	70	Director	Dr. Stevens has served as a member of our Board since June 2011. Dr. Stevens has worked in the FDA regulated life science industries since 1978. He has also been a consulting research pathologist since December 2006 for Premier Laboratory, LLC. He has been a board member of Cetya, Inc. since December 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. (2004-2013), Aqua Bounty Technologies, Inc. (2002-2012) and Smart Drug Systems, Inc. (1999-2006), and was an advisor to Bay City Capital (1999-2006). 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 that he should serve as a director of our company considering our business and structure.	June 2011

Name	Age	Position With Ampio	Principal Occupation and Areas of Relevant Experience For Directors	Director/Officer Since
Daniel G. Stokely [4]	51	Chief Financial Officer, Treasurer and Secretary	Mr. Stokely has more than 30 years of experience in finance and accounting. He began his career at Deloitte & Touche and since that time, he has spent the majority of his career in positions of financial leadership within both publicly traded and privately held pharmaceutical companies. Most recently, since 2012, he served as Executive Vice President and CFO of Sentynl Therapeutics Inc., a privately held specialty pharmaceutical company focused on in-licensing, acquisition, marketing, and distribution of development stage and commercially marketed prescription pain products, which was sold to Cadila Healthcare Ltd. in January 2017. From 2004 to 2012, Mr. Stokely served as Vice President of Finance and Chief Accounting Officer (“CAO”) of Victory Pharma, a privately-held specialty pharmaceutical company focused on in-licensing, internal product development, marketing, and distribution of pain specialty products, which was sold to Shionogi, Inc., a Japanese pharmaceutical company, in 2011. From 2001 to 2004, Mr. Stokely served as the Corporate Controller and CAO for Wireless Facilities, Inc. (currently Kratos Defense & Security Solutions), a publicly traded, global provider of communications and security services for the wireless communications industry. From 1994 to 2001, Mr. Stokely served as Corporate Controller of Dura Pharmaceuticals, a publicly traded pharmaceutical company that was sold to Elan Pharmaceuticals in late 2000. He has a bachelor’s degree in accounting from San Diego State University and is a Certified Public Accountant licensed in California.	July 2019

Name	Age	Position With Ampio	Principal Occupation and Areas of Relevant Experience For Directors	Director/Officer Since
Holli Cherevka [4]	36	Chief Operating Officer	Ms. Cherevka has served as our Chief Operating Officer ("COO") since September 2017. Prior to taking her current role, Ms. Cherevka served as our Vice President of Operations and oversaw the clinical, regulatory and manufacturing operations. Since starting at Ampio in January 2013, she has held roles the following additional roles of increasing responsibility including: Director of Clinical Trials (January 2013 – November 2013), Senior Director of Clinical Trials (November 2013 – May 2015), Vice President of Operations (May 2015 – September 2017) and COO (September 2017 – current). Previously, Ms. Cherevka was the Director of Business Development at the American College of Radiology (ACR) Image Metrix from 2011 to 2013. 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, and a board member of the Professional Science Master's in Biomedical Sciences (PSM) program at the University of Denver. She has represented Ampio Pharmaceuticals at conferences for the International Society of Pharmaceutical Engineers as well as at Global Investment Conferences and shareholder meetings.	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 family relationships to note between our directors or executive officers and employees. Raphael Bar-Or, a non-executive officer, is the son of Dr. Bar-Or, our former CSO and a director. Lindsay Thorne, a consultant, is the sister in-law of Holli Cherevka, our COO.

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 no one stockholder 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, 2019 to December 31, 2019, 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 business conduct and 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, 2019, there were (i) thirteen meetings of the Board, (ii) five meetings of the Audit Committee, (iii) nine meetings of the Compensation Committee, (iv) four meetings of the Nominating and Governance Committee, and (v) two meetings of the Disclosure Committee. No incumbent director attended fewer than seventy-five percent (75%) of the aggregate of (1) the total number of meetings of the Board, and (2) the total number of meetings held by all committees of the Board during the period that such director served.

Annual Meeting Attendance, Executive Sessions and Stockholder 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 2019 annual meeting was attended by all five of the directors serving on our Board.

We have not implemented a formal policy or procedure by which our stockholders can communicate directly with our Board. Nevertheless, every effort has been made to ensure that the views of stockholders are heard by the Board or individual directors, as applicable, and that appropriate responses are provided to stockholders in a timely manner. We believe that we are responsive to stockholder communications, and therefore have not considered it necessary to adopt a formal process for stockholder 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; (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 does not currently have a policy on whether the same person should serve as both the CEO and Chairman of the Board. Periodically, our Board assesses these roles and the Board leadership structure to ensure the interests of the Company and its stockholders are best served.

Both the Chairman and CEO positions are currently held by Michael Macaluso. Our lead independent director is Mr. Coelho. In that role, he presides over the executive sessions of the Board, during which our independent directors meet without management, and he serves as the principle liaison between management and the independent directors of the Board.

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 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 operate under separate charters approved by our Board, which charters are available on our website.

Audit Committee. We have separately designated standing audit committee established in accordance with section 3(a)(58)(A) of the Exchange Act. Our Audit Committee oversees our corporate accounting and financial reporting process. This committee also assists our Board 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 Dr. Stevens. Mr. Giles is our Audit Committee chairman and was appointed to our Audit Committee in August 2010. Our Board 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 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.

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 CEO;

- reviewing and approving compensation, corporate goals, and objectives relevant to compensation for executive officers other than our CEO;

- evaluating the performance of our executive officers considering established goals and objectives;

- developing and periodically reviewing with our Board a succession plan for our CEO; and

- administering our equity compensations plans for our employees and directors.

The members of our Compensation Committee are Messrs. Coelho, Giles and Dr. 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 have not yet established a succession plan for our CEO. Mr. Macaluso is performing to the satisfaction of the Board and, as such, 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 reviewing and recommending corporate governance policies and nominees for election to our Board. The Nominating and Governance Committee is responsible for, among other things:

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

The members of our Nominating and Governance Committee are currently Messrs. Coelho, Giles and Dr. Stevens. Mr. Coelho is the chairman of our Nominating and Governance Committee. Our Board has determined that 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 stockholders 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;
- providing or overseeing an annual mandatory training session to our Board 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; and
- certifying to the Senior Officers prior to the filing of each Form 10-K and Form 10-Q filings as to the Committee’s conclusions regarding its evaluation of the effectiveness of the Company’s Disclosure Controls.

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

Our Board may from time to time establish other committees.

Non-Employee Director Compensation

Our Compensation Committee established the following fees for payment to non-employee members of our Board or committees, for the fiscal year ended December 31, 2019:

	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; Disclosure	$ 20,000	
Each non-chair member	Audit	$ 12,000	
Each non-chair member	Compensation; Nominating and Governance; Disclosure	$ 10,000	
Committee Chairman Meeting Fees:			
Each meeting attended in-person	Audit; Compensation; Nominating and Governance; Disclosure	$ 2,500	
Each meeting attended telephonically or via web	Audit; Compensation; Nominating and Governance; Disclosure	$ 1,500	
Committee Member Meeting Fees:			
Each meeting attended in-person	Audit; Compensation; Nominating and Governance; Disclosure	$ 1,500	
Each meeting attended telephonically or via web	Audit; Compensation; Nominating and Governance; Disclosure	$ 1,000	
Annual Stock Award:			$20,000

The non-employee director compensation for fiscal 2019 included a grant to each independent director of options to purchase 30,000 shares of our common stock on the date of our prior year annual meeting of stockholders, vesting monthly over the succeeding twelve months. The date of the prior annual meeting of stockholders occurred on December 15, 2018. Dr. Bar-Or additionally received an option grant to purchase 30,000 shares of our common stock in October 2019 for his service as a non-employee director during all of fiscal 2019. Dr. Bar-Or's grant was 10/12th vested on the date of grant, with the remaining 2/12th vesting in full as of December 31, 2019.

Director Compensation for 2019

The table below summarizes the compensation paid by us to non-employee directors for the year ended December 31, 2019. Our employee director, Mr. Macaluso, does not receive additional compensation for his services as a member of our Board.

Name	Fees Earned or Paid in Cash	Stock Option Awards (1)	Stock Awards (2)	All Other Compensation	Total
David Bar-Or, M.D. (3)	$ 23,000	$ 11,000	$ 20,000	$	$ 54,000
Philip H. Coelho (4)	$ 112,000	$ 49,000	$ 20,000	$ —	$181,000
Richard B. Giles (5)	$ 102,000	$ 49,000	$ 20,000	$ —	$171,000
David Stevens, Ph.D. (6)	$ 98,000	$ 34,000	$ 20,000	$ —	$152,000

(1) On December 14, 2019, the date of the 2019 annual meeting, each of Messrs. Coelho and Giles and Drs. Bar-Or and Stevens was granted options to purchase 36,000 shares of common stock. These options have an exercise price of $0.465 per share. These options vest over the succeeding 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 11* to our financial statements included in this annual report on Form 10-K for the year ended December 31, 2019. Each of Messrs. Coelho and Giles and Dr. Stevens received additional value of Stock Option Awards in 2019 in connection with an option repricing program undertaken by the Company in September 2019 and further described in each of table notes (4), (5) and (6) below.

(2) On January 2, 2019, Messrs. Coelho, Giles and Dr. Stevens were each awarded 45,454 shares of common stock, at a price of $0.44 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 86,990 shares of common stock with a value of $120,000. On October 17, 2019, Dr. Bar-Or was awarded 45,228 shares of common stock, at a price of $0.4422, which was the closing price of our common stock on the date of grant per share, equivalent to $20,000. Since fiscal 2019, the aggregate number of stock awards to Dr. Bar-Or totaled 45,228 shares of common stock with a value of $20,000.

(3) Dr. Bar-Or became a non-employee director in October 2018 following his resignation from the position of CSO of the Company. The aggregate number of shares issuable upon exercise of option awards outstanding at December 31, 2019 for Dr. Bar-Or was 66,000, of which 30,000 were fully vested.

(4) Pursuant to an option repricing program undertaken by the Company in September 2019, 435,000 of Mr. Coelho’s options were cancelled and, in replacement thereof 369,750 options, which were fully vested upon grant, were issued. The value of the replacement stock option award was estimated using the Black-Scholes option pricing model and totaled $40,000. The aggregate number of shares issuable upon exercise of option awards outstanding at December 31, 2019 for Mr. Coelho was 656,304, of which 620,304 were fully vested.

(5) Pursuant to an option repricing program undertaken by the Company in September 2019, 430,000 of Mr. Giles’ options were cancelled and, in replacement thereof 365,500 options, which were fully vested upon grant, were issued. The value of the replacement stock option award was estimated using the Black-Scholes option pricing model and totaled $40,000. The aggregate number of shares issuable upon exercise of option awards outstanding at December 31, 2019 for Mr. Giles was 741,500, of which 705,500 were fully vested.

(6) Pursuant to an option repricing program undertaken by the Company in September 2019, 255,000 of Dr. Stevens’ options were cancelled and, in replacement thereof 216,750 options, which were fully vested upon grant, were issued. The value of the replacement stock option award was estimated using the Black-Scholes option pricing model and totaled $25,000. The aggregate number of shares issuable upon exercise of option awards outstanding at December 31, 2019 for Dr. Stevens was 342,750, of which 306,750 were fully vested.

Item 11. *Executive Compensation*

Executive Compensation

Named Executive Officers

For our fiscal year ended December 31, 2019, our Named Executive Officers were: (i) Michael Macaluso, our CEO, who has served as our CEO since January 2012, (ii) Daniel G. Stokely, our CFO, who has served as our CFO, Secretary and Treasurer since July 2019, (iii) Thomas E. Chilcott, our former CFO, Secretary and Treasurer who served as our CFO from June 2017 to June 2019, and (iv) Holli Cherevka, our current COO, who has served as our COO since September 2017. We had no other executive officers serving during the year ended December 31, 2019.

The following table shows for the fiscal years ended December 31, 2019 and December 31, 2018, 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)	All Other Compensation ($) (i)	Total ($) (j)
Named Executive Officers							
Michael Macaluso							
CEO, effective January 2012	2019	300,000	5,000	—	—	—	305,000
	2018	300,000	5,000	—	—	—	305,000
Daniel G. Stokely							
CFO, effective July 2019	2019	120,000 (2)	5,000	—	149,000 (2)	31,000 (2)	305,000
	2018	—	—	—	—	—	—
Thomas E. Chilcott							
Former CFO, resigned June 2019	2019	101,000 (3)	—	—	39,000 (3)	161,000 (3) (5)	301,000
	2018	225,000	30,000 (4)	—	34,000 (8)	—	289,000
Holli Cherevka							
COO, effective September 2017	2019	223,000 (6)	55,000 (7)	—	89,000 (6)	—	367,000
	2018	200,000	5,000	—	22,000 (8)	—	227,000

(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 11* to our financial statements included in this annual report on Form 10-K for the year ended December 31, 2019.

(2) Mr. Stokely was appointed CFO, effective July 2019, with an annual salary of $285,000. In connection with Mr. Stokely's employment, he was awarded 400,000 options with a fair value of $149,000. In addition, we have agreed to reimburse Mr. Stokely for certain commuting and housing expense up to a maximum of $6,000 per month for up to eight months. Of the $31,000 that was reimbursed for commuting and housing expense, $19,000 related to corporate housing, $9,000 related to traveling expense and $3,000 related to other expenses.

(3) Mr. Chilcott resigned from his position as CFO, Secretary and Treasurer, effective June 2019. In connection with his separation from the Company and the early termination of his employment agreement, Mr. Chilcott and the Company entered into a Separation Agreement, dated June 12, 2019 (the "Separation Agreement"). Under the Separation Agreement, Mr. Chilcott received severance pay in the amount of approximately $161,000, which was equivalent to (1) the amount of salary Mr. Chilcott would have received prior to the expiration of his employment agreement, plus (2) his earned and unused vacation benefits, plus (3) an additional six months of salary. Further, the Company agreed to accelerate the vesting of all of Mr. Chilcott's outstanding equity award grants, which would otherwise fully vest on June 15, 2019. Mr. Chilcott's outstanding stock options will remain exercisable until June 13, 2020. The incremental value of the modification of the stock option awards was estimated using the Black-Scholes option pricing model and totaled $39,000.

(4) Mr. Chilcott received a $25,000 bonus related to his performance during fiscal 2018.

(5) Mr. Chilcott was granted 75,000 options related to his performance during fiscal 2018, which had a fair value of $33,000.
(6) Ms. Cherevka entered into an employment agreement with the Company, effective September 2019, to continue her position as COO, at an annual salary of $280,000. In connection with Ms. Cherevka's employment, she was awarded 200,000 options with a fair value of $89,000.
(7) Ms. Cherevka received a $50,000 bonus related to her performance during fiscal 2019. She, and each of the other executives of the Company additionally received a $5,000 holiday bonus during fiscal 2019.
(8) 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 11* of the financial statements and within the Outstanding Equity Awards table contained in this section). The incremental value of repricing the options for Mr. Chilcott and Ms. Cherevka totaled $1,000 and $22,000, respectively.

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

Employment Agreements

We entered into an employment agreement with Mr. Michael Macaluso, CEO, 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.

On December 14, 2019, we entered into a new three-year employment agreement with Mr. Macaluso, which became effective on January 10, 2020 ("Start Date") immediately following the expiration of his prior employment agreement. In connection with his continued service as the Company's CEO and as a member of the Board, Mr. Macaluso will continue to receive an annual base salary of $300,000 with a term ending January 10, 2023. At the Start Date, Mr. Macaluso received a one-time equity award of 200,000 stock options at an exercise price per share equal to the closing price of the Company's common stock as reported on the New York Stock Exchange on the Start Date (50% of which will vest on the Start Date and 50% of which will vest on January 10, 2021). Mr. Macaluso will also be able to allocate incentive compensation to others through (i) a special cash bonus pool of $50,000, which he shall be able to allocate in his sole discretion to employees of the Company, and (ii) recommendations to the Compensation Committee of issuance of up to 100,000 stock options. Each of the cash and stock option bonus pools shall be fully allocated before December 31, 2020. As consideration for the incentive compensation pools, on the Start Date, Mr. Macaluso forfeited previously granted options to purchase 100,000 shares of common stock, which were originally granted on August 12, 2010 with an exercise price of $1.70 and were fully vested.

We entered into a three-year employment agreement with Mr. Daniel G. Stokely, CFO, and Corporate Secretary, on July 9, 2019 for his services beginning on July 31, 2019, which provided for an annual salary of $285,000 and a term ending July 31, 2022. In connection with the employment, Mr. Stokely was awarded 400,000 options to purchase common stock at an exercise price of $0.43, with 50% vesting upon grant and 50% after one year from effective date of employment. In addition, we initially agreed to reimburse Mr. Stokely for certain commuting and housing expense up to a maximum of $6,000 per month for up to six months. In December 2019, we extended the period of reimbursement for commuting and housing expenses for an additional two months.

We entered into an employment agreement with Mr. Thomas Chilcott, former CFO, on August 23, 2017, which provided for an annual salary of $200,000 and a term ending August 16, 2019. In connection with the employment agreement, Mr. Chilcott was awarded 200,000 options to purchase common stock at an exercise price of $0.48, with 50% vesting upon grant and 50% after one year from effective date of employment. On December 29, 2017, the Compensation Committee approved a salary increase for Mr. Chilcott of $25,000, effective January 1, 2018. On June 12, 2019, Mr. Chilcott resigned from his position as CFO, Secretary and Treasurer. Mr. Chilcott received severance pay of

approximately $161,000. In addition, Mr. Chilcott's outstanding stock options will remain exercisable for one year from his resignation date.

We entered into an employment agreement with Ms. Holli Cherevka, COO, on September 19, 2017, which provided for an annual salary of $200,000 and a term ending September 16, 2019. In connection with the 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 from effective date of employment. We entered into a new two-year employment agreement with Ms. Cherevka on September 16, 2019, which provides for an annual salary of $280,000 and has a term ending September 16, 2021. In connection with this new employment agreement, Ms. Cherevka was awarded 200,000 options to purchase Common Stock at an exercise price of $0.51, with 50% vesting upon grant and 50% after one year from effective date of employment.

Each officer is eligible to receive a discretionary annual bonus each year that will be determined by the Compensation Committee of the Board 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, and (ii) preparation and compliance with a fiscal budget. The targeted amount of the annual bonus for Mr. Macaluso, Mr. Stokely, 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, 2019:

	Option Awards					Stock Awards			
Name (a)	Number of Securities Underlying Unexercised Options Exercisable (#) (b)	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 Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#) (i)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($) (j)
Current Named Executive Officers									
Michael Macaluso	266,666	133,334 (1)	—	0.81	3/9/2027	—	—	—	—
Michael Macaluso	180,000	—	—	3.46	12/20/2024	—	—	—	—
Michael Macaluso	250,000	—	—	2.76	5/7/2022	—	—	—	—
Michael Macaluso	180,000	—	—	1.70	8/27/2020	—	—	—	—
Michael Macaluso	220,000	—	—	1.03	8/12/2020	—	—	—	—
Daniel G. Stokely	200,000	200,000 (2)	—	0.43	8/20/2029				
Thomas E. Chilcott	75,000	—	—	0.51	6/12/2020 (3)				
Thomas E. Chilcott	200,000	—	—	0.48	6/12/2020 (3)	—	—	—	—
Thomas E. Chilcott	100,000	— (3)	—	0.60	6/12/2020 (3)	—	—	—	—
Thomas E. Chilcott	75,000	—	—	0.75 (4)	6/12/2020 (3)	—	—	—	—
Holli Cherevka	100,000	100,000 (5)	—	0.51	9/16/2029				
Holli Cherevka	200,000	—	—	0.55	9/19/2027	—	—	—	—
Holli Cherevka	30,000	—	—	0.51	8/8/2027	—	—	—	—
Holli Cherevka	170,000	—	—	0.75 (4)	7/15/2026	—	—	—	—
Holli Cherevka	30,000	—	—	0.75 (4)	10/6/2024	—	—	—	—
Holli Cherevka	9,402	—	—	0.75 (4)	11/8/2023	—	—	—	—
Holli Cherevka	70,598	—	—	8.62	11/8/2023				
Holli Cherevka	45,000	—	—	0.75 (4)	4/2/2023	—	—	—	—
Holli Cherevka	35,000	—	—	0.75 (4)	1/14/2023	—	—	—	—

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

(2) The unexercisable options will become fully vested on July 31, 2020. The option awards remain exercisable until their expiration on the ten year anniversary of the date of grant subject to earlier forfeiture following termination of employment.

(3) In the separation agreement that we entered into with Mr. Chilcott, we agreed to accelerate the vesting of all of his outstanding equity award grants, which would have otherwise fully vested on June 15, 2019. Mr. Chilcott's outstanding stock options remain exercisable until June 12, 2020.
(4) These options were included in the one-time option repricing on October 1, 2018 (see further information in *Note 11* in the financial statements).
(5) The unexercisable options will become fully vested on September 16, 2020. The option awards remain exercisable until their expiration on the ten year anniversary of the date of grant subject to earlier forfeiture following termination of employment.

Potential Payments upon Termination or Change in Control

In June 2019, Mr. Chilcott resigned from his position as CFO of the Company and his employment terminated. In connection with his separation from the Company and early termination of his employment agreement, Mr. Chilcott and the Company entered into a Separation Agreement dated June 12, 2019 (the "Chilcott Separation Agreement"). Under the Chilcott Separation Agreement, Mr. Chilcott received approximately $161,000 of severance pay. Further, the Company agreed to accelerate the vesting of all of Mr. Chilcott's outstanding equity award grants, which would have otherwise vested on June 15, 2019. Mr. Chilcott's outstanding stock options remain exercisable until June 2020.

In July 2019, Mr. Stokely entered into an employment agreement with the Company (the "Stokely Agreement") and began his employment as the Company's new CFO. On September 16, 2019, Ms. Cherevka entered into a new employment agreement with the Company (the "Cherevka Employment Agreement") and on December 14, 2019, Mr. Macaluso entered into a new employment agreement that became effective on January 10, 2020 (the "Macaluso Employment Agreement", and collectively with the Stokely Employment Agreement and the Cherevka Employment Agreement, the "Executive Employment Agreements").

Under each of our Executive Employment Agreements, the respective member of our executive team (each, an "Executive"), if their employment is terminated without Cause, will be entitled to a lump sum severance payment equal to six months of his or her base salary in effect at the date of termination, less applicable withholding and certain offsetting payments (including offsets for any and all compensation that he or she may receive from other employment subsequent to his or her employment with the Company pursuant to a duty to mitigate such severance payment). In addition, the vesting and exercisability of all then outstanding equity awards (excluding the performance-based awards) held by our Executive will accelerate in full. Any performance-based award held by such Executive shall become vested and exercisable only if the applicable performance-based criteria are satisfied at the end of the applicable period relating to such award, at which time such performance-based award shall become vested and exercisable on a pro-rated basis by multiplying such award by a fraction, the numerator of which is the number of full months such executive was employed by the Company during the applicable performance period, and the denominator of which is the total number of months in such performance period. Any performance-based award for which the performance criteria are not satisfied within the applicable performance period shall terminate at the end of such period. If our Executive terminates his or her employment for Good Reason, such Executive will be entitled to three months of his or her base salary less applicable taxes and withholdings. All severance payments, less applicable taxes and withholdings, are subject to Our Executive's execution and delivery of a general release in a form acceptable to us, and is further conditioned upon complying with the confidentiality, non-solicitation, non-competition, intellectual property and post-termination cooperation obligations under his employment agreement. If the employment is terminated for Cause, no severance shall be payable by us.

"Good Reason" means, without our Executives written consent:

- a material reduction of his or her compensation (except where there is a general reduction also applicable to the other members of the senior executive team); or

- a material reduction in his or her overall responsibilities or authority or scope of duties (it being understood that the occurrence of a change in control shall not, by itself, necessarily constitute a reduction in his or her responsibilities or authority).

"Cause" means, in the sole discretion of a majority of membership of the Board:

- Our Executives failure or refusal to substantially perform his or her duties;

- personal or professional dishonesty that could reasonably be expected to have a materially adverse impact on the financial interests or business reputation of the Company;
- incompetence, willful misconduct, breach of fiduciary duty (including duties involving personal profit);
- breach of the Company's Code of Business Conduct and Ethics and personnel policies or compliance policies;
- material violation of the Sarbanes-Oxley requirements for officers of public companies that in the reasonable opinion of the Board will likely cause substantial financial harm or substantial injury to the reputation of the Company;
- willfully engaging in actions that in the reasonable opinion of the Board will likely cause substantial financial harm or substantial injury to the business reputation of the Company;
- willful violation of any law, rule, or regulation, or final cease-and-desist order (other than routine traffic violations or similar offenses);
- the unauthorized use or disclosure of any trade secret, proprietary, or confidential information of the Company (or any other party as to which our Executive owes an obligation of nondisclosure as a result of his or her relationship with the Company);
- failure to follow the reasonable and lawful directives of the CEO or the Board pertaining to his or her duties with the Company;
- commission of an act of fraud, embezzlement, or misappropriation by our Executive with respect to his or her relations with the Company or any of its employees, customers, agents, or representatives; or
- any material breach of any provision of the employment agreement with our Executive.

Our employment agreements with our Executives do not provide for the payment of a "gross-up" payment under Section 280G of the Code.

Recipient and Benefit	Cause; Without Good Reason;	Without Cause; Good Reason	Death; Disability	Change in Control
Michael Macaluso				
Salary	$ —	$ 150,000	$ —	$ —
Stock Options (1)	—	—	—	—
Total	$ —	$ 150,000	$ —	$ —
Daniel G. Stokely				
Salary	$ —	$ 142,500	$ —	$ —
Stock Options (1)	—	60,000	—	—
Total	$ —	$ 202,500	$ —	$ —
Holli Cherevka				
Salary	$ —	$ 140,000	$ —	$ —
Stock Options (1)	—	22,000	—	—
Total	$ —	$ 162,000	$ —	$ —

(1) Amounts represent the intrinsic value (that is, the value based upon the company's stock price on December 31, 2019 of $0.58 per share), minus the exercise price of the equity awards that would have become exercisable as of December 31, 2019.

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 February 14, 2020 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 February 14, 2020.

For purposes of calculating each person's or group's percentage ownership, stock options and warrants exercisable within 60 days after February 14, 2020 are included for that person or group but not the stock options or warrants of any other person or group. Ownership is based on 158,780,993 shares of common stock outstanding at February 14, 2020.

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		
Empery Asset Management, LP (2) 1 Rockefeller Plaza, Suite 1205 New York, NY 10020	12,827,571	8.1 %
CVI Investments, Inc. (3) C/O Heights Capital Management, Inc. 101 California Street, Suite 3250 San Francisco, CA 94111	12,454,835	7.8 %
Bruce Terker (4) 950 W. Valley Road, Suite 2900 Wayne, PA 19087	11,525,331	7.3 %
Directors and Name Executive Officers		
Michael Macaluso (5)	3,016,752	1.9 %
David Bar-Or (6)	118,287	0.1 %
Richard B. Giles (7)	1,068,108	0.6 %
Philip H. Coelho (8)	819,291	0.5 %
Holli Cherevka (9)	690,000	0.4 %
Thomas Chilcott (10)	450,000	0.3 %
David R. Stevens (11)	436,799	0.3 %
Daniel G. Stokely (12)	215,000	0.1 %
Directors and executive officers as a group (eight people)	6,814,237	4.2 %

(1) Based on shares issued and outstanding as the most recent practicable date, February 14, 2020.
(2) Based on a Schedule 13G filed on January 23, 2020 by Empery Asset Management, LP.
(3) Based on a Schedule 13G filed on February 14, 2019 by CVI Investments, Inc. and 6,250,000 shares of common stock issued as a result of a warrant exercise on October 29, 2019. Amount also includes warrants to purchase 600,000 shares that are exercisable within 60 days of February 14, 2020.
(4) Based solely on a Schedule 13G filed on January 7, 2020 by Bruce Terker, reporting beneficial ownership as of December 31, 2019.
(5) Includes options to purchase 1,230,000 shares that are exercisable within 60 days of February 14, 2020.
(6) Includes options to purchase 39,000 shares that are exercisable within 60 days of February 14, 2020.
(7) Includes options to purchase 714,500 shares that are exercisable within 60 days of February 14, 2020.
(8) Includes options to purchase 629,304 shares that are exercisable within 60 days of February 14, 2020.
(9) Includes options to purchase 690,000 shares that are exercisable within 60 days of February 14, 2020.
(10) In June 2019, Mr. Chilcott resigned from his position as Chief Financial Officer. Amount includes options to purchase 450,000 shares that are exercisable within 60 days of February 14, 2020.
(11) Includes options to purchase 315,750 shares that are exercisable within 60 days of February 14, 2020.
(12) In July 2019, Mr. Stokely was appointed to the position as Chief Financial Officer. Amount includes options to purchase 215,000 shares that are exercisable within 60 days of February 14, 2020.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth information regarding securities authorized for issuance under equity compensation plans as of December 31, 2019:

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights (#)	(b) Weighted average exercise price of outstanding options, warrants and rights ($)	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (#)
Equity compensation plans approved by stockholders	13,116,856	1.33	9,856,000
Equity compensation plans not approved by stockholders	-	-	-
Total	13,116,856	1.33	9,856,000

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, 2019 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 a policy that our executive officers, directors, nominees for election as directors, beneficial owners of more than 5% of any class of our common stock and any member of the immediate family of any of the foregoing persons, are not permitted to enter into a related party transaction with us without the prior consent of our Audit Committee, subject to the pre-approval exceptions described below. If advance approval is not feasible then the related party transaction will be considered at the Audit Committee’s next regularly scheduled meeting. In approving or rejecting any such proposal, our Audit Committee is to consider the relevant facts and circumstances available and deemed relevant 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 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 be independent. The rules of the NYSE American require that, subject to specified exceptions, each member of our Audit, Compensation, and Nominating and Governance be independent. Audit Committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. 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.

In October 2019, our Board undertook a review of its composition, the composition of its committees and the independence of each director. Based upon information provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board has determined that none of Messrs. Coelho, Giles or 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 also determined that Messrs. Giles, Coelho and Dr. Stevens, who comprise our Audit Committee, our Compensation Committee, and our Nominating and Governance Committee, satisfy the independence standards for those committees established by applicable SEC rules and the NYSE American rules. In making this determination, our Board considered the relationships that each non-employee director has with our company and all other facts and circumstances our Board deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

Item 14. ***Principal Accountant Fees and Services***

As disclosed in *Part II, Item 9 Changes in and Disagreements with Accountants on Accounting and Financial Disclosure*, we appointed Moss Adams LLP as the Company's independent registered public accounting firm for the Company's fiscal year ended December 31, 2019. In conjunction with the appointment of Moss Adams LLP on July 10, 2019, Plante Moran notified the Company of its resignation as the Company's independent registered public accounting firm, effective July 10, 2019.

The following tables present aggregate fees accrued for professional services rendered by our independent registered public accounting firms, both Moss Adams LLP and Plante Moran for the respective periods.

	Year Ended December 31,	
	2019	2018
Moss Adams LLP		
Annual Audit and Quarterly Review Fees	$212,000	$ —
Audit-related fees (1)	—	—
Tax fees (2)	—	—
Total fees	$212,000	$ —

	Year Ended December 31, 2019	2018
Plante Moran, PLLC		
Annual Audit and Quarterly Review Fees	$30,000	$238,000
Audit-related fees (1)	—	—
Tax fees (2)	15,000	16,000
Total fees	$45,000	$254,000

(1) Audit-related service fees would include employee benefit plan audits, due diligence related to mergers and acquisitions, accounting consultations and audits in connection with acquisitions, attest services related to financial reporting that are not required by statute or regulation and consultation concerning financial accounting and reporting standards. The Company did not incur expenses related to audit related services fees for the years ended December 31, 2019 or 2018,
(2) Tax service fees are comprised of federal and state services related to tax compliance, consulting 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 fees for services that generally only the auditor reasonable can provide, such as statutory auditors required domestically and internationally (including statutory audits required for insurance companies for purposes of state law); comfort letters; consents; assistance with and review of documents filed with the SEC; section 404 attestation services; other attest services that generally only the auditor can provide; work done by tax professionals for the audit or quarterly review; and accounting consultations billed as audit services, as well as other accounting and financial reporting consultation and research work necessary to comply with the standards of the PCAOB.

Audit-related services include, among others: employee benefit plan audits, due diligence related to mergers and acquisitions, accounting consultations and audits in connection with acquisitions, internal control reviews, attest services related to financial reporting that are not required by statute or regulation and consultation concerning financial accounting and reporting standards.

Tax services consist principally of assistance with federal and state 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.

All of the services of Moss Adams LLP and Plante Moran described above were pre-approved by the Audit Committee.

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.

- Reports of Independent Registered Public Accounting Firms
- Balance Sheets as of December 31, 2019 and 2018
- Statements of Operations for the years ended December 31, 2019 and 2018
- Statements of Stockholders' Equity for the years ended December 31, 2019 and 2018
- Statements of Cash Flows for the years ended December 31, 2019 and 2018
- 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. (Incorporated by reference from Registrant's Form 8-K filed March 8, 2010)
2.2	Securities Put and Guarantee Agreement dated March 2, 2010. (Incorporated by reference from Registrant's Form 8-K filed March 8, 2010)
3.1*	Certificate of Incorporation of the Registrant, as currently in effect.
3.2	Plan of Conversion of Chay Enterprises, Inc. to a Delaware corporation. (Incorporated by reference from Registrant's Form 8-K filed March 30, 2010)
3.3	Amended and Restated Bylaws of the Registrant, as currently in effect. (Incorporated by reference from Registrant's Form 10-Q filed November 14, 2018)
4.1	Specimen Common Stock Certificate of the Registrant. (Incorporated by reference from Registrant's Registration Statement on Form S-4 filed January 7, 2011)
4.2	Form of Warrant to Purchase Common Stock. (Incorporated by reference from Registrant's Form 8-K filed on August 29, 2016)
4.3	Form of Warrant to Purchase Common Stock. (Incorporated by reference from Registrant's Form 8-K filed on August 29, 2016)
4.4	Form of Warrant. (Incorporated by reference from Registrant's Form 8-K filed on August 13, 2018)
4.5	Description of Capital Stock of Ampio Pharmaceuticals, Inc.
10.1	Form of Director and Executive Officer Indemnification Agreement. (Incorporated by reference from Registrant's Form 8-K/A filed March 17, 2010)
10.2**	2010 Stock Incentive Plan and forms of option agreements. (Incorporated by reference from Registrant's Form 8-K/A filed March 17, 2010)
10.3**	Amendment of 2010 Stock and Incentive Plan. (Incorporated by reference from Registrant's Proxy Statement on Form 14A filed November 1, 2013)
10.4***	Sponsored Research Agreement dated September 1, 2009. (Incorporated by reference from Registrant's Form 8-K/A filed March 17, 2010)
10.5**	Employment Agreement, effective January 10, 2020 by and between Ampio Pharmaceuticals, Inc. and Michael Macaluso. (Incorporated by reference from Registrant's Form 8-K filed December 18, 2019)
10.6	Securities Purchase Agreement by and among Ampio Pharmaceuticals, Inc. and the Buyer (as defined therein), dated June 17, 2019. (Incorporated by reference from Registrant's Form 8-K filed June 17, 2019)
10.7	Lease Agreement by and between Ampio Pharmaceuticals, Inc. and NCWP – Inverness Business Park, LLC, dated December 13, 2013. (Incorporated by reference from Registrant's Form 8-K filed December 19, 2013)
10.8***	Human Serum Albumin Ingredient Purchase and Sale Agreement by and between Ampio Pharmaceuticals, Inc. and Supplier, dated October 10, 2013. (Incorporated by reference from Registrant's Form 10-K/A filed May 23, 2014)

10.9*, ***	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. (Incorporated by reference from Registrant's Form 8-K filed October 20, 2015)
10.10	Amendment No. 2 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. (Incorporated by reference from Registrant's Form 8-K filed October 20, 2015)
10.11 *	Amendment No. 3 to Human Serum Albumin Ingredient Purchase and Sale Agreement among Ampio Pharmaceuticals, Inc., Octapharma USA, Inc. and Nova Biologics, Inc., effective as of November 14, 2017.
10.12**	Employment Agreement between Ampio Pharmaceuticals, Inc. and Holli Cherevka, dated September 16, 2019. (Incorporated by reference from Registrant's Form 8-K filed September 20, 2019)
10.13**	Employment Agreement between Ampio Pharmaceuticals, Inc. and Daniel Stokely, dated July 9, 2019. (Incorporated by reference from Registrant's Form 8-K filed July 10, 2019)
10.14**	Amendment to Employment Agreement between Ampio Pharmaceuticals, Inc. and Daniel Stokely, dated August 20, 2019. (Incorporated by reference from Registrant's Form 8-K filed August 23, 2019)
10.15**	Stock Option Cancellation and Grant Agreement for Executive between Ampio Pharmaceuticals, Inc. and Daniel Stokely, dated August 20, 2019. (Incorporated by reference from Registrant's Form 8-K filed August 23, 2019)
10.16**	Letter dated November 7, 2019 re: Administrative Error in the Stock Option Cancellation and Grant Agreement for Executive between Ampio Pharmaceuticals, Inc. and Daniel Stokely, dated August 20, 2019. (Incorporated by reference from Registrant's Form 10-Q filed November 7, 2019)
10.17**	Separation Agreement between Ampio Pharmaceuticals, Inc. and Thomas Chilcott, III. (Incorporated by reference from Registrant's Form 8-K filed June 13, 2019)
10.18	Equity Distribution Agreement, dated April 12, 2019 between Ampio Pharmaceuticals, Inc. and Canaccord Genuity LLC. (Incorporated by reference from Registrant's Form 8-K filed on April 15, 2019)
10.19	Form of Lock-Up Agreement (Incorporated by reference from Registrant's Form 8-K filed June 17, 2019)
10.20	Placement Agency Agreement, dated June 17, 2019, by and among Ampio Pharmaceuticals, Inc. and ThinkEquity, a division of Fordham Financial Management, Inc. (Incorporated by reference from Registrant's Form 8-K filed June 17, 2019)
10.21	Warrant Exercise Agreement, dated as of October 28, 2019, between Ampio Pharmaceuticals, Inc. and the Holder (as defined therein). (Incorporated by reference from Registrant's Form 8-K filed October 29, 2019)
14.1*	Code of Business Conduct and Ethics.
16.1	Letter from Plante & Moran PLLC Regarding Change in Certifying Accountant, dated July 11, 2019. (Incorporated by reference from Registrant's Form 8-K filed July 11, 2019)
23.1*	Consent of Moss Adams LLP.
23.2*	Consent of Plante & Moran PLLC.
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, 2019 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.

* 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

SIGNATURES

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

AMPIO PHARMACEUTICALS, INC.

Date: February 21, 2020

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 February 21, 2020.

Signature	Title
/s/ Michael Macaluso Michael Macaluso	Chairman of the Board and Chief Executive Officer
/s/ Daniel G. Stokely Daniel G. Stokely	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.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of

Ampio Pharmaceuticals, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying balance sheet of Ampio Pharmaceuticals, Inc. (the "Company") as of December 31, 2019, the related statements of operations, stockholders' equity and cash flows for the year then ended, 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, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO").

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, 2019, and the results of its operations and its cash flows for the year then ended, 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, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by COSO.

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 negative cash flows from operations, and has an accumulated deficit, that raises 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.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company changed its method of accounting for leases effective January 1, 2019 due to the adoption of Accounting Standards Codification (ASC) 842.

Basis for Opinions

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 included in Item 9A. 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 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, 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 to 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 audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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/ Moss Adams LLP

Denver, Colorado

February 20, 2020

We have served as the Company's auditor since 2019.

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.

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 served as the Company’s auditor from 2010 to 2019.

Denver, Colorado

March 18, 2019

AMPIO PHARMACEUTICALS, INC.

Balance Sheets

	December 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 6,532,000	$ 7,585,000
Prepaid expenses and other	1,718,000	447,000
Total current assets	8,250,000	8,032,000
Fixed assets, net	4,748,000	5,998,000
Right-of-use asset	1,003,000	—
Total assets	$ 14,001,000	$ 14,030,000
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued expenses	$ 4,025,000	$ 1,324,000
Lease liability-current portion	259,000	60,000
Total current liabilities	4,284,000	1,384,000
Lease liability-long-term	1,210,000	477,000
Warrant derivative liability	2,064,000	6,933,000
Total liabilities	7,558,000	8,794,000
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred Stock, par value $0.0001; 10,000,000 shares authorized; none issued	—	—
Common Stock, par value $0.0001; 300,000,000 shares authorized as of 2019 and 200,000,000 shares authorized as of 2018; shares issued and outstanding - 158,644,757 as of December 31, 2019 and 110,941,516 as of December 31, 2018	16,000	11,000
Additional paid-in capital	191,060,000	176,228,000
Accumulated deficit	(184,633,000)	(171,003,000)
Total stockholders' equity	6,443,000	5,236,000
Total liabilities and stockholders' equity	$ 14,001,000	$ 14,030,000

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

AMPIO PHARMACEUTICALS, INC.

Statements of Operations

	Year Ended December 31, 2019	2018
Operating expenses		
Research and development	$ 12,622,000	$ 6,829,000
General and administrative	5,954,000	4,355,000
Total operating expenses	18,576,000	11,184,000
Other income (expense)		
Interest income (expense)	77,000	(5,000)
Derivative gain	4,869,000	45,298,000
Loss from disposal of fixed assets	—	(123,000)
Total other income (expense)	4,946,000	45,170,000
Net (loss) income	$ (13,630,000)	$ 33,986,000
Net (loss) income per common share:		
Basic	$ (0.10)	$ 0.46
Diluted	$ (0.14)	$ (0.12)
Weighted average number of common shares outstanding:		
Basic	130,601,500	73,358,034
Diluted	131,135,178	91,091,879

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

AMPIO PHARMACEUTICALS, INC.

Statements of Stockholders' Equity

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at December 31, 2017	80,060,345	$ 8,000	$ 170,804,000	$ (204,989,000)	$ (34,177,000)
Issuance of common stock for services	17,241	—	60,000	—	60,000
Stock-based compensation, net	—	—	444,000	—	444,000
Issuance of common stock in connection with the public offering, net of offering costs of $844,000	20,000,000	2,000	(2,000)	—	—
Options exercised, net	348,783	—	636,000	—	636,000
Warrants exercised	10,515,147	1,000	4,286,000	—	4,287,000
Net income	—	—	—	33,986,000	33,986,000
Balance at December 31, 2018	110,941,516	$ 11,000	$ 176,228,000	$ (171,003,000)	$ 5,236,000
Issuance of common stock for services	181,590	—	80,000	—	80,000
Stock-based compensation, net	—	—	405,000	—	405,000
Issuance of common stock in connection with the equity distribution agreement	254,984	—	142,000	—	142,000
Offering costs related to the issuance of common stock in connection with the equity distribution agreement	—	—	(144,000)	—	(144,000)
Issuance of common stock in connection with the public offering, net of offering costs of $1,243,000	30,000,000	3,000	10,754,000	—	10,757,000
Warrants exercised, net of offering costs of $277,000	17,266,667	2,000	3,595,000	—	3,597,000
Net loss	—	—	—	(13,630,000)	(13,630,000)
Balance at December 31, 2019	158,644,757	$ 16,000	$ 191,060,000	$ (184,633,000)	$ 6,443,000

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

AMPIO PHARMACEUTICALS, INC.

Statements of Cash Flows

	Year Ended December 31, 2019	2018
Cash flows from operating activities		
Net (loss) income	$ (13,630,000)	$ 33,986,000
Adjustments to reconcile net (loss) income to net cash used in operating activities		
Stock-based compensation, net	405,000	444,000
Depreciation and amortization	1,272,000	1,281,000
Loss from disposal of fixed assets	—	123,000
Issuance of common stock for services	80,000	60,000
Derivative gain	(4,869,000)	(45,298,000)
Changes in operating assets and liabilities		
Increase in prepaid expenses and other	(1,271,000)	(179,000)
Increase (decrease) in accounts payable and accrued expenses	2,700,000	(2,495,000)
Decrease in lease liability	(70,000)	(61,000)
Net cash used in operating activities	(15,383,000)	(12,139,000)
Cash flows used in investing activities		
Purchase of fixed assets	(22,000)	(564,000)
Net cash used in investing activities	(22,000)	(564,000)
Cash flows from financing activities		
Proceeds from sale of common stock in connection with the equity distribution agreement	142,000	—
Costs related to sale of common stock in connection with the equity distribution agreement	(144,000)	—
Proceeds from sale of common stock in connection with the public offering	12,000,000	8,000,000
Costs related to sale of common stock in connection with the public offering	(1,243,000)	(844,000)
Proceeds from warrant exercises	3,874,000	4,287,000
Costs related to warrant exercises	(277,000)	
Proceeds from option exercises	—	636,000
Net cash provided by financing activities	14,352,000	12,079,000
Net change in cash and cash equivalents	(1,053,000)	(624,000)
Cash and cash equivalents at beginning of period	7,585,000	8,209,000
Cash and cash equivalents at end of period	$ 6,532,000	$ 7,585,000
Non-cash transactions:		
Initial lease liability arising from the adoption of ASU 2016-02	$ 1,704,000	$ —
Initial recognition of right-of-use asset arising from the adoption of ASU 2016-02	1,168,000	—
Warrant derivative liability in connection with the public offering	—	8,009,000

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

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 pre-revenue clinical stage biopharmaceutical company, located in Englewood, CO, that is focused primarily on developing Ampion. Ampion is a compound that has been shown in pre-clinical and clinical studies to decrease inflammation by inhibiting specific pro-inflammatory compounds.

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

Note 2 – Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses, and related disclosures in the financial statements and accompanying notes. The Company bases its estimates on historical experience and on other assumptions believed to be reasonable under the circumstances. Significant items subject to such estimates and assumptions include the clinical trial accrual, going concern position, warrant derivative liability and related gains and losses, stock-based compensation, the projected useful lives and potential impairment of fixed assets, and the valuation allowance related to deferred tax assets.

Cash and Cash Equivalents

The Company considers 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.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents. The Company has no off-balance-sheet concentrations of credit risk, such as foreign exchange contracts, option contracts, or foreign currency hedging arrangements. The Company maintains cash and cash equivalent balances in the form of bank demand deposits and money market fund accounts with financial institutions that management believes are creditworthy. The Company periodically monitors its positions with, and the credit quality of, the financial institutions with which it invests. During the years ended as of December 31, 2019 and 2018, the Company has maintained balances in excess of federally insured limits.

Concentration of Supplier

The Company currently only contracts with one supplier to obtain the HSA needed to produce Ampion for clinical trials. The Company believes there are numerous other suppliers that could be substituted should the supplier become non-competitive.

Fixed Assets

Fixed assets are stated at cost less accumulated depreciation and amortization. Cost includes expenditures for equipment, leasehold improvements, replacements, and renewals. Maintenance and repairs are charged to expense as incurred. When assets are sold, retired, or otherwise disposed of, the cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is reflected in operations. The cost of property and equipment is depreciated

using the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized over the remaining life of the lease.

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, 2019 and 2018, no impairment existed for long-lived assets.

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, accounts payable and accrued expenses are carried at cost, which approximates fair value due to the short maturity of these instruments. The warrant derivative liability is recorded at estimated fair value based on utilization of the Black-Scholes and Monte Carlo warrant pricing models depending on facts and circumstances. See *Notes 8 and Note 9* for additional information on the warrant derivative liability.

Stock-Based Compensation

The Company accounts for share based payments by recognizing compensation expense based upon the estimated fair value of the stock options on the date of grant. The Company determines the estimated fair value of the stock options granted 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.

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.

Clinical Trial Accrual

The clinical trial accrual involves identifying services that third parties have performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for these services which remain uninvoiced as of the balance sheet date. In addition, the clinical trial accrual involves the measurement of milestone achievements achieved by the patients participating in the clinical trial and the associated costs which have not been invoiced as of the balance sheet date. The Company develops estimates of liabilities using its judgment based upon the facts and circumstances known at the time.

Research and Development

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

Adoption of Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-02, *"Leases (Topic 842)"*. The new standard established 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 finance and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. 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 other options for transition. The additional options for transition allowed 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 were effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years.

The Company adopted ASC 842 effective January 1, 2019 and elected to adopt the practical expedient permitted by ASU 2018-11 during the first quarter of 2019. As a result of the adoption, on January 1, 2019, the Company recognized a lease liability of approximately $1.7 million, which represented the present value of the remaining minimum lease payments using an estimated incremental borrowing rate of 5.75%. The Company also derecognized the lease liability as of December 31, 2018 of approximately $540,000 and recognized a ROU asset of approximately $1.2 million. Lease expense did not change materially as a result of the adoption of ASU 2016-02.

In June 2018, the FASB issued ASU 2018-07, *"Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting"*. ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions used to acquire goods and services from non-employees. Companies should apply the requirements of Topic 718 to non-employee awards except for certain exemptions specified in the amendment. The guidance was 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 adopted ASU 2018-07 during the first quarter of 2019 and the adoption of this guidance did not have a material impact on the Company's 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 were effective upon the issuance of this standard. A majority of the amendments in ASU 2018-09 were effective for fiscal years beginning after December 15, 2018. The Company adopted ASU 2018-09 during the first quarter of 2019 and the adoption of this guidance did not have a material impact on the Company's financial statements.

In July 2019, the FASB issued ASU 2019-07, *"Codification Updates to SEC Sections - Amendments to SEC Paragraphs Pursuant to SEC Final Rule Releases No. 33-10532, Disclosure Update and Simplification, and Nos. 33-10231 and 33-10442, Investment Company Reporting Modernization and Miscellaneous Updates (SEC Update)*." The updated guidance clarifies or improves the disclosure and presentation requirements of a variety of codification topics by aligning them with the SEC's regulations, thereby eliminating redundancies and making the codification easier to apply. This ASU is effective upon issuance and did not have a significant impact on the Company's financial statements and related disclosures.

Recent Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, *"Fair Value Measurement - Disclosure Framework (Topic 820)*". The updated guidance modified 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, however the Company has not yet adopted this ASU.

When adopted, the Company does not expect the adoption of this ASU to have a significant impact on its financial statements.

Note 3 – Going Concern

As of the year ended December 31, 2019, the Company had cash and cash equivalents of $6.5 million and a net loss of $13.6 million. The Company's working capital was $4.0 million, of which $1.7 million relates to prepaid expenses, as of December 31, 2019. The net loss is primarily attributable to operating expenses of $18.6 million, offset by the non-cash derivative gain of $4.9 million and $77,000 of interest income that was recognized during the year ended December 31, 2019. The Company used net cash in operations of $15.4 million for the year ended December 31, 2019. As of December 31, 2019, the Company had an accumulated deficit of $184.6 million and stockholders' equity of $6.4 million. In addition, as a pre-revenue clinical stage biopharmaceutical company, the Company has not generated any revenues or profits to date. These existing and on-going factors continue to raise substantial doubt about the Company's ability to continue as a going concern.

During the year ended December 31, 2019, the Company conducted a public offering of its securities through which it raised net proceeds of $10.8 million (see *Note 10*). In addition, the Company received net proceeds of $3.6 million from the exercise of investor warrants (see *Note 9)*. The Company has prepared an updated projection covering the period from January 1, 2020 through March 31, 2021 based on the requirements of ASC 205-40, "*Going Concern*", which reflects cash requirements for the on-going expenses for the base level of the business, which includes the current level of employees and corporate support level costs such as payroll, legal and accounting, patents and overhead at an average cash burn rate of approximately $900,000 per month. The Company's projection also reflects an appropriation of additional funds for regulatory approvals related to the completion and filing of the BLA with the FDA and, completion of the current AP-013 study (assuming injection of 1,034 patients) which is projected to be approximately $900,000 per month through the second quarter of 2020, which then decreases to $300,000 per month from the third quarter of 2020 through the fourth quarter of 2020. Based on the current projections, the Company expects that current cash resources and operating cash flows will be sufficient to sustain operations into the second quarter of 2020. The ability of the Company to continue its operations beyond this point is dependent on its ability to satisfy the Company's future cash needs, including but not limited to, private or public sales of securities, option/warrant exercises, structured debt financings and/or partnering/licensing transactions. In February 2020, the Company entered into a Sales Agreement with two agents to implement an "at-the-market" equity offering program under which the Company may issue and sell from time to time shares of its common stock (see *Note 16*). However, there is no assurance that the Company will be successful in satisfying its future cash needs such that the Company will be able to continue operations.

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 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 – Prepaid Expenses and Other

Prepaid expenses and other balances in the respective periods is as follows:

	December 31, 2019	December 31, 2018
Clinical trial deposit	$ 946,000	$ —
Insurance premiums	502,000	164,000
Biologics License Application ("BLA") consulting services deposit	182,000	182,000
Lease deposit	34,000	34,000
Other	29,000	48,000
Annual service agreements	25,000	19,000
Total prepaid expenses and other	$ 1,718,000	$ 447,000

Note 5 – Fixed Assets

Fixed assets consist of the following:

	Estimated Useful Lives in Years	As of December 31, 2018	Additions	Disposals	As of December 31, 2019
Manufacturing facility/clean room	3 - 8	$ 3,077,000	$ 4,000	$ —	$ 3,081,000
Leasehold improvements	10	6,075,000	—	—	6,075,000
Office furniture and equipment	5 - 10	511,000	9,000	—	520,000
Lab equipment	5 - 8	1,128,000	9,000	—	1,137,000
Less accumulated depreciation and amortization		(4,793,000)	(1,272,000)	—	(6,065,000)
Fixed assets, net		$ 5,998,000	$ (1,250,000)	$ —	$ 4,748,000

Depreciation expense for the respective periods is as follows:

	Year Ended December 31, 2019	2018
Depreciation Expense	$ 1,272,000	$ 1,281,000

Note 6 – Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses in the respective periods is as follows:

	December 31, 2019	December 31, 2018
Accounts payable	$ 151,000	$ 706,000
Clinical trial	3,288,000	407,000
Professional fees	317,000	99,000
Property taxes	96,000	97,000
Accrued compensation	72,000	—
Other	30,000	—
BLA consulting services	28,000	15,000
Director fees	22,000	—
Insurance premiums	21,000	—
Accounts payable and accrued expenses	$ 4,025,000	$ 1,324,000

Note 7 – Commitments and Contingencies

The following table summarizes the commitments and contingencies as of December 31, 2019 which are described below:

	Total	2020	2021	2022	2023	2024	Thereafter
Key clinical research trial obligations	$ 4,990,000	$ 4,990,000	$ —	$ —	$ —	$ —	$ —
BLA consulting services	1,143,000	1,143,000	—	—	—	—	—
Statistical analysis and programming consulting services	368,000	368,000	—	—	—	—	—
Employment agreements	2,145,000	883,000	783,000	466,000	13,000	—	—
Insurance premiums	21,000	21,000	—	—	—	—	—
	$ 8,667,000	$ 7,405,000	$ 783,000	$ 466,000	$ 13,000	$ —	$ —

Key Clinical Research Trial Obligations

In March 2019, the Company entered into a contract with a clinical research organization ("CRO") in connection with the AP-013 study for Ampion totaling $6.2 million and covering an initial trial size of 724 patients, which was subsequently increased by $4.1 million in January 2020 as a result of an increase in number of patients to 1,034. Therefore, the CRO contract totals $10.3 million. The Company had incurred and accrued cumulative costs totaling $5.9 million against the contract as of December 31, 2019. The amended contract has an outstanding obligation of $4.4 million as of December 31, 2019. The following table provides further detail of the CRO contract:

	December 31, 2019
Original contract	$ 6,180,000
Amendment to contract	4,075,000
Total Contract	$ 10,255,000
Initial deposit (included in original contract amount)	$ 861,000
Amendment to deposit	325,000
Expenses incurred applied to deposit	(240,000)
Remaining Deposit	$ 946,000
Expenses incurred/accrued (includes expenses applied to deposit)	$ 5,890,000
Total future commitment	$ 4,365,000

In June 2019, the Company entered into a contract with a patient recruitment services company in connection with the AP-013 study for Ampion totaling $264,000. In September 2019, the Company finalized contract negotiations to increase the contract from $264,000 to $377,000 as a result of an increased number of patients, from 724 to 1,034, required for the trial. The Company estimates that there will be an additional $20,000 to be incurred relating to printing supply for this contract. Therefore, the Company expects the contract to total $397,000. The Company has incurred cumulative costs under the current contract totaling $309,000 and had an outstanding obligation of $88,000 as of December 31, 2019.

In November 2019, the Company entered into a contract with clinical staff outsourcing firm to assist with the clinical trial, with an estimated cost totaling approximately $650,000. The Company had incurred and accrued cumulative costs

under the current contract totaling $113,000 and had outstanding future obligations totaling $537,000 as of December 31, 2019.

BLA Consulting Services

In March 2018, the Company entered into a BLA consulting services agreement for $1.2 million. This contract required a deposit of $364,000, of which $182,000 was funded and is recorded within the prepaids and other expense line item on the balance sheet. The Company incurred cumulative costs totaling $69,000 against this contract and had outstanding obligations totaling $1.1 million as of December 31, 2019. This contract does not have an expiration date. The Company incurs costs under the contract as sections of the BLA are drafted for the submission of the complete BLA to the U.S. Food and Drug Administration ("FDA").

Statistical Analysis and Programming Consulting Services

In May 2019, Ampio entered into a statistical analysis and programming consulting services agreement for $578,000, which had an outstanding obligation of $368,000 as of December 31, 2019. The Company had incurred cumulative costs totaling $210,000 against the contract as of December 31, 2019.

Employment Agreements

The Company entered into an employment agreement with Mr. Michael Macaluso, 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, the Company increased Mr. Macaluso's annual salary from $195,000 to $300,000. On December 20, 2014, the Company extended the employment agreement of Mr. Macaluso for three additional years, expiring January 9, 2017. On March 9, 2017, the Company extended his employment agreement with an expiration date of January 9, 2020. The Company entered into a new employment agreement with Mr. Macaluso during December 2019, effective January 10, 2020. The new employment agreement provides for an annual salary of $300,000 and term ending January 10, 2023, subject to certain automatic renewal provisions.

The Company entered into an employment agreement with Ms. Holli Cherevka, Chief Operating Officer, on September 19, 2017, which provided for an annual salary of $200,000, with an initial term ending September 19, 2019. On September 16, 2019, the Company entered into a new employment agreement with Ms. Cherevka, which by its terms cancelled the previous employment agreement on this date. The new employment agreement provides for an annual salary of $280,000 and a term ending September 16, 2021, subject to certain automatic renewal provisions.

The Company entered into an employment agreement with Mr. Daniel Stokely, Chief Financial Officer, on July 9, 2019, which provided for an annual salary of $285,000 and a term beginning July 31, 2019 and lasting for three years, subject to certain automatic renewal provisions. The employment agreement allows reimbursement of reasonable commuting and relocation expenses for up to six months. In December 2019, the Company entered into an amended employment agreement with Mr. Stokely to amend the timeframe to reimburse reasonable commuting and relocation expenses from six months to eight months.

Amounts noted above do not assume the continuity of employment beyond the contractual terms of each employee's existing employment agreements.

Insurance Premiums

In June 2019, Ampio entered into an insurance premium financing agreement for directors and officers insurance coverage with a third-party financing organization for a term of six months with an interest rate of 7.75% for $470,000, which represents 50% of the total annual premium costs. This obligation was paid in full as of December 31, 2019. As of December 31, 2019, the Company had a remaining balance of $21,000 related to annual insurance premiums payable to the Company's insurance broker.

Facility Lease

In December 2013, the Company entered into a 125-month non-cancellable operating lease for office space and a manufacturing facility. The effective date of the lease was May 1, 2014. The initial base rent of the lease was $23,000 per month. The total base rent over the term of the lease is approximately $3.3 million, which includes rent abatements and leasehold incentives. As discussed further within *Note 1*, the Company adopted the FASB issued ASC 842, *"Leases (Topic 842)"* effective January 1, 2019. With the adoption of ASC 842, the Company recorded an operating ROU asset and an operating lease liability on its balance sheet. The ROU asset represents the Company's right to use the underlying asset for the lease term and the lease obligation represents the Company's commitment to make the lease payments arising from the lease. ROU lease assets and obligations are recognized at the commencement date based on the present value of remaining lease payments over the lease term. As the Company's lease does not provide an implicit rate, the Company used an estimated incremental borrowing rate 5.75% based on the information available at the commencement date in determining the present value of the lease payments. Lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectations regarding the terms. The lease liability is classified as current or long-term on the balance sheet.

The following table provides a reconciliation of the Company's remaining undiscounted payments for its facility lease and the carrying amount of the lease liability presented in the balance sheet as of December 31, 2019:

	Facility Lease Payments	2020	2021	2022	2023	2024	Thereafter
Remaining Facility Lease Payments	$ 1,679,000	$ 335,000	$ 345,000	$ 355,000	$ 364,000	$ 280,000	$ —
Less: Discount Adjustment	(210,000)						
Total lease liability	$ 1,469,000						
Lease liability-current portion	$ 259,000						
Long-term lease liability	$ 1,210,000						

The following table provides a reconciliation of the Company's remaining ROU asset for its facility lease presented in the balance sheet as of December 31, 2019:

	Right-of-Use Asset
Initial recognition as of January 1, 2019	$ 1,168,000
Amortization	(165,000)
Balance as of December 31, 2019	$ 1,003,000

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

	Year Ended December 31, 2019	2018
Lease expense	$ 261,000	$ 260,000

Note 8 – Warrants

The Company has issued equity-classified warrants and liability warrants in conjunction with previous equity raises. The Company had a total of 2.7 million equity based-warrants and 4.4 million liability warrants outstanding as of December 31, 2019.

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, 2017	13,332,000	$ 0.73	4.01
Warrants issued in connection with the public offering	20,000,000	$ 0.40	4.62
Warrants exercised	(10,550,000)	$ 0.42	
Warrants expired	(499,000)	$ 3.24	
Outstanding at December 31, 2018	22,283,000	$ 0.51	4.25
Warrants issued in connection with the public offering	2,100,000	$ 0.50	4.47
Warrants exercised	(17,267,000)	$ 0.22	
Outstanding at December 31, 2019	7,116,000	$ 0.57	3.41

In connection with the June 2019 public offering, the Company issued Placement Agent Warrants to purchase an aggregate of 2.1 million shares of common stock at an exercise price of $0.50 with a term of five years. These warrants were accounted for as equity-based warrants (see *Note 10*).

In connection with the August 2018 confidentially marketed public offering, the Company issued investor 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 were accounted for under liability accounting and are recorded at fair value each reporting period. As of December 31, 2019 and 2018, these warrants had a fair value of $1.2 million and $5.2 million, respectively. Significant assumptions, using the Black-Scholes valuation model, as of December 31, 2019, December 31, 2018, and at issuance were as follows:

Assumptions for warrants issued August 13, 2018:	December 31, 2019	December 31, 2018	At Issuance
Exercise Price	$ 0.40	$ 0.40	$ 0.40
Volatility	132 %	130 %	122 %
Equivalent term (years)	3.62	4.62	5.00
Risk-free interest rate	1.64 %	2.50 %	2.75 %
Number of shares	2,400,000	15,600,000	20,000,000

In connection with the June 2017 registered direct offering, the Company issued investor warrants to purchase an aggregate of 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, 2019 and 2018, these warrants had a fair value of $800,000 and $1.7 million, respectively. Significant assumptions as of December 31, 2019 and 2018 were as follows:

Assumptions for warrants issued June 2, 2017:	December 31, 2019	December 31, 2018
Exercise Price	$ 0.76	$ 0.76
Volatility	139 %	134 %
Equivalent term (years)	2.42	3.42
Risk-free interest rate	1.60 %	2.47 %
Number of shares	2,027,000	6,094,000

The total value for the warrant derivative liability as of December 31, 2019 is approximately $2.0 million. See *Note 9* for additional information regarding the warrant derivative liability.

In October 2019, the Company entered into warrant exercise agreements with certain warrant holders from the 2017 and 2018 public offerings, which reduced the exercise price of the investor warrants from $0.76 (2017 public offering) and $0.40 (2018 public offering) to $0.215 per warrant. A total of 16.4 million warrants were exercised, which generated gross proceeds of $3.5 million. In connection with the warrant repricing, the Company paid its investment banker a fee of 7% of the gross proceeds plus reasonable out-of-pocket expenses, which totaled $277,000, and resulted in net proceeds of $3.2 million.

In addition to the warrant exercises referenced above, the Company had other warrant exercises during the year ended December 31, 2019. The Company issued 875,000 shares of common stock as a result of the exercise of investor warrants with an exercise price of $0.40 and received $350,000 related to these investor warrant exercises.

The combined net proceeds for the investor warrant exercises at December 31, 2019 was approximately $3.6 million.

In December 2018, the Company entered into a warrant exercise agreement with certain holders of the warrants from the August 2018 confidentially marketed public offering, which reduced the exercise price of the investor warrants from $0.40 to $0.30 per warrants. A total of 4.2 million warrants were exercised, which generated gross proceeds of approximately $1.3 million as of December 31, 2018. No additional costs were incurred related to these warrant exercises.

In addition to the warrants exercises reference 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 1.5 million 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 4.5 million 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 was approximately $4.3 million.

Note 9 – Fair Value Considerations

Authoritative guidance defines fair value as the price that would be received upon the sale of 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 based on market data obtained from sources not affiliated with the Company. Unobservable inputs are inputs that reflect the Company’s

assumptions of what market participants would use in pricing the asset or liability 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 that 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 financial instruments include cash and cash equivalents, accounts payable and accrued expenses, and warrant derivative liability. Warrants are recorded at estimated fair value-based utilization of the Black-Scholes or Monte Carlo warrant pricing model depending on the facts and circumstances surrounding the derivative.

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 the fair value hierarchy as of the date in which the even or change in circumstances caused the transfer. The Company has consistently applied the valuation techniques in all periods presented.

The following table presents the Company's financial assets and liabilities that were accounted for at fair value on a recurring basis as of December 31, 2019 and 2018, by level within the fair value hierarchy:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
December 31, 2019				
Liabilities:				
Warrant derivative liability	$ —	$ —	$ 2,064,000	$ 2,064,000
December 31, 2018				
Liabilities:				
Warrant derivative liability	$ —	$ —	$ 6,933,000	$ 6,933,000

The recurring 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, 2019, December 31, 2018, 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, 2018	$ 6,933,000
Warrant exercises	(353,000)
Modified warrant exercises	(5,967,000)
Change in fair value	1,451,000
Balance as of December 31, 2019	$ 2,064,000

Note 10 – Common Stock

Authorized Shares

The authorized shares increased from 200,000,000 shares of common stock as of December 31, 2018 to 300,000,000 shares of common stock as of December 31, 2019.

The following table summarizes the Company's remaining authorized shares available:

	December 31, 2019
Authorized shares	300,000,000
Common stock outstanding	158,644,757
Options Outstanding	6,000,332
Warrants Outstanding	7,116,524
Reserved for issuance under 2019 Stock and Incentive Plan	9,856,000
Available shares	118,382,387
Average Stock Price:	
30 day	$ 0.45
60 day	$ 0.41
90 day	$ 0.43

Shelf Registration

In March 2017, the Company filed a shelf registration statement on Form S-3 (the "Shelf Registration Statement") with the SEC to register the Company's 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 Statement was declared effective in April 2017 by the SEC and expires in April 2020. The Company plans to renew the shelf registration prior to the expiration date. Approximately $66.7 million remained available under the Shelf Registration Statement as of December 31, 2019. However, such availability may be limited due to the number of remaining authorized shares available for the Company to issue.

Public Offerings

In June 2019, the Company completed a public offering whereby it issued 30.0 million shares of its common stock at a stock price of $0.40, generating gross proceeds of $12.0 million. In connection with this offering, we entered into a Placement Agent Agreement with the placement agent. Pursuant to the Placement Agent Agreement, the placement agent received a 7% commission of $840,000, and $230,000 as compensation for other costs related to the offering and also received 2.1 million warrants with an exercise price of $0.50 and an expiration date of June 17, 2024 ("Placement Agent Warrants"). Such Placement Agent Warrants provide for cashless exercise, which the placement agent may elect if the Company does not have an effective registration statement registering, or the prospectus contained therein is not available for the issuance of, the shares underlying the warrants. Additionally, the Placement Agent Agreement contained certain restrictions that may prevent the Company from conducting an at-the-market offering or continuous equity financing in the near term and granted the placement agent a right of first refusal, that covers a period through June 2021, to act as the investment banker or placement agent on certain future transactions. The Company also incurred expenses related to legal, accounting, and other registration costs of $173,000. The shares were offered and sold pursuant to the Company's Shelf Registration Statement.

In August 2018, the Company completed a confidentially marketed public offering whereby it issued 20.0 million shares of its common stock at a stock price of $0.40, along with investor warrants to purchase up to 20.0 million shares of common stock, generating gross proceeds of $8.0 million. In connection with the offering, the underwriter received a 7% commission of $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.

The investor warrants have an exercise price of $0.40 per share and are exercisable immediately with a term of five years from issuance. Based on the terms of the warrant and related securities law, the contract does not meet the criteria within Accounting Standards Codification ("ASC") 815 "Derivatives and Hedging to permit the company to settle in unregistered shares. 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 ASC 815. 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 were offset against the net cash transaction proceeds, the non-cash charges exceeded 100% of the proceeds. Therefore, the Company was 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.

Equity Distribution Agreement

In April 2019, the Company entered into an Equity Distribution Agreement with a placement agent to implement an "at-the-market" equity program under which the Company, from time to time could offer and sell shares of its common stock, having an aggregate offering price of up to $24.65 million (the "Shares") through the placement agent. The Company had no obligation to sell any of the Shares and could at any time suspend sales under the Equity Distribution Agreement or terminate the Equity Distribution Agreement in accordance with its terms. The Company provided the placement agent with customary indemnification rights. The placement agent was entitled to a fixed commission of 3.0% of the gross proceeds from shares sold. The Company terminated the Equity Distribution Agreement in June 2019.

The following table summarizes the Company's sales under the Equity Distribution Agreement:

		Equity Distribution Agreement
Total shares of common stock sold		254,984
Average price per share	$	0.56
Gross Proceeds	$	142,000
Commissions earned by placement agent	$	4,000
Legal fees	$	140,000

Common Stock Issued for Services

The Company issued 181,590 and 17,241 shares of common stock valued at $80,000 and $60,000, respectively, to certain non-employee directors as part of their annual director compensation for fiscal years 2019 and 2018, respectively. The related compensation expense was recognized in the period the stock awards were issued.

Note 11 – Equity Instruments

Options

In December 2019, the Company's Board of Directors and stockholders approved the adoption of the Ampio Pharmaceuticals, Inc. 2019 Stock and Incentive Plan (the "2019 Plan"), under which shares were reserved for future issuance under restricted stock awards, options, and other equity awards. The 2019 Plan permits grants of equity awards to employees, directors and consultants. The stockholders have approved a total of 10.0 million shares to be reserved for issuance under the 2019 Plan. The Company's previous 2010 Stock and Incentive Plan (the "2010 Plan") was cancelled upon the adoption of the 2019 Plan.

The following table summarizes the activity of the 2010 Plan, along with the 2019 Plan and the available options to be granted as of December 31, 2019:

	2010 Plan
Total shares reserved for equity awards	11,700,000
Options granted	(14,505,000)
Add back: expired, forfeited and/or cancelled equity awards	6,367,000
Add back: options used in net exercise	192,000
Cancellation of 2010 Plan	(3,754,000)
Remaining shares available for future equity awards	—

	2019 Plan
Total shares reserved for equity awards	10,000,000
Options granted	(144,000)
Add back: expired, forfeited and/or cancelled equity awards	—
Add back: options used in net exercise	—
Remaining shares available for future equity awards	9,856,000

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, 2017	7,247,000	$ 2.87	5.16	$ —
Granted	285,000	$ 0.48		
Exercised	(410,000)	$ 2.06		
Forfeited	(3,000)	$ 1.02		
Expired or Cancelled	(1,693,000)	3.92		
Outstanding at December 31, 2018	5,426,000	$ 1.99	4.89	$ —
Granted	2,226,000	$ 0.57		
Exercised	—	$ —		
Forfeited	—	$ —		
Expired and/or Cancelled	(1,652,000)	$ 2.51		
Outstanding at December 31, 2019	6,000,000	$ 1.33	5.40	$ 169,000
Exercisable at December 31, 2019	5,416,000	$ 1.41	5.00	$ 114,000

Stock options outstanding at December 31, 2019 are summarized in the table below:

Range of Exercise Prices	Number of Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Lives
$0.40 - $2.00	4,972,000	$ 0.75	6.05
$2.01 - $5.00	840,000	$ 3.28	1.93
$5.01 - $8.62	188,000	$ 7.97	3.85
	6,000,000	$ 1.33	5.40

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 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. 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 of the vesting term plus 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 computed the fair value of options granted and modified during the period ended December 31, 2019 and December 31, 2018, using the following assumptions:

	Year Ended December 31,	
	2019	2018
Expected volatility	24 % - 187 %	101% - 215 %
Risk free interest rate	1.42% - 2.38 %	1.86% - 2.96 %
Expected term (years)	0.08 - 5.50	0.32 - 5.50

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 between the initial exercise price and $0.75 by (ii) the number of options being repriced). The Company 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 %
Expected term (years)	1.00
Risk free interest rate	2.60 %

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 December 31, 2019 and December 31, 2018:

	Year Ended December 31,	
	2019	2018
Research and development expenses		
Stock-based compensation	$ 89,000	$ 191,000
General and administrative expenses		
Issuance of common stock for services	80,000	60,000
Stock-based compensation	316,000	253,000
Total stock-based compensation	$ 485,000	$ 504,000
Unrecognized expense at December 31, 2019	130,000	
Weighted average remaining years to vest	0.57	

Note 12 – Income Taxes

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

	Years Ended December 31,	
	2019	2018
(Benefit) expense at federal statutory rate	(21.0)%	21.0 %
State, net of federal income tax impact	(4.1)%	(0.8)%
Stock-based compensation	4.8 %	2.3 %
Registered offering gain / warrant expense	(7.5)%	(28.1)%
Change in valuation allowance	27.8 %	5.6 %
Effective tax rate	0.0 %	0.0 %

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,	
	2019	2018
Long-term deferred income tax assets (liabilities):		
Accrued liabilities	$ 18,000	$ —
Interest expense carryforward	—	1,000
Deferred rent	115,000	132,000
Net operating loss carryforward	40,248,000	35,868,000
Share-based compensation	1,592,000	2,255,000
Unrealized loss on trading security	774,000	774,000
Property and equipment	(131,000)	(210,000)
Warrants	67,000	67,000
Less: Valuation allowance	(42,683,000)	(38,887,000)
Total long-term deferred income tax assets (liabilities)	$ —	$ —

As of December 31, 2019, Ampio has approximately $163.2 million in net operating loss (“NOL”) carryforwards that, subject to limitation, may be available in future tax years to offset taxable income. These net operating loss carryforwards expire from 2019 through 2037. Approximately $30.3 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.

The Company 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. The Company 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 the Company’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. The Company’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. The Company 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 2016 or for Colorado before 2015. 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.

Note 13 – Earnings Per Share

In the previously issued Form 10-K for the year ended December 31, 2018, the Company calculated basic and diluted earnings per share in a way, which was incorrect. The impact of this error to the Company’s previously reported diluted earnings per share for the year ended December 31, 2018 was an over-statement of $0.58. Based on the SEC Staff Accounting Bulletin (“SAB”) No. 99, Materiality, the Company assessed the materiality of the misstatement on both a quantitative and qualitative basis. Based on this assessment, the Company’s management determined that the diluted earnings per share calculation does not constitute a material misstatement and, as such, an amendment to the previously

filed Annual Report on Form 10-K was not necessary. As such, the Company has revised the previously issued financial statements for the year ended December 31, 2018 to correct for this error.

Basic earnings per share is computed by dividing net income (loss) available to common stockholders by the weighted-average number of shares of common stock outstanding during each period. Diluted earnings per share is computed by dividing net income (loss) available to common stockholders by the diluted weighted-average shares of common stock outstanding during each period. The Company's potential dilutive shares include stock options and warrants for the shares of common stock. The investor warrants are treated as equity in the calculation of diluted earnings per share in both the computation of the numerator and denominator. Since the Company operates at a net loss after adjusting for the derivative gain, all potentially dilutive shares are considered anti-dilutive and are excluded from the calculation of diluted net loss per share. The following table sets forth the calculations of basic and diluted earnings per share for the year ended December 31, 2019 and 2018:

	Year Ended December 31,		
	2019	2018	2018 (as previously reported)
Net Income (loss)	$ (13,630,000)	$ 33,986,000	$ 33,986,000
Less: decrease (increase) in fair value of investor warrants	(4,869,065)	(45,298,000)	—
Income (loss) available to common stockholders	$ (18,499,065)	$ (11,312,000)	$ 33,986,000
Basic and diluted weighted-average common shares outstanding	130,601,500	73,358,034	73,358,034
Add: dilutive effect of equity instruments	533,678	17,733,845	—
Diluted weighted-average shares outstanding	131,135,178	91,091,879	73,358,034
Earnings per share - basic	$ (0.10)	$ 0.46	$ 0.46
Earnings per share - diluted	$ (0.14)	$ (0.12)	$ 0.46

Note 14 – Litigation

On August 25, 2018, a purported stockholder of the Company commenced a putative class action lawsuit in the United States District Court for the Central District of California, captioned Shi v. Ampio Pharmaceuticals, Inc., et al., Case No. 18-cv-07476 (the "Securities Class Action"). Plaintiff in the Securities Class Action alleges that the Company and certain of its current and former officers violated the federal securities laws by misrepresenting and/or omitting material information regarding the AP-003 Phase III clinical trial of Ampion. The plaintiff asserts claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Securities and Exchange Commission Rule 10b-5, on behalf of a putative class of purchasers of the Company's common stock from December 14, 2017 through August 7, 2018. Plaintiff in the Securities Class Action seeks unspecified damages, pre-judgment and post-judgment interest, and attorneys' fees and costs. On September 27, 2019, the Court presiding over the Securities Class Action issued an order appointing a Lead Plaintiff and Lead Counsel, pursuant to the Private Securities Litigation Reform Act. Lead Plaintiff filed an amended complaint in late 2019. The Company filed a motion to dismiss the amended complaint on February 10, 2020. Plaintiffs' opposition is due in March and the Company then has the right to file a reply.

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, captioned Cetrone v. Macaluso, et al., Case No. 18-cv-07855 (the "Cetrone Action"), alleging primarily that the directors and officers of Ampio breached their fiduciary duties in connection with alleged misstatements and omissions regarding the AP-003 Phase III clinical trial of Ampion.

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. 18-cv-02558 (the "Theise Action"), which closely parallels the allegations in the Cetrone Action. A second derivative action was filed in the United States District Court for the District of Colorado and was consolidated with the Theise Action under the caption In re: Ampio Pharmaceuticals Inc. Stockholder Derivative Actions, Case No. 18-cv-02558. This consolidated action, and the Certrone Action in California, are stayed pending further developments in the Securities Class Action.

The Company believes that all claims asserted are without merit and intends to defend these lawsuits vigorously. However, it is possible that additional actions will be filed in the future. The Company currently believes the likelihood of a loss contingency related to these matters is remote and given the fact of where the claims exist in the litigation process, the Company is not in the position to provide an estimate and/or range of potential loss.

Note 15 – Employee Benefit Plan

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

Note 16 – Subsequent Events

In January 2020, the Company executed an amendment with the CRO as a result of an increased number of patients required for the current trial, which increased the contractual amount by $4.0 million. Therefore, the contract including the amendment totals $10.3 million (see Note 7 for additional information).

In addition, in January 2020, the Company awarded 34,059 shares of common stock to each independent director at a price of $0.5872 per share equivalent to $20,000, which was the closing price of our common stock on the date of grant.

On February 20, 2020, the Company entered into a Sales Agreement ("Sales Agreement") with two agents to implement an "at-the-market" equity offering program under which the Company, from time to time, may offer and sell shares of its common stock having an aggregate offering price up to $50.0 million (the "Shares") through the agents. Subject to the terms and conditions of the Sales Agreement, the agents will use their commercially reasonable efforts to sell the Shares from time to time, based upon the Company's instructions. The Company has no obligation to sell any of the Shares, and may at any time suspend sales under the Sales Agreement or terminate the Sales Agreement in accordance with its terms. The Company has provided the Agents with customary indemnification rights, and the agents will be entitled to an aggregate fixed commission of 4.0% of the gross proceeds (2.0% to each agent) from Shares sold.

EXHIBIT 4.5

DESCRIPTION OF CAPITAL STOCK

General

Our authorized capital stock consists of 300,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of undesignated preferred stock, $0.0001 par value, of which no preferred shares are issued or outstanding.

The following summary description of our capital stock is based on the provisions of our certificate of incorporation and bylaws and the applicable provisions of the Delaware General Corporation Law. This information is qualified entirely by reference to the applicable provisions of our certificate of incorporation, bylaws and the Delaware General Corporation Law. For information on how to obtain copies of our certificate of incorporation and bylaws, please see "Where You Can Find Additional Information" and "Incorporation of Certain Information by Reference."

Common Stock

As of February 14, 2020, there were 158,780,993 shares of our common stock outstanding. Holders of common stock will have voting rights for the election of our directors and all other matters requiring stockholder action, except with respect to amendments to our certificate of incorporation that alter or change the powers, preferences, rights or other terms of any outstanding preferred stock if the holders of such affected series of preferred stock are entitled to vote on such an amendment. There is no cumulative voting with respect to the election of directors, with the result that the holders of more than 50% of the shares voted for the election of directors can elect all of the directors. Holders of common stock will be entitled to one vote per share on matters to be voted on by stockholders and also will be entitled to receive such dividends, if any, as may be declared from time to time by our board of directors in its discretion out of funds legally available therefor. The payment of dividends, if ever, on the common stock will be subject to the prior payment of dividends on any outstanding preferred stock, of which there is currently none. Upon our liquidation or dissolution, the holders of common stock will be entitled to receive *pro rata* all assets remaining available for distribution to stockholders after payment of all liabilities and provision for the liquidation of any shares of preferred stock at the time outstanding. Our stockholders have no conversion, preemptive or other subscription rights and there are no sinking fund or redemption provisions applicable to the common stock.

Preferred Stock

Pursuant to our certificate of incorporation, our board of directors has the authority, without further action by the stockholders (unless such stockholder action is required by applicable law or stock exchange listing rules), to designate and issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the designations, powers, preferences, privileges and relative participating, optional or special rights and the qualifications, limitations or restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption and liquidation preferences, any or all of which may be greater than the rights of the common stock, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

The board of directors, without stockholder approval, can issue preferred stock with voting, conversion or other rights that could adversely affect the voting power and other rights of the holders of common stock. Preferred stock could be issued quickly with terms designed to delay or prevent a change in control of our company or make removal of management more difficult. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of the common stock and may adversely affect the voting power of holders of common stock and reduce the likelihood that common stockholders will receive dividend payments and payments upon liquidation.

Our board of directors will fix the designations, voting powers, preferences and rights of the each series, as well as the qualifications, limitations or restrictions thereof, of the preferred stock of each series that we offer under this prospectus and applicable prospectus supplements in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of that series of preferred stock. This description will include:

- the title and stated value;
- the number of shares we are offering;
- the liquidation preference per share;
- the purchase price per share;
- the dividend rate per share, dividend period and payment dates and method of calculation for dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- our right, if any, to defer payment of dividends and the maximum length of any such deferral period;
- the procedures for any auction and remarketing, if any;
- the provisions for a sinking fund, if any;
- the provisions for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption and repurchase rights;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into our common stock or other securities of ours, including depositary shares and warrants, and, if applicable, the conversion period, the conversion price, or how it will be calculated, and under what circumstances it may be adjusted;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange period, the exchange price, or how it will be calculated, and under what circumstances it may be adjusted;
- voting rights, if any, of the preferred stock;
- preemption rights, if any;
- restrictions on transfer, sale or other assignment, if any;
- whether interests in the preferred stock will be represented by depositary shares;
- a discussion of any material or special United States federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs;
- any limitations on issuances of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock being issued as to dividend rights and rights if we liquidate, dissolve or wind up our affairs; and

- any other specific terms, rights, preferences, privileges, qualifications or restrictions of the preferred stock.

The General Corporation Law of the State of Delaware, the state of our incorporation, provides that the holders of preferred stock will have the right to vote separately as a class (or, in some cases, as a series) on an amendment to our certificate of incorporation if the amendment would change the par value or, unless the certificate of incorporation provided otherwise, the number of authorized shares of the class or change the powers, preferences or special rights of the class or series so as to adversely affect the class or series, as the case may be. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

Delaware Anti-Takeover Law and Provisions of our Certificate of Incorporation and Bylaws

Delaware Anti-Takeover Law.

As a Delaware corporation, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally has an anti-takeover effect for transactions not approved in advance by our board of directors. This may discourage takeover attempts that might result in payment of a premium over the market price for the shares of common stock held by stockholders. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that such stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; or

- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) shares owned by:

  - persons who are directors and also officers; and

  - employee stock plans, in some instances; or

- at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Staggered board of directors

Our Delaware certificate of incorporation provides that our board of directors will be classified into three classes of directors of approximately equal size at a date selected by the board. Currently our board of directors is not classified. As a result, in most circumstances, a person can gain control of our board only by successfully engaging in a proxy contest at two or more annual meetings.

Advance notice requirements for stockholder proposals and director nominations

Our Delaware bylaws provide that stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders, must provide timely notice of their intent in writing. To be timely, a stockholder's notice needs to be delivered to our principal executive offices not later than the close of business on the 90th day nor earlier than the close of business on the

120th day prior to the first anniversary of the preceding year's annual meeting of stockholders. Our bylaws also specify certain requirements as to the form and content of a stockholders' meeting. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders.

Authorized but unissued shares

Our authorized but unissued shares of common stock and preferred stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Limitation on liability and indemnification of directors and officers

Our Delaware certificate of incorporation and bylaws provide that our directors and officers will be indemnified by us to the fullest extent authorized by Delaware law as it now exists or may in the future be
amended, against all expenses and liabilities reasonably incurred in connection with their service for or on our behalf. Our bylaws permit us to secure insurance on behalf of any officer, director or employee for any liability arising out of his or her actions, regardless of whether Delaware law would permit indemnification.

These provisions may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. Furthermore, a stockholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. We believe that these provisions, insurance and the indemnity agreements are necessary to attract and retain talented and experienced directors and officers.

Other than the two putative class action lawsuits in the United States District Court in the Central District of California, Napoli v. Ampio Pharmaceuticals, Inc., et al., Case No. 2:15-cv-03474-TJH and Stein v. Ampio Pharmaceuticals, Inc., et al., Case No. 2:15-cv-03640-TJH described in our Annual Report on Form 10-K and filed with the SEC on March 16, 2017, there is no pending litigation or proceeding involving any of our directors or officers where indemnification by us would be required or permitted, nor are we aware of any threatened litigation or proceeding that might result in a claim for such indemnification. Insofar as indemnification for liabilities arising under the Securities Act of 1933, or the Act, may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Corporate Stock Transfer, Inc., 3200 Cherry Creek Drive South, Suite 430, Denver, Colorado 80209.

Exhibit 10.11

AMENDMENT NO. 3 TO HUMAN SERUM ALBUMIN INGREDIENT PURCHASE AND SALE AGREEMENT

This Amendment (this "Amendment") No. 3 to the Human Serum Albumin Ingredient Purchase and Sale Agreement is made and entered into as of November 14, 2017 by and between Octapharma USA, Inc., a Virginia corporation ("Supplier"), and Ampio Pharmaceuticals, Inc., a Delaware corporation ("Customer"). Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Original Agreement (as defined below).

RECITALS

WHEREAS, Customer and Supplier previously entered into that certain Human Serum Albumin Ingredient Purchase and Sale Agreement dated October 10, 2013 and an Amendment 1 thereto dated February 27, 2015 and Amendment 2 thereto dated October 8, 2015 (together, the "Original Agreement"); and

WHEREAS, Customer and Supplier desire to amend the Original Agreement as set forth below.

AGREEMENT

NOW, THEREFORE, the parties hereto agree as follows:

1. Amendments to the Original Agreement.

   a. Customer and Supplier hereby agree that, notwithstanding anything to the contrary in the Original Agreement, (i) from the date of this Amendment through December 31, 2017, Customer shall have no obligation to purchase any Products and (ii) Supplier forgives any shortfalls in Customer's minimum purchase commitments prior to the date of this Amendment and customers purchase commitment will extend until Dec 31, 2020 to account for shortfall in 2017.

   b. Unless agreed upon by Octapharma due to further delay in customer's product approval beyond Dec 31, 2017, Octapharma reserves the right to legally enforce the terms of this contract going forward until Dec 31, 2020. Octapharma also reserves the right to increase pricing no more than 5% of current contracted per bottle price beginning in 2018 to account for increased production costs. The increase will be a one-time increase.

2. Miscellaneous.

   a. Except as effected by this Amendment, the terms and provisions of the Original Agreement shall remain unchanged and in full force and effect.

IN WITNESS WHEREOF, the undersigned has executed this Amendment No. 3 to the Human Serum Albumin Ingredient Purchase and Sale Agreement as of the date first written above.

CUSTOMER:

AMPIO PHARMACEUTICALS, INC.

By: /s/ Thomas Chilcott
Name: Thomas Chilcott
Title: Chief Financial Officer

SUPPLIER:

OCTAPHARMA USA, INC.

By: /s/ Flemming Nielsen
Name: Flemming Nielsen
Title: President

AUTHORIZED DISTRIBUTOR:

NOVA BIOLOGICS, INC.

By: /s/ Michael Crowley, Sr.
Name: Michael Crowley, Sr.
Title: President & CEO

AMPIO PHARMACEUTICALS, INC.
CODE OF BUSINESS CONDUCT AND ETHICS

Adopted August 14, 2010
Updated December 13, 2019

1. Introduction

This Code of Business Conduct and Ethics (the "Code") covers a wide range of business practices and procedures. It does not cover every issue that may arise, but it sets out basic principles to guide all directors, officers and employees of Ampio Pharmaceuticals, Inc. and its subsidiaries (collectively, "Ampio" or the "Company"). All directors, officers and employees are required to be familiar with the Code, comply with its provisions and report any suspected violations as described below in Section 24, Reporting Illegal or Unethical Behavior. The Code should also be provided to and followed by Ampio's agents and representatives, including consultants.

If you violate the standards in the Code, you may be subject to a varying degree of disciplinary action, up to and including termination of employment. *If you are in a situation that you believe may violate or lead to a violation of the Code, contact the Chief Executive Officer, the Chair of the Audit Committee or our outside counsel, Squire Patton Boggs, ATTN: Leah Brownlee ("Outside Counsel").*

If a law conflicts with a policy in the Code, you must comply with the law. If you have any questions about these conflicts, you should ask your supervisor how to handle the situation. However, this Code supersedes all other codes of conduct, policies, procedures, instructions, practices, rules or written or verbal representations to the extent that they are inconsistent with the Code. We are committed to continuously reviewing and updating our policies and procedures. The Code, therefore, is subject to modification by the Board of Directors of the Company (the "Board") or a committee thereof.

Nothing in this Code, in any Ampio policies and procedures or in other related communications (verbal or written) creates or implies an employment contract or term of employment or appointment for any person. Unless otherwise covered by an explicit written employment agreement with the Company (executed by authorized Company representatives), your employment with the Company is "at will," meaning it can be terminated by either you or the Company with or without notice and with or without cause.

2. Purpose

The Code seeks to deter wrongdoing and to promote:

Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;

Full, fair, accurate, timely and understandable disclosure in reports and documents that Ampio files with, or submits to, the Securities and Exchange Commission (the "SEC") and in other public communications made by Ampio;

Compliance with applicable governmental laws, rules and regulations;

The prompt internal reporting to an appropriate person or persons identified in the Code of violations of the Code; and accountability for adherence to the Code.

3. Compliance With Applicable Laws, Rules and Regulations

Obeying the law is the foundation on which Ampio's ethical standards are built. You must comply with applicable laws, rules and regulations. It is your responsibility to know enough about applicable laws, rules and regulations to determine when to seek advice from supervisors or other appropriate personnel.

4. Compliance at Ampio

Ampio's policy is to promote high standards of integrity by conducting its affairs honestly and ethically. Each director, officer and employee must act with integrity and observe the highest ethical standards of business conduct in his or her dealings with the Company's customers, suppliers, partners, service providers, competitors, employees and anyone else with whom he or she has contact in the course of performing his or her job. Ampio has established a structured compliance system to support legal and ethical actions throughout the Company. Compliance with this policy will be led by the Chief Financial Officer and the Audit Committee, but the responsibility for compliance is shared by all employees. The Chief Financial Officer will be responsible for overseeing the Ampio compliance system, including maintaining current policies, conducting training, auditing, monitoring, testing, communication, investigations and enforcement. The Chief Financial Officer will provide oversight for compliance strategy and keep the Board and the Audit Committee informed of significant compliance issues, risks and trends.

5. Conflicts of Interest

A "conflict of interest" exists when a person's private interests interfere or conflict in any way with the interests of Ampio, or impair, or could be perceived to impair a person's business judgment. Decisions should be made strictly based on Ampio's best interests, without regard to personal concerns. You should avoid situations that present potential conflicts of interest, either real or perceived, and should not engage in activities that would make it difficult or appear to make it difficult for you to perform your work objectively and effectively. Examples of when a conflict of interest or potential conflict of interest may arise include *but are not limited* to:

- When a director, officer or employee takes actions or has interests that may make it difficult to perform his or her work objectively and effectively.

- When a director, officer or employee, or a member of his or her family, receives improper personal benefits as a result of his or her position with Ampio.

- When an employee works simultaneously for a competitor or, except on our behalf, a customer or supplier. You are not allowed to work for a competitor in any capacity.

- When a director, officer or employee serves as a member of the board of directors or advisory board of any company that competes with Ampio.

- When a director, officer or employee invests in a customer, supplier, developer or competitor of Ampio. In deciding whether to make such an investment, you should consider the size and nature of the investment, your ability to influence decisions of Ampio or of the other company, your access to confidential information of Ampio or of the other company and the nature of the relationship between Ampio and the other company.

- When a director, officer or employee conducts Ampio business with a relative or significant other, or with a business with which a relative or significant other is associated in any significant role. Relatives include spouse, sister, brother, daughter, son, mother, father, grandparents, aunts, uncles, nieces, nephews, cousins, step relationships and in-laws. Significant others include persons living in a spousal or familial fashion (including same sex) with an employee, officer or director.

Conflicts of interest should be avoided and all potential conflicts of interest cases must promptly be disclosed fully to the Company. In the case of a conflict of interest involving a director, the Chief Executive Officer or any other executive officer, disclosure must be made to the Chairman of the Audit Committee, or if such conflict of interest involves the Chairman of the Audit Committee, disclosure shall be made to the other independent directors. Following such disclosure, the matter shall be considered by the full Board for approval or in order to determine what, if any, corrective action is required. In the case of a conflict of interest involving a non-executive employee, disclosure must be made to the Chief Executive Officer or the Outside Counsel. Following such disclosure, the matter shall be considered by the Chief Executive Officer or shall be considered pursuant to guidelines approved by the Chief Executive Officer in order to determine what, if any, corrective action is required. Conflicts of interest may not always be clear-cut, so if you have a question, you should consult with higher levels of management or the Chief Executive Officer or Outside Counsel. If you become aware of a conflict or potential conflict, you should bring it to the attention of your supervisor or other appropriate personnel or consult the procedures described in Section 24 of this Code.

6. Public Disclosure of Information

The federal securities laws require Ampio to disclose certain information in various reports that the Company must file with or submit to the SEC. In addition, from time to time, Ampio makes other public communications, such as issuing press releases.

Ampio expects all directors, officers and employees who are involved in the preparation of SEC reports or other public documents to ensure that the information disclosed in those documents is complete, fair, accurate, timely and understandable. To the extent that you have questions or concerns about the information contained in the SEC reports or other public documents or the process by which they are prepared, you should report those concerns to the Chair of Ampio’s Disclosure Committee.

To the extent that you reasonably believe that questionable accounting or auditing conduct or practices have occurred or are occurring, you should report those concerns to the Chair of Ampio’s Audit Committee.

7. Insider Trading

You are not permitted to use or share confidential information for stock trading purposes or for any other purpose, except the lawful conduct of our business. All non-public information about Ampio should be considered confidential information until it has been adequately disclosed to the public. Also, you may not trade in the securities of other companies about which you learn material, non-public information through the course of your employment with, or service to, Ampio. “Material non-public information” includes information that is not available to the public at large that could affect the market price of Ampio securities or another company’s securities and that a reasonable investor would consider important in deciding whether to buy, sell or hold the securities. To use material non-public information for personal financial benefit or to “tip” others who might make an investment decision on the basis of this information is not only unethical, but also illegal, and could result in criminal prosecution, in addition to the termination of your employment. In order to assist with compliance with laws against insider trading, the Company has adopted an Insider Trading Policy. A copy of this policy has been distributed to every employee and included within the Employee Handbook. If you have any questions regarding the Company’s Insider Trading Policy or as to whether information is material or has been adequately disclosed, please consult Ampio’s Outside Counsel.

8. Corporate Opportunities

You are prohibited from taking for yourself opportunities that are discovered through the use of corporate property, information or position without the informed prior written consent of the Board. You may not use corporate property or information obtained through your position with Ampio for improper personal gain, and you may not compete with Ampio directly or indirectly while employed with the Company or through the use of Ampio’s corporate information. Furthermore, you owe a duty to Ampio to advance its legitimate interests when such an opportunity arises.

9. Competition and Fair Dealing

Ampio is committed to outperforming its competition fairly and honestly. Misappropriating proprietary information, possessing trade secret information that was obtained without the owner’s consent or inducing such disclosures by past or present employees of other companies is prohibited and will result in termination from employment as well as other actions necessary to remedy your misappropriation, including, if appropriate, reporting to proper authorities. You should respect the rights of and deal fairly with Ampio’s customers, suppliers and competitors and their employees.

10. Antitrust and Competition Laws

Ampio’s policy is to comply fully with both the letter and spirit of antirust and competition laws. One general concept is that all companies should compete individually rather than enter into agreements with others to restrict competition. In order to avoid creating even the appearance of improper agreements, the Company prohibits:

- discussions or other contacts with competitors regarding price fixing, stabilization or discrimination;

- discussions or other contacts with suppliers and customers about issues that could unfairly restrict trade, such as excluding competitors from the marketplace;

- discussions or other contacts with competitors regarding territories or markets in which competitive products will be sold, allocation of markets or customers or limitations on the sale of products; and

- discussions or other contacts with others to boycott customers or suppliers.

Another general concept is that companies should not engage in unfair competitive practices. Each employee, officer and director of the Company will deal fairly and honestly with customers, suppliers, partners and competitors. No one will engage in any unfair dealing, which could include, but would not be limited to, the following: misrepresenting (affirmatively or by omission) material facts, abusing privileged or confidential information, obtaining market data and other information from unauthorized sources and making inaccurate or malicious statements about competitors or competitive products.

Many countries have antitrust or competition laws that vary significantly from U.S. laws. Antitrust and competition laws in other countries may regulate, among other things, distribution agreements; patent, copyright and trademark licenses; territorial and other restrictions on resellers and licensees; rebates and discounts to customers; refusals to deal; and licensing and pricing policies generally. All customers within the same competitive market must generally be treated on a fair and equitable basis with respect to prices, terms and trade promotion. Violation of antitrust and competition laws carry stiff financial penalties and sometimes jail sentences. Because the laws are complex, please consult the Outside Counsel before acting if you have any questions.

11. Gifts

The purpose of business entertainment and gifts in a commercial setting is to create good will and form sound working relationships, not to gain unfair advantage with Ampio’s business contacts. No gift or entertainment should ever be offered, given or provided to a third-party or accepted by you from a third-party unless it:

- is not a cash gift (including gift cards or other certificates with cash value),

- is consistent with customary business practices,

- is not excessive in value,

- cannot be construed as a bribe or payoff, and

- does not violate any laws or regulations.

You should take particular care to avoid accepting any favor or anything of value which could reasonably be interpreted as influencing your judgment in performing your duties for Ampio. Please discuss with your supervisors any gifts or proposed gifts that you are not certain are appropriate for receipt or for giving.

12. Discrimination and Harassment

The diversity of Ampio's employees is a tremendous asset. Ampio is firmly committed to providing equal opportunity in all aspects of employment (including without limitation hiring, promotion and termination) and will not tolerate any illegal discrimination, harassment or hostile work environment of any kind. Examples of such behavior include, but are not limited to, derogatory comments based on racial or ethnic characteristics and unwelcome sexual advances. Please consult the Company's Employee Handbook for more information on this topic.

13. Health and Safety

Ampio strives to provide its employees with a safe and healthy work environment. You are responsible for helping to maintain a safe and healthy workplace for all employees by following safety and health rules and reporting accidents, injuries and unsafe equipment, practices or conditions.

Violence and threatening behavior are not permitted. Employees should report to work in condition to perform their duties, free from the influence of illegal drugs or alcohol. The abuse of alcohol or illegal drugs in the workplace will not be tolerated and constitutes a violation of Company policy.

14. Regulatory Requirements

Ampio follows all applicable laws and regulations governing the manufacturing and distribution of drugs, devices and biological products. In particular, we observe all legal requirements applicable to the Company including, but not limited to those of the U.S. Food and Drug Administration and the U.S. Department of Health and Human Services Office of Inspector General, and we expect every employee to do likewise at all times. These requirements affect employees who work inside and outside the U.S. alike, as many U.S. regulatory requirements apply outside of national boundaries and international regulatory requirements may also apply to us from time to time. While there are many regulations to consider, regulation of advertising and promotion directly affects our everyday communications. Therefore, all employees are obligated to understand the basic rules with respect to labeling, promotion, off-label use, pharmaceutical samples and adverse event reporting. As a pharmaceutical company, Ampio is also subject to many healthcare rules and regulations designed to protect the public. As an Ampio employee, you must comply with the laws and regulations relating to the conduct of business in the pharmaceutical industry that address:

- fraud and abuse in federal healthcare programs (Medicare and Medicaid);
- improper influence of financial incentives on medical judgment;
- the Pharmaceutical Research and Manufacturers of America voluntary Code on Interactions with Healthcare Professionals ("PhRMA Code"); and
- protect patients and improve the quality of health care services.

15. Patient Privacy

During the course of business activities, we may have the opportunity to view a person's medical records, or learn the identity of a patient/study subject or other personal medical information. This information is entrusted to us with the understanding that it will be kept confidential. Employees must guard the confidentiality of all medical information in our possession at all times. Confidentiality applies 24 hours a day, 365 days a year, both inside and outside the workplace. The disclosure of confidential medical information is strictly prohibited by law in most countries. Please contact the Chief Executive Officer or Outside Counsel if you suspect that any confidential personal information has been improperly disclosed.

16. Record-Keeping

Ampio requires honest and accurate recording and reporting of information in order to make responsible business decisions and to comply with the law. For example, employees who must report their hours worked should only report the true and actual number of hours worked (whether for purposes of individual pay, for purposes of reporting such information to customers or any other reason). Ampio also requires each director and employee to disclose any transaction or arrangement among such individual or any family member or affiliated entity of such individual, on the one hand, and any other director, employee or any family member or affiliated entity of such other individual, on the other hand, that in any way relates to or arises out of such individual's professional or working relationship with Ampio.

Many employees regularly use business expense accounts, which must be documented and recorded accurately in accordance with the Company's policies. If you are not sure whether you may seek reimbursement for a certain expense, ask your supervisor or the Chief Financial Officer.

All of Ampio's books, records, accounts and financial statements must be maintained in reasonable detail, appropriately reflect Ampio's transactions and conform both to applicable legal requirements and to Ampio's system of internal controls.

Business records and communications (including internal or external e-mails) very often become public, and you should avoid exaggeration, derogatory or disrespectful remarks, guesswork or inappropriate characterizations of people and companies. This policy applies equally to e-mail, internal memos and formal reports. You should always remember that writings or images on your computer screen, screen savers and pictures or videos you retain or view on your computer screen must comply with the Company's policies including, without limitation, anti-harassment and anti-discrimination.

Records should always be retained or destroyed according to Ampio's record retention policies. In accordance with those policies, in the event of litigation or governmental investigation, you must not delete or alter any e-mail that is directly or indirectly related to the subject of the litigation or investigation, or otherwise take any action that could be construed as an effort to obstruct the litigation or investigation. A director or employee who is found to have violated this policy could be subject to termination from employment and criminal penalties, among other things.

17. Document Retention

Ampio has records retention and disposal procedures to ensure that Company records are maintained, stored and, when appropriate, destroyed in accordance with Ampio needs and in compliance with applicable legal, regulatory, environmental, tax, employment and trade requirements. You are expected to be familiar with the specific requirements applicable to your position. Regular document destruction must stop immediately if you are aware of a legal request for such documents or if Ampio's finance department has issued a document hold notice. If an employee is unsure whether a document has been placed under a legal hold, such employee should preserve and protect that document while the Chief Financial Officer is contacted.

18. Confidentiality and Proprietary Information

You must maintain the confidentiality of all trade secret, confidential and other proprietary information ("Confidential Information") entrusted to you by Ampio, except when disclosure is authorized by Ampio's established written policies, its Chief Executive Officer or is required by laws or regulations. Confidential Information includes all non-public information that might be of use to competitors, or harmful to Ampio, if disclosed, and information that suppliers and other business partners have entrusted to us. Non-exhaustive examples include intellectual property such as trade secrets, patents, trademarks and copyrights, as well as business or marketing plans, scientific and manufacturing ideas, designs, databases, records, salary information and any unpublished financial data and reports. The obligation to preserve Confidential Information continues even after employment ends. In connection with this obligation, every employee is required to execute a Confidentiality and Proprietary Information Agreement when he or she begins his or her employment with Ampio. Please contact the Chief Financial Officer if you need a copy of your signed Confidentiality and Proprietary Information Agreement or if you do not recall signing such an agreement at your hiring.

19. Protection and Proper Use of Ampio Assets

You should endeavor to protect Ampio's assets and ensure their efficient use. Any suspected incident of fraud or theft should immediately be reported for investigation. Ampio's assets should not be used for non-Ampio business, though limited incidental personal use of equipment is permitted. Your obligation to protect Ampio's assets includes protecting its Confidential Information. Unauthorized use or distribution of such information would violate Ampio policy and could also be illegal and result in civil or even criminal penalties.

20. Bribery and Corruption

Most countries have laws that forbid the making, offering or promise of any payment or anything of value (directly or indirectly) to a government official, particularly when the payment is intended to influence an official act or decision to award or retain business. Most commonly these rules apply to our interactions with the FDA and similar government agencies that approve and regulate our products. In addition, the U.S. Foreign Corrupt Practices Act ("FCPA") prohibits giving anything of value, directly or indirectly, to officials of foreign governments or foreign political candidates in order to obtain or retain business. As Ampio is a U.S. company, the FCPA applies to anyone who conducts business on behalf of Ampio, regardless of their nationality or where in

the world they are conducting business. We may also retain the services of scientists and doctors, many of whom are employees of public hospitals, universities and other institutions who are considered government officials. Accordingly, no payment of money, gifts, services, entertainment or anything of value is to be offered or made available in any amount, directly or indirectly to any federal, state, local or foreign government official or employee, candidate for public office or political party. Payments and benefits made to governmental entities themselves are not prohibited, unless such payments are used as a subterfuge for bribery.

Ampio also prohibits "commercial bribery" that refers to the furnishing of something of value to an intermediary without his or her supervisor's knowledge, with the intent to influence a third party's commercial conduct. Accordingly, the Company prohibits any employee, consultant, intermediary or other agent acting on such individual's behalf or on behalf of the Company from directly or indirectly engaging in commercial bribery.

The promise, offer or delivery of a gift, favor or other gratuity in violation of these rules may not only violate Ampio policy, but could also be a criminal offense. Ampio's Outside Counsel can provide guidance to you in this area.

21. Trade Issues

In a global marketplace, our contact with various parties around the world increases daily. The U.S. and other countries where Ampio products may be researched, the subject of clinical trials, manufactured or sold have laws that restrict or prohibit doing business with certain countries and parties. Likewise, while most countries regulate international trade (imports and exports generally), many countries also restrict or prohibit transactions involving certain products and technology. The U.S. also has laws that regulate how companies must respond to boycotts enforced by one set of countries against another. Employees responsible for shipping or receiving goods, technology or services must be familiar with relevant import, export, anti-boycott and other trade laws and how they apply, and adhere to those laws and all related Ampio compliance policies and procedures. For example, U.S. anti-boycott laws generally prohibit Ampio from furnishing any information to any Arab League countries, or companies in those countries, relating to our dealings or lack of any dealings with Israel. Employees must be alert to requests for any such information, as they are common in documents such as letters of credit and shipping documents. Not only is furnishing the information illegal, but U.S. law requires the Company to report any request for such information. Please report any such requests to the Outside Counsel.

22. Government Requests for Information

Ampio will cooperate fully with any government investigation. From time to time, government regulators may contact employees directly in the course of an investigation. You are free to decide on your own whether you wish to speak with a government investigator, and although we request that you inform the Outside Counsel if one contacts you, you are not required to do so. Whether you speak to an investigator directly without informing the Outside Counsel, or choose to inform the Outside Counsel of contact from a government agency, any information you convey to the agency must be truthful and accurate. No Ampio employee will be retaliated against for conveying truthful and accurate information to a government agency or for responding in good faith to an inquiry from a government agency with or without informing the Outside Counsel. Ampio urges

you, before sharing any Company information with a person who represents himself or herself to be affiliated with a government agency, to ensure and confirm that the person in fact holds an official government capacity.

23. Waivers of the Code

Waivers of the Code may only be granted by Ampio's Chief Executive Officer; provided, however, that any waiver of the Code for executive officers or directors may be granted only by the Board of Directors or the Audit Committee of the Board. Any such waiver of the Code for executive officers or directors, and the reasons for such waiver, will be disclosed in Ampio's public filings, as required by law or securities exchange regulations.

24. Reporting Illegal or Unethical Behavior and Non-Retaliation

You are required to talk to supervisors or other appropriate personnel about observed illegal or unethical behavior or when in doubt about the best course of action in a particular situation. Any employee who suspects a violation of this Code, any law or regulation, should bring the matter to the attention of the Chair of the Audit Committee or the Outside Counsel as soon as possible. After receiving a report of an alleged prohibited action, the Audit Committee or Outside Counsel must promptly take all appropriate actions necessary to investigate. All directors, officers and employees are expected to cooperate in any internal investigation of misconduct.

It is the policy of Ampio not to allow retaliation for reports of misconduct by others made in good faith by employees. You are required by Company policy to cooperate in internal investigations of misconduct and will not be subject to any form of retaliation for your participation in the same.

You may, on an anonymous basis, submit a good-faith concern regarding questionable accounting or auditing matters without fear of dismissal or retaliation of any kind by contacting the Chair of the Audit Committee. Contact information is set forth in the Employee Handbook, on the Company's web site and in the Company's proxy statements filed with the SEC. You may also report, on an anonymous basis, any violations of this Code, or any law or regulation, through the Company's whistleblower hotline (www.intouchwebsite.com/Ampio) (the "Whistleblower Hotline").

25. Enforcement

Ampio will ensure prompt and consistent action against violations of this Code.

If, after investigating a report of an alleged prohibited action by any non-executive employee, the Chief Executive Officer or Outside General Counsel determines that a violation of this Code has occurred, the Chief Executive Officer will take such preventative or disciplinary action, as he/she deems appropriate, including, but not limited to, reassignment, demotion, dismissal and, in the event of criminal conduct or other serious violations of the law, notification of appropriate governmental authorities.

If, after investigating a report of an alleged prohibited action by any executive employee or director the Audit Committee or Outside General Counsel, determines that a violation of this Code has occurred, the Audit Committee or Outside General Counsel will report such determination to the

Board of Directors. Upon receipt of a determination that there has been a violation of this Code, the Board of Directors will take such preventative or disciplinary action, as it deems appropriate, including, but not limited to, reassignment, demotion, dismissal and, in the event of criminal conduct or other serious violations of the law, notification of appropriate governmental authorities.

26. Review of Code

The Board of Directors, the Nominating and Governance Committee and/or the Audit Committee shall at least annually review and reassess this Code and submit any recommended changes to the Board for its consideration.

27. Upholding the Standards - Our Commitment and Yours

We must all work to ensure prompt and consistent action against violations of the Code. However, in some situations it is difficult to know if a violation has occurred. Since we cannot anticipate every situation that will arise, it is important that we have a way to approach a new question or problem. These are the steps to keep in mind:

- Make sure you have all the facts. In order to reach the right solutions, we must be as fully informed as possible.

- Ask yourself: What specifically am I being asked to do? Does it seem unethical or improper? These questions will enable you to focus on the specific question you are faced with and the alternatives you have. Use your judgment and common sense; if something seems unethical or improper, it probably is.

- Clarify your responsibility and role. In most situations, there is shared responsibility. Are your colleagues informed? It may help to get others involved and discuss the problem.

- Discuss the problem with your supervisor. This is the basic guidance for all situations. In many cases, your supervisor will be more knowledgeable about the question and will appreciate being brought into the decision-making process. It is your supervisor's responsibility to help solve problems.

- Seek help from Ampio resources. In the rare case where it may not be appropriate to discuss an issue with your supervisor or if you do not feel comfortable approaching your supervisor with your question, discuss it with the Chief Executive Officer, the Chair of the Audit Committee or with the Outside Counsel.

Once again, you may report legal or ethical violations on a confidential or anonymous basis and without fear of retaliation to the email address of any of these persons or to the Whistleblower Hotline. If your situation requires that your identity be kept secret, your anonymity will be protected to the greatest extent possible. In this regard, Ampio encourages you to draft and send such an emailed report using a non-Company computer, to assist in the protection of your anonymity, or by using the Whistleblower Hotline. Ampio does not permit retaliation of any kind against employees for good-faith reports of ethical violations and you should never feel pressured to violate a law or policy.

Always ask first, act later. If you are unsure of what to do in any situation, seek guidance.

ACKNOWLEDGMENT OF RECEIPT AND REVIEW

I, _____, acknowledge that I have received and read a copy of Ampio Pharmaceutical, Inc.'s Code of Ethics and Business Conduct. I understand the contents of the Code and I agree to comply with the policies and procedures set out in the Code.

I understand that I should approach the Chief Executive Officer, the Chair of the Nominating and Governance Committee, the Chair of the Audit Committee or Outside Counsel if I have any questions about the Code generally or any questions about reporting a suspected conflict of interest or other violation of the Code.

_____
[NAME]

_____
[PRINTED NAME]

_____
[DATE]

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-217094) and Form S-8 (No. 333-235853) of our report dated February 20, 2020, relating to the 2019 financial statements of Ampio Pharmaceuticals, Inc. (which report expresses an unqualified opinion and includes explanatory paragraphs regarding the Company's going concern uncertainty and the adoption of a new accounting standard) and the effectiveness of internal control over financial reporting of Ampio Pharmaceuticals, Inc., as of December 31, 2019 appearing in this Annual Report on Form 10-K for the year ended December 31, 2019.

/s/ Moss Adams LLP

Denver, Colorado
February 20, 2020

EXHIBIT 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in Ampio Pharmaceuticals, Inc.'s Registration Statements on Form S-8 (File No. 333-235853) and Form S-3 (File No. 333-217094) of our report dated March 18, 2019, relating to the financial statements, which includes an explanatory paragraph regarding the substantial doubt about Ampio Pharmaceuticals, Inc.'s ability to continue as a going concern, which appears in this Annual Report on Form 10-K.

/s/ Plante & Moran, PLLC

February 21, 2020
Denver, Colorado

EXHIBIT 31.1

CERTIFICATION

I, Michael Macaluso, certify that:

1. I have reviewed this Annual Report on Form 10-K of Ampio Pharmaceuticals, Inc. for the year ended December 31, 2019;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, considering the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Michael Macaluso

Michael Macaluso

Chief Executive Officer

Date: February 21, 2020

EXHIBIT 31.2

CERTIFICATION

I, Daniel G. Stokely, certify that:

1. I have reviewed this Annual Report on Form 10-K of Ampio Pharmaceuticals, Inc. for the year ended December 31, 2019;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, considering the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Daniel G. Stokely

Daniel G. Stokely

Chief Financial Officer, Secretary and Treasurer

Date: February 21, 2020

EXHIBIT 32.1

18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Ampio Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof ("Report"), each of the undersigned officers of the Company, certifies to his knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Section 906), the following:

(1) The Report fully complies with the requirements of section 13(a) and 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Michael Macaluso
Michael Macaluso
Chief Executive Officer

/s/ Daniel G. Stokely
Daniel G. Stokely
Chief Financial Officer, Secretary and Treasurer

Date: February 21, 2020

This certification accompanies the annual report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Ampio Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Ampio Pharmaceuticals, Inc. and will be retained by Ampio Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.