SECURITIES & EXCHANGE COMMISSION EDGAR FILING

BIOVIE INC.

Form: 10-K

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Corporate Issuer CIK: 1580149

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

FOR THE FISCAL YEAR ENDED JUNE 30, 2019

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

For the transition period from _____to _____

Commission File Number: **333-190635**

BIOVIE INC.

(Exact name of registrant as specified in its charter)

Nevada	**46-2510769**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Empl. Ident. No.)*

2120 Colorado Avenue Suite 230
Santa Monica, CA 90404
(Address of principal executive offices, Zip Code)

(312)-283-5793
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered

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

$.0001 par value Class A common stock

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 Act
Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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 (§ 232.405 of this chapter) 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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 ☒

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

The Aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter, December 30, 2018 was $2,501,218.

There were 647,930,147 shares of the Registrant's $0.0001 par value Class A common stock outstanding as of September 24, 2019.

BIOVIE INC.

FORM 10-K INDEX

FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, and Section 27A of the Securities Act of 1933. Any statements contained in this report that are not statements of historical fact may be forward-looking statements. When we use the words “intends,” “estimates,” “predicts,” “potential,” “continues,” “anticipates,” “plans,” “expects,” “believes,” “should,” “could,” “may,” “will” or the negative of these terms or other comparable terminology, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties, which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. These factors include our research and development activities, distributor channel; compliance with regulatory impositions; and our capital needs. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

Except as may be required by applicable law, we do not undertake or intend to update or revise our forward-looking statements, and we assume no obligation to update any forward-looking statements contained in this report as a result of new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the Securities and Exchange Commission that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The Company assumes no obligation and does not intend to update these forward-looking statements, except as required by law. When used in this report, the terms “BioVie”, “Company”, “we”, “our”, and “us” refer to BioVie, Inc.

PART I

ITEM 1. DESCRIPTION OF BUSINESS

Introduction

We are a clinical-stage company pursuing the discovery, development, and commercialization of innovative drug therapies. We are currently focused on developing and commercializing BIV201 (continuous infusion terlipressin), a novel approach to the treatment of ascites due to chronic liver cirrhosis. Our therapy BIV201 is based on a drug that is approved in about 40 countries to treat related complications of liver cirrhosis (part of the same disease pathway as ascites), but not yet available in the United States. BIV201's active agent is a potent vasoconstrictor and has shown efficacy for reducing portal hypertension in studies around the world. The goal is for BIV201 to interrupt the ascites disease pathway, thereby halting the cycle of accelerating fluid generation in ascites patients.

In April 2017, we entered into a CRADA with the McGuire Research Institute Inc. in Richmond, VA, and began administering BIV201 to patients in September 2017. In April 2019, we announced top-line results for our Phase 2a clinical trial of BIV201 (continuous infusion terlipressin) in six patients with refractory ascites due to advanced liver cirrhosis. On June 18, 2019, we met with representatives of the FDA for Type C Guidance Meeting to plan our next clinical study following the recently completed Phase 2a clinical trial. We discussed our clinical development efforts with the FDA and proposed trial endpoints. While the FDA has not provided final guidance nor do we have certainty as to what that guidance would entail, our goal remains to proceed into a Phase 2b/3 or Phase 3 clinical trial in a manner consistent with what was reviewed with the FDA. We may still need to address certain risks associated with unvalidated quality of life measures. In July 2019, the FDA provided meeting minutes for the June 18, 2019 meeting that documented general agreement with the Company's proposed randomized study design. The FDA also provided its suggestions and guidance regarding primary and secondary endpoints and other key aspects of our clinical trial design and the Company is incorporating those suggestions as it moves forward. We are developing a proprietary novel liquid formulation of terlipressin that is intended to improve convenience for outpatient administration and avoid potential formulation errors when pharmacists reconstitute the powder version.

BIV201 (continuous infusion terlipressin) has the potential to improve the health of thousands of patients suffering from life-threatening complications of liver cirrhosis due to hepatitis, NASH, and alcoholism. We have patented a method of treating a patient diagnosed with ascites due to liver cirrhosis by administering BIV201 (terlipressin) as a continuous infusion within specified doses over a specified duration. The FDA has granted Fast-Track status and Orphan Drug designation for the most common of these complications, ascites, which represents a significant unmet medical need. Patients with cirrhosis and ascites account for an estimated 116,000 U.S. hospital discharges annually, with frequent early readmissions. Those requiring paracentesis (removal of ascites fluid) experience an average hospital stay lasting 8 days incurring over $86,000 in medical costs (*HCUP Nationwide Readmissions Database 2016*). This translates into a total addressable ascites market size for BIV201 therapy exceeding $500 million based on Company estimates. The FDA has never approved any drug specifically for treating ascites. BIV201 received Orphan Drug designation for hepatorenal syndrome ("HRS") in November 2018.

The BIV201 development program began at LAT Pharma LLC. On April 11, 2016, we acquired LAT Pharma LLC and the rights to its BIV201 development program and currently own all development and marketing rights to BIV201. We and PharmaIN, Corp. ("PharmaIN"), LAT Pharma's former partner focused on the development of new modified product candidates in the same therapeutic field but not including BIV201, had agreed to pay royalties equal to less than 1% of future net sales of each company's ascites drug development programs, or if such program is licensed to a third party, less than 5% of each company's net license revenues. On December 24, 2018, we returned our partial ownership rights to the PharmaIN modified terlipressin development program and simultaneously paid the remaining balance due on a related debt. PharmaIN's rights to our program remain unchanged. We have an issued U.S. Patent covering the use of BIV201 for the treatment of patients diagnosed with ascites due to liver cirrhosis in the outpatient setting using ambulatory pump infusion, and have corresponding patent applications pending in Japan, Europe, China and Hong Kong.

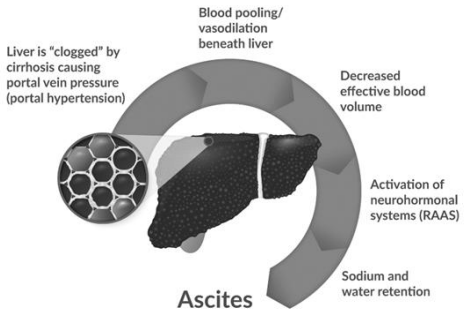
About Ascites and Liver Cirrhosis

About 600,000 Americans and millions worldwide suffer from liver cirrhosis. Cirrhosis is the 8th leading cause of death due to disease in the US, killing more than 40,000 people each year. The condition results primarily from hepatitis, alcoholism, and fatty liver disease linked to obesity. Ascites is a common complication of advanced liver cirrhosis, involving kidney dysfunction and the accumulation of large amounts of fluid in the abdominal cavity.

The Need for an Ascites Therapy

With no medications approved by the FDA specifically for treating ascites, an estimated 40% of patients die within two years of diagnosis. Certain drugs approved for other uses such as diuretics may provide initial relief, but patients may fail to respond to treatment as ascites worsens. This represents a critical unmet medical need. US treatment costs for liver cirrhosis, including ascites and other complications, are estimated at more than $5 billion annually.

The Ascites Development Pathway



* RAAS stands for the renin-angiotension-aldosterone system which regulates fluid balance

Most experts agree that ascites develops through a sequence of events illustrated by the above diagram. High blood pressure in the vein that supplies blood to the liver, called “portal hypertension,” occurs as increasing liver damage (fibrosis) impedes blood flow through the liver. This causes vasodilation and blood pooling in the central or “splanchnic” region of the body and low blood volume in the arteries. The decrease in effective blood volume activates a signaling pathway (“neurohormonal systems”) which tells the kidneys to retain large amounts of salt and water in an effort to increase blood volume. Ultimately the retention of excess sodium and water leads to the formation of ascites as these substances “weep” from the liver and lymph system and collect in the patient’s abdomen.

The BIV201 Mechanism of Action

BIV201 is being developed by BioVie with the goal of alleviating the portal hypertension and correcting splanchnic vasodilation, thereby increasing effective blood volume and reducing the signals to the kidneys to retain excess salt and water. If successful, BIV201 could halt the cycle of accelerating fluid generation in ascites patients and reduce the need for the frequent and painful paracentesis procedures many of these patients currently require.

Future Possible BIV201 Indications

Based on investigative studies around the world of the active agent in BIV201, terlipressin, our new drug candidate has potential future applications in other life-threatening conditions due to liver cirrhosis, such as those listed below. Securing marketing approvals for any of these new uses will require well-controlled clinical trials to satisfy the FDA and/or other countries' regulatory requirements, none of which have commenced at this time. The Company may be unable to, or chose not to, pursue the development BIV201 for these indications.

- Bleeding Esophageal Varices (BEV): The bursting of blood vessels lining the esophagus due to high blood pressure ("portal hypertension") in the vein which supplies blood to the liver resulting as a result of advanced liver cirrhosis. This situation requires emergency treatment to avoid blood loss and death.

- Hepatorenal syndrome (HRS): As their disease progresses liver cirrhosis patients' kidneys may begin to fail, and this deadly condition may set in. It often occurs once a patient no longer responds to (off-label) drugs used to control ascites. The second stage is called "type 1 HRS" and requires hospitalization as multiple organ failure and death may occur. We obtained Orphan Drug designation for BIV201 in the U.S. for the treatment of HRS on November 21, 2018.

Efflux Pump Antibiotics Program

Prior to the Merger of Lat Pharma LLC and NanoAntibiotics Inc. in April 2016, the Company was exclusively developing novel nanotechnology anti-infective drugs to combat multi-drug resistant bacteria. We are at an early stage of discovery and development of broad spectrum antibiotics for gram-negative and gram-positive bacterial infections. Developing this technology in-house is resource-intensive with respect to time, personnel and capital necessary for scientific discovery. For further development of our nanoantibiotic technology we will need to find and license additional nanotechnology to complete our planned products. Presently this program is inactive as we are focusing our efforts on BIV201.

Intellectual Property

BioVie relies on a combination of patent, trade secret, other intellectual property laws (such as FDA data exclusivity), nondisclosure agreements, and other measures to protect our proposed products. We require our employees, consultants, and advisors to execute confidentiality agreements and to agree to disclose and assign to us all inventions conceived during the workday, using our property, or which relate to our business. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain and use information that we regard as proprietary. In May 2017 we announced the issuance of a U.S. patent 9,655,945 directed to a method of treating a patient diagnosed with ascites due to liver cirrhosis by administering BIV201 as a continuous infusion within specified doses over a specified duration. This patent has been challenged by Mallinckrodt Pharmaceuticals Ireland Limited ("Mallinckrodt") in an IPR proceeding before the PTAB. In July 2017 we announced filing an application for similar patent coverage in Japan, and subsequently filed for patent protection in Europe, China and Hong Kong. BioVie has secured Orphan Drug designations in the U.S. for the treatment of hepatorenal syndrome (received November 21, 2018) and treatment of ascites due to all etiologies except cancer (received September 8, 2016). We have applied for an additional Orphan Drug designation which could be granted in 2019.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. Any pharmaceutical candidate that we develop must be approved by the FDA before it may be legally marketed in the United States and by the appropriate foreign regulatory agency before it may be legally marketed in foreign countries.

United States Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, or FDCA, and implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. Biologics are subject to regulation by the FDA under the FDCA, the Public Health Service Act, or the PHSA, and related regulations, and other federal, state and local statutes and regulations. Biological products include, among other things, viruses, therapeutic serums, vaccines and most protein products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices or other applicable regulations;
- Submission to the FDA of an Investigational New Drug Application, or an IND, which must become effective before human clinical trials may begin;
- Performance of adequate and well-controlled human clinical trials according to the FDA's current good clinical practices, or GCPs, to establish the safety and efficacy of the proposed drug or biologic for its intended use;
- Submission to the FDA of a New Drug Application, or an NDA, for a new drug product, or a Biologics License Application, or a BLA, for a new biological product;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the drug or biologic is to be produced to assess compliance with the FDA's current good manufacturing practice standards, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's or biologic's identity, strength, quality and purity;
- Potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the NDA or BLA; and
- FDA review and approval of the NDA or BLA.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources. There can be no certainty that approvals will be granted.

Clinical trials involve the administration of the drug or biological candidate to healthy volunteers or patients having the disease being studied under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted in accordance with the FDA's good clinical practices requirements. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until it is completed.

Human clinical trials prior to approval are typically conducted in three sequential Phases that may overlap or be combined:

- *Phase 1.* The drug or biologic is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients having the specific disease.
- *Phase 2.* The drug or biologic is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule for patients having the specific disease.
- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials, which usually involve more subjects than earlier trials, are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, at least two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA or BLA.

Post-approval studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and may be required by the FDA as part of the approval process.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA by the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and develop additional information about the chemistry and physical characteristics of the drug or biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug or biological candidate and, among other things, must include methods for testing the identity, strength, quality and purity of the final drug or biologic. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug or biological candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug or biologic, proposed labeling and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

The FDA reviews all NDAs and BLAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA or BLA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA.

After the NDA or BLA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things, whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, purity and potency. In addition to its own review, the FDA may refer applications for novel drug or biological products or drug or biological products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the approval process, the FDA also will determine whether a risk evaluation and mitigation strategy, or REMS, is necessary to assure the safe use of the drug or biologic. If the FDA concludes that a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without a REMS, if required.

Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is to be manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGMP. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable it will outline the deficiencies in the submission and often will request additional testing or information.

The NDA or BLA review and approval process is lengthy and difficult and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA will issue a "complete response" letter if the agency decides not to approve the NDA or BLA. The complete response letter usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting an NDA or BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has Orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the Orphan product has exclusivity or obtain approval for the same product but for a different indication for which the Orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or biological product as defined by the FDA or if our drug or biological candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar but not identical benefits in the European Union.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drug and biological products that meet certain criteria. Specifically, new drug and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a Fast Track product, the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

Any product submitted to the FDA for marketing approval, including those submitted to a Fast Track program, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared with marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA generally requires that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies to establish safety and efficacy for the approved indication. Failure to conduct such studies or conducting such studies that do not establish the required safety and efficacy may result in revocation of the original approval. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch or subsequent marketing of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Post-Approval Requirements

Any drug or biological products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information on an annual basis or as required more frequently for specific events, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, prohibitions against promoting drugs and biologics for uses or in patient populations that are not described in the drug's or biologic's approved labeling (known as "off-label use"), rules for conducting industry-sponsored scientific and educational activities, and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including the immediate discontinuation of noncomplying materials, adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs and biologics for off-label uses, manufacturers may not market or promote such off-label uses.

We will need to rely, on third parties for the production of our product candidates. Manufacturers of our product candidates are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of comprehensive records and documentation. Drug and biologic manufacturers and other entities involved in the manufacture and distribution of approved drugs and biologics are also required to register their establishments and list any products made there with the FDA and comply with related requirements in certain states, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in serious and extensive restrictions on a product, manufacturer, or holder of an approved NDA or BLA, including suspension of a product until the FDA is assured that quality standards can be met, continuing oversight of manufacturing by the FDA under a "consent decree," which frequently includes the imposition of costs and continuing inspections over a period of many years, and possible withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could otherwise restrict the distribution or use of the product.

Employees

Our business is managed by our officers. Our Chairman and Chief Executive Officer, Terren Peizer began devoting part-time efforts to the Company's activities in July 2018. Our President and Chief Operating Officer, Jonathan Adams, began devoting full-time efforts to the Company on July 1, 2017. Our Chief Financial Officer and Corporate Secretary, Wendy Kim, devotes part-time efforts to the Company's activities. Our Chief Scientific Officer began devoting full-time efforts and our Chief Medical Officer began devoting part-time efforts to the Company in November 2018 and previously were each consultants to the Company. We also rely on a team of highly experienced scientific, medical, and regulatory consultants to conduct its product development activities.

ITEM 1A. RISK FACTORS

Our business, financial condition, operating results and prospects are subject to the following risks. Additional risks and uncertainties not presently foreseeable to us may also impair our business operations. If any of the following risks or the risks described elsewhere in this report actually occurs, our business, financial condition or operating results could be materially adversely affected. In such case, the trading price of our common stock could decline, and our stockholders may lose all or part of their investment in the shares of our common stock.

This Form 10-K contains forward-looking statements that involve risks and uncertainties. These statements can be identified by the use of forward-looking terminology such as "believes," "expects," "intends," "plans," "may," "will," "should," "predict" or "anticipation" or the negative thereof or other variations thereon or comparable terminology. Actual results could differ materially from those discussed in the forward- looking statements as a result of certain factors, including those set forth below and elsewhere in this Form 10-K.

Risks Relating to Our Business and Industry

We have no products approved for commercial sale, have never generated any revenues and may never achieve revenues or profitability, which could cause us to cease operations.

We have no products approved for commercial sale and, to date, we have not generated any revenues. Our ability to generate revenue depends heavily on (a) successful development program and thereafter demonstration in human clinical trials that BIV201, our product candidate, is safe and effective; (b) our ability to seek and obtain regulatory approvals, including, without limitation, with respect to the indications we are seeking; (c) successful commercialization of our product candidates; and (d) market acceptance of our products. There are no assurances that we will achieve any of the forgoing objectives. Furthermore, our product candidate is in the development stage, and we have not evaluated it in full human clinical trials. If we do not successfully develop and commercialize our product candidate we will not achieve revenues or profitability in the foreseeable future, if at all. If we are unable to generate revenues or achieve profitability, we may be unable to continue our operations.

We are a development stage company with a limited operating history, making it difficult for you to evaluate our business and your investment.

BioVie Inc. was incorporated on April 10, 2013. We are a development stage biopharmaceutical company with a potential therapy that has not been fully evaluated in clinical trials, and our operations are subject to all of the risks inherent in the establishment of a new business enterprise, including but not limited to the absence of an operating history, the lack of commercialized products, insufficient capital, expected substantial and continual losses for the foreseeable future, limited experience in dealing with regulatory issues, the lack of manufacturing experience and limited marketing experience, possible reliance on third parties for the development and commercialization of our proposed products, a competitive environment characterized by numerous, well-established and well capitalized competitors and reliance on key personnel.

Since inception, we have not established any revenues or operations that shall provide financial stability in the long term, and there can be no assurance that we will realize our plans on our projected timetable in order to reach sustainable or profitable operations.

Investors are subject to all the risks incident to the creation and development of a new business and each Investor should be prepared to withstand a complete loss of his, her or its investment. Furthermore, the accompanying financial statements have been prepared assuming that we will continue as a going concern. We have not emerged from the development stage, and may be unable to raise further equity. These factors raise substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Because we are subject to these risks, you may have a difficult time evaluating our business and your investment in our Company. Our ability to become profitable depends primarily on our ability to develop drugs, to obtain approval for such drugs, and if approved, to successfully commercialize our drugs, our research and development (“R&D”) efforts, including the timing and cost of clinical trials; and our ability to enter into favorable alliances with third-parties who can provide substantial capabilities in clinical development, regulatory affairs, sales, marketing and distribution.

Even if we successfully develop and market BIV201, we may not generate sufficient or sustainable revenue to achieve or sustain profitability, which could cause us to cease operations and cause you to lose all of your investment.

Our U.S. patent claims covering BIV201 have been challenged by a large pharmaceutical corporation with significantly greater resources than us. There can be no assurance regarding our ability to maintain patent protection for any potential products until such matters have been resolved before the Patent Trials and Appeals Board.

On April 30, 2018, we received notice that Mallinckrodt had petitioned the U.S. Patent and Trademark Office (“USPTO”) to institute an Inter Partes Review of our U.S. Patent No. 9,655,945 titled “Treatment of Ascites” (the “’945 patent”). Inter Partes Review is a trial proceeding conducted with the USPTO Patent Trial and Appeal Board (PTAB) to review the patentability of one or more claims of a patent. Such review is limited to grounds of novelty and obviousness on the basis of prior art consisting of patents and printed publications.

On August 15, 2018, we submitted a Preliminary Response to the PTAB providing a rationale as to why, in our opinion, Mallinckrodt's request to institute the IPR should not be granted. On November 14, 2018, the PTAB granted institution of the IPR challenge after determining that there was a reasonable likelihood of success in proving that at least one of our 14 claims was unpatentable. On March 7, 2019, we submitted a Patent Owner's Response and a Patent Owner's Contingent Motion to Amend our patent claims, and Declaration of Dr. Jaime Bosch, MD, PhD, our medical expert. On June 26 and June 28, 2019, we submitted a Patent Owner's Reply In Support Of Its Contingent Motion To Amend Under 37 C.F.R.§ 42.121 to amend our patent claims and a Patent Sur-Reply supported by the Supplemental Declaration of Dr. Jaime Bosch to the Reply and the Opposition to Motion to Amend, filed by Petitioner Mallinckrodt, filed June 6, 2019. On July 29, 2019, we submitted a Patent Owner's Opposition to Petitioner's Motion to Strike. On July 17, 2019, we received from the PTAB an Order Oral Hearing in response to our request of an Oral Hearing, which was held on August 12, 2019. We are actively defending the '945 patent and we are exploring the possibility of settlement with Mallinckrodt. However, there can be no assurance that a favorable outcome will result, or if settlement is reached that the PTAB will accept it. Although the PTAB encourages settlement, in view of public-interest considerations, the PTAB may continue the proceeding to a final written decision even if the parties settle. If the IPR is not terminated due to settlement, the PTAB is statutorily required to issue its final written decision in this case before November 14, 2019 (within one year from the date of institution).

We cannot guarantee investors that we will be successful in defending Mallinckrodt's challenge against our patent. An unfavorable decision could reduce the scope of, or cancel, our patent rights, and allow third parties to commercialize our technology or products and compete directly with us, without payment to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to exploit our intellectual property or develop or commercialize current or future product candidates. Our ability to establish or maintain a technological or competitive advantage over our competitors and/or market entrants may be diminished because of these uncertainties. For these and other reasons, our intellectual property may not provide us with any competitive advantage.

In addition, you should note that as of June 30, 2019, no adjustments or accruals have been reflected in our financial statements related to this matter.

If the FDA or comparable foreign regulatory authorities approve generic versions of any of our products that receive marketing approval, or such authorities do not grant our products appropriate periods of exclusivity before approving generic versions of our products, the sales of our products could be adversely affected.

Once a new drug application ("NDA") is approved, the product covered thereby becomes a "reference listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of abbreviated new drug applications ("ANDAs") in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference listed drug has expired. The United States Federal Food, Drug, and Cosmetic Act ("FDCA") provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity ("NCE"). Specifically, in cases where such exclusivity has been granted, an ANDA may not be submitted to the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference listed drug.

While we believe that BIV201 contains active ingredients that would be treated as NCEs by the FDA and, therefore, if approved, should be afforded five years of data exclusivity, the FDA may disagree with that conclusion and may approve generic products after a period that is less than five years. If the FDA were to award NCE exclusivity to someone other than us, we believe that we would still be awarded three year "Other" exclusivity protection from generic competition, which is awarded when an application or supplement contains reports of new clinical investigations (not bioavailability studies) conducted or sponsored by an applicant and essential for approval. Manufacturers may seek to launch these generic products following the expiration of the applicable marketing exclusivity period, even if we still have patent protection for our product. If we do not maintain patent protection and data exclusivity for our product candidates, our business may be materially harmed.

Competition that our products may face from generic versions of our products could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates.

If we fail to obtain or maintain Orphan Drug exclusivity for BIV201, we will have to rely on our data and marketing exclusivity, if any, and on our intellectual property rights, which may reduce the length of time that we can prevent competitors from selling generic versions of BIV201.

We have obtained Orphan Drug designation for BIV201 in the U.S. for the treatment of hepatorenal syndrome (received November 21, 2018) and treatment of ascites due to all etiologies except cancer (received September 8, 2016). Under the Orphan Drug Act, the FDA may designate a product as an Orphan Drug if it is a drug intended to treat a rare disease or condition, defined, in part, as a patient population of fewer than 200,000 in the U.S. In the EU, Orphan Drug designation may be granted to drugs intended to treat, diagnose or prevent a life-threatening or chronically debilitating disease having a prevalence of no more than five in 10,000 people in the EU. The company that first obtains FDA approval for a designated Orphan Drug for the associated rare disease receives marketing exclusivity for use of that drug for the stated condition for a period of seven years. Orphan Drug exclusive marketing rights may be lost under several circumstances, including a later determination by the FDA that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug. Similar regulations are available in the EU with a ten-year period of market exclusivity.

Even though BioVie has obtained Orphan Drug designation for its lead product candidate, and intends to seek other Orphan Drug designations for BIV201, and Orphan Drug designation for other product candidates, there is no assurance that BioVie will be the first to obtain marketing approval for any particular rare indication. Further, even though BioVie has obtained Orphan Drug designation for its lead product candidate, or even if BioVie obtains Orphan Drug designation for other potential product candidates, such designation may not effectively protect BioVie from competition because different drugs can be approved for the same condition and the same drug can be approved for different conditions and potentially used off-label in the Orphan indication. Even after an Orphan Drug is approved, the FDA can subsequently approve the same drug for the same condition for several reasons, including, if the FDA concludes that the later drug is safer or more effective or makes a major contribution to patient care. Orphan Drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process.

In addition, other companies have received Orphan Drug designations for terlipressin. Mallinckrodt Hospital Products IP Limited received Orphan Drug designation in 2004 for terlipressin for the treatment of Hepatorenal Syndrome and Ferring Pharmaceuticals Inc. received Orphan Drug designation in 1986 for terlipressin for the treatment of bleeding esophageal varices. If Mallinckrodt Hospital Products IP Limited receives FDA approval for terlipressin for the treatment of Hepatorenal Syndrome before we do, they may obtain a competitive advantage associated with being the first to market. Further, in connection with obtaining marketing approval for terlipressin for the treatment of Hepatorenal Syndrome, Mallinckrodt Hospital Products IP Limited would also obtain Orphan Drug exclusivity for terlipressin, that could prevent our approval for the same indication for seven years, although we could continue to pursue other indications for the drug.

If Ferring Pharmaceuticals Inc. receives FDA approval for terlipressin for the treatment of bleeding esophageal varices, they would also obtain a competitive advantage associated with being the first to market. In connection with obtaining marketing approval for terlipressin for the treatment of bleeding esophageal varices, Ferring Pharmaceuticals Inc. would also obtain Orphan Drug exclusivity for terlipressin, but we do not believe that Orphan Drug exclusivity for Ferring Pharmaceuticals Inc.'s terlipressin product would have an adverse effect on our ability to market BIV201, as the same drug would be approved for different indications under FDA rules, and we can maintain Orphan Drug exclusivity for BIV201 for the different indication.

We will need to raise substantial additional capital in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms, which could have a materially adverse effect on our business.

Developing biopharmaceutical products, including conducting pre-clinical studies and clinical trials and establishing manufacturing capabilities, requires substantial funding. As of June 30, 2019, we had cash and cash equivalents of approximately $340,000. Although we entered into a Securities Purchase Agreement on September 24, 2019 with our controlling stockholder regarding bridge financing in the form of up to $2.0 million in convertible debt and warrants, of which $500,000 has been drawn to date, additional financing will be required to fund the research and development of our product candidates. We have not generated any product revenues, and do not expect to generate any revenues until, and only if, we develop, and receive approval to sell our product candidates from the FDA and other regulatory authorities for our product candidates.

We may not have the resources to complete the development and commercialization of any of our proposed product candidates. We will require additional financing to further the clinical development of our product candidates. In the event that we cannot obtain the required financing, we will be unable to complete the development necessary to file an NDA with the FDA for BIV201. This will delay research and development programs, preclinical studies and clinical trials, material characterization studies, regulatory processes, the establishment of our own laboratory or a search for third party marketing partners to market our products for us, which could have a materially adverse effect on our business.

The amount of capital we may need will depend on many factors, including the progress, timing and scope of our research and development programs, the progress, timing and scope of our preclinical studies and clinical trials, the time and cost necessary to obtain regulatory approvals, the time and cost necessary to establish our own marketing capabilities or to seek marketing partners, the time and cost necessary to respond to technological and market developments, changes made or new developments in our existing collaborative, licensing and other commercial relationships, and new collaborative, licensing and other commercial relationships that we may establish.

Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs, through public or private equity offerings, debt financings, or corporate collaboration and licensing arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. In addition, we could be forced to discontinue product development and reduce or forego attractive business opportunities. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates, or grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

Our fixed expenses, such as rent and other contractual commitments, will likely increase in the future, as we may enter into leases for new facilities and capital equipment and/or enter into additional licenses and collaborative agreements. Therefore, if we fail to raise substantial additional capital to fund these expenses, we could be forced to cease operations, which could cause you to lose all of your investment.

We have limited experience in drug development and may not be able to successfully develop any drugs, which would cause us to cease operations.

We have never successfully developed a new drug and brought it to market. Our management and clinical teams have experience in drug development but they may not be able to successfully develop any drugs. Our ability to achieve revenues and profitability in our business will depend on, among other things, our ability to develop products internally or to obtain rights to them from others on favorable terms; complete laboratory testing and human studies; obtain and maintain necessary intellectual property rights to our products; successfully complete regulatory review to obtain requisite governmental agency approvals; enter into arrangements with third parties to manufacture our products on our behalf; and enter into arrangements with third parties to provide sales and marketing functions. If we are unable to achieve these objectives we will be forced to cease operations and you will lose all of your investment.

Development of pharmaceutical products is a time-consuming process, subject to a number of factors, many of which are outside of our control. Consequently, if we are unsuccessful or fail to timely develop new drugs, we could be forced to discontinue our operations.

Our lead product candidate, BIV201, has been cleared by the FDA to undergo testing in a mid-stage (Phase 2a) clinical trial. On June 18, 2019, we met with representatives of the FDA for Type C Guidance Meeting to plan our next clinical study following the recently completed Phase 2a clinical trial. We discussed our clinical development efforts with the FDA and proposed trial endpoints. While the FDA has not provided final guidance nor do we have certainty as to what that guidance would entail, our goal remains to proceed into a Phase 2b/3 or Phase 3 clinical trial in a manner consistent with what was reviewed with the FDA. We may still need to address certain risks associated with unvalidated quality of life measures and the FDA expressed concern about the inadequacy of the topline results of our Phase 2a clinical trial and their views that an additional Phase 2 clinical trial would be advisable. In July 2019, the FDA provided meeting minutes for the June 18, 2019 meeting that documented general agreement with the Company proposed randomized study design. The FDA also provided its suggestions and guidance regarding primary and secondary endpoints and other key aspects of our clinical trial design and the Company is incorporating those suggestions as it moves forward.

Further development and extensive testing will be required to determine its technical feasibility and commercial viability. Our success will depend on our ability to achieve scientific and technological advances and to translate such advances into reliable, commercially competitive drugs on a timely basis. Drugs that we may develop are not likely to be commercially available, at a minimum, for a few years, if ever. The proposed development schedules for our product candidates may be affected by a variety of factors, including technological difficulties, proprietary technology of others, and changes in government regulation, many of which will not be within our control. Any delay in the development, introduction or marketing of our product candidates could result either in such drugs being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects and other risk factors described elsewhere in this document, we may not be able to successfully complete the development or marketing of any drugs which could cause us to cease operations.

We may fail to successfully develop and commercialize our product candidate(s) if it is found to be unsafe or ineffective in clinical trials; does not receive necessary approval from the FDA or foreign regulatory agencies; fails to conform to a changing standard of care for the disease it seeks to treat; or is less effective or more expensive than current or alternative treatment methods.

Drug development failure can occur at any stage of clinical trials and as a result of many factors, there can be no assurance that we or our collaborators will reach our anticipated clinical targets. Even if we or our collaborators complete our clinical trials, we do not know what the long-term effects of exposure to our product candidates will be. Furthermore, our product candidates may be used in combination with other treatments and there can be no assurance that such use will not lead to unique safety issues. Failure to complete clinical trials or to prove that our product candidates are safe and effective would have a material adverse effect on our ability to generate revenue and could require us to reduce the scope of or discontinue our operations, which could cause you to lose all of your investment.

We have no manufacturing experience, and the failure to comply with all applicable manufacturing regulations and requirements could have a materially adverse effect on our business.

We have never manufactured products in the highly regulated environment of pharmaceutical manufacturing, and our team has limited experience in the manufacture of drug therapies. There are numerous regulations and requirements that must be maintained to obtain licensure and permitting required prior to the commencement of manufacturing, as well as additional requirements to continue manufacturing pharmaceutical products. We currently do not own or lease facilities that could be used to manufacture any products that might be developed by us, and have contracted with an experienced Contract Manufacturing Organization (“CMO”) to perform the manufacturing of our new product candidate BIV201. In addition, we do not have the resources at this time to acquire or lease suitable facilities. If we or our CMO fail to comply with regulations, to obtain the necessary licenses and knowhow or to obtain the requisite financing in order to comply with all applicable regulations and to own or lease the required facilities in order to manufacture our products, we could be forced to cease operations, which would cause you to lose all of your investment.

In addition, the FDA and other regulatory authorities require that product candidates and drug products be manufactured according to current good manufacturing practices (“cGMP”). Any failure by our third-party manufacturers to comply with cGMP could lead to a shortage of BIV201. In addition, such failure could be the basis for action by the FDA to withdraw approval, if granted to us, and for other regulatory action, including seizure, injunction or other civil or criminal penalties.

BIV201 and any other product candidate that we develop may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. If we need to find another source of drug substance or drug product for BIV201, we may not be able to identify, or reach agreement with, commercial-scale manufacturers on commercially reasonably terms, or at all. If we are unable to do so, we will need to develop our own commercial-scale manufacturing capabilities, which would: impact commercialization of BIV201 in the U.S. and other countries where it may be approved; require a capital investment by us that could be quite costly; and increase our operating expenses.

If our existing third-party manufacturers, or the third parties that we engage in the future to manufacture a product for commercial sale or for our clinical trials, should cease to continue to do so for any reason, we likely would experience significant delays in obtaining sufficient quantities of product for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of BIV201 or any other product candidate that we develop, or the drug substances used to manufacture it, it will be more difficult for us to compete effectively, generate revenue, and further develop our products. In addition, if we are unable to assure a sufficient quantity of the drug for patients with rare diseases or conditions, we may lose any Orphan Drug exclusivity to which the product otherwise would be entitled.

We do not currently have the sales and marketing personnel necessary to sell products, and the failure to hire and retain such staff could have a materially adverse effect on our business.

We are an early stage development company with limited resources. Even if we had products available for sale, which we currently do not, we have not secured sales and marketing staff at this early stage of operations to sell products. We cannot generate sales without sales or marketing staff and must rely on officers to provide any sales or marketing services until such personnel are secured, if ever. If we fail to hire and retain the requisite expertise in order to market and sell our products or fail to raise sufficient capital in order to afford to pay such sales or marketing staff, then we could be forced to cease operations and you could lose all of your investment.

Even if we were to successfully develop approvable drugs, we will not be able to sell these drugs if we or our third-party manufacturers fail to comply with manufacturing regulations, which could have a materially adverse effect on our business.

If we were to successfully develop approvable drugs, before we can begin selling these drugs, we must obtain regulatory approval of our manufacturing facility and process or the manufacturing facility and process of the third party or parties with whom we may outsource our manufacturing activities. In addition, the manufacture of our products must comply with the FDA's current Good Manufacturing Practices regulations, commonly known as GMP regulations. The GMP regulations govern quality control and documentation policies and procedures. Our manufacturing facilities, if any in the future, and the manufacturing facilities of our third-party manufacturers will be continually subject to inspection by the FDA and other state, local and foreign regulatory authorities, before and after product approval. We cannot guarantee that we, or any potential third-party manufacturer of our products, will be able to comply with the GMP regulations or other applicable manufacturing regulations. The failure to comply with all necessary regulations would have a materially adverse effect on our business and could force us to cease operations and you could lose all of your investment.

We must comply with significant and complex government regulations, compliance with which may delay or prevent the commercialization of our product candidates, which could have a materially adverse effect on our business.

The R&D, manufacture and marketing of product candidates are subject to regulation, primarily by the FDA in the United States and by comparable authorities in other countries. These national agencies and other federal, state, local and foreign entities regulate, among other things, R&D activities (including testing in animals and in humans) and the testing, manufacturing, handling, labeling, storage, record keeping, approval, advertising and promotion of the product that we are developing. Noncompliance with applicable requirements can result in various adverse consequences, including approval delays or refusals to approve drug licenses or other applications, suspension or termination of clinical investigations, revocation of approvals previously granted, fines, criminal prosecution, recalls or seizures of products, injunctions against shipping drugs and total or partial suspension of production and/or refusal to allow a company to enter into governmental supply contracts.

The process of obtaining FDA approval has historically been costly and time consuming. Current FDA requirements for a new human drug or biological product to be marketed in the United States include: (a) the successful conclusion of pre-clinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety; (b) filing with the FDA of an IND application to conduct human clinical trials for drugs or biologics; (c) the successful completion of adequate and well-controlled human clinical investigations to establish the safety and efficacy of the product for its recommended use; and (d) filing by a company and acceptance and approval by the FDA of a NDA for a drug product or a biological license application (BLA) for a biological product to allow commercial distribution of the drug or biologic. A delay in one or more of the procedural steps outlined above could be harmful to us in terms of getting our product candidates through clinical testing and to market, which could have a materially adverse effect on our business.

The FDA reviews the results of the clinical trials and may order the temporary or permanent discontinuation of clinical trials at any time if it believes the product candidate exposes clinical subjects to an unacceptable health risk. Investigational drugs used in clinical studies must be produced in compliance with cGMP rules pursuant to FDA regulations.

Sales outside the United States of products that we develop will also be subject to regulatory requirements governing human clinical trials and marketing for drugs and biological products and devices. The requirements vary widely from country to country, but typically the registration and approval process takes several years and requires significant resources.

If we experience delays or discontinuations of our clinical trials by the FDA or comparable authorities in other countries, or if we fail to obtain registration or other approvals of our products or devices then we could be forced to cease our operations and you will lose all of your investment.

Even if we are successful in developing BIV201, our product candidate, we have limited experience in conducting or supervising clinical trials that must be performed to obtain data to submit in concert with applications for approval by the FDA. The regulatory process to obtain approval for drugs for commercial sale involves numerous steps. Drugs are subjected to clinical trials that allow development of case studies to examine safety, efficacy, and other issues to ensure that sale of drugs meets the requirements set forth by various governmental agencies, including the FDA. In the event that our protocols do not meet standards set forth by the FDA, or that our data is not sufficient to allow such trials to validate our drugs in the face of such examination, we might not be able to meet the requirements that allow our drugs to be approved for sale which could have a materially adverse effect on our business.

We can provide no assurance that our product candidate will obtain regulatory approval or that the results of clinical studies will be favorable.

The business plan we have developed for the next twenty-four months is to complete the Phase 2 clinical development program for our lead new product candidate BIV201, commence a pivotal Phase 3 trial required for new drug approval, and to pursue other key milestones such as additional patent issuances and U.S. Orphan Drug designations. Due to our financial constraints, we may not have the resources necessary to complete our application. In light of the FDA meeting minutes, we plan to proceed to larger Phase 2b/3 or Phase 3 clinical trials upon receipt of the net proceeds of through our capital raising efforts. There is no guarantee the FDA will approve a Phase 2b/3 or Phase 3 trial, and even if they do our financial constraints may prevent us from undertaking clinical trials.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and disclosure of our trade secrets or proprietary information could compromise any competitive advantage that we have, which could have a materially adverse effect on our business.

Our success depends, in part, on our ability to protect our proprietary rights to the technologies used in our products. We depend heavily upon confidentiality agreements with our officers, employees, consultants and subcontractors to maintain the proprietary nature of our technology. These measures may not afford us complete or even sufficient protection, and may not afford an adequate remedy in the event of an unauthorized disclosure of confidential information. If we fail to protect and/or maintain our intellectual property, third parties may be able to compete more effectively against us, we may lose our technological or competitive advantage, and/or we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property. In addition, others may independently develop technology similar to ours, otherwise avoiding the confidentiality agreements, or produce patents that would materially and adversely affect our business, prospects, financial condition and results of operations, in which event you could lose all of your investment.

We may be unable to obtain or protect intellectual property rights relating to our products, and we may be liable for infringing upon the intellectual property rights of others, which could have a materially adverse effect on our business.

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies. In 2017 the USPTO issued the '945 patent directed to a method of treating a patient diagnosed with ascites due to liver cirrhosis by administering BIV201 (continuous infusion terlipressin) as a continuous infusion within specified doses over a specified duration. We cannot assure investors that we will continue to innovate and file new patent applications, or that if filed any future patent applications will result in granted patents with respect to the technology owned by us or licensed to us. Further, we cannot predict how long it will take for such patents to issue, if at all. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated or circumvented. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies, product candidates and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

Any patents we have obtained or do obtain may be challenged by re-examination or otherwise invalidated or eventually found unenforceable. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. If we were to initiate legal proceedings against a third party to enforce a patent related to one of our products or services, the defendant in such litigation could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, as are validity challenges by the defendant against the subject patent or other patents before the USPTO. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement, failure to meet the written description requirement, indefiniteness, and/or failure to claim patent eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent intentionally withheld material information from the USPTO, or made a misleading statement, during prosecution. Additional grounds for an unenforceability assertion include an allegation of misuse or anticompetitive use of patent rights, and an allegation of incorrect inventorship with deceptive intent. Third parties may also raise similar claims before the USPTO even outside the context of litigation. The outcome is unpredictable following legal assertions of invalidity and unenforceability. With respect to the validity question, for example, we cannot be certain that no invalidating prior art existed of which we and the patent examiner were unaware during prosecution. These assertions may also be based on information known to us or the Patent Office. If a defendant or third party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the claims of the challenged patent. Such a loss of patent protection would or could have a material adverse impact on our business.

The standards that the United States Patent and Trademark Office (and foreign countries) use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others.

Further, we rely on a combination of trade secrets, know-how, technology and nondisclosure, and other contractual agreements and technical measures to protect our rights in the technology. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the U.S., and we may encounter significant problems in protecting our proprietary rights in these countries.

We do not believe that BIV201, the product candidate we are currently developing, infringes upon the rights of any third parties nor are they infringed upon by third parties. However, there can be no assurance that our technology will not be found in the future to infringe upon the rights of others or be infringed upon by others. Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our products or product candidates infringe. For example, pending applications may exist that provide support or can be amended to provide support for a claim that results in an issued patent that our product infringes. In such a case, others may assert infringement claims against us, and should we be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. In addition to any damages we might have to pay, we may be required to obtain licenses from the holders of this intellectual property. We may fail to obtain any of these licenses or intellectual property rights on commercially reasonable terms. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Conversely, we may not always be able to successfully pursue our claims against others that infringe upon our technology. Thus, the proprietary nature of our technology or technology licensed by us may not provide adequate protection against competitors.

The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Moreover, the cost to us of any litigation or other proceeding relating to our patents and other intellectual property rights, even if resolved in our favor, could be substantial, and the litigation would divert our management's efforts. We may not have sufficient resources to bring any such action to a successful conclusion. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations and you could lose all of your investment.

We depend upon our management and their loss or unavailability could put us at a competitive disadvantage which could have a material adverse effect on our business.

We currently depend upon the efforts and abilities of our executive management team of Terren Peizer, our Chief Executive Officer, Jonathan Adams, our President and Chief Operating Officer, and Wendy Kim, our Chief Financial Officer and Corporate Secretary. Mr. Adams serves the Company full-time and Ms. Kim serves the Company part-time. The loss or unavailability of the services of either of these individuals for any significant period of time could have a material adverse effect on our business, prospects, financial condition and results of operations which may cause you to lose all of your investment. We have not obtained, do not own, nor are we the beneficiary of key-person life insurance.

We may not be able to attract and retain highly skilled personnel, which could have a materially adverse effect on our business.

Our ability to attract and retain highly skilled personnel is critical to our operations and expansion. We face competition for these types of personnel from other pharmaceutical companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human and other resources than us. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If we are not successful in attracting and retaining these personnel, our business, prospects, financial condition and results of operations will be materially and adversely affected.

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with enterprises equipped with more substantial resources than us, which could cause us to curtail or cease operations.

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition based primarily on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain government approval for testing, manufacturing and marketing.

We compete with biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions, government agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

Although there are not currently any therapies approved by the FDA specifically for the treatment of ascites due to liver cirrhosis, we still face significant competitive and market risk. Other companies, such as Mallinckrodt Inc., are developing therapies for severe complications of advanced liver cirrhosis, which may in the future be developed for the treatment of ascites, and these therapies could compete indirectly or directly with our product candidate. There may be other competitive development programs of which we are unaware. Even if our product candidate is ultimately approved by the FDA, there is no guarantee that once it is on the market doctors will adopt it in favor of current ascites treatment procedures such as diuretics and paracentesis. These competitive and market risks could have a material adverse effect on our business, prospects, financial condition and results of operations which may cause you to lose all of your investment.

Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of the market introduction of some of our potential product candidate or of competitors' products may be an important competitive factor. Accordingly, the relative speed with which we can develop drugs, complete pre-clinical testing, clinical trials, approval processes and supply commercial quantities to market are important competitive factors. We expect that competition among drugs approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent protection.

The successful development of biopharmaceuticals is highly uncertain. A variety of factors including, pre-clinical study results or regulatory approvals, could cause us to abandon the development of our product candidates.

Successful development of biopharmaceuticals is highly uncertain and is dependent on numerous factors, many of which are beyond our control.

Products that appear promising in the early phases of development may fail to reach the market for several reasons. Pre-clinical study results may show the product to be less effective than desired (e.g., the study failed to meet its primary objectives) or to have harmful or problematic side effects. Products may fail to receive the necessary regulatory approvals or may be delayed in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis or a IND and later NDA, preparation, discussions with the FDA, an FDA request for additional pre-clinical or clinical data or unexpected safety or manufacturing issues; manufacturing costs, pricing or reimbursement issues, or other factors that make the product not economical. Proprietary rights of others and their competing products and technologies may also prevent the product from being commercialized.

Success in pre-clinical and early clinical studies does not ensure that large-scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product to the next, and may be difficult to predict. There can be no assurance that any of our products will develop successfully, and the failure to develop our products will have a materially adverse effect on our business and will cause you to lose all of your investment.

There may be conflicts of interest among our officers, directors and stockholders.

Certain of our executive officers and directors and their affiliates are engaged in other activities and have interests in other entities on their own behalf or on behalf of other persons. Neither we nor any of our shareholders will have any rights in these ventures or their income or profits. In particular, our executive officers or directors or their affiliates may have an economic interest in or other business relationship with partner companies that invest in us or are engaged in competing drug development. Our executive officers or directors may have conflicting fiduciary duties to us and third parties. The terms of transactions with third parties may not be subject to arm's length negotiations and therefore may be on terms less favorable to us than those that could be procured through arm's length negotiations. Although we have established an audit committee comprised solely of independent directors to oversee transactions between us and our insiders, we do not have any formal policies in place to deal with such conflicting fiduciary duties should such a conflict arise.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or detect fraud. Consequently, investors could lose confidence in our financial reporting and this may decrease the trading price of our common stock.

We must maintain effective internal controls to provide reliable financial reports and detect fraud. We have concluded that our disclosure controls and procedures internal controls, as well as internal controls over financial reporting, are effective. Failure to implement changes to our internal controls or any others that we identify as necessary to establish an effective system of internal controls could harm our operating results and cause investors to lose confidence in our reported financial information. Any such loss of confidence would have a negative effect on the trading price of our common stock.

We may enter into employment agreements with our executive officers and compensation payable thereunder may not be based on arms-length negotiations.

Certain of our current executive officers also serve as directors of our Board of Directors, and we have not yet formed an independent compensation committee to determine compensation and to approve employment agreements. Therefore, compensation which may be paid by us to our management under current arrangements may not have been determined based on arms-length negotiations. We may grant stock options and other equity incentives to our executive officers and directors that are consistent with the nature of the pharmaceutical industry. Although we have established a compensation committee in connection with our capital raise efforts and anticipated uplisting to the Nasdaq Capital Market ("Nasdaq"), comprised of only independent directors, there can be no assurance made that the consideration which may be payable to management will reflect the true market value of services provided to us.

RISKS RELATING TO OUR COMMON STOCK

There is a risk of dilution of your percentage ownership of Common Stock in the Company.

We have the right to raise additional capital or incur borrowings from third parties to finance its business. We may also implement public or private mergers, business combinations, business acquisitions and similar transactions pursuant to which it would issue substantial additional capital stock to outside parties, causing substantial dilution in the ownership of the Company by our existing stockholders. Our Board of Directors has the authority, without the consent of any of the stockholders, to cause us to issue more shares of common stock and/or preferred stock at such price and on such terms and conditions as are determined by the Board of Directors in its sole discretion. As of September 24, 2019, there were warrants outstanding to purchase an aggregate of 171,833,216 shares of common stock at exercise prices ranging from $0.015 to $0.60 per share. The issuance of additional shares of capital stock by us will dilute your ownership percentage in the Company and could impair our ability to raise capital in the future through the sale of equity securities.

Certain stockholders who are also officers and directors of the Company may have significant control over our management.

Our directors and executive officers currently own an aggregate of 558,659,030 shares of our common stock, which currently constitutes 86.2% of our issued and outstanding common stock. As a result, directors and executive officers may have a significant influence on our affairs and management, as well as on all matters requiring member approval, including electing and removing members of our Board of Directors, causing us to engage in transactions with affiliated entities, causing or restricting our sale or merger, and certain other matters. Our Chairman and Chief Executive Officer, Mr. Terren Peizer, may be deemed to beneficially own the shares held by Acuitas. Such concentration of ownership and control could have the effect of delaying, deferring or preventing a change in control of us even when such a change of control would be in the best interests of our stockholders.

There is not now, and there may never be, an active, liquid and orderly trading market for our common stock, which may make it difficult for you to sell your shares of our common stock.

There is not now, nor has there been since our inception, any significant volume of trading activity in our common stock or an active market for shares of our common stock, and an active trading market for our shares may never develop or be sustained. As a result, investors in our common stock must bear the economic risk of holding those shares for an indefinite period of time. Although our common stock is quoted on the OTCQB Marketplace, or OTCQB, over-the-counter quotation system, trading of our common stock on such system has only recently commenced and continues to be extremely limited and sporadic and at very low volumes. Although we have applied to list our common stock on Nasdaq and should our common stock be listed on the Nasdaq, an active trading market for our common stock may never develop or be sustained. If an active market for our common stock does not develop, it may be difficult for you to sell shares of our common stock without depressing the market price for the shares or at all. Further, an unestablished trading market for our common stock may also impair our ability to raise capital by selling additional equity in the future, and may impair our ability to enter into strategic partnerships or acquire companies or products by using shares of our common stock as consideration.

Our common stock is subject to the "penny stock" rules of the SEC and the trading market in our securities is limited, which makes transactions in our stock cumbersome and may reduce the value of an investment in our stock.

Under U.S. federal securities legislation, our common stock currently constitutes a "penny stock". Penny stock is any equity security that has a market price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require that a broker or dealer approve a potential investor's account for transactions in penny stocks, and the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased. In order to approve an investor's account for transactions in penny stocks, the broker or dealer must obtain financial information and investment experience objectives of the person, and make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks. The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prepared by the Securities and Exchange Commission (the "SEC") relating to the penny stock market, which, in highlight form sets forth the basis on which the broker or dealer made the suitability determination. Brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our stock. Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

We may, in the future, issue additional common stock, which would reduce investors' percent of ownership and may dilute our share value.

As of June 30, 2019, our Articles of Incorporation authorize the issuance of 800,000,000 shares of common stock. As of September 24, 2019, we had 647,930,147 shares of common stock outstanding. Accordingly, we may issue up to an additional 152,069,853 shares of common stock. The future issuance of common stock may result in substantial dilution in the percentage of our common stock held by our then existing shareholders. We may value any common stock in the future on an arbitrary basis. The issuance of Common Stock for future services or acquisitions or other corporate actions may have the effect of diluting the value of the shares held by our investors, might have an adverse effect on any trading market for our common stock and could impair our ability to raise capital in the future through the sale of equity securities.

We have a large number of restricted shares outstanding, a portion of which may be sold under Rule 144 which may reduce the market price of our shares.

Of the 647,930,147 shares of common stock issued and outstanding as of September 24, 2019, 89,271,117 shares are held by non-affiliates and 558,659,030 are owned by affiliates of the Company, consisting of our officers and directors or entities controlled by them. The majority of our common stock, including all of the affiliates' securities are deemed "restricted securities" within the meaning of Rule 144 as promulgated under the Securities Act.

It is anticipated that all of the "restricted securities" will be eligible for resale under Rule 144. In general, under Rule 144, subject to the satisfaction of certain other conditions, a person, who is not an affiliate (and who has not been an affiliate for a period of at least three months immediately preceding the sale) and who has beneficially owned restricted shares of our common stock for at least six months is permitted to sell such shares without restriction, provided that there is sufficient public information about us as contemplated by Rule 144. An affiliate who has beneficially owned restricted shares of our common stock for a period of at least one year may sell a number of shares equal to one percent of our issued and outstanding common stock approximately every three months.

The respective holding periods for the shares issued to affiliates and non-affiliates holding restricted securities commenced and were issued between May 17, 2013 and June 30, 2013. The possibility that substantial amounts of our common stock may be sold under Rule 144 into the public market may adversely affect prevailing market prices for the common stock and could impair our ability to raise capital in the future through the sale of equity securities.

Any failure to maintain effective internal control over financial reporting could harm us.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. 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 in accordance with U.S. generally accepted accounting principles ("GAAP"). Under standards established by the Public Company Accounting Oversight Board ("PCAOB"), a deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or personnel, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. The PCAOB defines a material weakness as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented, or detected and corrected, on a timely basis.

If we are unable to assert that our internal control over financial reporting is effective, or when required in the future, if our independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be adversely affected and we could become subject to litigation or investigations by the stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources.

The lack of public company experience of our management team could adversely impact our ability to comply with the reporting requirements of U.S. securities laws, which could have a materially adverse effect on our business.

Our officers have limited public company experience, which could impair our ability to comply with legal and regulatory requirements such as those imposed by Sarbanes-Oxley Act of 2002. Such responsibilities include complying with federal securities laws and making required disclosures on a timely basis. Any such deficiencies, weaknesses or lack of compliance could have a materially adverse effect on our ability to comply with the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which is necessary to maintain our public company status. If we were to fail to fulfill those obligations, our ability to continue as a U.S. public company would be in jeopardy in which event you could lose your entire investment in our Company.

We are considered a smaller reporting company and is exempt from certain disclosure requirements, which could make our stock less attractive to potential investors.

Rule 12b-2 of the Exchange Act defines a "smaller reporting company" as an issuer that is not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent that is not a smaller reporting company and that:

- Had a public float of less than $250 million as of the last business day of its most recently completed fiscal quarter, computed by multiplying the aggregate number of worldwide number of shares of its voting and non-voting common equity held by non-affiliates by the price at which the common equity was last sold, or the average of the bid and asked prices of common equity, in the principle market for the common equity; or

- In the case of an initial registration statement under the Securities Act or the Exchange Act for shares of its common equity, had a public float of less than $250 million as of a date within 30 days of the date of the filing of the registration statement, computed by multiplying the aggregate worldwide number of such shares held by non-affiliates before the registration plus, in the case of a Securities Act registration statement, the number of such shares included in the registration statement by the estimated public offering price of the shares; or

- In the case of an issuer who had annual revenue of less than $100 million during the most recently completed fiscal year for which audit financial statements are available, had a public float as calculated under paragraph (1) or (2) of this definition that was either zero or less than $700 million.

As a “smaller reporting company” we are not required and may not include a Compensation Discussion and Analysis (“CD&A”) section in our proxy statements; we provide only 3 years of business development information; provide fewer years of selected data; and have other “scaled” disclosure requirements that are less comprehensive than issuers that are not “smaller reporting companies” which could make our stock less attractive to potential investors, which could make it more difficult for you to sell your shares.

We have not held regular annual meetings of stockholders in the past, and if we are required by the Nevada District Court to hold an annual meeting pursuant to Nevada Revised Statutes §78.345(1), it could result in the unanticipated expenditure of funds, time and other Company resources.

Section 1 of Article II of our bylaws provides that an annual meeting of stockholders shall be held each year on a date and at a time designated by our Board of Directors. Section 78.345(1) of the Nevada Revised Statutes provides that if there is a failure to hold the annual meeting for a period of 18 months after the last election of directors, stockholders owning at least 15% of the voting power of the outstanding common stock may apply to the Nevada district court to order the election of directors.

We have not held regular annual meetings of stockholders in the past because a substantial majority of our stock is owned by a small number of stockholders, making it easy to obtain written consent in lieu of a meeting when necessary. In light of our historical liquidity constraints, handling matters by written consent has allowed us to save on financial and administrative resources required to prepare for and hold such annual meetings. Additionally, we have applied to list our common stock on Nasdaq, and should our common stock be listed on Nasdaq, we will be obligated to hold regular annual meetings of stockholders in the future. It is currently contemplated that we will hold such meetings beginning in 2020 should we be so listed in 2019.

To our knowledge, no stockholder or director has requested our management to hold such an annual meeting and no stockholder or director has applied to the Nevada district court seeking an order directing us to hold a meeting of stockholders. However, if one or more stockholders or directors were to apply to the Nevada district court seeking such an order, and if the Nevada district court were to order an annual meeting before we were prepared to hold one, the preparation for the annual meeting of stockholders and the meeting itself could result in the unanticipated expenditure of funds, time, and other Company resources.

We are subject to the periodic reporting requirements of the Exchange Act, which require us to incur audit fees and legal fees in connection with the preparation of such reports. These additional costs will negatively affect our ability to earn a profit.

We are required to file periodic reports with the SEC pursuant to the Exchange Act and the rules and regulations thereunder. In order to comply with such requirements, our independent registered auditors have to review our financial statements on a quarterly basis and audit our financial statements on an annual basis. Moreover, our legal counsel has to review and assist in the preparation of such reports. Factors such as the number and type of transactions that we engage in and the complexity of our reports cannot accurately be determined at this time and may have a major negative effect on the cost and amount of time to be spent by our auditors and attorneys. However, the incurrence of such costs is an expense to our operations and thus has a negative effect on our ability to meet our overhead requirements and earn a profit.

Because we do not intend to pay any cash dividends on our common stock, our stockholders will not be able to receive a return on their shares unless they sell them.

We intend to retain any future earnings to finance the development and expansion of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Unless we pay dividends, our stockholders will not be able to receive a return on their shares unless they sell them. There is no assurance that stockholders will be able to sell shares when desired.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

On October 1, 2018, the Company executed a lease agreement with Acuitas Group Holdings, LLC (related party) for the Company's office space at 2120 Colorado Avenue, Santa Monica, CA 90404. The lease is a month-to-month lease that may be cancelled upon 30 days' written notice and requires monthly payments of $1,000.

ITEM 3. LEGAL PROCEEDINGS

To our knowledge, neither the Company nor any of our officers or directors is a party to any material legal proceeding or litigation and such persons know of no material legal proceeding or contemplated or threatened litigation, other than as described below. There are no judgments against us or our officers or directors. None of our officers or directors has been convicted of a felony or misdemeanor relating to securities or performance in corporate office.

On April 30, 2018, we received notice that Mallinckrodt had petitioned the U.S. Patent and Trademark Office ("USPTO") to institute an *Inter Partes* Review of our U.S. Patent No. 9,655,945 titled "Treatment of Ascites" (the "'945 patent"). *Inter Partes* Review is a trial proceeding conducted with the USPTO Patent Trial and Appeal Board (PTAB) to review the patentability of one or more claims of a patent. Such review is limited to grounds of novelty and obviousness on the basis of prior art consisting of patents and printed publications. For further information regarding these proceedings, please see footnote 7 to our financial statements appearing elsewhere in this annual report.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

ITEM 5. MARKET FOR COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITES

Unregistered Sales of Securities

All sales of unregistered securities during the year ended June 30, 2019 were previously disclosed in a Quarterly Report on Form 10-Q or Current report on Form 8-K.

Issuer Purchases of Common Stock

During the fourth quarter of the year ended June 30, 2019, there were no issuer repurchases of shares of common stock. On June 24, 2019, Acuitas agreed to exchange certain of its existing warrants for common stock for an aggregate of 1,526,333 shares of common stock

ITEM 6. SELECTED FINANCIAL DATA

Not Required.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of the Company's financial condition and the results of operations should be read in conjunction with the Financial Statements and Notes thereto appearing elsewhere in this report.

Overview

We are a clinical stage biotechnology company engaged in the discovery, development and commercialization of therapies targeting life-threatening complications of liver cirrhosis. Our initial disease target is ascites, a serious medical condition affecting about 100,000 Americans and many times more worldwide. Our therapeutic product candidate BIV201 is based on a drug that is approved in about 40 countries to treat related complications of liver cirrhosis (part of the same disease pathway as ascites), but not yet available in the US. The active agent in BIV201, terlipressin, is a potent vasoconstrictor which is in use for various medical conditions around the world. The goal is for BIV201 to interrupt the ascites disease pathway, thereby halting the cycle of accelerating fluid generation in ascites patients.

BioVie accomplished the following key milestones during the twelve months ended June 30, 2019:

- In July 2018, we completed an equity investment with Acuitas and other investors that provided gross proceeds of $3.2 million to BioVie.
- In November 2018, the Company announced that BIV201 had been granted an Orphan Drug designation for hepatorenal syndrome.
- In February 2019, we completed patient enrollment in our mid-stage (Phase 2a) clinical trial of BIV201 for the treatment of refractory ascites.
- In April 2019, we announced top-line results for the Phase 2a clinical trial of BIV201 in six patients.
- On June 18, 2019, we met with representatives of the U.S. Food &Drug Administration ("FDA") for a Type C Guidance Meeting to plan our next clinical study following the recently completed Phase 2a clinical trial. We discussed our clinical development efforts with the FDA and proposed trial endpoints. While the FDA has not provided final guidance nor do we have certainty as to what that guidance would entail, our goal remains to proceed into a Phase 2b/3 or Phase 3 clinical trial in a manner consistent with what was reviewed with the FDA. We may still need to address certain risks associated with unvalidated quality of life measures. In July 2019, the FDA provided its meeting minutes for the June 18, 2019 meeting that documented general agreement with the Company proposed randomized study design. The FDA also provided its suggestions and guidance regarding primary and secondary endpoints and other key aspects of our clinical trial design and the Company is incorporating those suggestions as it moves forward.
- In August 2019, we developed a proprietary novel liquid formulation of terlipressin that is intended to improve convenience for outpatient administration and avoid potential formulation errors when pharmacists reconstitute the powder version.

Results of Operations

Comparison of the Year Ended June 30, 2019 to the Year Ended June 30, 2018

Summary of Operating Expenses

Total operating expenses for fiscal year ended June 30, 2019 were $2,497,000 compared to $2,372,000 for the year ended June 30, 2018. The net increase of $125,000 was primarily due to an increase in research and development expenses of $637,000 as the Company resumed and completed its Phase 2a clinical trial program during the year and hired 1 full time employee and 1 half time employee in November 2018, who were previously consultants; offset by a reduction in selling, general and administrative expenses of $512,000 which represented the issuance of common stock in August 2017 and January 2018 as compensation for professional services.

Research and Development

Research and development expenses for the year ended June 30, 2019 increased by $637,000 to $1,008,000 from $371,000 for fiscal year ended June 30, 2018. The increase was primary attributed to the Phase 2a clinical trial activities which began and was completed during the year and the hiring of 1 full time and 1 half time employee in November 2018, who were previously consultants.

Selling, General and Administrative

Selling, general and administrative expenses declined by $513,000 to $1,259,000 for the fiscal year ended June 30, 2019 compared to $1,772,000 for the fiscal year ended June 30, 2018. The reduction in expense was primarily related to compensation paid in BioVie common stock during the fiscal year ended June 30, 2018 related to financial and strategic advisory services provided of approximately $642,000 which did not occur during fiscal year ended June 30, 2019.

Liquidity and Capital Resources

At June 30, 2019 the Company had approximately $340,000 in cash and cash equivalents and had completed its Phase 2a clinical trial of the BIV201 therapy. On September 24, 2019, the Company entered into a Securities Purchase Agreement with its controlling stockholder regarding bridge financing (the “Bridge Financing”) in the form of up to $2.0 million in convertible debt and warrants, of which $500,000 has been drawn to date. Amounts borrowed under the Bridge Financing must be repaid with the proceeds of our potential public offering of equity securities referred to below. As further discussed below, the Company is pursuing various options to raise further financing to continue the testing and development of its product. If the Company is not successful in raising additional funds it may reduce its monthly spend and potentially delay the implementation of the larger scale Phase 2b Clinical trial until sufficient funding is secured.

As of June 30, 2019, the Company had an accumulated deficit of approximately $7.3 million and as a development stage enterprise, the Company expects substantial losses in future periods. The accompanying annual financial statements were prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company’s future operations are dependent on the success of the Company’s ongoing development and commercialization effort, as well as continuing to secure additional financing.

We cannot assure you that our drug candidate will be developed, work, or receive regulatory approval; that we will ever earn revenues sufficient to support our operations or that we will ever be profitable. Furthermore, since we have no committed source of financing, we cannot assure you that we will be able to raise money as and when we need it to continue our operations. If we cannot raise funds as and when we need them, we may be required to severely curtail, or even to cease, our operations.

Additionally, in April 2019, to facilitate our planned uplisting to Nasdaq and related potential future issuances and sales of our equity securities for ordinary corporate finance and general corporate purposes and as recommended by our Board of Directors ("Board"), our stockholders approved an amendment to our Articles of Incorporation to effect a reverse split of our outstanding Class A common stock in the range of 50:1 to 200:1, as determined by our Board. Following that approval, we filed a Registration Statement on Form S-1 (Registration No. 333-231136) (the "S-1 Registration Statement") pursuant to which we anticipate completing an offering of our equity securities with proceeds sufficient, after repayment of amounts owed under the Bridge Financing, to enable the launch and completion of the BIV201 Phase 2b study and fund our internal operations for at least the next twelve months. There can be no assurance, however, that we will achieve effectiveness of the S-1 Registration Statement or successfully complete an offering thereunder.

Management intends to attempt to secure additional required funding primarily through additional equity or debt financings. We may also seek to secure required funding through sales or out-licensing of intellectual property assets, seeking partnerships with other pharmaceutical companies or third parties to co-develop and fund research and development efforts, or similar transactions. However, there can be no assurance that we will be able to obtain required funding. If we are unsuccessful in securing funding from any of these sources, we will defer, reduce or eliminate certain planned expenditures in our research protocols. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that could result in our stockholders losing some or all of their investment in us.

These circumstances raise substantial doubt on our ability to continue as a going concern. These financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might result from this uncertainty.

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect or change on the Company's financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors. The term "off-balance sheet arrangement" generally means any transaction, agreement or other contractual arrangement to which an entity unconsolidated with the Company is a party, under which the Company has (i) any obligation arising under a guarantee contract, derivative instrument or variable interest; or (ii) a retained or contingent interest in assets transferred to such entity or similar arrangement that serves as credit, liquidity or market risk support for such assets.

Critical Accounting Policies and Estimates

Stock-based Compensation

The Company has accounted for stock-based compensation under the provisions of FASB ASC 718 – "Stock Compensation" which requires the use of the fair-value based method to determine compensation for all arrangements under which employees and others receive shares of stock or equity instruments (stock options and common stock purchase warrants). For employee awards, the fair value of each stock option award is estimated on the date of grant using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. For non-employees, the fair value of each stock option award is estimated on the measurement date using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. For non-employees, the Company utilizes the graded vesting attribution method under which the entity treats each separately vesting portion (tranche) as a separate award and recognizes compensation cost for each tranche over its separate vesting schedule. Expected volatilities are based on historical volatility of peer companies and other factors estimated over the expected term of the stock options. For employee awards, the expected term of options granted is derived using the "simplified method" which computes expected term as the average of the sum of the vesting term plus the contract term. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term. We recognize forfeitures when they occur.

Goodwill

Goodwill represents costs in excess of fair values assigned to the underlying net assets of acquired businesses. We test goodwill annually, or when a triggering event occurs between annual impairment tests, to determine if impairment exists and if the use of indefinite life is currently applicable. The Company did not recognize any goodwill impairments for the years ended June 30th, 2018 and, 2019, respectively.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of the assets to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets and would be charged to earnings.

Recent accounting pronouncements

The Company considers the applicability and impact of all Accounting Standard Updates ("ASU's"). ASU's not discussed below were assessed and determined to be either not applicable or expected to have minimal impact on our balance sheets or statement of operations.

In June 2018, the FASB issued ASU 2018-07, "Compensation - Stock Compensation (Topic 718): Improvements to non-employee share based accounting", which simplifies the accounting for non-employee share-based payment transactions. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The standard will be effective for the Company in the first quarter of fiscal year 2020. The Company does not expect that the adoption of this ASU will have a significant impact on its financial statements.

In July 2017, the FASB issued Accounting Standards Update ("ASU") No. 2017-11. "Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features, II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. ASU 2017-11 revises the guidance for instruments with down round features in Subtopic 815-40, Derivatives and Hedging – Contracts in Entity's Own Equity, which is considered in determining whether an equity-linked financial instrument qualifies for a scope exception from derivative accounting. An entity still is required to determine whether instruments would be classified in equity under the guidance in Subtopic 815-40 in determining whether they qualify for that scope exception. If they do qualify, freestanding instruments with down round features are no longer classified as liabilities. ASU 2017-11 is effective for annual and interim periods beginning December 15, 2018, and early adoption is permitted, including adoption in an interim period. ASU 2017-11 provides that upon adoption, an entity may apply this standard retrospectively to outstanding financial instruments with a down round feature by means of a cumulative-effect adjustment to the opening balance of retaining earnings in the fiscal year and interim period adopted. The Company has adopted ASU2017-11 retrospectively as of January 1, 2019. The adoption of this ASU did not have an impact on the financial statement.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS

Our financial information required to be filed hereunder are indexed under Item 15 of this report and are incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

Not required.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We have evaluated, with the participation of our principal executive and our principle financial officer, the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15(d)-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of the effectiveness of internal control 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 policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of June 30, 2019 using the criteria established in Internal Control Integrated Framework ("2013 Framework") issued by the Committee of Sponsoring Organization of the Treadway Commission ("COSO"). Based on our evaluation using those criteria, our management has concluded that, as of June 30, 2019, our internal control over financial reporting was effective 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 for the reasons discussed above.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal controls over financial reporting during the fourth quarter of year ended June 30, 2019, that materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

Part III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth certain information regarding our Board of Directors, our executive officers, and some of our key employees, as of the date of this report.

Name	Age	Director Since	Position
Terren Peizer	60	2018	Chairman & Chief Executive Officer
Jonathan Adams	56	2016	President & Chief Operating Officer
Joanne Wendy Kim	64	--	Chief Financial Officer and Corporate Secretary
Patrick Yeramian, MD	61	--	Chief Medical Officer
Penelope Markham, PhD	53	--	Chief Scientific Officer
Jim Lang	54	2016	Independent Director
Cuong Do	53	2016	Independent Director
Hari Kumar	63	2017	Independent Director
Michael Sherman	60	2017	Independent Director
Richard J. Berman	76	2019	Independent Director

According to our Bylaws, the directors shall be elected at the annual meeting of the stockholders and each director shall be elected to serve until his successor shall be elected and shall qualify. A director need not be a stockholder. Directors shall not receive any stated salary for their services as directors or as members of committees, but by resolution of the Board of Directors a fixed fee and expenses of attendance may be allowed for attendance at each meeting. The Bylaws shall not be construed to preclude any director from serving the Company in any other capacity as an officer, agent or otherwise, and receiving compensation therefor.

There are no familial relationships among any of our directors or officers. Mr. Terren Peizer, Chairman of the Board of Directors and Chief Executive Officer, is also the founder of Catasys, Inc. a U.S. reporting company listed on Nasdaq on whose board Mr. Sherman also serves. Additionally, Jim Lang currently serves as a director at OptimizeRX, a U.S. reporting company that is listed on the Nasdaq stock exchange. None of our other directors or officers is or has been a Director or has held any form of directorship in any other U.S. reporting companies. None of our directors or officers has been affiliated with any Company that has filed for bankruptcy within the last five years. We are not aware of any proceedings to which any of our officers or directors, or any associate of any such officer or director, is a party that are adverse to the Company. We are also not aware of any material interest of any of our officers or directors that is adverse to our own interests.

Mr. Terren Peizer, Chairman of the Board of Directors and Chief Executive Officer, is an entrepreneur, investor, and financier with a particular interest in healthcare, having founded and successfully commercialized several healthcare companies. Mr. Peizer is the founder of Catasys, Inc., a leader in behavioral and mental health management services, having served as the Chairman of the Board of Directors and CEO of Catasys since inception in 2004. Mr. Peizer also is the Founder, Chairman and CEO and majority shareholder of NeurMedix, Inc., a biotechnology Company with a focus on inflammatory, neurological and neuro-degenerative diseases. Mr. Peizer is Chairman of Acuitas Group Holdings, LLC, his personal holding company that owns his portfolio Company interests. Through Acuitas, he owns Crede Capital Group, LLC, an industry leader in investing in micro and small capitalization public equities, having invested over $1.2 billion directly into portfolio companies. Previously he was Chairman of Cray, Inc., the leading supercomputing Company, and held senior executive positions at various publicly-traded growth companies and with the investment banking firms Goldman Sachs, First Boston, and Drexel Burnham Lambert. He received his B.S.E. in finance from The Wharton School of Finance and Commerce.

Mr. Jonathan Adams has served as the Company's Chief Executive Officer and Chief Financial Officer from the time acquired LAT Pharma LLC on April 11, 2016 until July 2018. In July 2018, he began serving as the Company's President and Chief Operating Officer. He founded LAT Pharma LLC and served as its Chief Executive Officer prior to its acquisition. Mr. Adams is a co-inventor of the Company's patent covering the use of terlipressin to treat ascites patients. He has over 29 years of biopharmaceutical industry experience, including corporate finance, company acquisitions and licensing deals, marketing and sales support. At Searle Pharmaceuticals he was a member of the global launch team for Celebrex, and he has worked on launching numerous new drugs and medical devices. Mr. Adams earned a BS at Cornell University and an MBA at the Tuck School at Dartmouth.

Ms. Joanne Wendy Kim has served as the Company's Chief Financial Officer since October 2018. Ms. Kim previously served as CFO for several companies throughout her career, most recently with Landmark Education Enterprises, and she has provided interim CFO services to various organizations through Group JWK from 2016 to 2018. In her various roles, Ms. Kim oversaw corporate finance and operational groups, closed eight acquisitions, secured bank financings, developed and implemented new business strategies, managed risk and implemented new financial policies and procedures. As a CPA, Ms. Kim provided accounting, SEC filing review and other business consultative services to clients serving as a Director at BDO USA, LLP's National Office SEC Department in 2008-2016 and as a Senior Manager at KPMG in earlier part of her career. She brings more than 30 years of accounting experience to this position. Ms. Kim earned her BBA in accounting and finance at California State University, Long Beach.

Dr. Patrick Yeramian has served as the Company's Chief Medical Officer since November 2018. Dr. Yeramian has over 25 years of experience in the pharmaceutical industry. He has supervised the clinical development of new drugs, biopharmaceuticals, cellular therapy agents, and vaccines as well as having held a prominent role in the approval of several new drug (metronidazole – Flagyl MR ®), biological (interferon alpha – Multiferon®, nafarelin – Synarel®) and device (Inerpan®) applications in the U.S. in the EC and the granting of over 20 successful INDs and IMPDs. Dr Yeramian was the Medical Director of the Vaccine and Gene Therapy Institute, Florida from October 2011 to February 2015 and a consulting Medical Director for Tapimmune Inc. from February 2015 to January 2017 and Kantum Diagnostics from March 2017 to March 2019. Dr. Yeramian currently serves as the Medical Director of Amylyx Inc. (since March 2019) and as the General Manager of DLx Therpeutics LLC (since January 2018). Previously he served as Chief Medical Officer at Viragen, Inc. where he was responsible for development of global clinical and regulatory strategies and for implementation of clinical programs worldwide. Earlier Dr. Yeramian also served as Director of clinical research at GD Searle where he supervised the clinical programs for antibiotics, antivirals, sepsis/thrombosis, and cancer vaccines. Dr. Yeramian holds a Medical Degree from the University of Paris together with a Master of Clinical Science in experimental oncology and a Graduate Degree in molecular virology. He also earned a Master of Business Administration from Rutgers University. He completed his medical residency in oncology at the Saint-Louis Hospital in Paris.

Dr. Penelope Markham has served as the Company's Chief Scientific Officer since November 2018. She was previously our Chief Scientist. Dr. Markham served as a Technical Consultant at LAT Pharma for 7 years prior to our acquisition of LAT Pharma. She has spent 15 years in immunology, infectious disease, bacteriology and drug discovery research. Dr. Markham was a co-founder and Research Director for Influx, Inc. involved in antibiotic drug discovery. She has been a member of NIH grant review panels and consulted for several pharmaceutical companies in a variety of therapeutic areas including Orphan Drug development. Dr. Markham has more than 20 publications in peer-reviewed journals and three patents. She holds a BS in Biochemistry from the University College Cork, Ireland, a Masters from Strathclyde University, Scotland, and a PhD from Rush University, Chicago.

Mr. Cuong Do has been President, Global Strategy Group, at Samsung since February 2015. Mr. Do helps to set the strategic direction for Samsung Group's diverse business portfolio. He was previously the Chief Strategy Officer for Merck from October 2011 to March 2014, Tyco Electronics, and Lenovo. Mr. Do is a former senior partner at McKinsey & Company, where he spent 17 years and helped build the healthcare, high tech and corporate finance practices. He holds a BA from Dartmouth College, and an MBA from the Tuck School of Business at Dartmouth.

Mr. Jim Lang is currently CEO of Water Street Capital's and JLL Partner's Global Life Sciences Services Platform. He formerly served as the CEO of Decision Resources Group (DRG), which he transformed into a leading healthcare data and analytics firm. Prior to that, Jim was CEO of IHS Cambridge Energy Research Associates (IHS CERA), a recognized leader in energy industry subscription information products, and formerly the President of Strategic Decisions Group (SDG), a leading global strategy consultancy. Mr. Lang holds a BS summa cum laude in electrical and computer engineering from the University of New Hampshire and an MBA with Distinction from the Tuck School of Business. Jim Lang currently also serves as a Director at OptimizeRX, a Nasdaq listed Company.

Hari Kumar, PhD held positions of increasing responsibility at Roche Pharma culminating in serving as Global Business Development Director, and in 2007 assumed the role of Chief Business Officer for Amira Pharmaceuticals. He led the sale of Amira to Bristol-Myers Squibb in 2011 for $475 million. He then served as Chief Executive Officer (CEO) for Panmira Pharmaceuticals LLC, which is developing anti-inflammatory compounds, and in 2013 became CEO for Adheron Therapeutics, which Roche Pharma acquired in 2015 for $580 million. Dr. Kumar earned a PhD in immunology in 1984.

Richard J. Berman was Chairman of National Investment Managers, a company with $12 billion pension administration assets from 2006-2011. Mr. Berman is a director of four other public healthcare companies: Catasys, Inc., Advaxis, Inc., Cryoport Inc. and Immuron Ltd. and a public fintech company, Cuentas, Inc. From 1998-2000, he was employed by Internet Commerce Corporation (now Easylink Services) as Chairman and CEO, and was a director from 1998-2012. Previously, Mr. Berman was Senior Vice President of Bankers Trust Company, where he started the M&A and Leveraged Buyout Departments; created the largest battery company in the world in the 1980's by merging Prestolite, General Battery and Exide and advised on over $4 billion of M&transactions (completed over 300 deals). He is a past Director of the Stern School of Business of NYU where he obtained his BS and MBA. He also has US and foreign law degrees from Boston College and The Hague Academy of International Law, respectively.

Michael Sherman JD retired from his position as a Managing Director at Barclays Plc in 2018, where he had worked since 2008. Previously he was a Managing Director at Lehman Brothers, Inc. He has worked in investment banking for 30 years. Mr. Sherman has significant experience in healthcare finance, most recently assisting on a $450 million convertible transaction for Neurocrine Biosciences. He has worked on successful financial transactions for Teva Pharmaceutical Industries, Amgen Inc., Cubist Pharmaceuticals, Merck & Co., and Cardinal Health, among other companies. After graduating from the University of Pennsylvania, Michael Sherman received his JD, cum laude, from the Harvard Law School.

Section 16(a) beneficial ownership reporting compliance

Committees of the Board of Directors

Our Board of Directors has three standing committees: an audit committee, a compensation committee and a nominating and corporate governance committee. Both our audit committee and our compensation committee are composed solely of independent directors. Subject to phase-in rules, the rules of Nasdaq and Rule 10A-3 of the Exchange Act require that the audit committee of a listed company be comprised solely of independent directors, and the rules of Nasdaq require that the compensation committee and the nominating and corporate governance committee of a listed company be comprised solely of independent directors. Each committee operates under a charter approved by our Board of Directors and will have the composition and responsibilities described below.

Audit committee

We have established an audit committee of the Board of Directors. The members of our audit committee are Michael Sherman, Jim Lang and Richard J. Berman, each of which is an independent director within the meaning of the Nasdaq rules. Mr. Sherman serves as chairman of the audit committee.

We have adopted an audit committee charter, detailing the principal functions of the audit committee, including:

- assisting board oversight of (1) the integrity of our financial statements, (2) our compliance with legal and regulatory requirements, (3) our independent auditor's qualifications and independence, and (4) the performance of our internal audit function and independent auditors; the appointment, compensation, retention, replacement, and oversight of the work of the independent auditors and any other independent registered public accounting firm engaged by us;

- pre-approving all audit and non-audit services to be provided by the independent auditors or any other registered public accounting firm engaged by us, and establishing pre-approval policies and procedures; reviewing and discussing with the independent auditors all relationships the auditors have with us in order to evaluate their continued independence;

- setting clear policies for audit partner rotation in compliance with applicable laws and regulations;

- obtaining and reviewing a report, at least annually, from the independent auditors describing (1) the independent auditor's internal quality-control procedures and (2) any material issues raised by the most recent internal quality-control review, or peer review, of the audit firm, or by any inquiry or investigation by governmental or professional authorities, within the preceding five years respecting one or more independent audits carried out by the firm and any steps taken to deal with such issues;

- meeting to review and discuss our annual audited financial statements and quarterly financial statements with management and the independent auditor, including reviewing our specific disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations"; reviewing and approving any related party transaction required to be disclosed pursuant to Item 404 of Regulation S-K promulgated by the SEC prior to us entering into such transaction; and

- reviewing with management, the independent auditors, and our legal advisors, as appropriate, any legal, regulatory or compliance matters, including any correspondence with regulators or government agencies and any employee complaints or published reports that raise material issues regarding our financial statements or accounting policies and any significant changes in accounting standards or rules promulgated by the Financial Accounting Standards Board, the SEC or other regulatory authorities.

Compensation Committee

We have established a compensation committee of the Board of Directors. The members of our Compensation Committee are Mr. Berman, Mr. Kumar and Mr. Sherman. Mr. Berman serves as chairman of the compensation committee.

We have adopted a compensation committee charter, which details the principal functions of the compensation committee, including:

- reviewing and approving on an annual basis the corporate goals and objectives relevant to our Chief Executive Officer's compensation, evaluating our Chief Executive Officer's performance in light of such goals and objectives and determining and approving the remuneration (if any) of our Chief Executive Officer based on such evaluation;

- reviewing and making recommendations to our Board of Directors with respect to the compensation, and any incentive-compensation and equity-based plans that are subject to board approval of all of our other officers;

- reviewing our executive compensation policies and plans;

- implementing and administering our incentive compensation equity-based remuneration plans; assisting management in complying with our proxy statement and annual report disclosure requirements;

- approving all special perquisites, special cash payments and other special compensation and benefit arrangements for our officers and employees;

- producing a report on executive compensation to be included in our annual proxy statement; and reviewing, evaluating and recommending changes, if appropriate, to the remuneration for directors.

The charter also provides that the compensation committee may, in its sole discretion, retain or obtain the advice of a compensation consultant, independent legal counsel or other adviser and will be directly responsible for the appointment, compensation and oversight of the work of any such adviser. However, before engaging or receiving advice from a compensation consultant, external legal counsel or any other adviser, the compensation committee will consider the independence of each such adviser, including the factors required by Nasdaq and the SEC.

Nominating and governance committee

We have established a nominating and corporate governance committee of the Board of Directors. The members of our nominating and corporate governance committee are Mr. Do, Mr. Lang and Mr. Kumar. Mr. Do serves as chair of the nominating and corporate governance committee.

We have adopted a nominating and corporate governance committee charter, which details the purpose and responsibilities of the nominating and corporate governance committee, including:

- identifying, screening and reviewing individuals qualified to serve as directors, consistent with criteria approved by the Board of Directors, and recommending to the Board of Directors candidates for nomination for election at the annual meeting of stockholders or to fill vacancies on the Board of Directors;

- developing and recommending to the Board of Directors and overseeing implementation of our corporate governance guidelines;

- coordinating and overseeing the annual self-evaluation of the Board of Directors, its committees, individual directors and management in the governance of the company; and

- reviewing on a regular basis our overall corporate governance and recommending improvements as and when necessary.

The charter also provides that the nominating and corporate governance committee may, in its sole discretion, retain or obtain the advice of, and terminate, any search firm to be used to identify director candidates, and will be directly responsible for approving the search firm's fees and other retention terms.

We have not formally established any specific, minimum qualifications that must be met or skills that are necessary for directors to possess. In general, in identifying and evaluating nominees for director, the Board of Directors considers educational background, diversity of professional experience, knowledge of our business, integrity, professional reputation, independence, wisdom, and the ability to represent the best interests of our stockholders. Prior to our initial business combination, holders of our public shares will not have the right to recommend director candidates for nomination to our Board of Directors.

Compensation Committee Interlocks and Insider Participation

None of our officers currently serves, or in the past year has served, as a member of the compensation committee of any entity that has one or more officers serving on our Board of Directors.

CODE OF ETHICS

We have adopted a code of conduct and ethics meeting the requirements of Section 406 of the Sarbanes-Oxley Act of 2002. We believe our code of conduct and ethics is reasonably designed to deter wrongdoing and promote honest and ethical conduct; provide full, fair, accurate, timely and understandable disclosure in public reports; comply with applicable laws; ensure prompt internal reporting of violations; and provide accountability for adherence to the provisions of the code of ethic. Our code of conduct and ethics is available on our website.

A copy of our code of conduct and ethics is filed as an exhibit to this Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

We did not pay any compensation to any of our executive officers prior to the start of our fiscal year ending June 30, 2019; however, we did accrue salary for Mr. Adams in accordance with his related employment agreements for all periods subsequent to their effective dates.

		Annual Compensation					
Name and Principal Position	**Year**	**Salary**	**Bonus**	**Stock Awards**	**Option Awards(1)**	**All Other Compensation**	**Total**
Terren Peizer	2019	$ —	$ —	$ 7,000	$ —	$ —	$ 7,000
Chief Executive Officer and Chairman(2)							
Jonathan Adams	2019	$250,000	$ —	$ 7,000	$ 11,789	$ —	$268,789
President and Chief Operating Officer(2)	2018	$250,000	$ —	$ —	$ 30,978	$ —	$280,978

(1) The aggregate grant date fair value of such awards were computed in accordance with Financial Accounting Standards Board ASC Topic 718, Stock Compensation (ASC Topic 718), and do not take into account estimated forfeitures related to service-based vesting conditions, if any. The valuation assumptions used in calculating these values are discussed in Note 8 of the Notes to Consolidated Financial Statements appearing elsewhere herein. These amounts do not represent actual amounts paid or to be realized. Amounts shown are not necessarily indicative of values to be achieved, which may be more or less than the amounts shown as awards may subject to time-based vesting.

(2) Mr. Peizer became our Chief Executive Officer and Chairman in July 2018 at which time Mr. Adams became President and Chief Operating Officer, having previously served as our Chief Executive Officer and Chief Financial Officer, Treasurer and Corporate Secretary. The stock awards received by Mr. Peizer and Mr. Adams represented 200,000 shares of common stock and vested in full upon grant.

Narrative Disclosures to Summary of Compensation Table

Employment Agreements

On April 11, 2016, we entered into an employment agreement with Mr. Adams, pursuant to which Mr. Adams is entitled to receive $250,000 as annual salary. The agreement was effective beginning April 11, 2016 and expired on July 2, 2019. Currently Mr. Adams is on a month-to-month contract with an annual salary of $250,000. In the event Mr. Adams's employment is terminated without "Good Cause" (as defined therein), Mr. Adams will be entitled to receive his base salary for the remainder of the term of the agreement, subject to the provision of a mutual release of all claims against the Company.

On July 9, 2018, Mr. Adams, our President and Chief Operating Officer, entered into an Accord and Debt Satisfaction Agreement with us, pursuant to which he agreed to release us from all liabilities (including the original contract dated March 23, 2017 to defer payment of his accrued salary, the promissory note issued by us to defer payment of accrued salary and subsequent unpaid salary), for an aggregate amount of $534,722, and received a cash payment of $25,694 in satisfaction. The gain of $509,028 on the settlement of debt was reflected as additional paid in capital.

Option/SAR Grants

In connection with his employment agreement, on April 11, 2016 Mr. Adams received options to acquire 24,000 shares exercisable at $0.06 per share, the closing price on that date. These options vested and became exercisable as follows: (i) 1,000,000 shares on April 11, 2017, (ii) 1,000,000 shares on April 11, 2018, and (iii) 1,000,000 shares on April 11, 2019.

Between November 16, 2016 and May 19, 2017, we issued options to acquire 1,000,000 exercisable at an average price of $0.24 per share to consultants and members of our Board of Directors for services provided to us.

Compensation of Directors

There are no arrangements pursuant to which our directors are or will be compensated in the future for any services provided to the Company, except that each director shall receive stock options and common share grants as remuneration for their service in lieu of cash compensation. For the fiscal year ended June 30, 2019, each director received 100,000 stock options on the one-year anniversary of his or her service to the Company with an exercise price equal to the closing stock price on the day of the option grant. The total value of the options granted to directors for the fiscal year ended June 30, 2019 was $8,804 based on the Black-Scholes option value method. Each director also receives a stock grant of 200,000 common shares for every year of service. On January 2, 2019, our directors received a combined grant of 1,400,000 shares of common stock with a face value of $49,000 based on the closing stock price of $0.035 on the grant date.

Long-Term Incentive Plans and Awards

Other than the options granted as described above and our recently adopted 2019 Omnibus Equity Incentive Plan (the "2019 Plan"), we do not currently have any long-term incentive plans that provide compensation intended to serve as incentive for performance. Since prior to such grants, no individual grants or agreements regarding future payouts under non-stock price-based plans had been made to any executive officer or any director or any employee or consultant since our inception, no future payouts under non-stock price-based plans or agreements had been granted or entered into or exercised by our officer or director or employees or consultants.

2019 Omnibus Equity Incentive Plan

On April 30, 2019, our Board of Directors and our stockholders approved and adopted the 2019 Plan, subject to complying with the notification requirements of Regulation 14C of the Exchange Act which were complied with effective May 29, 2019. The 2019 Plan allows us, under the direction of our Board of Directors or a committee thereof, to make grants of stock options, restricted and unrestricted stock and other stock-based awards to employees, including our executive officers, consultants and directors. The 2019 Plan allows for the issuance of up to 31,645,367 shares of common stock pursuant to new awards granted under the 2019 Plan. This description is qualified in its entirety by reference to the actual terms of the 2019 Plan, a copy of which is filed as an exhibit to this Form 10-K.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information as of September 24, 2019 regarding the beneficial ownership of our common stock by:

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

The percentage ownership information shown in the table is based upon 647,930,147 shares of common stock outstanding as of September 23, 2019.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. Except as otherwise indicated, each person or entity named in the table has sole voting and investment power with respect to all shares of our capital shown as beneficially owned, subject to applicable community property laws.

In computing the number and percentage of shares beneficially owned by a person as of a particular date, shares that may be acquired by such person (for example, upon the exercise of options or warrants) within 60 days of such date are counted as outstanding, while these shares are not counted as outstanding for computing the percentage ownership of any other person.

The address of each holder listed below, except as otherwise indicated, is c/o BioVie Inc., 2120 Colorado Avenue, #230, Santa Monica , California 90404.

Name and Address of Beneficial Owner	Number of Common Shares of Beneficial Ownership (1)	Percentage of Beneficial Ownership
Terren Peizer(2)	547,241,666	82.5 %
Jonathan Adams(3)	11,829,430	1.8 %
Joanne Wendy Kim(4)	100,000	*
Patrick Yeramian, MD(4)	300,000	*
Penolope Markham, PhD(5)	1,636,410	*
Cuong Do(6)	21,037,888	3.2 %
James Lang(7)	5,578,788	*
Hari Kumar(8)	940,909	*
Michael Sherman(9)	4,285,472	*
Richard J. Berman	—	—
All directors and executive officers as a group (ten persons):	**592,950,563**	**89.5 %**

*Less than 1%

(1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. In accordance with SEC rules, shares of common stock issuable upon the exercise of options or warrants which are currently exercisable or which become exercisable within 60 days following the date of the information in this table are deemed to be beneficially owned by, and outstanding with respect to, the holder of such option or warrant, however none of the persons listed hereinabove has the right to acquire beneficial ownership in any other shares of the Company.
Subject to community property laws where applicable, to our knowledge, each person listed is believed to have sole voting and investment power with respect to all shares of common stock owned by such person.

(2) All shares and warrants are held of record by Acuitas Group Holdings, LLC, a limited liability company 100% owned by Terren S. Peizer, and as to which, Mr. Peizer may be deemed to beneficially own or control. Mr. Peizer disclaims beneficial ownership of any such securities. Does not include 334,989,500 shares and warrants to purchase 334,989,500 shares expected to be issued to Acuitas upon completion of the Company proposed public offering. Giving effect to such issuance and the completion of such offering, Acuitas would beneficially own shares in total, or approximately 63% of the outstanding shares of common stock.

(3) Includes warrants to purchase 1,070,455 shares of common stock and options to purchase 300,000 shares of common stock, all of which are exercisable within the next 60 days. Common stock beneficially owned by Mr. Adams includes 140,000 and 150,000 shares of common stock held of record by Mr. Adams, as custodian for Elliott P. Adams and Jeremy P. Adams, respectively; and 365,000 shares of common stock held of record by Elliott P. Adams. Each of Elliott P. Adams and Jeremy P. Adams are family members of Mr. Adams and, as a result, Mr. Adams may be deemed to beneficially own shares held by (or for the benefit of) such family members.

(4) Represents options to purchase shares of common stock exercisable in the next 60 days.

(5) Includes options to purchase 300,000 shares of common stock exercisable in the next 60 days.

(6) Includes warrants to purchase 8,883,267 shares of common stock and options to purchase 300,000 shares of common stock, all of which are exercisable within the next 60 days. All shares of common stock, warrants and options are held of record by Do & Rickles Investments, LLC, a limited liability company 100% owned by Cuong Do and his wife, and as such, Mr. Do may be deemed to beneficially own or control.

(7) Includes warrants to purchase 2,348,485 shares of common stock and options to purchase 300,000 shares of common stock, all of which are exercisable in the next 60 days.

(8) Includes warrants to purchase 113,636 shares of common stock and options to purchase 800 shares of common stock, which are exercisable within the next 60 days.

(9) Includes warrants to purchase 1,700,691 shares of common stock and options to purchase 200,000 shares of common stock, all of which are exercisable within the next 60 days. Common stock held by Michael Sherman includes 1,666,600 shares of the common stock held of record by Sherman Children's Trust Brian Krisber, Trustee. All shares of common stock, warrants and options are deemed to be beneficially owned or controlled by Michael Sherman.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

During the period commencing July 1, 2015 and through the date of this report, we have not engaged in any transactions with any officer, director or holder of more than 5% of our common stock, except as follows:

Purchase of Preferred Stock

On July 3, 2018, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with Acuitas Group Holdings, LLC ("Acuitas") and certain other purchasers identified in the Purchase Agreement (together with Acuitas, the "Purchasers") pursuant to which (i) the Purchasers agreed to purchase an aggregate of 2,133,332 shares of the our Series A Convertible Preferred Stock (the "Preferred Stock") at a price per share of $1.50 per share of Preferred Stock (the "Initial Sale") and (ii) we agreed to issue warrants (the "Warrants") to purchase 213,333,200 shares of common stock, each subject to the terms and conditions set forth in the Purchase Agreement, for an aggregate consideration of $3.2 million. We received $160,000 of the $3.2 million in April and May 2018 as prepaid equity. Acuitas also received an additional 833,333 Warrants in connection with the payoff of a note issued by us in favor of Acuitas. The Initial Sale and issuance of the Warrants occurred on July 3, 2018. In addition, Acuitas had the option to purchase up to an additional 200,000,000 shares of common stock at a price per share of $0.015, and warrants on the same terms as the Warrants, within two weeks following the one year anniversary of the closing of the Initial Sale (the "Subsequent Sale") in the event that we did not obtain $3,000,000 of funding through various non-dilutive grants prior to the one year anniversary of the closing of the Initial Sale, less any federal or FDA grant funding received by the Company. Acuitas is controlled by our Chairman and Chief Executive Officer, Terren Peizer and the Purchasers included Jonathan Adams, James Lang, Cuang Do and Michael Sherman, who are members of our Board of Directors.

The Purchase Agreement contained customary representations and warranties. In connection with the disclosure schedule associated with the representations and warranties, we also disclosed customary information, including the following: (i) the existence of the Mallinckrodt petition before the U.S. Patent Trial and Appeal Board, (ii) our capitalization, (iii) our obligation to pay a low single digit royalty on the net sales of BIV201 (continuous infusion terlipressin) to be shared among LAT Pharma LLC members, PharmaIN Corporation and The Barrett Edge, Inc. pursuant to the Agreement and Plan of Merger, dated April 11, 2016, by and between LAT Pharma LLC and us, (iv) our obligation to pay a low single digit royalty on net sales of all terlipressin products covered by specified patents up to a maximum of $200,000 per year pursuant to the Technology Transfer Agreement, dated July 25, 2016, by and between us and the University of Padova (Italy), and (v) certain recent issuances of common stock by us.

Each share of Preferred Stock automatically converted into 100 shares of common stock upon the filing with the Secretary of State of the State of Nevada of a Certificate of Amendment to our Articles of Incorporation (the "Amendment") on August 13, 2018 that increased the number of authorized shares of common stock to 800,000,000. The Amendment was approved by the written consent of the holders of more than a majority of our issued and outstanding common stock on July 3, 2018 and was filed with the Secretary of State of the State of Nevada 20 calendar days following the distribution of our Definitive Information Statement on Schedule 14 that was filed with the SEC on July 13, 2018.

Pursuant to a letter agreement dated June 24, 2019, Acuitas agreed to modify its existing rights under the Purchase Agreement so that:

- Acuitas agreed to immediately exchange its existing Warrants for common stock such that it will have effectively exercised its Warrants in full pursuant to a cashless exercise thereof at an assumed current market price of $0.36 per share and, as a result received an aggregate of 95% of the shares covered thereby, or 190,791,666 shares of common stock;

- Acuitas agreed to (i) waive its rights to a 50% adjustment of the purchase price of the Preferred Stock in the Initial Sale, the exercise price of the Warrants and the price per share in the Subsequent Sale in the event of certain reductions in the useful life of our current intellectual property rights, and (ii) effectively exercise its rights to purchase securities in a Subsequent Sale pursuant to a “cashless purchase” at an assumed current market price of approximately $0.09 per share, conditioned in each case on the listing of our common stock on Nasdaq or the raising of $2.0 million in additional funds in the form of another securities offering, in either case not later than November 30, 2019, which will result Acuitas having irrevocably waived its rights to an adjustment in the purchase price of the Preferred Stock in the Initial Sale and the exercise price of the Warrants and the purchase price of per share in the Subsequent Sale upon the issuance by us of an aggregate of 167,494,750 shares of common stock (the “Subsequent Sale Shares”) to Acuitas, which is expected to occur concurrently with the closing of the Company’s proposed public offering;

- Acuitas shall in exchange for the foregoing agreements and waivers have the option to purchase additional shares of common stock and warrants to purchase one share of common stock for each share of common stock purchased during the period from September 1, 2019 to November 30, 2019 at the then-effective purchase price of the Preferred Stock in the Initial Sale (the “Funding Option”), provided that any shares issued pursuant to any exercise of the Funding Option will reduce share-for-share the amount of shares issued pursuant to the deemed exercise of its rights to purchase securities in a Subsequent Sale mentioned above. Assuming the closing of this offering occurs on or prior to September 1, 2019, such option will terminate upon such closing. In the event such closing occurs subsequent to September 1, 2019 and prior to November 30, 2019, we anticipate that Acuitas may elect to continue to fund our on-going clinical trials and operations by means of exercising such Funding Option, with any shares so purchased being deducted from the amount of Subsequent Sale Shares deliverable at closing as described above.

On September 24, 2019, BioVie Inc., a Nevada corporation (the “Company”), entered into a Securities Purchase Agreement (the “2019 Purchase Agreement”) with Acuitas pursuant to which (i) Acuitas agreed to purchase a 10% OID Convertible Delayed Draw Debenture (the “Debenture”) due September 20, 2020 in aggregate commitment amount of up to $2.0 million, and (ii) the Company issued 140,625,000 shares (the “Commitment Shares”) of the Company’s Class A Common Stock (the “Common Stock”) and warrants (the “Commitment Warrants”) to purchase an equal number of shares, each subject to the terms and conditions set forth in the Purchase Agreement. The Debentures accrue additional principal at the rate of 6% per annum and interest at the rate of 10% per annum, are convertible into shares of Common Stock $0.032 per share or, subsequent to the closing of the Company’s planned public offering of shares of Common Stock (the “Public Offering”) as described in its Registration Statement on Form S-1 (File No. 333-231136), the lower of $0.032 or 80% of the offering price to the public in the Public Offering and are mandatorily redeemable upon such closing at 100% of the accrued principal amount and unpaid interest to the date of redemption. The Commitment Warrants are five year warrants, exercisable upon the earlier of the effectiveness of the Company’s currently pending reverse stock split and December 1, 2019 at the lower of $0.032 or 80% of the offering price to the public in the Public Offering. Upon entering into the Purchase Agreement, the Company drew an initial $500,000 under the Debenture and in accordance with the Purchase Agreement, Acuitas received an additional 15,625,000 warrants (the “Bridge Warrants”) having the same terms as the Commitment Warrants. Any future draws under the Debenture, which may be made from and after October 15, 2019, November 15, 2019 and December 15, 2019 in equal tranches of $500,000 each, will entitle Acuitas to receive additional Bridge Warrants in equal amount upon such funding.

Pursuant to the 2019 Purchase Agreement, Acuitas has agreed to further modify its existing rights under the Purchase Agreement dated July 3, 2018 with the Company so that Acuitas' previous agreement in June 2019 to waive its rights to a 50% adjustment of the purchase price of the Preferred Stock in the July 2018 transaction, the exercise price of the warrants in such transaction and the price per share in a purchase option triggered on July 3, 2019 (any such purchase, a "Subsequent Sale") in the event of certain reductions in the useful life of our current intellectual property rights, and effectively exercise its rights to purchase securities in a Subsequent Sale pursuant to a "cashless purchase" at an assumed current market price of approximately $0.09 per share, conditioned in each case on the listing of the Company's common stock on Nasdaq or the raising of $2.0 million in additional funds in the form of another securities offering, in either case not later than November 30, 2019, such that Acuitas will have irrevocably waived its rights to an adjustment in the purchase price of the Preferred Stock in the Initial Sale and the exercise price of the Warrants and the purchase price of per share in the Subsequent Sale upon the issuance by us of an aggregate of 334,989,500 shares of Common Stock and 334,989,500 warrants having the same terms as the Commitment Warrants to Acuitas, which is currently expected with the closing of the Public Offering. In addition, the 2019 Purchase Agreement provides that, should the underwriters in the Public Offering exercise their option to purchase additional securities during the 45 days following closing and the issuance of such securities would result in Acuitas' beneficial ownership (on a fully diluted basis) of shares of Common Stock being below 60%, Acuitas shall be issued a number of additional shares of Common Stock and warrants having the same terms as the Commitment Warrants to result in its beneficial ownership (on a fully diluted basis) of shares of Common Stock equaling 60%.

Issuance of Shares in Settlement of Debt

During the fiscal year ended June 30, 2019, we settled $1,475,765 of debt including $1,313,765 owed to related parties, by issuing 975,361 shares of common stock with a fair value of $1,150,135. See Notes 5 and 6 to the accompanying financial statements appearing elsewhere in this report.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table shows what the auditor billed for the audit and other services for the years ended June 30, 2019 and 2018.

	Year Ended June 30, 2019	Year Ended June 30, 2018
Audit Fees	$ 63,000	$ 22,000
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total	$ 63,000	$ 22,000

Audit Fees—This category includes the audit of the Company's annual financial statements, review of financial statements included in the Company's Form 10-Q Quarterly Reports and services that are normally provided by the independent auditors in connection with engagements for those years.

Audit-Related Fees —N/A

Tax Fees—N/A

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1),(2) Financial Statements

The Financial Statements listed on page F-1 of this document are filed as part of this filing.

(a)(3) **Exhibits**

The following is a list of exhibits filed as a part of this report:

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger, dated April 11, 2016, among the Company, LAT Acquisition Corp and LAT Pharma, LLC (incorporated by reference to Exhibit 2.1 the Company's Current Report on Form 8-K filed on April 15, 2016).
3.1	Articles of Incorporation of the Company as filed with the Secretary of State of Nevada (incorporated by reference to Exhibit 3.1 to the Company's registration statement on Form S-1 filed on August 15, 2013, File No. 333-190635).
3.2	Certificate of Amendment to Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 22, 2016).
3.3	Certificate of Amendment to Articles of Incorporation (incorporated by reference to Appendix A to the Company's Information Statement on Schedule 14C filed on July 13, 2018).
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 3, 2018).
3.5	Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's registration statement on Form S-1 filed on August 15, 2013, File No. 333-190635).
4.1	Specimen Certificate representing shares of Class A Common Stock. (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1, File No. 333-231136)
4.2	Form of Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on September 25, 2019).
4.3	Form of 10% OID Convertible Delayed Draw Debenture (incorporated by reference to Exhibit 4.1 the Company's Current Report on Form 8-K filed on September 25, 2019).
4.4	Description of Securities
10.1	Securities Purchase Agreement, dated as of July 3, 2018, by and among BioVie Inc., Acuitas Group Holdings, LLC and the Purchasers identified therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 3, 2018).
10.2	Employment Agreement between Jonathan Adams and the Company dated, April 11, 2016. (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1, File No. 333-231136)
10.4	Amendment No. 1 to Employment Agreement between Jonathan Adams and the Company dated July 3, 2018. (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1, File No. 333-231136)
10.5	Letter Agreement between Acuitas Group Holdings, LLC and the Company dated June 24, 2019. (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1, File No. 333-231136)
10.6	BioVie Inc. 2019 Omnibus Equity Incentive Plan (incorporated by reference to Appendix D to the Definitive Information Statement on Schedule 14C, filed on May 8, 2019)
10.7	Securities Purchase Agreement dated as of September 24, 2019 by and among BioVie Inc. and Acuitas Group Holdings, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 25, 2019)
14.1	Code of Conduct and Ethics of BioVie Inc. (incorporated by reference to Exhibit 14.1 to the Company's Registration Statement on Form S-1, File No. 333-231136).
31.1	Rule 13a-14(a) Certification
31.2	Rule 13a-14(a) Certification
32.1	Certification Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification Pursuant to 18 U.S.C Section 1350, as Adopted Pursuant to section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Calculation Linkbase Document
101.LAB	XBRL Taxonomy Label Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

Signatures

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

BIOVIE INC.

By: /s/ Terren Peizer
Name: Terren Peizer
Title: Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

Person	Capacity	Date
/s/ Terren Peizer Terren Peizer	Chairman and Chief Executive Officer (Principal Executive Officer)	September 26, 2019
/s/ J. Wendy Kim J. Wendy Kim	Chief Financial Officer and Corporate Secretary (Principal Financial Officer)	September 26, 2019
/s/ Jonathan Adams Jonathan Adams	President, Chief Operating Officer and Director	September 26, 2019
/s/ Cuong Do Cuong Do	Director	September 26, 2019
/s/ Jim Lang Jim Lang	Director	September 26, 2019
/s/ Hari Kumar Hari Kumar	Director	September 26, 2019
/s/ Michael Sherman Michael Sherman	Director	September 26, 2019
/s/ Richard J. Berman Richard J. Berman	Director	September 26, 2019

BioVie, Inc.
Index to Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
BioVie. Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheet of BioVie, Inc. (the “Company") as of June 30, 2019 and the related statements of operations, changes in stockholders’ equity, and cash flows for the year then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 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.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company’s recurring losses from operations and negative cash flows from operating activities 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 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audit. 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit 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. We believe that our audit provides a reasonable basis for our opinion.

/s/ EisnerAmper LLP

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

EISNERAMPER LLP
Iselin, New Jersey
September 25, 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of BioVie, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of BioVie, Inc. (the Company) as of June 30, 2018, and the related statements of operations, stockholders' equity, and cash flows for each of the year then ended, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2018, and the results of its operations and its cash flows the year ended June 30, 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit 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. We believe that our audit provide a reasonable basis for our opinion.

/s/ D. Brooks and Associates CPA's, P.A.

We have served as the Company's auditor since 2017 through January 18, 2019.

Palm Beach Gardens, Florida
October 4, 2018

BioVie Inc.
Balance Sheets

	June 30, 2019	June 30, 2018
ASSETS		
CURRENT ASSETS:		
Cash	$ 339,923	$ 45,800
Other Assets	334,150	—
Total Current Assets	674,073	45,800
OTHER ASSETS:		
Intangible Assets, Net	1,554,603	1,783,980
Goodwill	345,711	345,711
Total Other Assets	1,900,314	2,129,691
TOTAL ASSETS	$ 2,574,387	$ 2,175,491
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts Payable and accrued expenses	$ 443,480	$ 884,207
Accrued Payroll	—	354,167
Total Current Liabilities	443,480	1,238,374
LONG-TERM LIABILITIES:		
Demand Promissory Note	—	250,000
Notes Payable, Related Parties	—	575,918
Total Long-Term Liabilities	—	825,918
TOTAL LIABILITIES	443,480	2,064,292
Commitments and contingencies (Note 7)		
STOCKHOLDERS' EQUITY		
Preferred stock; $0.001 par value; 10,000,000 shares authorized; 0 shares issued and outstanding	—	—
Common stock, $0.0001 par value; 800,000,000 and 300,000,000 shares authorized at June 30, 2019 and June 30, 2018, respectively; 507,305,147 and 98,503,199 shares issued and outstanding at June 30, 2019 and June 30, 2018, respectively	50,730	9,850
Additional paid in capital	9,342,249	4,870,475
Accumulated deficit	(7,262,072)	(4,769,126)
Total Stockholders' Equity	2,130,907	111,199
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 2,574,387	$ 2,175,491

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

BioVie Inc.
Statements of Operations

	Year ended June 30, 2019	Year ended June 30, 2018
REVENUE	$ —	$ —
OPERATING EXPENSES:		
Amortization	229,377	229,377
Research and development expenses	1,008,100	370,852
Selling, general and administrative expenses	1,259,096	1,771,937
TOTAL OPERATING EXPENSES	2,496,573	2,372,166
LOSS FROM OPERATIONS	(2,496,573)	(2,372,166)
OTHER EXPENSE (INCOME):		
Gain on settlement of debt	(51,400)	—
Interest expense	273	40,960
Interest income	(1,159)	(4)
TOTAL OTHER EXPENSE (INCOME), NET	(52,286)	40,956
NET LOSS	$ (2,444,287)	$ (2,413,122)
Deemed dividend related to ratchet adjustment	48,659	20,995
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	$ (2,492,946)	$ (2,434,117)
NET LOSS PER SHARE BASIC AND DILUTED	$ (0.01)	$ (0.03)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING BASIC AND DILUTED	317,451,272	95,758,079

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

BioVie Inc.
Statements of Changes in Stockholders' Equity
For the Years Ended June 30, 2019 and 2018

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance, June 30, 2017	—	$ —	91,925,000	$ 9,193	$3,483,135	$ (2,335,009)	$ 1,157,319
Issuance of shares and warrants for cash	—	—	1,729,699	172	444,827	—	444,999
Issuance of shares for services	—	—	4,748,500	475	642,375	—	642,850
Options vested	—	—	—	—	238,165	—	238,165
Exercise of options for cash	—	—	100,000	10	1,990	—	2,000
Issuance of warrants for services	—	—	—	—	12,469	—	12,469
Issuance of warrants with debt	—	—	—	—	26,519	—	26,519
Deemed dividends for ratchet adjustment to warrants	—	—	—	—	20,995	(20,995)	—
Net loss	—	—	—	—	—	(2,413,122)	(2,413,122)
Balance, June 30, 2018	—	$ —	98,503,199	$ 9,850	$4,870,475	$ (4,769,126)	$ 111,199
Issuance of preferred stock in a private placement	2,133,332	3,200,000	—	—	3,200,000	—	3,200,000
Conversion of preferred stock to common stock	(2,133,332)	(3,200,000)	213,333,200	21,333	(21,333)	—	—
Issuance of shares in exchange for debt settlement	—	—	975,361	98	1,150,037	—	1,150,135
Issuance of shares for services			1,400,000	140	48,860	—	49,000
Stock option compensation	—	—	—	—	64,860	—	64,860
Cashless exercise of warrants	—	—	193,093,387	19,309	(19,309)	—	—
Deemed dividends for ratchet adjustment to warrants	—	—	—	—	48,659	(48,659)	—
Net loss	—	—	—	—	—	(2,444,287)	(2,444,287)
Balance, June 30, 2019	—	$ —	507,305,147	$ 50,730	$9,342,249	$ (7,262,072)	$ 2,130,907

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

BioVie Inc.
Statements of Cash Flows

	Year ended June 30, 2019	Year ended June 30, 2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (2,444,287)	$ (2,413,122)
Adjustments to reconcile net loss to net cash to cash used in operating activities:		
Common shares issued for service	49,000	655,319
Amortization of intangible assets	229,377	229,377
Amortization of debt discount		26,519
Stock based compensation expense	64,860	238,165
Gain on settlement of debt	51,400	
Changes in operating assets and liabilities		
Other assets	(334,150)	
Accounts payable and accrued expenses	(117,777)	413,234
Accrued payroll	—	229,167
Net cash used in operating activities	(2,501,577)	(621,341)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Repayment of debt	(244,300)	(35,000)
Proceeds from issuance of preferred shares	3,040,000	250,000
Proceeds from issuance of common stock and warrants	—	446,999
Net cash provided by financing activities	2,795,700	661,999
Net increase in cash	294,123	40,658
Cash, beginning of period	45,800	5,140
Cash, end of period	$ 339,923	$ 45,800
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$ —	$ —
Cash paid for taxes	$ —	$ —
SCHEDULE OF NON-CASH FINANCING ACTIVITIES:		
Conversion of preferred shares to common stock	$ 3,200,000	$ —
Settlement of debt by issuance of common stock and forgiveness of debt	$ 1,150,135	$ —
Cashless exercise of warrants	$ 19,309	$ —
Deemed dividends for ratchet adjustments to warrants	$ 48,659	$ —

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

BioVie Inc.
Notes to Financial Statements
For the Years Ended June 30, 2019 and 2018

1. Background Information

We are a clinical-stage company pursuing the discovery, development, and commercialization of innovative drug therapies. We are currently focused on developing and commercializing BIV201 (continuous infusion terlipressin), a novel approach to the treatment of ascites due to chronic liver cirrhosis. Our therapy BIV201 is based on a drug that is approved in about 40 countries to treat related complications of liver cirrhosis (part of the same disease pathway as ascites), but not yet available in the United States. BIV201's active agent is a potent vasoconstrictor and has shown efficacy for reducing portal hypertension in studies around the world. The goal is for BIV201 to interrupt the ascites disease pathway, thereby halting the cycle of accelerating fluid generation in ascites patients.

In April 2017, we entered into a CRADA with the McGuire Research Institute Inc. in Richmond, VA, and began administering BIV201 to patients in September 2017. In April 2019, we announced top-line results for our Phase 2a clinical trial of BIV201 (continuous infusion terlipressin) in six patients with refractory ascites due to advanced liver cirrhosis. On June 18, 2019, we met with representatives of the FDA for Type C Guidance Meeting to plan our next clinical study following the recently completed Phase 2a clinical trial. We discussed our clinical development efforts with the FDA and proposed trial endpoints. While the FDA has not provided final guidance nor do we have certainty as to what that guidance would entail, our goal remains to proceed into a Phase 2b/3 or Phase 3 clinical trial in a manner consistent with what was reviewed with the FDA. We may still need to address certain risks associated with unvalidated quality of life measures. In July 2019, the FDA provided meeting minutes for the June 18, 2019 meeting that documented general agreement with the Company proposed randomized study design. The FDA also provided its suggestions and guidance regarding primary and secondary endpoints and other key aspects of our clinical trial design and the Company is incorporating those suggestions as it moves forward. We are developing a proprietary novel liquid formulation of terlipressin that is intended to improve convenience for outpatient administration and avoid potential formulation errors when pharmacists reconstitute the powder version.

BIV201 has the potential to improve the health of thousands of patients suffering from life-threatening complications of liver cirrhosis due to hepatitis, nonalcoholic steatohepatitis (NASH), and alcoholism. It has FDA Fast-Track status and Orphan Drug designation for the most common of these complications, ascites, which represents a significant unmet medical need. The FDA has never approved any drug specifically for treating ascites. The Company has secured a US Patent covering the use of BIV201 for the treatment of ascites patients in the outpatient setting using ambulatory pump infusion, and has filed patent applications for its product candidate in Japan, and Europe, Hong Kong, and China. BIV201 also received Orphan Drug designation for hepatorenal syndrome ("HRS") in November 2018.

The BIV201 development program began at LAT Pharma LLC. On April 11, 2016, the Company acquired LAT Pharma LLC and the rights to its BIV201 development program. The Company currently owns all development and marketing rights to its drug candidate. The Company and PharmaIN, Corp. ("PharmaIN"), LAT Pharma's former partner focused on the development of new modified drug candidates in the same therapeutic field but not including BIV201, had agreed to pay royalties equal to less than 1% of future net sales of each company's ascites drug development programs, or if such program is licensed to a third party, less than 5% of each company's net license revenues. On December 24, 2018, the Company returned its partial ownership rights to the PharmaIN modified terlipressin development program and simultaneously paid the remaining balance due on a related debt. PharmaIN, Corp.'s rights to our program remain unchanged.

The Company's activities are subject to significant risks and uncertainties including failure to secure additional funding to properly execute the Company's business plan.

BioVie Inc.
Notes to Financial Statements
For the Years Ended June 30, 2019 and 2018

2. Liquidity and Going Concern

The Company's operations are subject to a number of factors that can affect its operating results and financial conditions. Such factors include, but are not limited to: the results of clinical testing and trial activities of the Company's products, the Company's ability to obtain regulatory approval to market its products, competition from products manufactured and sold or being developed by other companies, the price of, and demand for, Company products, the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products, and the Company's ability to raise capital. The Company's financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has experienced losses since inception and has an accumulated deficit of approximately $7.3 million at June 30, 2019. In addition, the Company has not generated any revenues and no revenues are anticipated in the foreseeable future. The Company's future operations are dependent on the success of the Company's ongoing development and commercialization efforts, as well as continuing to secure additional financing.

In July 2018, the Company completed a capital raise from Acuitas Group Holding, LLC ("Acuitas") and other purchasers and received net proceeds of $3.2 million (see note 8 "Equity Transactions") and resumed further clinical development of BIV201 and completed its Phase 2a clinic trial program. The Company is pursuing various options to raise further financing to continue the testing and development of its product. If the Company is not successful in raising additional funds it may reduce its monthly spend and potentially delay the implementation of the larger scale Phase 2b Clinical trial until sufficient funding is secured.

Additionally, in April 2019, to facilitate our planned uplisting to the NASDAQ Stock Market and related potential future issuances and sales of our equity securities for ordinary corporate finance and general corporate purposes and as recommended by our Board of Directors ("Board"), our stockholders approved an amendment to our Articles of Incorporation to effect a reverse split of our outstanding Class A common stock in the range of 50:1 to 200:1, as determined by our Board. Following that approval, we filed a Registration Statement on Form S-1 (Registration No. 333-231136) (the S-1 Registration Statement) pursuant to which we anticipate completing an offering of our equity securities with proceeds sufficient to enable the launch and completion of the BIV201 Phase 2b study and fund our internal operations for at least the next twelve months. There can be no assurance, however, that we will achieve effectiveness of the S-1 Registration Statement or successfully complete an offering thereunder.

The future viability of the Company is largely dependent upon its ability to raise additional capital to finance its operations. Management expects that future sources of funding may include sales of equity, obtaining loans, or other strategic transactions. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient financing on terms acceptable to the Company, if at all, to fund continuing operations. These circumstances raise substantial doubt on the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

BioVie Inc.
Notes to Financial Statements
For the Years Ended June 30, 2019 and 2018

3. Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company bases its estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheet and the amounts of expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, accounting for share-based compensation, accounting for derivatives and accounting for income taxes. Actual results could differ from those estimates.

Cash

The Company considers all highly liquid instruments with original maturities of three months or less to be cash equivalents. Cash is maintained at one financial institution and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to these balances. All of the Company's cash balances were fully insured at June 30, 2019.

Other Assets

Other Assets consists of direct cost related to capital raise and filing of the registration statement legal fees and investment banking fees incurred to raise capital. The costs will be expensed once the Company raises the capital.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value for applicable assets and liabilities, we consider the principal or most advantageous market in which we would transact and we consider assumptions market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions, and risk of nonperformance. This guidance also establishes a fair value hierarchy to prioritize inputs used in measuring fair value as follows:

- Level 1: Observable inputs such as quoted prices in active markets;
- Level 2: Inputs, other than quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions

The Company's financial instruments include cash, accounts payable, related party loans and a demand promissory note. The carrying amounts of cash and accounts payable approximate their fair value, due to the short-term nature of these items.

BioVie Inc.
Notes to Financial Statements
For the Years Ended June 30, 2019 and 2018

3. Significant Accounting Policies (continued)

Long-Term Notes Payable

The Company's long-term notes payable include accrued payroll to officers and accrued payments to third party consultants.

Research and Development

Research and development expenses consist primarily of costs associated with the preclinical and/ or clinical trials of drug candidates, compensation and other expenses for research and development, personnel, supplies and development materials, costs for consultants and related contract research and facility costs. Expenditures relating to research and development are expensed as incurred.

Income Taxes

The Company uses the asset and liability method of accounting for deferred income taxes. Deferred income taxes are measured by applying enacted statutory rates to net operating loss carryforwards and to the differences between the financial reporting and tax bases of assets and liabilities. Deferred tax assets are reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax assets will not be realized.

The Company recognizes uncertainty in income taxes in the financial statements using a recognition threshold and measurement attribute of a tax position taken or expected to be taken in a tax return. The Company applies the "more-likely-than-not" recognition threshold to all tax positions, commencing at the adoption date of the applicable accounting guidance, which resulted in no unrecognized tax benefits as of such date. Additionally, there have been no unrecognized tax benefits subsequent to adoption. The Company has opted to classify interest and penalties that would accrue, if any, according to the provisions of relevant tax law as general and administrative expenses, in the statements of operations. For the years ended June 30, 2019 and 2018 there was no such interest or penalty.

Net Loss per Common Share

Basic net loss per common share is computed by dividing the net loss before deemed dividend by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding and potentially outstanding shares of common stock during the period to reflect the potential dilution that could occur from common shares issuable through stock options, warrants, convertible preferred stock and convertible debentures. Due to the net loss for the period, such amounts were excluded from the diluted loss since their effect was considered anti-dilutive.

The table below shows the number of outstanding stock options and warrants as of June 30, 2019 and June 30, 2018:

	June 30, 2019 Number of Shares	June 30, 2018 Number of Shares
Stock Options	7,250,000	5,150,000
Warrants	15,583,216	4,774,015
Total	**22,833,216**	**9,924,015**

BioVie Inc.
Notes to Financial Statements
For the Years Ended June 30, 2019 and 2018

3. Significant Accounting Policies (continued)

Stock-based Compensation

The Company has accounted for stock-based compensation under the provisions of FASB ASC 718 – "Stock Compensation" which requires the use of the fair-value based method to determine compensation for all arrangements under which employees and others receive shares of stock or equity instruments (stock options and common stock purchase warrants). For employee awards, the fair value of each stock option award is estimated on the date of grant using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. For non-employees, the fair value of each stock option award is estimated on the measurement date using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. For non-employees, the Company utilizes the graded vesting attribution method under which the entity treats each separately vesting portion (tranche) as a separate award and recognizes compensation cost for each tranche over its separate vesting schedule. Expected volatilities are based on historical volatility of peer companies and other factors estimated over the expected term of the stock options. For employee awards, the expected term of options granted is derived using the "simplified method" which computes expected term as the average of the sum of the vesting term plus the contract term. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term. We recognize forfeitures as they occur.

Goodwill

Goodwill is recorded when the purchase price paid for an acquisition exceeds the fair value of net identified tangible and intangible assets acquired. The Company performs an annual impairment test of goodwill and further periodic tests to the extent indicators of impairment develop between annual impairment tests. The Company's impairment review process compares the fair value of the reporting unit to its carrying value, including the goodwill related to the reporting unit. To determine the fair value of the reporting unit, the Company may use various approaches including an asset or cost approach, market approach or income approach or any combination thereof. These approaches may require the Company to make certain estimates and assumptions including future cash flows, revenue and expenses. These estimates and assumptions are reviewed each time the Company tests goodwill for impairment and are typically developed as part of the Company's routine business planning and forecasting process. While the Company believes its estimates and assumptions are reasonable, variations from those estimates could produce materially different results. The Company did not recognize any goodwill impairments for the years ended June 30th, 2018 and June 30th, 2019.

Impairment of Long-Lived Assets

Long-lived assets, including intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset.

If the carrying amount of an asset exceeds its undiscounted estimated future cash flows, an impairment review is performed. An impairment charge is recognized in the amount by which the carrying amount of the asset exceeds the fair value of the asset. Generally, fair value is determined using valuation techniques such as expected discounted cash flows or appraisals, as appropriate. Assets to be disposed of would be separately presented in the balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and are no longer depreciated or amortized. The assets and liabilities of a disposed group classified as held for sale would be presented separately in the appropriate asset and liability sections of the balance sheet.

BioVie Inc.
Notes to Financial Statements
For the Years Ended June 30, 2019 and 2018

3. Significant Accounting Policies (continued)

Reclassifications

Certain prior year amounts have been reclassified for consistency with current year presentation. These reclassifications had no effect on the reported results of operations.

Recent accounting pronouncements

The Company considers the applicability and impact of all Accounting Standard Updates ("ASU's"). ASU's not discussed below were assessed and determined to be either not applicable or expected to have minimal impact on our balance sheets or statement of operations.

In June 2018, the FASB issued ASU 2018-07, "Compensation – Stock Compensation (Topic 718): Improvements to Non-employee share based accounting", which simplifies the accounting for non-employee share-based payment transactions. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The standard will be effective for the Company in the first quarter of fiscal year 2020, although early adoption is permitted (but no sooner than the adoption of Topic 606). The Company does not expect that the adoption of this ASU will have a significant impact on its financial statements.

In July 2017, the FASB issued Accounting Standards Update ("ASU") No. 2017-11. "Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features, II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. ASU 2017-11 revises the guidance for instruments with down round features in Subtopic 815-40, Derivatives and Hedging – Contracts in Entity's Own Equity, which is considered in determining whether an equity-linked financial instrument qualifies for a scope exception from derivative accounting. An entity still is required to determine whether instruments would be classified in equity under the guidance in Subtopic 815-40 in determining whether they qualify for that scope exception. If they do qualify, freestanding instruments with down round features are no longer classified as liabilities. ASU 2017-11 is effective for annual and interim periods beginning December 15, 2018, and early adoption is permitted, including adoption in an interim period. ASU 2017-11 provides that upon adoption, an entity may apply this standard retrospectively to outstanding financial instruments with a down round feature by means of a cumulative-effect adjustment to the opening balance of retaining earnings in the fiscal year and interim period adopted. The Company is currently in the process of assessing the impact of this ASU on its financial statements.

BioVie Inc.
Notes to Financial Statements
For the Years Ended June 30, 2019 and 2018

4. Intangible Assets

Intellectual property, stated at cost, less accumulated amortization consists of the following:

	June 30, 2019	June 30, 2018
Intellectual Property	$ 2,293,770	$ 2,293,770
Less Accumulated Amortization	(739,167)	(509,790)
Intellectual Property, Net	$ 1,554,603	$ 1,783,980

Amortization expense amounted to $229,377 and $229,377 for the years ended June 30, 2019 and 2018, respectively. The Company amortizes intellectual property over the expected original useful lives of 10 years.
Estimated future amortization expense is as follows:

Year ending June 30,	
2020	229,377
2021	229,377
2022	229,377
2023	229,377
2024	229,377
Thereafter	407,718
	$ 1,554,603

5. Renegotiated Debt

On July 19, 2018, Geis-Hides Consulting LLC entered into an Accord and Debt Satisfaction Agreement with the Company in which the consulting firm agreed to release the Company from all liabilities arising from the Original Contract and Debt Repayment Plan dated December 15, 2013 totaling $132,000 and received cash of $65,000 and 260,000 common shares in satisfaction. The common shares were valued at the market price on the date of settlement at $0.06 per common share. The gain of $51,400 on the settlement of debt was reflected on the Statements of Operations as “other income” for the year ended June 30, 2019.

BioVie Inc.
Notes to Financial Statements
For the Years Ended June 30, 2019 and 2018

6. Related Party Transactions

On March 23, 2017, Barrett Ehrlich agreed to defer the payment of his consulting fee debt of $173,333 until December 31, 2019, through the issuance of a Promissory note. The promissory note does not carry any interest charge as long as the amount is paid in full before December 31, 2019. The consulting fee debt was reclassified from a current liability to a long-term liability on the balance sheet. Any portion of the balance due under the note that remains unpaid after December 31, 2019 will accrue interest at a rate of 5% per annum until paid in full.

On August 8, 2018, Barrett Ehrlich (Independent contractor, related party to Elliot Ehrlich and shareholder) on behalf of The Barrett Edge Inc. ("Barrett") entered into an Accord and Debt Satisfaction Agreement with the Company in which Barrett agreed to release the Company from all liabilities including the original contract to defer payment of accrued consulting fees dated March 23, 2017, the promissory note issued by the Company to defer payment of accrued consulting fees; loan to the Company for $14,000, and subsequent unpaid consulting fees, totaling $543,014, and received cash of $131,333 and 493,333 common shares in satisfaction. The common shares were valued at the market price on the date of settlement at $0.13 per common share. The gain of $361,548 on the settlement of debt was reflected in the additional paid in capital for the year ended June 30, 2019.

On March 23, 2017, Elliot Ehrlich agreed to forgive 50% of his salary debt of $444,056. The adjusted salary debt is $222,028. Elliot Ehrlich also agreed to defer the payment of his salary debt of $222,028 until December 31, 2019, through the issuance of a Promissory note. The promissory note does not carry any interest charge as long as the amount is paid in full before December 31, 2019. The salary debt was reclassified from a current liability to a long-term liability on the balance sheet and the salary debt forgiven had been reflected on the income statement as other income. Any portion of the balance due under the note that remains unpaid after December 31, 2019 will accrue interest at a rate of 5% per annum until paid in full.

On July 9, 2018, Elliot Ehrlich (former CEO and shareholder) entered into an Accord and Debt Satisfaction Agreement with the Company in which he agreed to release the Company from all liabilities including the original contract to defer payment of accrued salary dated March 23, 2017, totaling the amount of $222,028 the promissory note issued by the Company to defer payment of accrued salary; and received cash of $22,273 and 222,028 common shares in satisfaction. The common shares were valued at the market price on the date of settlement at $0.06 per common share. The gain of $186,503 on the settlement of debt was reflected in the additional paid in capital for the year ended June 30, 2019.

On March 23, 2017, Jonathan Adams agreed to defer the payment of his salary debt of $180,555 until December 31, 2019, through the issuance of a Promissory note. The promissory note does not carry any interest charge as long as the amount is paid in full before December 31, 2019. The salary debt was reclassified from a current liability to a long-term liability on the balance sheet. Any portion of the balance due under the note that remains unpaid after December 31, 2019 will accrue interest at a rate of 5% per annum until paid in full.

On July 9, 2018, Jonathan Adams (COO) entered into an Accord and Debt Satisfaction Agreement with the Company in which he agreed to release the Company from all liabilities including the original contract to defer payment of his accrued salary dated March 23, 2017, the promissory note issued by the Company to defer payment of accrued salary; and subsequent unpaid salary, totaling the amount of $534,722, and received cash of $25,694 in satisfaction. The gain of $509,028 on the settlement of debt was reflected in the additional paid in capital for the year ended June 30, 2019.
The outstanding balance of the long-term note payable at June 30, 2019 and 2018 was $0 and $575,918, respectively.

See note 8 "Equity Transactions", for other related party transactions with Acuitas Group Holdings, LLC ("Acuitas") and board of director members.

BioVie Inc.
Notes to Financial Statements
For the Years Ended June 30, 2019 and 2018

7. Commitments and Contingencies

Office Lease

On October 1, 2018, the Company executed a lease agreement with Acuitas Group Holdings, LLC (related party) for the Company's Corporate office space at the Acuitas' offices at 11100 Wilshire Boulevard, Los Angeles , CA 90025. The lease is a month-to-month lease that may be cancelled upon 30 days' written notice and requires monthly payments of $1,000. On July 1, 2019, the Company's office moved with Acuitas' new offices to 2120 Colorado Avenue Ste 230, Santa Monica, CA 90404.

Challenge to US Patent

On April 30, 2018, we received notice that Mallinckrodt had petitioned the U.S. Patent and Trademark Office ("USPTO") to institute an Inter Partes Review of our U.S. Patent No. 9,655,945 titled "Treatment of Ascites" (the "'945 patent"). Inter Partes Review is a trial proceeding conducted with the USPTO Patent Trial and Appeal Board (PTAB) to review the patentability of one or more claims of a patent. Such review is limited to grounds of novelty and obviousness on the basis of prior art consisting of patents and printed publications.

On August 15, 2018, we submitted a Preliminary Response to the PTAB providing a rationale as to why, in our opinion, Mallinckrodt's request to institute the IPR should not be granted. On November 14, 2018, the PTAB granted institution of the IPR challenge after determining that there was a reasonable likelihood of success in proving that at least one of our 14 claims was unpatentable. On March 7, 2019, we submitted a Patent Owner's Response and a Patent Owner's Contingent Motion to Amend our patent claims, and Declaration of Dr. Jaime Bosch, MD, PhD, our medical expert. On June 26 and June 28, 2019, we submitted a Patent Owner's Reply In Support Of Its Contingent Motion To Amend Under 37 C.F.R.§ 42.121 to amend our patent claims and a Patent Sur-Reply supported by the Supplemental Declaration of Dr. Jaime Bosch to the Reply and the Opposition to Motion to Amend, filed by Petitioner Mallinckrodt, filed June 6, 2019. On July 29, 2019, we submitted a Patent Owner's Opposition to Petitioner's Motion to Strike. On July 17, 2019, we received from the PTAB an Order Oral Hearing in response to our request of an Oral Hearing which was held on August 12, 2019 at 1:00PM EST. We are actively defending the '945 patent and we are exploring the possibility of settlement with Mallinckrodt. However, there can be no assurance that a favorable outcome will result, or if settlement is reached that the PTAB will accept it. A reasonable estimate cannot be made at this time. Although the PTAB encourages settlement, in view of public-interest considerations, the PTAB may continue the proceeding to a final written decision even if the parties settle. If the IPR is not terminated due to settlement, the PTAB is statutorily required to issue its final written decision in this case before November 14, 2019 (within one year from the date of institution). At June 30, 2019, no adjustments or accruals have been reflected in our financial statements related to this matter.

Royalty Agreements

Pursuant to the Agreement and Plan of Merger entered into on April 11, 2016 between LAT Pharma LLC and NanoAntibiotics, Inc., BioVie is obligated to pay a low single digit royalty on net sales of BIV201 (continuous infusion terlipressin) to be shared among LAT Pharma Members, PharmaIn Corporation; and The Barrett Edge, Inc.

The Company and PharmaIN Corporation, LAT Pharma's former partner focused on the development of new modified drug candidates in the same therapeutic field but not including BIV201, had agreed to pay royalties equal to less than 1% of future net sales of each company's ascites drug development programs, or if such program is licensed to a third party, less than 5% of each company's net license revenues. On December 24, 2018, the Company returned its partial ownership rights to the PharmaIN modified terlipressin development program and simultaneously paid the remaining balance due on a related debt. PharmaIN, Corp. rights to our program remain unchanged.

Pursuant to the Technology Transfer Agreement entered into on July 25, 2016 between BioVie and the University of Padova (Italy), BioVie is obligated to pay a low single digit royalty on net sales of all terlipressin products covered by US patent no. 9,655,645 and any future foreign issuances capped at a maximum of $200,000 per year.

BioVie Inc.
Notes to Financial Statements
For the Years Ended June 30, 2019 and 2018

8. Equity Transactions

Stock Options

The following table summarizes the activity relating to the Company's stock options for the years ended June 30, 2018 and 2019:

	Options	Weighted-Average Exercise Price	Weighted Remaining Average Contractual Term	Aggregate Intrinsic Value
Outstanding at June 30, 2017	4,000,000	$ 0.10	5.9	$ 142,000
Granted	1,250,000	$ 0.15	5.0	$ —
Options Exercised	(100,000)	$ 0.02	—	$ —
Outstanding at June 30, 2018	5,150,000	$ 0.12	5.8	$ 142,000
Granted	2,100,000	$ 0.04	4.5	$ 131,000
Options Exercised or Forfeited	—	$ —	—	$ —
Outstanding at June 30, 2019	7,250,000	$ 0.10	5.2	$ 273,000
Exercisable at June 30, 2019	7,250,000	$ 0.10	5.2	$ —

The fair value of each option grant on the date of grant is estimated using the Black-Scholes Option – Pricing model reflecting the following weighted-average assumptions:

	June 30,	
	2019	2018
Expected life of options (In years)	5	5
Expected volatility	69.77%	103.13%
Risk free interest rate	2.60%	2.28%
Dividend Yield	0%	0%

Expected volatility is based on the historical volatilities of three comparable companies of the daily closing price of their respective common stock and the expected life of options is based on historical data with respect to employee exercise periods. The Company accounts for forfeitures as they are incurred.

The Company recorded stock-based compensation expense of $64,860 for the year ended June 30, 2019 and $238,165 for the year ended June 30, 2018.

BioVie Inc.
Notes to Financial Statements
For the Years Ended June 30, 2019 and 2018

8. Equity Transactions (continued)

The following is a summary of stock options outstanding and exercisable by exercise price as of June 30, 2019:

Exercise Price	Outstanding	Weighted Average Contract Life	Exercisable
$ 0.03	700,000	4.6	700,000
$ 0.05	1,300,000	4.3	1,300,000
$ 0.06	3,100,000	6.7	3,100,000
$ 0.07	100,000	4.3	100,000
$ 0.10	500,000	3.6	500,000
$ 0.20	200,000	3.3	200,000
$ 0.21	550,000	2.8	550,000
$ 0.22	100,000	2.7	100,000
$ 0.23	200,000	3.1	200,000
$ 0.25	500,000	2.4	500,000
Total	7,250,000		7,250,000

Issuance of Shares for Cash

In July 2017 and August 2017, the Company sold and issued an aggregate of 886,364 shares of common stock and warrants to purchase 443,182 shares of common stock in a private placement transaction for aggregate gross proceeds of approximately $195,000. The purchase price for the common stock and warrants was $0.22 per share. The warrants are exercisable at an exercise price of $0.60 at any time from date of issuance until 5 years from the date of issuance.

Between July 2017 and September 2017, the Company sold an aggregate of 250,000 shares of common stock in transactions under the Aspire Equity Line for aggregate gross proceeds of $50,000. The average purchase price for the common stock was $0.20 per share.

In October 2017, the Company sold and issued an aggregate of 159,091 shares of common stock and warrants to purchase 79,545 shares of common stock in a private placement transaction for aggregate gross proceeds of approximately $35,000. The purchase price for the common stock and warrants was $0.22 per share. The warrants are exercisable at an exercise price of $0.60 at any time from date of issuance until 5 years from the date of issuance.

In November 2017, the Company also sold and issued an aggregate of 68,182 shares of common stock and warrants to purchase 34,091 shares of common stock in a private placement transaction for aggregate gross proceeds of approximately $15,000. The purchase price for the common stock and warrants was $0.22 per share. The warrants are exercisable at an exercise price of $0.60 at any time from date of issuance until 5 years from the date of issuance.

BioVie Inc.
Notes to Financial Statements
For the Years Ended June 30, 2019 and 2018

8. Equity Transactions (continued)

In January 2018, the Company sold an aggregate of 333,333 shares of common stock and warrants to purchase 333,333 shares of common stock to a member of its board of directors for aggregate gross proceeds of $50,000. The purchase price for the common stock and warrants was $0.15 per share. The warrants are exercisable at an exercise price of $0.15 at any time from date of issuance until 7 years from the date of issuance.

On July 3, 2018, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with Acuitas Group Holdings, LLC ("Acuitas")and certain other purchasers identified in the Purchase Agreement (together with Acuitas, the "Purchasers") pursuant to which (i) the Purchasers agreed to purchase an aggregate of 2,133,332 shares of the our Series A Convertible Preferred Stock (the "Preferred Stock") at a price per share of $1.50 per share of Preferred Stock (the "Initial Sale") and (ii) we agreed to issue warrants (the "Warrants") to purchase 213,333,200 shares of common stock, each subject to the terms and conditions set forth in the Purchase Agreement, for an aggregate consideration of $3.2 million. We received $160,000 of the $3.2 million in April and May 2018 as prepaid equity. Acuitas also received an additional 833,333 Warrants in connection with the payoff of a note issued by us in favor of Acuitas. The Initial Sale and issuance of the Warrants occurred on July 3, 2018. In addition, Acuitas had the option to purchase up to an additional 200,000,000 shares of common stock at a price per share of $0.015, and warrants on the same terms as the Warrants, within two weeks following the one year anniversary of the closing of the Initial Sale (the "Subsequent Sale") in the event that we did not obtain $3,000,000 of funding through various non-dilutive grants prior to the one year anniversary of the closing of the Initial Sale, less any federal or FDA grant funding received by the Company. Acuitas is controlled by our Chairman and Chief Executive Officer, Terren Peizer and the Purchasers included Jonathan Adams, James Lang, Cuang Do and Michael Sherman, who are members of our Board of Directors.

The Purchase Agreement contained customary representations and warranties. In connection with the disclosure schedule associated with the representations and warranties, we also disclosed customary information, including the following: (i) the existence of the Mallinckrodt petition before the U.S. Patent Trial and Appeal Board, (ii) our capitalization, (iii) our obligation to pay a low single digit royalty on the net sales of BIV201 (continuous infusion terlipressin) to be shared among LAT Pharma LLC members, PharmaIN Corporation and The Barrett Edge, Inc. pursuant to the Agreement and Plan of Merger, dated April 11, 2016, by and between LAT Pharma LLC and us, (iv) our obligation to pay a low single digit royalty on net sales of all terlipressin products covered by specified patents up to a maximum of $200,000 per year pursuant to the Technology Transfer Agreement, dated July 25, 2016, by and between us and the University of Padova (Italy), and (v) certain recent issuances of common stock by us.

Each share of Preferred Stock automatically converted into 100 shares of common stock upon the filing with the Secretary of State of the State of Nevada of a Certificate of Amendment to our Articles of Incorporation (the "Amendment") on August 13, 2018 that increased the number of authorized shares of common stock to 800,000,000. The Amendment was approved by the written consent of the holders of more than a majority of our issued and outstanding common stock on July 3, 2018 and was filed with the Secretary of State of the State of Nevada 20 calendar days following the distribution of our Definitive Information Statement on Schedule 14 that was filed with the SEC on July 13, 2018.

Pursuant to the Purchase Agreement, Terren Peizer, the Chairman of Acuitas, was appointed as a member of the Company's Board of Directors (the "Board") and as the Chief Executive Officer of the Company, effective July 3, 2018. The issuance of the Preferred Stock, the Warrants and the underlying common stock under the Purchase Agreement is exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act.

BioVie Inc.
Notes to Financial Statements
For the Years Ended June 30, 2019 and 2018

8. Equity Transactions (continued)

Pursuant to a letter agreement dated June 24, 2019, Acuitas has agreed to modify its existing rights under the Purchase Agreement so that:

- Acuitas agreed to immediately exchange its existing 200,833,333Warrants for common stock such that it will have effectively exercised its Warrants in full pursuant to a cashless exercise thereof at an assumed current market price of $0.36 per share and, as a result received an aggregate of 95% of the shares covered thereby, or 190,761,666 shares of common stock;

- Acuitas agreed to (i) waive its rights to a 50% adjustment of the purchase price of the Preferred Stock in the Initial Sale, the exercise price of the Warrants and the price per share in the Subsequent Sale in the event of certain reductions in the useful life of our current intellectual property rights, and (ii) effectively exercise its rights to purchase securities in a Subsequent Sale pursuant to a "cashless purchase" at an assumed current market price of approximately $0.09 per share, conditioned in each case on the listing of our common stock on NASDAQ or the raising of $2.0 million in additional funds in the form of another securities offering, in either case not later than November 30, 2019, which will result Acuitas having irrevocably waived its rights to an adjustment in the purchase price of the Preferred Stock in the Initial Sale and the exercise price of the Warrants and the purchase price of per share in the Subsequent Sale upon the issuance by us of an aggregate of 167,494,750 shares of common stock (the "Subsequent Sale Shares") to Acuitas.

Issuance of Warrants for Cash and Cashless Exercise of Warrants

In December 2017, the Company issued warrants for cash to purchase 2,500,000 shares of common stock in a private placement transaction for aggregate gross proceeds of $100,000. The purchase price for the warrants were $0.04 per warrant. The warrants are exercisable at an exercise price of $0.20 at any time from date of issuance until 7 years from the date of issuance. As a result of the conversion of the Series A Preferred Stock in July 2018, the exercise of warrants to purchase 2,500,000 shares of common stock was reduced from $0.15 per share to $0.015 per share. On August 4, 2018, the Company issued 2,241,913 shares of common stock pursuant to a cashless exercise of warrants to purchase 2,500,000 shares at an exercise price of $0.015 per share.

On May 13, 2019, the Company issued 59,808 shares of common stock pursuant to a cashless exercise of warrants to purchase 59,808 shares at an exercise price of $0.11 per share.

On June 24, 2019, the Company issued 190,761,666 shares of common stock pursuant to a cashless exercise of warrants to purchase 200,833,333 shares at an exercise price of $0.36 per share.

Issuance of Warrants Services

In January 2018, the Company issued warrants to purchase 105,000 shares of common stock in exchange for services. The warrants are exercisable at an exercise price of $0.15 any time from the date of issuance until 7 years from the date of issuance. The warrants were valued at $9,444. The fair value of the warrants granted was estimated using the Black Scholes Method and the following assumptions: volatility – 166.7%; Term – 7 years; Risk Free Rate – 2.48%; dividend rate – 0.00%

In February 2018, the Company issued warrants to purchase 105,000 shares of common stock in a termination agreement. The warrants are exercisable at an exercise price of $0.15 any time from the date of issuance until 7 years from the date of issuance. The warrants were valued at $3,025. The fair value of the warrants granted was estimated using the Black Scholes Method and the following assumptions: volatility – 166.7%; Term – 7 years; Risk Free Rate – 2.81%; dividend rate – 0.00%

BioVie Inc.
Notes to Financial Statements
For the Years Ended June 30, 2019 and 2018

8. Equity Transactions (continued)

Issuance of Shares for Services

In August 2017, the Company issued 1,500,000 shares of common stock to Aspire Capital in exchange for services. The shares were valued at $0.22 per share which was the trading price on date of issuance, and the value of the services were $330,000.

In November 2017, the Company issued 150,000 shares of common in exchange for services. The shares were valued at $0.23 per share which was the trading price on date of issuance, and the value of the services were $34,500.

In January 2018, The Company issued 30,000 shares of common stock in exchange for services. The shares were valued at $0.13 per share which was the trading price on date of issuance, and the value of the services were $3,900.

In January 2018, the Company issued 1,400,000 shares of common stock as compensation for the Board of Directors. The shares were valued at $0.15 per share which was the trading price on date of issuance, and the value of the compensation was $210,000.

In February 2018, the Company issued 600,000 shares of common stock in exchange for services. The shares were valued at $0.0475 per share which was the trading price on date of issuance, and the value of the services were $28,500.

In April 2018, the Company issued 300,000 shares of common in exchange for services. The shares were valued at $0.045 per share, and the value of the services were $13,500. In April 2018, the Company issued 150,000 shares of common in exchange for services. The shares were valued at $0.024 per share which was the trading price on date of issuance, and the value of the services were $3,600.

In May 2018, the Company issued 250,000 shares of common in exchange for services. The shares were valued at $0.018 per share which was the trading price on date of issuance, and the value of the services were $4,500.

In May 2018, the Company issued 68,500 shares of common in exchange for services. The shares were valued at $0.10 per share which was the trading price on date of issuance, and the value of the services were $6,850.

In June 2018, the Company issued 300,000 shares of common in exchange for services. The shares were valued at $0.025 per share which was the trading price on date of issuance, and the value of the services were $7,500.

On January 2, 2019, the Company issued 1,400,000 shares of common stock as part of the annual board of director compensation. The share price on date of issuance was $0.035 per share.

Issuance of Shares in Settlement of Debt

During the year ended June 30, 2019, the Company settled $1,475,765 of debt and accrued compensation including $1,313,765 owed to related parties, by issuing 975,361 shares of common stock with a fair value of $1,150,135. See notes 5 and 6.

Issuance of Stock Options

In November 2017, the Company extended the maturity date of stock options to acquire 800,000 shares at exercise prices ranging from $0.21 to $0.25 issued to the board of directors between November 2016 and December 2016 by 3 years. The Company recorded an incremental expense of $79,491 based on the increase in fair value of the options.

BioVie Inc.
Notes to Financial Statements
For the Years Ended June 30, 2019 and 2018

8. Equity Transactions (continued)

In June 2018, 100,000 shares of stock options were exercised for $2,000.

On October 1, 2018, the Company issued stock options to purchase 100,000 shares of common stock to the Chief Financial Officer as part of her compensation. The stock options were issued and are exercisable at an exercise price of $0.07 at any time from date of issuance and expire in 5 years from the date of issuance.

On October 13, 2018, the Company issued stock options to purchase 100,000 shares of common stock as part of their annual board of director compensation. The stock options were issued and are exercisable at $0.05 at any time from date of issuance and expire in 5 years from the date of issuance.

On October 27, 2018, the Company issued stock options to purchase 100,000 shares of common stock as part of their annual board of director compensation. The stock options were issued and are exercisable at $0.05 at any time from date of issuance and expire in 5 years from the date of issuance

On November 10, 2018, the Company issued stock options to purchase 100,000 shares of common stock as part of their annual board of director compensation. The stock options are exercisable at an exercise price of $0.05 at any time from date of issuance and expire in 5 years from the date of issuance.

On January 19, 2019, the Company issued stock options to purchase 100,000 shares of common stock to each of five key employees or consultants and two company directors as part of his or her annual compensation, for an aggregate total of 700,000 stock options. The stock options are exercisable at an exercise price of $0.025 at any time from date of issuance until 5 years from the date of issuance.

On March 11, 2019, the Company issued stock options to purchase 1,000,000 shares of common stock to an investor relations (IR) consultant. The stock options were issued and are exercisable at $0.05 at any time from date of issuance and expire in 5 years from the date of issuance.

Warrant Price Adjustment

In December 2017, the Company issued warrants to purchase 2,500,000 shares of common stock in a private placement transaction for aggregate gross proceeds of $100,000. The warrants were exercisable at an exercise price of $0.20 at any time from date of issuance until 7 years from the date of issuance. The warrants have a down round feature that reduces the exercise price if the Company sells stock for a lower price. In January 2018, the Company sold shares at $0.15, which therefore triggered the reduction in the strike price. The Company calculated the difference in fair value of the warrants between the stated exercise price and the reduced exercise price and recorded $20,995 as a deemed dividend. In July 2018, the Company sold shares at $0.015, which therefore triggered the reduction in the strike price. The Company calculated the difference in fair value of the warrants between the stated exercise price and the reduced exercise price and recorded $44,889 as a deemed dividend. The fair value of the warrants granted was estimated using the Black Scholes Method.

In January and February 2018, the Company issued warrants to purchase 210,000 shares of common stock in exchange for banking services which was recognized at fair value. The warrants were exercisable at an exercise price of $0.15 at any time from date of issuance until 7 years from the date of issuance. The warrants have a down round feature that reduces the exercise price if the Company sells stock for a lower price. In July 2018, the Company sold shares at $0.015, which therefore triggered the reduction in the strike price. The Company calculated the difference in fair value of the warrants between the stated exercise price and the reduced exercise price and recorded $3,770 as a deemed dividend. The fair value of the warrants granted was estimated using the Black Scholes Method.

BioVie Inc.
Notes to Financial Statements
For the Years Ended June 30, 2019 and 2018

8. Equity Transactions (continued)

The following table summarizes the warrants that have been issued:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
Outstanding at June 30, 2017	6,173,864	$ 0.50	0.5	
Granted	3,600,151	$ 0.22	5.3	
Expired	(5,000,000)	$ 0.50	—	
Outstanding at June 30, 2018	4,774,015	$ 0.29	5.5	$ —
Granted	214,166,533	$ 0.36	5.6	$ 1,159,988
Expired		$ —	—	$ —
Exercised	(203,357,332)	$ 0.36	—	$ —
Outstanding and exercisable at June 30, 2019	15,583,216	$ 0.36	5.6	$ 1,202,678

Of the above warrants, 1,173,864 expire in fiscal year ending June 30, 2022, 601,819 expire in fiscal year ending June 30, 2023 and 13,807,533 expire in fiscal year ended June 30, 2025.

9. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

At June 30, 2018, the Company has a Net Operating Loss ("NOL") carryforward of approximately $1,800,000. The NOL expires during the years 2032 to 2037. Realization of any portion of the $832,186 of net deferred tax assets at June 30, 2018 is not considered more likely than not by management; accordingly, a valuation allowance has been established for the full amount. The valuation allowance as of June 30, 2018 was $832,186. The change in the valuation allowance from June 30, 2017 to June 30, 2018 amounted to $357,231.

At June 30, 2019, the Company had a Net Operating Loss ("NOL") carryforward of approximately $5,700,000. NOL's generated prior to 2018 will expire during the years 2032 to 2037. Realization of any portion of the $1,680,613 deferred tax assets at June 30, 2019 is not considered more likely than not by management; accordingly, a valuation allowance has been established for the full amount, which as of June 30, 2019 was $1,680,613. The change in the valuation allowance during the year ended June 30, 2019 amounted to $848,427. The Company does not have any uncertain tax positions or events leading to uncertainty in a tax position. The Company's 2016, 2017 and 2018 Corporate Income Tax Returns are subject to Internal Revenue Service examination.

On December 22, 2017, the Tax Cuts and Jobs Act (the "Act") was signed into law. The Act decreases the U.S. corporate federal income tax rate from a maximum of 35% to a flat 21% effective January 1, 2018. The Act also includes a number of other provisions including, among others, the elimination of net operating loss carrybacks and limitations on the use of future losses, NOL's generated in 2018 and later having an indefinite life, the repeal of the Alternative Minimum Tax regime, and the repeal of the domestic production activities deduction. The impact on the Company's financial statements is immaterial, primarily because the Company has a valuation allowance on deferred tax assets.

BioVie Inc.
Notes to Financial Statements
For the Years Ended June 30, 2019 and 2018

9. Income Taxes (continued)

Given the significant complexity of the Act and anticipated additional implementation guidance from the Internal Revenue Service, further implications of the Act may be identified in future periods.

Significant components of the Company's deferred tax assets are as follows:

	June 30, 2019	June 30, 2018
Deferred tax assets:		
Tax loss carryforward	$ 1,624,887	$ 555,064
Intangible assets	$ 36,917	19,277
Stock based compensation	$ 18,809	257,845
Valuation Allowance	$ (1,680,613)	(832,186)
Net deferred tax assets	$ —	$ —

Since management of the Company believes that it is more likely than not that the net deferred tax assets will not provide future benefit, the Company has established a 100 percent valuation allowance on the net deferred tax assets as of June 30, 2019 and 2018. The Company's NOL carryover up to the date of the July 2018 financing will be subject to Section 382 usage limitations since a greater than 50% ownership change took place from the financing event.

Reconciliation of the differences between income tax benefit computed at the federal and state statutory tax rates and the provision for income tax benefit for the years ended June 30, 2019 and 2018 is as follows:

	2019	2018
Income tax expense (benefit) at federal statutory rate	21%	34%
State taxes, net of federal benefit	8%	5%
Change in valuation allowance	-29%	-39%
	—	—

10. Subsequent Events

On September 24, 2019, BioVie Inc., a Nevada corporation (the "Company"), entered into a Securities Purchase Agreement (the "Purchase Agreement") with Acuitas Group Holdings, LLC ("Acuitas") pursuant to which (i) Acuitas agreed to purchase a 10% OID Convertible Delayed Draw Debenture (the "Debenture") due September 20, 2020 in aggregate commitment amount of up to $2.0 million, and (ii) the Company issued 140,625,000 shares (the "Commitment Shares") of the Company's Class A Common Stock (the "Common Stock") and warrants (the "Commitment Warrants") to purchase an equal number of shares, each subject to the terms and conditions set forth in the Purchase Agreement. The Debentures accrue additional principal at the rate of 6% per annum and interest at the rate of 10% per annum, are convertible into shares of Common Stock $0.032 per share or, subsequent to the closing of the Company's planned public offering of shares of Common Stock (the "Public Offering") as described in its Registration Statement on Form S-1 (File No. 333-231136), the lower of $0.032 or 80% of the offering price to the public in the Public Offering and are mandatorily redeemable upon such closing at 100% of the accrued principal amount and unpaid interest to the date of redemption. The Commitment Warrants are five year warrants, exercisable upon the earlier of the effectiveness of the Company's currently pending reverse stock split and December 1, 2019 at the lower of $0.032 or 80% of the offering price to the public in the Public Offering. Upon entering into the Purchase Agreement, the Company drew an initial $500,000 under the Debenture and in accordance with the Purchase Agreement, Acuitas received an additional 15,625,000 warrants (the "Bridge Warrants") having the same terms as the Commitment Warrants. Any future draws under the Debenture, which may be made from and after October 15, 2019, November 15, 2019 and December 15, 2019 in equal tranches of $500,000 each, will entitle Acuitas to receive additional Bridge Warrants in equal amount upon such funding.

BioVie Inc.
Notes to Financial Statements
For the Years Ended June 30, 2019 and 2018

10. Subsequent Events (continued)

Pursuant to the Purchase Agreement, Acuitas has agreed to further modify its existing rights under the Purchase Agreement dated July 3, 2018 with the Company so that Acuitas' previous agreement in June 2019 to waive its rights to a 50% adjustment of the purchase price of the Preferred Stock in the July 2018 transaction, the exercise price of the warrants in such transaction and the price per share in a purchase option triggered on July 3, 2019 (any such purchase, a "Subsequent Sale") in the event of certain reductions in the useful life of our current intellectual property rights, and effectively exercise its rights to purchase securities in a Subsequent Sale pursuant to a "cashless purchase" at an assumed current market price of approximately $0.09 per share, conditioned in each case on the listing of the Company's common stock on NASDAQ or the raising of $2.0 million in additional funds in the form of another securities offering, in either case not later than November 30, 2019, such that Acuitas will have irrevocably waived its rights to an adjustment in the purchase price of the Preferred Stock in the Initial Sale and the exercise price of the Warrants and the purchase price of per share in the Subsequent Sale upon the issuance by us of an aggregate of 334,989,500 shares of Common Stock and 334,989,500 warrants having the same terms as the Commitment Warrants to Acuitas, which is currently expected with the closing of the Public Offering. In addition, the Purchase Agreement provides that, should the underwriters in the Public Offering exercise their option to purchase additional securities during the 45 days following closing and the issuance of such securities would result in Acuitas' beneficial ownership (on a fully diluted basis) of shares of Common Stock being below 60%, Acuitas shall be issued a number of additional shares of Common Stock and warrants having the same terms as the Commitment Warrants to result in its beneficial ownership (on a fully diluted basis) of shares of Common Stock equalling 60%.

DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

References to "BioVie" and the "Company" herein are, unless the context otherwise indicates, only to BioVie Inc. and not to any of its subsidiaries.

The following description of the Company's capital stock and provisions of the Company's Articles of Incorporation, bylaws and the Nevada corporations law are summaries and are qualified in their entirety by reference to our Articles of Incorporation and our bylaws. We have filed copies of these documents with the SEC as exhibits to the Annual Report on Form 10-K to which this description has been filed as an exhibit. Pursuant to our Articles of Incorporation, as amended, our authorized capital stock consists of 800,000,000 shares of Class A common stock, par value of $0.0001 per share (referred to as the Company's common stock), and 10,000,000 shares of preferred stock, par value $0.001 per share, to be designated from time to time by the Company's Board of Directors.

Common Stock

BioVie is authorized to issue up to 800,000,000 shares of Class A common stock, par value $0.0001 per share. Each outstanding share of common stock entitles the holder thereof to one vote per share on all matters. The Company's bylaws provide that elections for directors shall be by a plurality of votes. Stockholders do not have preemptive rights to purchase shares in any future issuance of common stock. Upon our liquidation, dissolution or winding up, and after payment of creditors and preferred stockholders, if any, the Compay's assets will be divided pro-rata on a share-for-share basis among the holders of the shares of common stock.

The holders of shares of common stock are entitled to dividends out of funds legally available when and as declared by BioVie's Board of Directors. The Company's Board of Directors has never declared a dividend and does not anticipate declaring a dividend in the foreseeable future.

All of the issued and outstanding shares of common stock are duly authorized, validly issued, fully paid and non-assessable. To the extent that additional shares of our common stock are issued, the relative interests of existing stockholders will be diluted.

As of September 24, 2019, there were 647,930,147 shares of common stock outstanding.

Preferred Stock

BioVie is authorized to issue up to 10,000,000 shares of preferred stock, par value $0.001 per share, in one or more classes or series within a class as may be determined by the Company's Board of Directors, who may establish, from time to time, the number of shares to be included in each class or series, may fix the designation, powers, preferences and rights of the shares of each such class or series and any qualifications, limitations or restrictions thereof. Any preferred stock so issued by the Board of Directors may rank senior to the common stock with respect to the payment of dividends or amounts upon liquidation, dissolution or winding up of BioVie, or both. Moreover, under certain circumstances, the issuance of preferred stock or the existence of the unissued preferred stock might tend to discourage or render more difficult a merger or other change of control.

As of September 24, 2019, there were no shares of our preferred stock outstanding.

Anti-Takeover Effects of Our Articles of Incorporation and Bylaws

The Company's Articles of Incorporation and bylaws contain certain provisions that may have anti-takeover effects, making it more difficult for or preventing a third party from acquiring control of us or changing BioVie's Board of Directors and management. According to the Company's Articles of Incorporation and bylaws, neither the holders of common stock nor the holders of any preferred stock that may be issued in the future have cumulative voting rights in the election of directors. The combination of the present ownership by a few stockholders of a significant portion of our issued and outstanding common stock and lack of cumulative voting makes it more difficult for other stockholders to replace BioVie's Board of Directors or for a third party to obtain control of the Company by replacing its Board of Directors.

Anti-Takeover Effects of Nevada Law

Business Combinations

The "business combination" provisions of Sections 78.411 to 78.444, inclusive, of the Nevada Revised Statutes, or NRS, generally prohibit a Nevada corporation with at least 200 stockholders from engaging in various "combination" transactions with any interested stockholder for a period of two years after the date of the transaction in which the person became an interested stockholder, unless the transaction is approved by the board of directors prior to the date the interested stockholder obtained such status or the combination is approved by the board of directors and thereafter is approved at a meeting of the stockholders by the affirmative vote of stockholders representing at least 60% of the outstanding voting power held by disinterested stockholders, and extends beyond the expiration of the two-year period, unless:

- the combination was approved by the board of directors prior to the person becoming an interested stockholder or the transaction by which the person first became an interested stockholder was approved by the board of directors before the person became an interested stockholder or the combination is later approved by a majority of the voting power held by disinterested stockholders; or
- if the consideration to be paid by the interested stockholder is at least equal to the highest of: (a) the highest price per share paid by the interested stockholder within the two years immediately preceding the date of the announcement of the combination or in the transaction in which it became an interested stockholder, whichever is higher, (b) the market value per share of common stock on the date of announcement of the combination and the date the interested stockholder acquired the shares, whichever is higher, or (c) for holders of preferred stock, the highest liquidation value of the preferred stock, if it is higher.
-

A "combination" is generally defined to include mergers or consolidations or any sale, lease exchange, mortgage, pledge, transfer, or other disposition, in one transaction or a series of transactions, with an "interested stockholder" having: (a) an aggregate market value equal to 5% or more of the aggregate market value of the assets of the corporation, (b) an aggregate market value equal to 5% or more of the aggregate market value of all outstanding shares of the corporation, (c) 10% or more of the earning power or net income of the corporation, and (d) certain other transactions with an interested stockholder or an affiliate or associate of an interested stockholder.

In general, an "interested stockholder" is a person who, together with affiliates and associates, owns (or within two years, did own) 10% or more of a corporation's voting stock. The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire the Company even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Control Share Acquisitions

The “control share” provisions of Sections 78.378 to 78.3793, inclusive, of the NRS apply to “issuing corporations” that are Nevada corporations with at least 200 stockholders, including at least 100 stockholders of record who are Nevada residents, and that conduct business directly or indirectly in Nevada. The control share statute prohibits an acquirer, under certain circumstances, from voting its shares of a target corporation’s stock after crossing certain ownership threshold percentages, unless the acquirer obtains approval of the target corporation’s disinterested stockholders. The statute specifies three thresholds: one-fifth or more but less than one-third, one-third but less than a majority, and a majority or more, of the outstanding voting power. Generally, once an acquirer crosses one of the above thresholds, those shares in an offer or acquisition and acquired within 90 days thereof become “control shares” and such control shares are deprived of the right to vote until disinterested stockholders restore the right. These provisions also provide that if control shares are accorded full voting rights and the acquiring person has acquired a majority or more of all voting power, all other stockholders who do not vote in favor of authorizing voting rights to the control shares are entitled to demand payment for the fair value of their shares in accordance with statutory procedures established for dissenters’ rights.

A corporation may elect to not be governed by, or “opt out” of, the control share provisions by making an election in its articles of incorporation or bylaws, provided that the opt-out election must be in place on the 10th day following the date an acquiring person has acquired a controlling interest, that is, crossing any of the three thresholds described above. We have not opted out of the control share statutes, and will be subject to these statutes if we are an “issuing corporation” as defined in such statutes.

The effect of the Nevada control share statutes is that the acquiring person, and those acting in association with the acquiring person, will obtain only such voting rights in the control shares as are conferred by a resolution of the stockholders at an annual or special meeting. The Nevada control share law, if applicable, could have the effect of discouraging takeovers of the Company.

Trading Market

The Company’s common stock trades on the OTCQB Marketplace under the ticker “BIVI.”

Transfer Agent and Registrar

The Company’s independent stock transfer agent is West Coast Stock Transfer, Inc., located at 721 N. Vulcan Ave., Suite 205, Encinitas, California 92024. Their phone number is (619) 664-4780.

Disclosure of Commission Position on Indemnification for Securities Act Liabilities

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, the Company has been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULE 13-a-14(a) and 15d-14(a)
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, Terren Peizer, certify that:

1. I have reviewed this annual report on Form 10-K of Biovie, Inc.;

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, in light of 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, including its consolidated subsidiaries, 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 the 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.

Date: September 26, 2019

/s/ Terren S. Peizer

Terren S. Peizer
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULE 13-a-14(a) and 15d-14(a)
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, Joanne Wendy Kim, certify that:

1. I have reviewed this annual report on Form 10-K of Biovie, Inc.;

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, in light of 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, including its consolidated subsidiaries, 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 the 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.

Date: September 26, 2019

/s/ Joanne Wendy Kim
Joanne Wendy Kim
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Annua; Report of Biovie, Inc., (the "Company") on Form 10-K for the year ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Terren Peizer, Chief Executive Officer and Chairman of the Board of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m (a) or 78o(d)); and

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

Date: September 26, 2019

/s/ Terren S. Peizer

Terren S. Peizer
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 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 Biovie, Inc., (the "Company") on Form 10-K for the year ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joanne Wendy Kim, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m (a) or 78o(d)); and

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

Date: September 26, 2019

/s/ Joanne Wendy Kim

Joanne Wendy Kim
Chief Financial Officer
(Principal Financial and Accounting Officer)