

# SECURITIES & EXCHANGE COMMISSION EDGAR FILING

**BIOVIE INC.**

**Form: 10-K**

**Date Filed: 2016-09-28**

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, 2016**

**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: **000-55292**

**BIOVIE INC. (F/K/A NANOANTIBIOTICS, INC.)**

*(Exact name of registrant as specified in its charter)*

**Nevada**

*(State or other jurisdiction of  
incorporation or organization)*

**46-2510769**

*(I.R.S. Empl. Ident. No.)*

**100 Cummings Center, Suite 247-C  
Beverly, MA 01915**

*(Address of principal executive offices, Zip Code)*

**(312)-283-5793**

*(Registrant's telephone number, including area code)*

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

\$.0001 par value common  
stock

Over the Counter Bulletin Board

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files).

Yes

No

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

Large Accelerated Filer

Accelerated Filer

Non-Accelerated Filer

Smaller reporting company

(Do not check if a smaller reporting company)

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 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 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 fourth fiscal quarter, June 30, 2016 was \$31,377,600.

There were 87,160,001 shares of the Registrant's \$0.0001 par value common stock outstanding as of June 30, 2016.

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BIOVIE INC. (F/K/A NANOANTIBIOTICS, INC.)

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**BIOVIE INC. (F/K/A NANOANTIBIOTICS, INC.)**

This Annual Report on Form 10-K and the documents incorporated herein by reference contain forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on current expectations, estimates and projections about BioVie Inc.'s industry, management beliefs, and assumptions made by management. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict; therefore, actual results and outcomes may differ materially from what is expressed or forecasted in any such forward-looking statements.

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ITEM 1. DESCRIPTION OF BUSINESS

Introduction

BioVie, Inc. (F/K/A NanoAntibiotics, Inc., the "Company") is a development stage enterprise that was incorporated in the state of Nevada on April 10, 2013. The Company is engaged in the discovery, development and commercialization of a therapy targeting ascites due to liver cirrhosis. Ascites due to liver cirrhosis is a life-threatening condition affecting about 100,000 Americans and many times more worldwide. Our therapy BIV201 is based on a drug that is approved in about 50 countries to treat related complications of liver cirrhosis (part of the same disease pathway as ascites), but not yet available in the US. 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. 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. We are currently completing the work necessary to file our investigational new drug (IND) application, and aim to commence clinical trials should the FDA approve our application.

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.

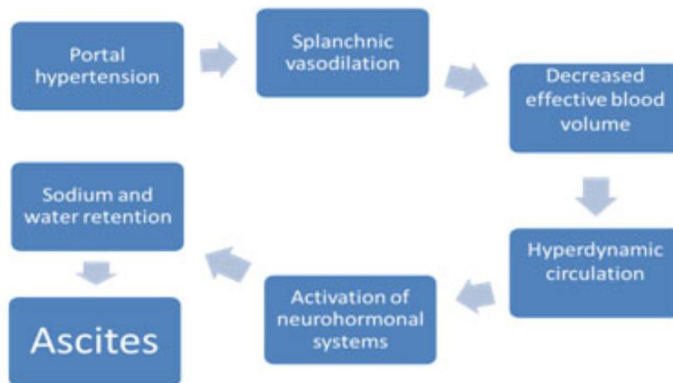
About Ascites and Liver Cirrhosis

About 1 million Americans and millions worldwide suffer from liver cirrhosis. Cirrhosis is the 12th leading cause of death due to disease in the US, killing an estimated 27,000 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 Needs 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 \$4 billion annually.

The Ascites Development Pathway



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, BIV201 has the potential for 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.

- Esophageal variceal bleed (EVB): 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.
- Hyponatremia: This term refers to “low salt in the bloodstream,” another dangerous condition which can occur as a result of advanced liver cirrhosis.

### **Joint Venture and Possible Access to Early-Stage Compounds**

The Company has an Agreement with PharmaIN Corporation (Bothell, WA) providing certain limited rights and information on their program to develop novel modified terlipressin compounds. Although at an early stage, these compounds hold the promise of simpler and potentially safer dosing for patients outside the hospital. If this program makes significant advances, BioVie may contact PharmaIN to explore a licensing opportunity.

The Company and PharmaIN have exchanged small (low single-digit) ownership rights to each other’s ascites drug development programs, and may work together to advance both of them to eventual product commercialization.

## **Efflux Pump Antibiotics Program**

Prior to the Merger 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 trade secrecy and patent strategy to protect our confidential information and seek market exclusivity for our products. The Company has submitted patent filings for BIV201 technology in the US and Japan as well as submitted a PCT in Europe. Additionally, BioVie has applied for US Orphan Drug Designation for its new drug candidate since the estimated number of ascites patients (about 100,000 Americans) meets the required patient population size.

## **Research and Development**

For the year ended June 30, 2016, the Company spent \$37,901 in research and development activities.

## **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:



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- 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.

Before testing any compounds with potential therapeutic value in humans, the drug or biological candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the drug or biological candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug or biological candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot assure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trial.

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 Chief Executive Officer and Chief Financial Officer, Jonathan Adams, and our President and Secretary, Amrit Shahzad, each devote part time to the Company's activities. There are no additional employees.

## **ITEM 1A. RISK FACTORS**

**THE SECURITIES BEING OFFERED INVOLVE A HIGH DEGREE OF RISK AND, THEREFORE, SHOULD BE CONSIDERED EXTREMELY SPECULATIVE. THEY SHOULD NOT BE PURCHASED BY PERSONS WHO CANNOT AFFORD THE POSSIBILITY OF THE LOSS OF THE ENTIRE INVESTMENT. PROSPECTIVE INVESTORS SHOULD READ THE ENTIRE PROSPECTUS, INCLUDING ALL EXHIBITS, AND CAREFULLY CONSIDER, AMONG OTHER FACTORS THE FOLLOWING RISK FACTORS.**

### **Risks Relating to Our Business and Industry**

***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. (FKA NanoAntibiotics, Inc.) was incorporated on April 10, 2013. We are a development stage biopharmaceutical company with a potential therapy that we have not 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 the Company will realize its plans on its 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 the Company will continue as a going concern. The Company has 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 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 our drug candidates, 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

***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 drug 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 drug candidate is in the development stage, and we have not evaluated it in human clinical trials. If we do not successfully develop and commercialize our drug 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 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, 2016, we had cash and cash equivalents totaling \$123,757. Other than our cash on hand, we currently have no commitments or arrangements for any additional financing 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 drug 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 drug candidate. We will require additional financing to further the clinical development of our drug candidate. In the event that we cannot obtain the required financing, we will be unable to complete the development necessary to file an investigational new drug application with the FDA for BIV201, our drug candidate. 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; 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 limited experience in drug development and 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 drug candidate is in early developmental stage. 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 for a few years, if ever. The proposed development schedules for our drug candidate 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 drug 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, the unproven technology involved and the other factors described elsewhere in this prospectus, we may not be able to complete successfully the development or marketing of any drugs which could cause us to cease operations.



We may fail to successfully develop and commercialize our drug candidate 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 and 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 drug candidate will be. Furthermore, our drug candidate 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 drug candidate is 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. 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 do not own or lease facilities currently that could be used to manufacture any products that might be developed by the Company, nor do we have the resources at this time to acquire or lease suitable facilities. If we 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.

***We do not 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 drug candidate, which could have a materially adverse effect on our business.***

The R&D, manufacture and marketing of drug 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 New Drug Application (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 drug 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 drug candidate exposes clinical subjects to an unacceptable health risk. Investigational drugs used in clinical studies must be produced in compliance with current good manufacturing practice (GMP) 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 drug 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 affect on our business.

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

The business plan we have developed for the next twelve months is to complete the work necessary to file our investigational new drug (IND) application with the FDA. Due to our financial constraints we may not have the resources necessary to complete our application. If the FDA approves our IND application, we will aim to commence clinical trials in the US. There is no guarantee the FDA will approve our IND application, and even if they do our financial constraints may prevent us from undertaking clinical trials.

The testing, marketing and manufacturing of any product for use in the United States will require approval from the FDA. We cannot predict with any certainty the amount of time necessary to obtain such FDA approval and whether any such approval will ultimately be granted. Preclinical and clinical trials may reveal that one or more products are ineffective or unsafe, in which event further development of such products could be seriously delayed or terminated. Moreover, obtaining approval for certain products may require testing on human subjects of substances whose effects on humans are not fully understood or documented. Delays in obtaining FDA or any other necessary regulatory approvals of any proposed drug and failure to receive such approvals would have an adverse effect on the drug's potential commercial success and on our business, prospects, financial condition and results of operations. In addition, it is possible that a proposed drug may be found to be ineffective or unsafe due to conditions or facts that arise after development has been completed and regulatory approvals have been obtained. In this event, we may be required to withdraw such proposed drug from the market. To the extent that our success will depend on any regulatory approvals from government authorities outside of the United States that perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist and should it result in our drug candidates failing to receive regulatory approval you could lose all of your investment.

***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.***

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. 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 and 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. There can be no assurance that any patent applications we have filed will ultimately result in the issuance of a patent with respect to the technology owned by us or licensed to us. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards that the United States Patent and Trademark Office 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.

We do not believe that BIV201, the drug 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. 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, enter into royalty agreements, or redesign our drug candidates so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. 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.

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. 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 management team of Jonathan Adams, our Chief Executive Officer and Chief Financial Officer, and Amrit Shahzad, our President and Secretary. Both of these individuals serve 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, the Company still faces significant competitive and market risk. Other companies, such as Mallinckrodt Inc., are developing therapies for severe complications of advanced liver cirrhosis, which may in future be developed for the treatment of ascites, and these therapies could compete indirectly or directly with our drug candidate. There may be other competitive development programs of which we are unaware. Even if our drug 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 drug 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 drug 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 the Company is not aware of any conflict that has arisen to date, we do not have any policy in place to deal with such should such a conflict arise.

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

The Company's current executive officers also serve as directors of the Company, and the Company does not have an independent compensation committee to determine compensation and to approve employment agreements. Therefore, compensation which may be paid by the Company to its management may not be determined based on arms-length negotiations. The Company may grant stock options and other equity incentives to its executive officers and directors that are consistent with the nature of the pharmaceutical industry. 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 the Company.

**RISKS RELATING TO OUR COMMON STOCK**

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

The Company has the right to raise additional capital or incur borrowings from third parties to finance its business. The Company 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 its existing stockholders. Our Board of Directors has the authority, without the consent of any of the stockholders, to cause the Company 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 in its sole discretion. The issuance of additional shares of capital stock by the Company 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.***

The directors and executive officers of the Company currently own an aggregate 10,137,932 shares, which currently constitutes 11.6% of the Common Stock of the Company. As a result, directors and executive officers may have a significant influence on the affairs and management of the Company, as well as on all matters requiring member approval, including electing and removing members of the Company's Board of Directors, causing the Company to engage in transactions with affiliated entities, causing or restricting the sale or merger of the Company, and certain other matters. Such concentration of ownership and control could have the effect of delaying, deferring or preventing a change in control of the Company even when such a change of control would be in the best interests of the Company's stockholders.

***There is very little liquidity in our Common Stock and we may not be successful at obtaining a quotation on a recognized quotation service. In such event it may be difficult for you to sell your shares.***

The OTC Bulletin Board and similar quotation services are often characterized by low trading volumes, and price volatility, which may make it difficult for an investor to sell our Common Stock on acceptable terms. If trades in our Common Stock are not quoted on a quotation facility, it may be very difficult for an investor to find a buyer for their shares in our Company.

***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 will constitute “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 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.***

Our Articles of Incorporation authorize the issuance of 300,000,000 shares of Common Stock. As of June 30, 2016, the Company had 87,160,001 shares of Common Stock outstanding. Accordingly, we may issue up to an additional 212,839,999 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 87,160,001 shares of Common Stock currently issued and outstanding, and assuming no Warrants are exercised, 77,022,069 shares are held by non-affiliates and 10,137,932 are owned by affiliates of the Company, consisting of our officers and directors and a large shareholder. All of these securities are deemed “restricted securities” within the meaning of Rule 144 as promulgated under the Securities Act. Other than the 5,000,000 shares previously issued to the selling security holders in the Private Placement and other than the 5,000,000 shares underlying the Warrants purchased in the Private Placement, none of the above described shares are being offered for sale in this prospectus. Consequently, the sale of such shares is subject to Rule 144.

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.

***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 lack 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. Our officers and directors have never been responsible for managing a publicly traded company. 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.

***The Company is 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 \$75 million as of the last business day of its most recently completed second fiscal quarter, computed by multiplying the aggregate 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 principal market for the common equity; or
- In the case of an initial registration statement under the Securities Act or Exchange Act for shares of its common equity, had a public float of less than \$75 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 whose public float as calculated under paragraph (1) or (2) of this definition was zero, had annual revenues of less than \$50 million during the most recently completed fiscal year for which audited financial statements are available.



As a “smaller reporting company” (in addition to and without regard to our status as an “emerging growth 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 financial 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.

***The Company is considered an “emerging growth company” and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our Common Stock less attractive to investors.***

We are an “emerging growth company,” as defined in the Jumpstart our Business Startups Act of 2012, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (A) following the fifth anniversary of our first sale of common equity securities pursuant to an effective registration statement, (B) in which we have total annual gross revenue of at least \$1.0 billion, or (C) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter, and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

We cannot predict if investors will find our Common Stock less attractive because we will rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile when trading occurs.

***We intend to become subject to the periodic reporting requirements of the Exchange Act, which will 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.***

Following the effective date of the registration statement in which this prospectus is included, we will be required to file periodic reports with the Securities and Exchange Commission pursuant to the Exchange Act and the rules and regulations thereunder. In order to comply with such requirements, our independent registered auditors will have to review our financial statements on a quarterly basis and audit our financial statements on an annual basis. Moreover, our legal counsel will have 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 will be an expense to our operations and thus have a negative effect on our ability to meet our overhead requirements and earn a profit.

However, for as long as we remain an “emerging growth company” we intend to take advantage of certain exemptions from various reporting requirements until we are no longer an “emerging growth company.”

We also qualify as a smaller reporting company, and so long as we remain a smaller reporting company, we benefit from the same exemptions and exclusions as an emerging growth company. In the event that we cease to be an emerging growth company as a result of a lapse of the five year period, but continue to be a smaller reporting company, we would continue to be subject to the exemptions available to emerging growth companies until such time as we were no longer a smaller reporting company.

After, and if ever, we are no longer an “emerging growth company,” we expect to incur significant additional expenses and devote substantial management effort toward ensuring compliance with those requirements applicable to companies that are not “emerging growth companies,” including Section 404 of the Sarbanes-Oxley Act.

***The JOBS Act allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies, which means that our financial statements may not be comparable to companies that comply with public company effective dates, which could make our Common Stock less attractive to investors.***

Since we have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act, this election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

***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. DESCRIPTION OF PROPERTY**

On January 1, 2014 the company executed a lease agreement with Cummings Properties for the company’s office of 270 square feet at 100 Cummings Center, Suite 247-C, Beverly, MA 01915. The lease is for a term of five years from January 1, 2014 to December 30, 2018 and requires monthly payments of \$357 (\$4,284 annually for each of the five years, total aggregate of \$21,420).

**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. 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.

**ITEM 4. MINE SAFETY DISCLOSURE**

None

**PART II****ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS**

The Company's Common Stock trades on the over-the-counter market on the National Association of Securities Dealers, Inc. OTC Bulletin Board System ("OTCBB") under the symbol "BIVI." The following table sets forth the range of high and low closing bid quotations of the Common Stock as reported by the OTCBB for each fiscal quarter for the years ended June 30, 2016 and 2015. High and low bid quotations reflect inter-dealer prices without adjustment for retail mark-ups, markdowns or commissions and may not necessarily represent actual transactions.

	<b>Bid Prices</b>			
	<b>Low</b>		<b>High</b>	
Quarter ended June 30, 2016	\$	0.06	\$	0.36
Quarter ended March 31, 2016	\$	0.10	\$	0.19
Quarter ended December 31, 2015	\$	0.12	\$	0.20
Quarter September 30, 2015	\$	0.12	\$	0.38

On June 30, 2016, the closing bid price of the Company's Common Stock as reported by the OTC was \$0.36 and there were approximately 87 shareholders of record.

**DIVIDENDS**

We have not paid any cash dividends on our common or preferred stock and do not anticipate paying any such cash dividends in the foreseeable future. Earnings, if any, will be retained to finance future growth. We may issue shares of our common stock and preferred stock in private or public offerings to obtain financing, capital or to acquire other businesses that can improve our performance and growth. Issuance and or sales of substantial amounts of common stock could adversely affect prevailing market prices in our common stock.

**Common Stock**

During the year ended June 30, 2016, there was no modification of any instruments issued herein for the fourth quarter, defining the rights of holders of the Company's common stock and no limitation or qualification of the rights evidenced by the Company's common stock as a result of the issuance of any other class of securities or the modification thereof.

The Company recognizes all share-based payments to employees, including grants of employee stock options, as compensation expense in the financial statements based on their fair values. That expense will be recognized over the period during which an employee is required to provide services in exchange for the award, known as the requisite service period (usually the vesting period).

**ITEM 6. SELECTED FINANCIAL DATA**

Not Required

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

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.

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 document.

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements. In order to comply with the terms of the safe harbor, the Company notes that in addition to the description of historical facts contained herein, this report contains certain forward-looking statements that involve risks and uncertainties as detailed herein and from time to time in the Company's other filings with the Securities and Exchange Commission and elsewhere. Such statements are based on management's current expectations and are subject to a number of factors and uncertainties, which could cause actual results to differ materially from those, described in the forward-looking statements. These factors include, among others: (a) the Company's fluctuations in sales and operating results; (b) risks associated with international operations; (c) regulatory, competitive and contractual risks; (d) product development risks; (e) the ability to achieve strategic initiatives, including but not limited to the ability to achieve sales growth across the business segments through a combination of enhanced sales force, new products, and customer service; and (f) pending litigation.

We are a development stage biotechnology company engaged in the discovery, development and commercialization of a therapy targeting ascites due to liver cirrhosis. Ascites due to liver cirrhosis is a life-threatening condition affecting about 100,000 Americans and many times more worldwide. Our therapy BIV201 is based on a drug that is approved in about 50 countries to treat related complications of liver cirrhosis (part of the same disease pathway as ascites), but not yet available in the US. 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. We are currently completing the work necessary to file our investigational new drug (IND) application, and aim to commence clinical trials should the FDA approve our application. 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.

We have incurred \$432,028 of operating expenses for the year ended June 30, 2016. We are now engaged in organizational activities and sourcing compounds and materials. We anticipate incurring other costs associated with equipment purchases and general and administrative expenses, including employee salaries and benefits, legal expenses, and other costs associated with an early stage, publicly-traded company.

The amounts that we actually spend for any specific purpose may vary significantly, and will depend on a number of factors including, but not limited to, the pace of progress of our research and development, market conditions, and our ability to qualify vendors. In addition, we may use a portion of any net proceeds to acquire complementary compounds; however, we do not have plans for any acquisitions at this time. We will have significant discretion in the use of any net proceeds. Investors will be relying on the judgment of our management regarding the application of the proceeds of any sale of our Common Stock.

#### **Requirement for Additional Capital**

The Company has engaged in limited research and development activities. We currently do not have sufficient funds to meet our planned drug development for the next twelve (12) months and we may not be able to obtain the necessary financing on terms and conditions acceptable to the Company. Assuming that we are successful in raising additional financing, we plan to incur the following expenses over the next twelve (12) months:

- Research and Development of \$45,000, which includes planned costs for the development of BIV201.
- Corporate overhead of \$15,000, which includes budgeted legal, accounting and other costs expected to be incurred; and
- Staffing costs of \$250,000.

The Company had approximately \$123,757 of cash on hand at June 30, 2016 and will be unable to proceed with its planned drug development, meet its administrative expense requirements, capital costs, or staffing costs without obtaining additional net financing of approximately \$250,000 to \$500,000 to meet its near-term budgetary needs.

The Company has limited experience with pharmaceutical drug development. As such these budget estimates may not be accurate. In addition, the actual work to be performed can only be broadly projected, as is normal with any scientific work. As further work is performed, additional work may become necessary or change in plans or workload may occur. Such changes may have an adverse impact on our estimated budget. Such changes may also have an adverse impact on our projected timeline of drug development.

Management intends to use capital and debt financing, as required, to fund the Company's operations. There can be no assurance that the Company will be able to obtain the additional capital resources necessary to fund its anticipated obligations for the next twelve (12) months.

## Capital Resources and Liquidity

As of June 30, 2016, we had \$123,757 of cash on hand in our corporate bank account. The Company is considered to be a development stage company and will continue in the development stage until generating revenues from the sales of its products or services. As a result, the report of the independent registered public accounting firm on our financial statements as of June 30, 2016, contains an explanatory paragraph regarding a substantial doubt about our ability to continue as a going concern.

We do not have sufficient funds for the next (12) twelve months and must raise cash to implement our strategy and stay in business. If we are unable to raise additional funds to develop our compounds, we may be required to scale back our development plans by reducing expenditures for employees, consultants, business development, and other envisioned expenditures. This could reduce our ability to develop BIV201, our drug candidate, and implement our business plan. In that event, investors should anticipate that their entire investment may be lost and there may be no ability to profit from this investment.

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.

If we are unable to raise additional funds, we will need to do one or more of the following:

- delay, scale-back or eliminate some or all of our research and product development programs;
- provide licenses to third parties to develop and commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves;
- seek strategic alliances or business combinations;
- attempt to sell our company;
- cease operations; or
- declare bankruptcy.

We believe that our existing cash and cash equivalents will not be sufficient to meet our operating and capital requirements until June 30, 2017. Any debt financing secured by us in the future could involve restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. We may not be able to secure additional debt or equity financing in a timely manner, or at all, which could require us to scale back our business plan and operations.

The above conditions raise substantial doubt about our ability to continue as a going concern. The financial statements included elsewhere herein were prepared under the assumption that we would continue our operations as a going concern. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. Without additional funds from debt or equity financing, sales of our intellectual property or technologies, or from a business combination or a similar transaction, we will soon exhaust our resources and will be unable to continue operations. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in us.

Our 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.

### **Emerging Growth Company**

We are an “emerging growth company” under the federal securities laws and will be subject to reduced public company reporting requirements. In addition, Section 107 of the JOBS Act also provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are choosing to take advantage of the extended transition period for complying with new or revised accounting standards.

### **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**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

We believe that the following critical policies affect our more significant judgments and estimates used in preparation of our financial statements.

Equipment is recorded at cost and depreciated on a declining balance and straight-line basis over their estimated useful lives, principally two to seven years. Accelerated methods are used for tax depreciation. Maintenance and repairs are charged to operations when incurred. Betterments and renewals are capitalized. When furniture and equipment are sold or otherwise disposed of, the asset account and related accumulated depreciation account are relieved, and any gain or loss is included in operations.

Research and development costs are charged to operations when incurred and are included in operating expenses.

### **New Accounting Pronouncements**

For a description of recent accounting standards, including the expected dates of adoption and estimated effects, if any, on our financial statements, see “Note 3: Significant Accounting Policies: Recent Accounting Standards” in Part II, Item 8 of this Form 10-K.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not Applicable.

**ITEM 8. FINANCIAL STATEMENTS**

**BioVie, Inc. (F/K/A NanoAntibiotics Inc.)**

Financial Statements

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**REPORT OF REGISTERED INDEPENDENT AUDITORS**

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

We have audited the accompanying balance sheets of BioVie Inc. (F/K/A NanoAntibiotics, Inc.) as of June 30, 2016 and 2015 and the related statements of operations, stockholders' equity, and cash flows for the years ended June 30, 2016 and 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with standards of the Public Company Accounting Oversight Board (United States of America). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of BioVie Inc. (F/K/A NanoAntibiotics, Inc.) as of June 30, 2016 and 2015 and the results of its operations and its cash flows for the years ended June 30, 2016 and 2015 in conformity with accounting principles generally accepted in the United States of America.

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 has incurred an operating loss since inception. Further, as of June 30, 2016, the Company has not earned any revenues. These and other factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plan regarding these matters is also described in Note 2 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Respectfully submitted,

*Weinberg & Baer LLC*

Weinberg & Baer LLC  
Baltimore, Maryland  
September 27, 2016

BioVie Inc. (F/K/A NanoAntibiotics, Inc.)  
Balance Sheets

	June 30, 2016	June 30, 2015
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash	\$ 123,757	267,481
Prepaid expenses	6,982	2,000
Total Current Assets	<u>130,739</u>	<u>269,481</u>
<b>OTHER ASSETS:</b>		
Intangible Assets (Net of Amortization)	2,242,734	—
Goodwill	345,711	—
Total Fixed Assets	<u>2,588,445</u>	<u>—</u>
<b>TOTAL ASSETS</b>	<b>\$ 2,719,184</b>	<b>269,481</b>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts Payable and accrued expenses	\$ 293,633	650
Related Party Loan	10,000	
Accrued Payroll	499,612	322,950
Total Current Liabilities	<u>803,244</u>	<u>323,600</u>
<b>STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Preferred stock; \$0.001 par value; 10,000,000 shares authorized; 0 shares issued and outstanding	—	—
Common stock, \$0.0001 par value; 300,000,000 shares authorized; shares issued and 87,160,000 and 87,210,000 shares issued and outstanding, respectively	8,716	8,721
Additional paid in capital	2,911,560	514,485
Prepaid services paid for with common stock	—	(4,911)
Accumulated deficit	(1,004,337)	(572,414)
Total Stockholders' Equity (Deficit)	<u>1,915,939</u>	<u>(54,119)</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>	<b>\$ 2,719,184</b>	<b>269,481</b>

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

**BioVie Inc. (F/K/A NanoAntibiotics, Inc.)**  
**Statements of Operations**

	<u>For the Year Ended June 30, 2016</u>	<u>For the Year Ended June 30, 2015</u>
<b>REVENUE:</b>		
Sales	\$ —	\$ —
	<u>—</u>	<u>—</u>
<b>COST OF GOODS SOLD</b>	<u>—</u>	<u>—</u>
<b>GROSS MARGIN</b>	<u>—</u>	<u>—</u>
<b>OPERATING EXPENSES</b>		
Amortization	51,036	
Research and development expenses	37,901	4,196
Payroll expenses	184,537	161,931
Professional fees	143,235	50,779
Selling, general and administrative expenses	15,319	16,471
<b>TOTAL OPERATING EXPENSES</b>	<u>432,028</u>	<u>233,377</u>
<b>LOSS FROM OPERATIONS</b>	<u>(432,028)</u>	<u>(233,377)</u>
<b>OTHER EXPENSE (INCOME)</b>		
Interest expense	81	—
Interest income	(186)	(369)
<b>TOTAL OTHER EXPENSE (INCOME)</b>	<u>(105)</u>	<u>(369)</u>
<b>NET LOSS</b>	<u>\$ (431,923)</u>	<u>\$ (233,008)</u>
<b>NET LOSS PER COMMON SHARE, BASIC AND DILUTED</b>	<u>\$ (0.00)</u>	<u>\$ (0.00)</u>
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING, BASIC AND DILUTED</b>	<u>87,198,875</u>	<u>87,210,000</u>

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

**BioVie Inc. (F/K/A NanoAntibiotics, Inc.)**  
**Statement of Changes in Stockholders' Equity**  
**For the Years Ended June 30, 2016 and 2015**

	Common Stock		Additional Paid in Capital	Prepaid Services Paid with Common Stock	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance, June 30, 2014	87,210,000	8,721	514,485	(12,411)	(339,406)	171,389
Amortization of prepaid services paid with common stock	—	—	—	7,500	—	7,500
Net loss	—	—	—	—	(233,008)	(233,008)
Balance, June 30, 2015	87,210,000	8,721	514,485	(4,911)	(572,414)	(54,119)
Retirement of Shares	(39,869,999)	(5)	—	—	—	(5)
Shares Issued for Acquisition	39,820,000	—	2,397,075	—	—	2,397,075
Prepaid services paid with common stock	—	—	—	4,911	—	4,911
Net loss	—	—	—	—	(431,923)	(431,923)
Balance, June 30, 2016	<u>87,160,001</u>	<u>8,716</u>	<u>2,911,560</u>	<u>—</u>	<u>(1,004,337)</u>	<u>1,915,939</u>

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

**BioVie Inc. (F/K/A NanoAntibiotics, Inc.)  
Statements of Cash Flows**

	<u>For the Year Ended June 30, 2016</u>	<u>For the Year Ended June 30, 2015</u>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (431,923)	\$ (233,008)
Adjustments to reconcile net loss to net cash to cash used by operating activities:		
Amortization of prepaid common stock for services	4,911	7,500
Amortization of intangible assets	51,036	—
Share based compensation expense	7,875	—
Changes in operating assets and liabilities:		
Increase in prepaid expenses	(4,982)	(2,000)
Increase (decrease) in:		
Accounts Payable	42,790	650
Accrued Payroll	176,662	161,475
Net cash used by operating activities	<u>(163,631)</u>	<u>(65,383)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Cash acquired through the merger	<u>9,912</u>	<u>—</u>
Net cash provided by investing activities	<u>9,912</u>	<u>—</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Retirement of common stock	<u>(5)</u>	<u>—</u>
Net cash provided by financing activities	<u>(5)</u>	<u>—</u>
Net decrease in cash	(143,724)	(65,383)
<b>Cash, beginning of period</b>	<u>267,481</u>	<u>332,864</u>
<b>Cash, end of period</b>	<u>\$ 123,757</u>	<u>\$ 267,481</u>
<b>SUPPLEMENTAL CASH FLOW INFORMATION:</b>		
Cash paid for interest	<u>\$ —</u>	<u>\$ —</u>
<b>Non-cash investing activities</b>		
Fair value of assets acquired, net of cash acquired	2,283,858	—
Fair value of liabilities assumed	260,193	—

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

**BioVie Inc. (F/K/A NanoAntibiotics, Inc.)**  
**Notes to Financial Statements**  
**For the Years Ended June 30, 2016 and 2015**

## **1. Background Information**

BioVie Inc. (F/K/A NanoAntibiotics, Inc.) (the "Company") is a development stage enterprise that was incorporated in the state of Nevada on April 10, 2013. The Company is engaged in the discovery, development and commercialization of a therapy targeting ascites due to liver cirrhosis. Ascites due to liver cirrhosis is a life-threatening condition affecting about 100,000 Americans and many times more worldwide. Our therapy BIV201 is based on a drug that's approved in about 50 countries to treat related complications of liver cirrhosis (part of the same disease pathway as ascites), but not yet available in the US. 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. 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. We currently own all development and marketing rights to our drug candidate. The Company and PharmaIN have exchanged small (low single-digit) ownership rights to each other's ascites drug development programs. The Company recently filed patent applications for its drug candidate in the US and Japan, as well as a PCT in Europe. We are currently completing the work necessary to file our investigational new drug (IND) application, and aim to commence clinical trials should the FDA approve our application.

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.

## **2. Going Concern**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. For the year ended June 30, 2016, the Company had a net loss of \$431,923. As of June 30, 2016, the Company has not earned any revenues. In view of these matters, the Company's ability to continue as a going concern is dependent upon the Company's ability to begin operations and to achieve a level of profitability. Since inception, the Company has financed its activities principally from the sale of public equity securities. The Company intends on financing its future development activities and its working capital needs largely from the sale of public equity securities with some additional funding from other traditional financing sources, including term notes and proceeds from sub-licensing agreements until such time that funds provided by operations are sufficient to fund working capital requirements. The financial statements of the Company do not include any adjustments relating to the recoverability and classification of recorded assets, or the amounts and classifications of liabilities that might be necessary should the Company be unable to continue as a going concern.

## **3. Significant Accounting Policies**

### *Basis of Presentation*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

*Cash*

Cash is maintained at financial institutions and, at times, balances may exceed federally insured limits. We have never experienced any losses related to these balances. All of our non-interest bearing cash balances were fully insured at June 30, 2016, and our interest bearing cash balances may exceed federally insured limits.

*Financial Instruments*

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

*Research and Development*

Research and development costs are charged to operations when incurred and are included in operating expenses. The Company expensed \$37,901 and \$4,196 for research and development for the years ended June 30, 2016 and 2015, respectively.

*Income Taxes*

Deferred income tax assets and liabilities arise from temporary differences associated with differences between the financial statements and tax basis of assets and liabilities, as measured by the enacted tax rates, which are expected to be in effect when these differences reverse. Deferred tax assets and liabilities are classified as current or non-current, depending on the classification of the assets or liabilities to which they relate. Deferred tax assets and liabilities not related to an asset or liability are classified as current or non-current depending on the periods in which the temporary differences are expected to reverse.

The Company follows the provisions of FASB ASC 740-10 "Uncertainty in Income Taxes" (ASC 740-10), January 1, 2007. The Company has not recognized a liability as a result of the implementation of ASC 740-10. A reconciliation of the beginning and ending amount of unrecognized tax benefits has not been provided since there are no unrecognized benefits at June 30, 2016 and since the date of adoption. The Company has not recognized interest expense or penalties as a result of the implementation of ASC 740-10. If there were an unrecognized tax benefit, the Company would recognize interest accrued related to unrecognized tax benefits in interest expense and penalties in operating expenses.

*Earnings (Loss) per Share*

Basic earnings per share are computed by dividing net income by the weighted average number of shares of common stock outstanding during the year. Diluted earnings per common share are computed by dividing net income by the weighted average number of shares of common stock outstanding and dilutive options outstanding during the year. For the year ended June 30, 2016 all outstanding options have been excluded from the calculation of the diluted net loss per share since their effect was anti-dilutive.

*Stock-based Compensation*

The Company recognizes all share-based payments to employees, including grants of employee stock options, as compensation expense in the financial statements based on their fair values. That expense will be recognized over the period during which an employee is required to provide services in exchange for the award, known as the requisite service period (usually the vesting period).

*Fair Value Measurements*

In September 2006, the Financial Accounting Standards Board (FASB) introduced a framework for measuring fair value and expanded required disclosure about fair value measurements of assets and liabilities. The Company adopted the standard for those financial assets and liabilities as of the beginning of the 2013 fiscal year and the impact of adoption was not significant. FASB Accounting Standards Codification (ASC) 820 "*Fair Value Measurements and Disclosures*" (ASC 820) defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy are described below:

Level 1 - Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2 - Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly, including quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; inputs other than quoted prices that are observable for the asset or liability (e.g., interest rates); and inputs that are derived principally from or corroborated by observable market data by correlation or other means.

Level 3 - Inputs that are both significant to the fair value measurement and unobservable.

Fair value estimates discussed herein are based upon certain market assumptions and pertinent information available to management as of June 30, 2015. The respective carrying value of certain on-balance-sheet financial instruments approximated their fair values due to the short-term nature of these instruments. These financial instruments include accrued payroll.

*Recent accounting pronouncements*

The Company has reviewed recent accounting pronouncements issued by the FASB (including its EITF), the AICPA, and the SEC and did not or are not believed by management to have a material impact on the Company's financial statements.



#### 4. Related Party Loan

LAT Pharma was given a zero-interest bearing loan by the company's General Partner, Jonathan Adams in the amount of \$5,000 in August 2015 and \$5,000 in November 2015. The total of \$10,000 was outstanding when the Company merged with LAT Pharma. As of June 30<sup>th</sup>, 2016 the Company has an outstanding loan of \$10,000 payable on demand to the CEO, Jonathan Adams.

#### 5. Commitments and Contingencies

##### Office Lease

On January 1, 2014 the Company executed a lease agreement with Cummings Properties for the company's office of 270 square feet at 100 Cummings Center, Suite 247-C, Beverly, MA 01915. The lease is for a term of five years from January 1, 2014 to December 30, 2018 and requires monthly payments of \$357 (\$4,284 annually for each of the five years, total aggregate of \$21,420).

##### Employment Agreements

On April 11, 2016 the Company entered into an employment agreement with CEO Jonathan Adams. The Company's agreement provides for a three-year term with minimum annual base salary of \$250,000 per year. Effective April 11, 2016, the (previous) CEO/CFO resigned.

#### 6. Income Taxes

Deferred taxes are recorded for all existing temporary differences in the Company's assets and liabilities for income tax and financial reporting purposes. Due to the valuation allowance for deferred tax assets, as noted below, there were no net deferred tax benefit or expense for the year ended June 30, 2016.

There is no current or deferred income tax expense or benefit allocated to continuing operations for the year ended June 30, 2016.

The provision for income taxes is different from that which would be obtained by applying the statutory federal income tax rate to income before income taxes. The items causing this difference are as follows:

	June 30, 2016	June 30, 2015
Tax expense (benefit) at US. statutory rate	\$ (146,889)	\$ (79,200)
State income tax expense (benefit): net of federal benefit	\$ (21,659)	\$ (11,700)
Effect of non-deductible expenses		
Other		
Change in valuation allowance	\$ 168,548	\$ 90,900
	<u>\$ —</u>	<u>\$ —</u>

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at June 30, 2016 are as follows:

Deferred tax assets (liability), noncurrent:

Net operating loss	\$	431,923
Valuation allowance		(431,923)
	\$	—

Change in valuation allowance:

Balance, June 30, 2015	\$	223,300
Increase in valuation allowance		168,548
Balance, June 30, 2016		391,848

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, 2016.

As of June 30, 2016, the Company had federal and state net operating loss carry-forwards totaling approximately \$1,004,000 which begin expiring in 2022.

## 7. Purchase of LAT Pharma

On April 11, 2016, the Company entered into and consummated an Agreement and Plan of Merger (the "Merger Agreement"), with LAT Acquisition Corp., a Nevada corporation and wholly-owned subsidiary of the Company ("Acquisition") and LAT Pharma, LLC an Illinois limited liability company ("LAT"). Pursuant to the terms of the Merger Agreement, Acquisition merged with and into LAT in a statutory triangular merger (the "Merger") with LAT surviving as a wholly-owned subsidiary of the Company. As consideration for the Merger, the Company issued the interest holders of LAT (the "LAT Holders") an aggregate of 39,820,000 shares of our Common Stock issued to the LAT Holders in accordance with their pro rata ownership of LAT membership interests prior to the Merger. Following the Merger, the Registrant will continue the development of LAT's lead clinical therapeutic candidate Continuous low-dose Infusion (CI) Terlipressin.

Immediately prior to the Merger, the Company had 87,210,000 shares of Common Stock issued and outstanding. In connection with the Merger, certain shareholders of the Company collectively agreed to retire and cancel an aggregate of 39,869,999 shares of Common Stock. Following the consummation of the Merger, the issuance of the Merger Shares of the 39,820,000 shares of Common Stock, the Company had 87,160,001 shares of Common Stock issued and outstanding and the LAT Holders beneficially own 39,820,000 shares or approximately forty-six percent (46%) of such issued and outstanding Common Stock.

Under the purchase method of accounting, the transaction was valued for accounting purposes at \$2,389,200, which was the estimated fair value of the consideration paid by the Company. The estimate was based on the consideration paid of 39,820,000 shares of common stock valued based on the closing price on 04/11/2016 of \$0.06 per share.

## Table of Contents

The assets and liabilities of LAT Pharma, Inc. were recorded at their respective fair values as of the closing date of the Merger Agreement, and the following table summarizes these values based on the balance sheet at April 11, 2016.

\$ 2,303,682	Assets Purchased
260,193	Liabilities Assumed
<u>2,043,489</u>	Net Assets Purchased
2,389,200	Purchase Price
<u>\$ 345,711</u>	Goodwill from Purchase

Intangible asset detail

\$ 2,293,770	Intangible Intellectual Property
345,711	Goodwill
<u>\$ 2,639,481</u>	Intangible Asset from Purchase

Under the 338(h)(10) election, all goodwill and intangibles related to the acquisition of LAT Pharma will be fully deductible for tax purposes.

The intangible intellectual property is amortized over 10 years.

	<u>June 2016</u>	<u>June 2015</u>
Intangible Assets subject to Amortization	\$2,293,770	\$ —
Amortization Expense in current year	\$ 51,036	\$ —
Accumulated Amortization at year end	\$ 51,036	\$ —

The current year amortization expense has been amortized for the period from April 11, 2016 to June 30, 2016. The estimated Amortization expense for each of the five succeeding fiscal years will be approximately \$229,300 per year.

## 8. Stock Options

In connection with the employment agreement signed with the Chief Financial Officer on April 11, 2016, Jonathan Adams was granted options to acquire 3 million shares exercisable at \$0.06 per share, the closing price on that date. These Options Group A shall become vested and exercisable (i) as to 1 million shares on April 11, 2017, (ii) as to 1 million shares on April 11, 2018, and (iii) as to 1 million shares on April 11, 2019.

The fair market value of the stock options is estimated using the Black Scholes valuation model and the Company uses the following methods to determine its underlying assumptions: expected volatilities are based on the historical volatilities of 3 comparable companies of the daily closing price of their respective common stock; the expected term of options granted is based on the average time outstanding method; and the risk free interest rate is based on the US Treasury bonds issued with similar life terms to the expected life of the grant.

The following key assumptions were used in the valuation model to value stock option grants for each respective period:

Valuation Date	4/11/2016	4/11/2016	4/11/2016
Stock Price	\$ 0.06	\$ 0.06	\$ 0.06
Exercise Price	\$ 0.06	\$ 0.06	\$ 0.06
Term (expected term for options)	1.00	2.00	3.00
Volatility	56.49%	58.45%	97.82%
Annual Rate of Quarterly Dividends	0.00%	0.00%	0.00%
Discount Rate - Bond Equivalent Yield	0.53%	0.70%	0.85%
<b>Call Option Value (\$Millions)</b>	<b>\$ 0.01</b>	<b>\$ 0.02</b>	<b>\$ 0.04</b>
<b>Fair Value</b>	<b>\$ 13,467</b>	<b>\$ 19,523</b>	<b>\$ 36,489</b>

Stock option transactions under the Company's plans for the years ended June 30, 2016 is summarized below:

Options	Shares (Thousands)	Weighted- Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (Thousands)
Outstanding at July 1, 2015	—	—	—	—
Granted	3,000	0.06	2	—
Exercised	—	—	—	—
Forfeited	—	—	—	—
Outstanding at June 30, 2016	3,000	0.06	2	—

The compensation expense includes \$7,875 related to the stock options described above.

### 9. Subsequent Events

Subsequent to year end 49,999 shares were issued and sold by the Company for 10 cents per share.

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

None.

**ITEM 9A(T). CONTROLS AND PROCEDURES**

**Disclosure Controls and Procedures**

The Company's Chief Executive Officer and Chief Financial Officer has evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the fiscal period ending June 30, 2016 covered by this Annual Report on Form 10-K. Based upon such evaluation, the Chief Executive Officer and acting Chief Financial Officer has concluded that, as of the end of such period, the Company's disclosure controls and procedures were not effective as required under Rules 13a – 15(e) and 15d – 15(e) under the Exchange Act. This conclusion by the Company's Chief Executive Officer and Chief Financial Officer does not relate to reporting periods after June 30, 2016.

***Management's Report on Internal Control over Financial Reporting***

Management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) and 15d – 15(f) of the Exchange Act) of the Company. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

The Company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

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

Management, under the supervision of the Company's Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that the Company's internal control over financial reporting was not effective as of June 30, 2016 under the criteria set forth in the *Internal Control – Integrated Framework*.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Management has determined that material weaknesses exist due to a lack of formalized controls and procedures as well as a lack of segregation of duties, as well as the absence of an independent audit committee chair, resulting from the Company's limited resources.

***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting that occurred during the fourth fiscal quarter ended June 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

**Part III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

Set forth below is certain information concerning the directors and executive officers of the Company.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Jonathan Adams	53	Chief Executive Officer and Chief Financial Officer
Amrit Shahzad	60	President and Secretary
Cuong Do	51	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 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. None of our Directors or officers is or has been a Director or has held any form of directorship in any other U.S. reporting companies except as mentioned above. None of our Directors or officers has been affiliated with any company that has filed for bankruptcy within the last five years. The Company is not aware of any proceedings to which any of the Company's 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.

**Information**

Mr. Jonathan Adams has served as the Company's Chief Executive Officer and Chief Financial Officer since it acquired LAT Pharma LLC on April 11, 2016. He founded LAT Pharma LLC and served as its Chief Executive Officer prior to its acquisition. Mr. Adams has over 26 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. Amrit Shahzad has served as the Company's President and Secretary since it acquired LAT Pharma LLC on April 11, 2016. Ms. Shahzad has worked in the biopharmaceutical industry for more than 25 years. Prior to starting her own consulting firm in 2014, she worked in a variety of leadership roles at Roche, Amgen and Ikaria, and has been on the board of several startup companies. She has extensive business and corporate development experience including corporate venture funds. Her transactional experience spans multiple therapeutic areas, technologies, and platforms. Ms. Shahzad holds a medical degree (MBBS) from Lady Hardinge Medical College in New Delhi, India, and an MBA from Rutgers University.

Mr. Cuong Do is currently Executive Vice President, Global Strategy Group, at Samsung. Mr. Do helps to set the strategic direction for Samsung Group's diverse business portfolio. He was previously the Chief Strategy Officer for Merck, a leading US pharmaceuticals company, 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.

#### **Qualifications**

Jonathan Adams's qualifications to serve on our Board of Directors are primarily based on his founding of LAT Pharma LLC and his over 26 years of biopharmaceutical industry experience. As Chief Executive of LAT Pharma LLC, Mr. Adams worked to develop CIPT Technology and secured Orphan Drug Designation for a BIV201 analogue (this new drug candidate is no longer in development). Mr. Adams's biopharmaceutical experience includes work in corporate finance, company acquisitions and licensing deals, marketing and sales support.

Amrit Shahzad's qualifications to serve on our Board of Directors are primarily based on her more than 25 years of biopharmaceutical industry experience. Prior to starting her own consulting firm in 2014, Ms. Shahzad worked in a variety of leadership roles at Roche, Amgen and Ikaria, and has been on the board of several startup companies. She has extensive business and corporate development experience including corporate venture funds. Her transactional experience spans multiple therapeutic areas, technologies, and platforms.

Cuong Do's qualifications to server on our Board of Directors are primarily based on his decades of experience as an executive in the pharma, biotech, and other high technology industries. . He was previously the Chief Strategy Officer for Merck, a leading US pharmaceuticals company, 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.

#### **AUDIT COMMITTEE**

We do not have an audit committee or an audit committee financial expert. Our corporate financial affairs are simple at this stage of development and each financial transaction can be viewed by any officer or Director at will.

#### **CODE OF ETHICS**

We have adopted a code of ethics meeting the requirements of Section 406 of the Sarbanes-Oxley Act of 2002. We believe our code of 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 ethics is filed as an exhibit to this Form 10-K.

**ITEM 11. EXECUTIVE COMPENSATION**

We have not paid any compensation to any of our executive officers, however, we did accrue the Chief Executive Officer's salary per the employment agreements effective July 1, 2013 and subsequently April 11, 2016.

**Summary Compensation Table**

Name and Principal Position	Year (1)	Annual Compensation		Long Term Compensation				All Other Compensation	Total
		Salary	Bonus	Stock Awards	Option Awards	Non-Equity Incentive Plan Compensation	Nonqualified Deferred Compensation Earnings		
<b>Jonathan Adams</b> Chief Executive Officer and Chief Financial Officer, Treasurer and Corporate Secretary	2016	\$ 250,000	\$ —	\$ —	\$ 7,875	\$ —	\$ —	\$ —	\$ 259,025
<b>Elliot Ehrlich</b> Chief Executive Officer and Chief Financial Officer, Treasurer and Corporate Secretary	2015	\$ 150,000	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 150,000
	2014	\$ 150,000	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 150,000

(1) We were incorporated on April 10, 2013.

**Employment Agreement**

On April 11, 2016, the Company entered into an employment agreement with the Company's Chief Executive Officer paying \$250,000 in annual salary. The agreement was effective beginning April 11, 2016 and expires on April 10, 2019.

**Option/SAR Grants**

In connection with the employment agreement signed with the Chief Financial Officer on April 11, 2016, Jonathan Adams received options to acquire 3 million shares exercisable at \$0.06 per share, the closing price on that date. These Options Group A shall become vested and exercisable (i) as to 1 million shares on April 11, 2017, (ii) as to 1 million shares on April 11, 2018, and (iii) as to 1 million shares on April 11, 2019.

No other stock options had been granted as of June 30, 2016.

**Long-Term Incentive Plans and Awards**

Other than the options granted to the Chief Executive Officer as described above, the Company does not have any long-term incentive plans that provide compensation intended to serve as incentive for performance. Since prior to this grant, 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.

**Compensation of Directors**

There are no arrangements pursuant to which our Director is or will be compensated in the future for any services provided as a Director.



**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS****Long-Term Incentive Plans and Awards**

Other than the options granted to the Chief Executive Officer on April 11, 2016 as described previously, the Company does not have any long-term incentive plans that provide compensation intended to serve as incentive for performance. Since prior to this grant, 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.

**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth certain information concerning the ownership of the Common Stock by (a) each person who, to the best of our knowledge, beneficially owned on that date more than 5% of our outstanding Common Stock, (b) each of our Directors and executive officers and (c) all current Directors and executive officers as a group. The following table is based upon an aggregate of 87,160,001 shares of our Common Stock outstanding as of the date of this prospectus.

<u>Name and Address of Beneficial Owner</u>	<u>Number of Shares of Common Stock Beneficially Owned or Right to Direct Vote (1)</u>	<u>Percent of Common Stock Beneficially Owned or Right to Direct Vote (1)</u>
Jonathan Adams	6,168,066	7.1 %
Amrit Shahzad	1,298,512	1.5 %
Cuong Do	2,671,354	3.1%
<b>All Directors and executive officers as a group (Three persons):</b>	<b>10, 137, 932</b>	<b>11.6%</b>
<b>Other 5% or Greater Beneficial Owners:</b>		
Elliot Ehrlich 9511 Collins Ave #807 Surfside, FL 33154	7,400,000	8.5 %
Leo and Helene Ehrlich (2) 7846 Tennyson Ct. Boca Raton, FL 33433	8,500,000	9.75 %
Rebecca Guttman (2) 655 Ibsen St., Woodmere, NY 11598	8,500,000	9.75 %
RGN Brothers Trust	8,500,000	9.75%

- (1) Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission 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.

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

None

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The following table shows what Weinberg & Baer LLC billed for the audit and other services for the years ended June 30, 2016 and 2015.

	<b>Year Ended June 30, 2016</b>	<b>Year Ended June 30, 2015</b>
Audit Fees	\$ 12,000	\$ 12,000
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
<b>Total</b>	<b>\$ 12,000</b>	<b>\$ 12,000</b>

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

Overview—The Company’s Board reviews, and in its sole discretion pre-approves, our independent auditors’ annual engagement letter including proposed fees and all audit and non-audit services provided by the independent auditors. Accordingly, all services described under “Audit Fees,” “Audit-Related Fees,” and “Tax Fees” were pre-approved by our Company’s Board. The Board may not engage the independent auditors to perform the non-audit services proscribed by law or regulation.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Regulation

Number	Exhibit
31.1	<a href="#">Rule 13a-14(a) Certification</a>
32.1	<a href="#">Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
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. (F/K/A NANOANTIBIOTICS, INC.)**

Signature	Titles	Date
<u>/s/ Jonathan Adams</u> Jonathan Adams	Chief Executive Officer and Chief Financial Officer	September 28, 2016
<u>/s/ Amrit Shahzad</u> Amrit Shahzad	President and Secretary	September 28, 2016

**CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002  
AND RULE 13-A14 OF THE EXCHANGE ACT OF 1934**

**CERTIFICATION**

I, Jonathan Adams, certify that:

1. I have reviewed this annual report on Form 10-K of BioVie Inc. (F/K/A NanoAntibiotics, 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.

Signature	Titles	Date
<u>/s/ Jonathan Adams</u> Jonathan Adams	Chief Executive Officer, Chief Financial Officer, Principal Executive Officer and Principal Financial and Accounting Officer, Treasurer and Chairman of the Board	September 28, 2016

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**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER 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. formerly known as Nanoantibiotics, Inc., (the "Company") on Form 10-K for the year ended June 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jonathan Adams, Chief Executive Officer, Chief Financial Officer, Principal Executive Officer and Principal Financial and Accounting Officer, Treasurer 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, 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; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Signature	Titles	Date
<u>/s/ Jonathan Adams</u> Jonathan Adams	Chief Executive Officer, Chief Financial Officer, Principal Executive Officer and Principal Financial and Accounting Officer, Treasurer and Chairman of the Board	September 28, 2016

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