

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 December 31, 2016

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT

For the transition period from _____ to _____

333-147193

(Commission file number)

FluoroPharma Medical, Inc.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation or organization)

20-8325616

(IRS Employer Identification No.)

8 Hillside Avenue, Suite 108

Montclair, NJ 07042

(973) 744-1565

(Address and telephone number of principal executive offices)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.

Yes No

Indicate by check mark whether the issuer (1) 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 during the preceding 12 months (or such shorter period that the registrant was required to submit and post such files. Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in the definitive proxy or information statement incorporated by reference in Part III of this Form 10-K or amendment to Form 10-K. Yes No

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

Act. (Check one):

Large accelerated filer []

Accelerated filer []

Non-accelerated filer []

Smaller reporting company [X]

(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 [X]

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of June 30, 2016, was \$7,391,435.

As of March 27, 2017, there were 34,262,264 shares of common stock outstanding.

Index

Page
Number

PART I. FINANCIAL INFORMATION

| | | |
|-----------------|----------------------------------|----|
| <u>Item 1.</u> | <u>Business</u> | 1 |
| <u>Item 1A.</u> | <u>Risk Factors</u> | 9 |
| <u>Item 1B.</u> | <u>Unresolved Staff Comments</u> | 21 |
| <u>Item 2.</u> | <u>Properties</u> | 21 |
| <u>Item 3.</u> | <u>Legal Proceedings</u> | 21 |
| <u>Item 4.</u> | <u>Mine Safety Disclosures</u> | 21 |

PART II.

| | | |
|-----------------|---|----|
| <u>Item 5.</u> | <u>Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> | 22 |
| <u>Item 6.</u> | <u>Selected Financial Data</u> | 23 |
| <u>Item 7.</u> | <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | 23 |
| <u>Item 7A.</u> | <u>Quantitative and Qualitative Disclosures About Market Risk</u> | 28 |
| <u>Item 8.</u> | <u>Financial Statements and Supplementary Data</u> | 28 |
| <u>Item 9.</u> | <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u> | 28 |
| <u>Item 9A.</u> | <u>Controls and Procedures</u> | 28 |
| <u>Item 9B.</u> | <u>Other Information</u> | 29 |

PART III.

| | | |
|-----------------|---|----|
| <u>Item 10.</u> | <u>Directors, Executive Officers, and Corporate Governance</u> | 29 |
| <u>Item 11.</u> | <u>Executive Compensation</u> | 33 |
| <u>Item 12.</u> | <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u> | 37 |
| <u>Item 13.</u> | <u>Certain Relationships and Related Transactions, and Director Independence</u> | 38 |
| <u>Item 14.</u> | <u>Principal Accounting Fees and Services</u> | 38 |

PART IV.

| | | |
|-----------------|---|----|
| <u>Item 15.</u> | <u>Exhibits and Financial Statement Schedules</u> | 39 |
| <u>Item 16.</u> | <u>Form 10-K Summary</u> | 40 |

| | | |
|-------------------|--|----|
| <u>SIGNATURES</u> | | 41 |
|-------------------|--|----|

FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K (including the section regarding Management's Discussion and Analysis or Plan of Operation) contains forward-looking statements regarding our business, financial condition, results of operations and prospects. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates" and similar expressions or variations of such words are intended to identify forward-looking statements, but are not deemed to represent an all-inclusive means of identifying forward-looking statements as denoted in this Annual Report on Form 10-K. Additionally, statements concerning future matters are forward-looking statements.

Although forward-looking statements in this Annual Report on Form 10-K reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, without limitation, those specifically addressed under the heading "Risks Factors" below, as well as those discussed elsewhere in this Annual Report on Form 10-K. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. We file reports with the United States Securities and Exchange Commission ("SEC"). Our electronic filings with the SEC (including our Annual Reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports) are available free of charge on the SEC's website at <http://www.sec.gov>. You can also read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. You can obtain additional information about the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet site (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us.

We undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this Annual Report on Form 10-K, except as required by law. Readers are urged to carefully review and consider the various disclosures made throughout the entirety of this Annual Report, which are designed to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

Item 1. Description of Business

Overview

FluoroPharma Medical, Inc. ("we", the "Company" or the "Registrant") is a biopharmaceutical company specializing in discovering, developing and commercializing molecular imaging pharmaceuticals with initial applications in the area of cardiology. Molecular imaging pharmaceuticals are radiopharmaceuticals that enable early detection and/or assessment of disease through the visualization of subtle changes in biochemical and biological processes. Our initial focus has been on the development of novel cardiovascular imaging agents that can more efficiently and effectively detect and assess acute and chronic forms of coronary artery disease, or CAD. We currently have two clinical-stage molecular imaging pharmaceutical product candidates: 18-F TPP (BFPET) and 18-F FCPHA (CardioPET).

Corporate History

FluoroPharma Medical, Inc. (f/k/a Commercial E-Waste Management Inc.) was organized in January 2007 under the laws of the State of Nevada to serve as an electronics waste management solution provider, specializing in the collection, retirement, storage and remarketing of excess, damaged or obsolete electronic assets. FluoroPharma Inc. was organized in June 2003 under the laws of the State of Delaware to engage in the discovery, development and commercialization of proprietary products for the positron emission tomography (PET) market. Pursuant to an Agreement and Plan of Merger by and among FluoroPharma Medical, Inc., FluoroPharma, Inc., and FPI Merger Corporation., a wholly owned Delaware subsidiary of FluoroPharma Medical, Inc. ("MergerCo"), on May 16, 2011, MergerCo merged with and into FluoroPharma Inc., and FluoroPharma Inc., as the surviving corporation, became a wholly owned subsidiary of FluoroPharma Medical, Inc. (the "Merger"). Since the Merger, we have conducted our business through our wholly-owned subsidiary.

Our Product Candidates

BFPET (18-F FTTP)

Our BFPET program employs a ([18F]-labeled cationic lipophilic tetraphenylphosphonium ion (18-FTTP) as an imaging agent designed for use in stress-testing for patients with presumptive or proven CAD. 18-F FTTP measures the extent and severity of cardiovascular disease through the detection of ischemic (i.e. reversible and viable) and infarcted (i.e., irreversibly damaged) myocardial (i.e., heart) tissue. Its mechanism of action allows it to enter the myocardial cells of the heart muscle in direct proportion to blood flow and membrane potential--the most important indicators of adequate cardiac blood supply. Since ischemic and infarcted myocardial cells take up significantly less 18-F FTTP than normal healthy myocardial cells do, 18-F FTTP can distinguish ischemic and infarcted cells from those that are healthy. If approved, 18-F FTTP will represent one of the first molecular imaging blood flow agents commercialized for use in the cardiovascular segment of the PET imaging market. 18-F FTTP may also provide information on cardiac mitochondrial membrane potential, enabling global and regional assessment of the electro-physiologic integrity of the myocardium.

Currently, cardiac perfusion imaging is performed routinely with SPECT tracers such as Sestamibi, Tetrofosmin, Thallium-201 or the PET tracers Rubidium-82 and N-13 ammonia. However, the industry standard SPECT imaging has a diagnostic accuracy of approximately 75%, with research indicating that 10% of patients cleared as "normal" were subsequently found to be "abnormal" using PET imaging. The current PET tracer Rubidium-82 has experienced an FDA recall and high cost issues, while N-13 ammonia is produced in a cyclotron and must be used locally within a matter of minutes due to a very short physical half-life. The introduction of a Fluorine-labeled myocardial agent, with its longer half-life enabling the existing supply-chain potential, would be a catalyzing event toward advancing the role of PET imaging in cardiovascular disease and improving diagnostic imaging.

18-F FTTP successfully completed a Phase I clinical trial in 12 healthy volunteers with no adverse events and no clinically significant changes noted in follow-up clinical and laboratory testing. The results of the trial demonstrated the required dosimetry, safety profile and high-resolution myocardial imaging pharmacokinetics to justify a controlled Phase II clinical trial. We have announced that we will begin Phase II trials at Massachusetts General Hospital to assess its efficacy in CAD subjects; and expect enrollment to commence in 2017.

CardioPET (18-F FCPHA)

Our CardioPET program employs Trans-9-[18F]-Fluoro-3, 4-Methyleneheptadecanoic Acid (18-F FCPHA) as a molecular imaging agent designed to assess myocardial blood flow and metabolism in patients with CAD, including patients unable to perform exercise cardiac stress-testing. 18-F FCPHA allows for the potential detection of ischemic (i.e. reversible and viable) and infarcted (i.e. irreversibly damaged) myocardial tissue in patients with presumptive or proven acute and chronic CAD and related cardiac diseases.

In addition, 18-F FCPHA could be useful for assessing myocardial viability for the prediction of improvement prior to and/or following revascularization in patients with acute CAD, including myocardial infarction (heart attack). 18-F FCPHA allows for the identification of compromised but viable heart tissue, which is important since revascularization in those patients with substantial viable myocardium results in improved left ventricular function and survival. Importantly, 18-F FCPHA, if approved, may have several significant advantages for assessing cardiac viability using PET, and would likely represent the first imaging agent available in the U.S. for use in patients with chronic CAD and underlying metabolic disorders. 18-F FCPHA is designed to provide the fatty-acid metabolic component for assessing myocardial metabolism and viability, which play a central role in the progression of diabetes and heart failure.

The safety and tolerability of 18-F FCPHA have been demonstrated in a Phase I trial conducted at the Massachusetts General Hospital. Enrollment in a Phase IIa trial has been completed at four sites in Belgium to assess its safety and efficacy in CAD patients. This Phase IIa study was an open label trial designed to assess the safety and diagnostic performance of 18-F FCPHA compared with standard-of-care myocardial perfusion imaging, and angiography as a gold standard of epicardial coronary artery disease. Specifically, the Phase IIa trial consisted of approximately 30 individuals with known or suspected stable chronic CAD who underwent imaging at rest and after pharmacologic and exercise stress-testing for the evaluation of suspected or proven CAD. Interim safety and imaging results were presented in February 2014. The enrollment for the Phase IIa clinical trial of CardioPET was closed in December 2014. Analysis was performed and a full clinical study report (CSR) was completed and submitted to FAMHP (Europe) in July of 2016. A briefing package will be submitted to US FDA with the annual IND update in May of 2017.

Strategic Alliances and Commercial Agreements

License Agreement with Massachusetts General Hospital

We have two exclusive technology licenses with Massachusetts General Hospital (“MGH”) which we entered into on June 26, 2014 (collectively, the “Agreements”). Those agreements replace the single license agreement with MGH dated April 27, 2009, as amended by letter dated June 21, 2011 and agreement dated October 31, 2011 (the “Original Agreement”). The Agreements provide exclusive licenses for our two lead product candidates, BFPET and CardioPET, two of the three cardiac imaging technologies covered by the Original Agreement. The Agreements were entered into primarily for the purpose of separating our rights and obligations with respect to our different product development programs. Each of the Agreements requires us to pay MGH an initial license fee of \$175,000 and annual license maintenance fees of \$125,000 each. The Agreements require us to meet certain obligations, including, but not limited to, meeting certain development milestones relating to clinical trials and filings with the United States Food and Drug Administration. MGH has the right to cancel or make non-exclusive certain licenses on certain patents should we fail to meet stipulated obligations and milestones. Additionally, upon commercialization, we are required to make specified milestone payments and royalties on commercial sales. On August 10, 2016, we entered into agreements with MGH to amend the Agreements to include the potential to license technical information in addition to intellectual property. We are amortizing the cost of these intangible assets over the remaining useful life of the Agreements of 10 years.

We believe that we maintain a good relationship with MGH and will be able to obtain waivers or extension of our obligations under the Agreements, should the need arise. If MGH were to refuse to provide us with a waiver or extension of any of our obligations or were to cancel or make the license non-exclusive, this would have a material adverse impact on our business as we may be unable to commercialize products without exclusivity and would lose our competitive edge for portions of the patent portfolio.

License Agreement with Sinotau USA

We have two exclusive license agreements (the “Licenses”) with Sinotau USA, Inc., a wholly-owned subsidiary of Hainan Sinotau Pharmaceutical Co., Ltd. (“Sinotau”), a pharmaceutical organization. Sinotau is responsible for developing and commercializing the Company’s proprietary cardiac PET imaging assets, CardioPET and BFPET, in China and Canada. Sinotau also retains a first right of refusal to license the technology for development in Australia and Singapore. In accordance with the Licenses, the Company is entitled to upfront payments of \$550,000, milestone payments totaling \$1,450,000 upon the completion of certain development activities and royalties on future sales made by Sinotau. As of December 31, 2016, the Company has received payments of \$775,000 in accordance with the terms of the Licenses.

Clinical Research Agreements

Beginning in September 2012, we entered into Clinical Research Services Agreements with SGS Life Science Services (Belgium), Biomedical Systems (St. Louis, MO), and MERGE eClinical OS (Morrisville, NC) for clinical research services relating to our CardioPET Phase II study to assess myocardial perfusion and fatty acid uptake in coronary artery disease (“CAD”) patients. The Phase IIa trial was described above. As of December 31, 2016 the Company has terminated its agreement with SGS and recorded a gain on settlement of accounts payable of \$84,842 in other income in the statement of operations. The Company has made all required payments to SGS and all settlement terms have been met. In addition, we engaged FGK Representative Service GmbH to serve as our sponsor in compliance with the laws governing clinical trials conducted in the European Union. In December 2014, we announced that the enrollment for a Phase II clinical trial of CardioPET was closed. We believed that this trial had acquired sufficient patient data allowing for the assessment of the pharmaceutical's safety and quality of 18-F FCPHA generated cardiac images in humans.

The Company currently maintains clinical research agreements with Pharmaceutical Product Development, LLC (Wilmington, NC), Cardiovascular Imaging Technologies (CVIT, Kansas City, MO), clinical research organizations engaged in the business of managing clinical research programs and providing clinical development and other related services, for the services relating to the BFPET Phase II study.

Product Development and Commercialization

We intend to develop our products through the completion of Phase II and/or Phase III studies at which point we will seek to partner with organizations having the resources required to undertake the further development, regulatory approval and commercialization of our proprietary products.

We believe that while the overall regulatory process for molecular imaging products is currently similar to those governing therapeutic agents, the development timelines may be significantly shorter. Whereas typical clinical trials involving therapeutic agents include efficacy endpoints such as survival, time to disease progression, and progression free survival, all of which must be monitored over long periods (often years), diagnostic imaging agents often take significantly less time to evaluate. This shortened clinical development period relative to therapeutics is a function of the speed with which a molecular imaging study takes place—on the order of several hours, as compared to months. Also, because the results of the scan are instantaneous, the clinical trials do not initially require long-term follow-up for primary endpoints that may take significant periods of time to evaluate. Many PET centers in the U.S. routinely perform 5 to 20 PET scans per day. Based on the foregoing, we believe our first product may be able to be commercialized within five years.

Market Opportunity

Each year, millions of patients undergo molecular imaging studies in the United States. Approximately half of these studies are performed to detect and evaluate ischemic heart disease and myocardial infarction in patients with acute and chronic forms of CAD. These studies provide clinical benefit in the initial evaluation of patients with suspected but unproven CAD, and in those patients in whom a diagnosis of CAD has been established and information on prognosis or risk is required. Molecular imaging studies are used for detecting the presence or absence of critical coronary artery stenosis, providing prognostic information on long-term outcomes, and stratifying patient risk for adverse cardiac events.

We believe that our market opportunity is a direct function of the prevalence of coronary artery disease, and the number of molecular imaging studies anticipated to be performed per year using SPECT and PET imaging technologies. This is reflected in the more than 12 million scans in the U.S. alone for patients with suspected acute or chronic forms of CAD. We expect the market for 18-F FTTP, if approved, will be driven by its use (i) as a blood flow imaging agent in combination with stress-testing for the identification of ischemic and infarcted tissue in patients with chronic CAD; and/or (ii) for the assessment of left ventricular mechanical function and myocardial mitochondrial membrane integrity. We expect that the market for 18-F FCPHA, if approved, will derive from the approximately 19 million patients in the U.S. annually with chronic forms of CAD and underlying metabolic disorders that contribute to high risk of diabetes and heart failure. Because we believe there is no product currently on the market that may allow for an at-rest assessment of significant portions of this population, we believe 18-F FCPHA may be readily adopted by the cardiology community for the assessment of ischemia and metabolic risk in this patient pool, with the long-term goal of providing guidance for the therapeutics used for glucose and fatty acid modulation in diabetes, and ischemic or non-ischemic heart failure.

Competition

We operate in a highly competitive segment of the pharmaceutical market. If any of our products are approved for commercialization, we will face competition for market share from large pharmaceutical and biotechnology companies such as Lantheus, Bracco, GE Healthcare and Mallinckrodt, academic institutions, government agencies, and private and public research institutions engaged in the development and commercialization of existing standard of care products, as well as novel cardiac imaging agents. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than do we. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for products. We also may compete with these organizations to recruit scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Intellectual Property

We believe that clear and extensive patent coverage for our technologies, both domestic and international, is central to our long-term success and intend to continue to allocate resources to protection of our intellectual property accordingly. We have obtained the licenses to our patents and patent applications from MGH, the patent assignee in each case. The issued patents covering our 18-F FCPHA and 18-F FTTP technologies include both composition and method of use patents within the field of diagnostic cardiology that expire in 2025.

We also depend upon the skills, knowledge, experience and know-how of our management and research and development personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely and will in the future rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

Governmental Regulations

Government authorities in the United States and foreign countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, sampling, marketing and import and export of pharmaceutical products. Our molecular imaging pharmaceuticals in the United States will be subject to FDA regulation as drugs under the Federal Food, Drug and Cosmetic Act, or FDCA, and require FDA approval prior to commercial distribution. The process of obtaining governmental approvals and complying with ongoing regulatory requirements requires the expenditure of substantial time and financial resources. In addition, statutes, rules, regulations and policies may change and new legislation or regulations may be issued that could delay such approvals. If we fail to comply with applicable regulatory requirements at any time during the product development process, approval process, or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawals of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of our operations, injunctions, fines, civil penalties or criminal prosecution. Any agency enforcement action could have a material adverse effect on us.

The U.S. regulatory scheme for the development and commercialization of new pharmaceutical products can be divided into three distinct stages as described below.

Preclinical Stage

The preclinical stage involves the characterization, product formulation and animal testing necessary to prepare an Investigational New Drug application, or IND, for submission to the FDA. The IND must be reviewed and authorized by the FDA before the drug can be tested in humans. Once a new pharmaceutical agent has been identified and selected for further development, preclinical testing is conducted to confirm pharmacological activity, to generate safety data, to evaluate prototype dosage forms for appropriate release and activity characteristics, and to confirm the integrity and quality of the material to be used in clinical trials. A bulk supply of the active ingredient to support the necessary dosing in initial clinical trials must be secured. Data from the preclinical investigations and detailed information on proposed clinical investigations are compiled in an IND submission and submitted for FDA approval before human clinical trials may begin. If the FDA does not formally communicate an objection to the IND within 30 days, the specific clinical trials outlined in the IND may go forward.

Clinical Stage

The clinical stage of drug development follows a successful IND submission and involves the activities necessary to demonstrate the safety, tolerability, efficacy, and dosage of the substance in humans, as well as the ability to produce the substance in accordance with the FDA's cGMP requirements. Data from these activities are compiled in a New Drug Application, or NDA, requesting approval to market the drug for a given use, or indication. Clinical trials must be conducted under the supervision of qualified investigators in accordance with good clinical practice, and according to IND-approved protocols detailing, among other things, the study objectives and the parameters, or endpoints, to be used in assessing safety and efficacy. Each trial must be reviewed, approved and conducted under the auspices of an independent Institutional Review Board, or IRB, and each trial, with limited exceptions, must include all subjects' informed consent. The clinical evaluation stage typically involves the following sequential process:

Phase I clinical trials are conducted in a limited number of healthy subjects to determine the drug's safety, tolerability, and biological performance. The total number of subjects in Phase I clinical trials varies, but is generally in the range of 20 to 80 people (or less in some cases, such as drugs with significant human experience).

Phase II clinical trials involve administering the drug to subjects suffering from the target disease or condition to evaluate the drug's potential efficacy and appropriate dose. The number of subjects in Phase II trials is typically several hundred subjects or less.

Phase III clinical trials are performed after preliminary evidence suggesting effectiveness has been obtained and safety, tolerability, and appropriate dosing have been established. Phase III clinical trials are intended to gather additional data needed to evaluate the drug's overall benefit-risk relationship of the drug and to provide adequate instructions for its use. Phase III trials usually include from several hundred to several thousand subjects.

Throughout the clinical testing stage, samples of the product made in different batches are tested for stability to establish shelf life constraints. In addition, increasingly large-scale production protocols and written standard operating procedures must be developed for each aspect of commercial manufacture and testing.

The clinical trial stage is both costly and time-consuming, and may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted under an IND and may, at its discretion, reevaluate, alter, suspend, or terminate the testing at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request additional clinical testing as a condition to product approval. Additionally, new government requirements may be established that could delay or prevent regulatory approval of our products under development. Furthermore, institutional review boards, which are independent entities constituted to protect human subjects in the institutions in which clinical trials are being conducted, have the authority to suspend clinical trials in their respective institutions at any time for a variety of reasons, including safety issues.

New Drug Application and Review

After the successful completion of Phase III clinical trials, the sponsor of the new drug submits an NDA to the FDA requesting approval to market the product for one or more indications. An NDA is a comprehensive, multi-volume application that includes, among other things, the results of all preclinical and clinical studies, information about the drug's composition, and the sponsor's plans for producing, packaging, and labeling the drug. In most cases, the NDA must be accompanied by a substantial user fee. FDA has 60 days after submission to review the completeness and organization of the application, and may refuse to accept it for continued review, or refuse to file, if the application is found deficient. After filing, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use. Drugs that successfully complete NDA review may be marketed in the United States, subject to all conditions imposed by the FDA.

Prior to granting approval, the FDA generally conducts an inspection of the facilities, including outsourced facilities that will be involved in the manufacture, production, packaging, testing and control of the drug product for cGMP compliance. The FDA will not approve the application unless cGMP compliance is satisfactory. If the FDA determines that the marketing application, manufacturing process, or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and will often request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the marketing application does not satisfy the regulatory criteria for approval and refuse to approve the application by issuing a "not approvable" letter.

The length of the FDA's review can range from a few months to several years or more. Once an NDA is in effect, significant changes such as the addition of one or more new indications for use generally require prior approval of an NDA including additional clinical trials or other data required to demonstrate that the product as modified remains safe and effective.

Fast Track Review

The Food and Drug Administration Modernization Act of 1997, or the Modernization Act, establishes a statutory program for relatively streamlined approval of “Fast Track” products, which are defined under the Modernization Act as new drugs or biologics intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs for this condition. Fast Track status requires an official designation by the FDA.

Abbreviated New Drug Application and Review

An Abbreviated New Drug Application, or ANDA, is a type of NDA that is used for the review and approval of a generic drug product. A generic drug product is one that is the same as a previously approved innovator drug product, which means it has the same active ingredient, dosage form, and strength, route of administration, quality, performance characteristics, and intended use. An ANDA is generally not required to include preclinical and clinical data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to the previously approved drug, which means that it performs in the same manner. None of the products currently under development by FluoroPharma will be eligible for ANDA approval, although it is possible that competing products based on our product could be approved by this route at some future time.

Section 505(b)(2) Applications

If a proposed drug product represents only a limited change from a product that has already been approved by the FDA, yet differs in more ways than those permitted under the ANDA requirements, then the applicant may be able to submit a type of NDA referred to as a 505(b)(2) application. In effect, a 505(b)(2) applicant is permitted to rely on information in the scientific literature, or previous safety and efficacy determinations by the FDA, rather than submitting the full complement of clinical or other data that would otherwise be required for NDA approval. However, the 505(b)(2) sponsor must provide any additional clinical or other data needed to supplement and/or establish the relevance and applicability of prior findings for the new product formulation. We do not expect any of our current drug portfolio to be granted approval via this process as our products are novel and patent protected.

Post-Approval Phase

Once the FDA has approved a new drug for marketing, the product becomes available for physicians to prescribe in the United States. After approval, we must comply with post-approval requirements, including ongoing compliance with cGMP regulations, delivering periodic reports to the FDA, submitting descriptions of any adverse reactions reported, and complying with drug sampling and distribution requirements. We are required to maintain and provide updated safety and efficacy information to the FDA. We are also required to comply with requirements concerning advertising and promotional labeling.

Compliance with post-approval requirements will require us to expend time, money, and effort on an ongoing basis. We expect to use third party manufacturers to produce certain of our products in clinical and commercial quantities. Future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

In addition, discovery of problems with a product or the failure to comply with requirements may result in restrictions including withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay further marketing. Newly discovered or developed safety or efficacy data may require changes to a product’s approved labeling, including the addition of new warnings and contraindications. Also, the FDA may require post-market testing and surveillance to monitor the product’s safety or efficacy, including additional clinical studies, known as Phase IV trials, to evaluate long-term effects.

Other Regulation in the United States

Healthcare Reimbursement

Government and private sector initiatives to limit the growth of healthcare costs including price regulation, competitive pricing, coverage and payment policies, and managed-care arrangements, are continuing in many countries where we do business, including the United States. These changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective medical products. Government programs, including Medicare and Medicaid, private healthcare insurance and managed-care plans have attempted to control costs by limiting the amount of reimbursement they will pay for procedures or treatments. This has created an increasing level of price sensitivity among customers for diagnostic products. Even though a new medical product may have been cleared for commercial distribution, we may find limited demand for the product until full reimbursement approval has been obtained from governmental and private third-party payers.

Environmental Regulation

We are also subject to various environmental laws and regulations both within and outside the United States. Like many other pharmaceutical and medical device companies, our operations involve the use of substances, including hazardous wastes, which are regulated under environmental laws, primarily manufacturing and sterilization processes. We do not expect that compliance with environmental protection laws will have a material impact on our consolidated results of operations, financial position or cash flow. These laws and regulations are all subject to change, however, and we cannot predict what impact, if any, such changes might have on our business, financial condition or results of operations.

Foreign Regulation

Whether or not we obtain FDA approval for a product, we must obtain approval from the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement also vary greatly from country to country. Although governed by the applicable jurisdiction, clinical trials conducted outside of the United States typically are administered under a three-phase sequential process similar to that discussed above for pharmaceutical products.

Under European Union regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is available for medicines produced by biotechnology or which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. This authorization is a marketing authorization approval, or MAA. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. This procedure is referred to as the mutual recognition procedure, or MRP.

In addition, regulatory approval of prices is required in most countries other than the United States. We face the risk that the prices which result from the regulatory approval process would be insufficient to generate an acceptable return to us or our collaborators.

Employees

As of December 31, 2016, we had four full-time employees.

Item 1A. Risk Factors.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below with all of the other information included in this annual report before making an investment decision. If any of the possible adverse events described below actually occurs, our business, results of operations or financial condition would likely suffer. In such an event, the market price of our common stock could decline and you could lose all or part of your investment.

Risks Related to Our Finances, Capital Requirements and Other Financial Matters

We are an early stage company with a history of operating losses that are expected to continue and we are unable to predict the extent of future losses, whether we will generate significant revenues or whether we will achieve or sustain profitability.

We are a company in the early stage and our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We have incurred net losses every year since our inception in 2003 and have generated no revenue from product sales or licenses to date. Our operations have been limited to organizing and staffing our company, acquiring, developing and securing the proprietary rights for, and undertaking pre-clinical development and clinical trials of our product candidates. As of December 31, 2016, we had an accumulated deficit of approximately \$35.2 million. We expect to make substantial expenditures and incur increasing operating costs in the future and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses, whether we will ever generate significant revenues or if we will ever achieve or sustain profitability.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, curtail or eliminate one or more of our research and development programs.

Our operations have consumed substantial amounts of cash since inception. At December 31, 2016, we had cash and cash equivalents of approximately \$25,000, which we expect will be sufficient, together with the proceeds from our recent private placements, to fund our operations through March 2017. We will need to seek substantial additional financing to continue our activities beyond such date. We have no bank lines of credit or other arrangements or commitments for such financing and we may not be successful in our efforts to raise needed capital on acceptable terms, if at all. If we are unable to obtain sufficient funding, through a corporate collaboration, debt or equity financing or otherwise, we will be required to curtail or discontinue one or more of our product development programs.

We received a report from our independent registered public accounting firm with an explanatory paragraph for the year ended December 31, 2016 with respect to our ability to continue as a going concern, the existence of which may adversely affect our stock price and our ability to raise capital.

In their report dated March 31, 2017, our independent registered public accounting firm expressed substantial doubt about our ability to continue as a going concern. We have incurred losses and negative cash flows from operations since inception, have an accumulated deficit as of December 31, 2016 and require additional financing to fund future operations. Our ability to continue as a going concern is subject to our ability to obtain necessary funding from outside sources, including obtaining additional funding from the sale of our securities.

Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing may involve covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions, among other restrictions. In addition, if we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

If we fail to maintain an effective system of internal control, we may not be able to report our financial results accurately or to prevent fraud. Any inability to report and file our financial results accurately and timely could harm our reputation and adversely impact the trading price of our common stock.

Effective internal control is necessary for us to provide reliable financial reports and prevent fraud. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed. As a result, our small size and any current internal control deficiencies may adversely affect our financial condition, results of operation and access to capital. We have not performed an in-depth analysis to determine if historical un-discovered failures of internal controls exist, and may in the future discover areas of our internal control that need improvement.

Risks Related to Our Business and Industry

Our product candidates are at an early stage of development and may not be successfully developed or commercialized.

Our product candidates are in the early stage of development and will require substantial further capital expenditures, development, testing, and regulatory clearances prior to commercialization. Of the large number of drugs in development, only a small percentage successfully complete the United States Food and Drug Administration, or FDA, regulatory approval process and are commercialized. Accordingly, even if we are able to obtain the requisite financing to fund our development programs, we cannot assure you that our product candidates will be successfully developed or commercialized. We are subject to the risk that some or all of our proposed products:

- will be found to be ineffective or unsafe;
- will not receive necessary regulatory clearances;
- will be unable to get to market in a timely manner;
- will not be capable of being produced in commercial quantities at reasonable costs;
- will not be successfully marketed; or
- will not be widely accepted by the medical community.

We may experience unanticipated problems relating to product development, testing, regulatory compliance, manufacturing, marketing and competition, and our costs and expenses could exceed current estimates. We cannot predict whether we will successfully develop and commercialize any products.

If we fail to obtain U.S. regulatory approval of our current or future product candidates, we will be unable to commercialize these potential products in the United States.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable health authorities in foreign markets. In the United States, we are not permitted to market our product candidates unless and until we receive FDA approval. The process of obtaining FDA approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. In addition to the significant clinical testing requirements, our ability to obtain marketing approval for these products depends on obtaining the final results of required non-clinical testing, including characterization of the manufactured components of our product candidates and validation of our manufacturing processes. With respect to foreign markets, approval procedures vary among countries and, in addition to the aforementioned risks, can involve additional product testing, administrative review periods and agreements with pricing authorities. Approval of a product candidate in the U.S. or foreign markets may be delayed, limited or denied for many reasons, including, but not limited to:

- disagreement with the design or implementation of our clinical trials;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- our failure to demonstrate to the satisfaction of the FDA or other regulatory agency that a product candidate is safe and effective for any indication;
- the results of clinical trials may not meet the level of statistical significance required for approval;
- our inability to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks; or
- the manufacturing processes or facilities of third party manufacturers with which we or our collaborators contract for clinical and commercial supplies may not be acceptable.

Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

Any regulatory approvals that we or our partners receive for our product candidates may also be subject to limitations on the indicated uses for which the product candidate may be marketed or contain requirements for potentially costly post-marketing follow-up studies. The subsequent discovery of previously unknown problems with the product candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product candidate and withdrawal of the product candidate from the market.

U.S. manufacturing, labeling, storage and distribution activities also are subject to strict regulating and licensing by the FDA. Our failure, or the failure of any manufacturing facilities that supply our product candidates, to continue to meet regulatory standards or to remedy any deficiencies could result in corrective action by the FDA or these other authorities, including the interruption or prevention of marketing, closure of such facilities, and fines or penalties.

Regulatory authorities also will require post-marketing surveillance to monitor and report to the FDA potential adverse effects of our product candidates. If approved, any of our product candidates' subsequent failure to comply with applicable regulatory requirements could, among other things, result in warning letters, fines, suspension or revocation of regulatory approvals, product recalls or seizures, operating restrictions, injunctions and criminal prosecutions.

Delays in the commencement of our clinical trials could result in increased costs and delay our ability to pursue regulatory approval.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory clearance to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining Investigator Review Board, or IRB, or ethics committee approval to conduct a clinical trial at a prospective site;
- identifying, recruiting and enrolling patients to participate in a clinical trial; and
- retaining patients who have initiated a clinical trial but may withdraw due to adverse events from the compounds, insufficient efficacy, fatigue with the clinical trial process or personal issues.

Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for our product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate. Clinical trials may also be delayed as a result of ambiguous or negative interim results or difficulties in obtaining sufficient quantities of product manufactured in accordance with regulatory requirements. Further, a clinical trial may be modified, suspended or terminated by us, an IRB, an ethics committee or a data safety monitoring committee overseeing the clinical trial, any clinical trial site with respect to that site, or the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues or any determination that the clinical trial presents unacceptable health risks; and
- lack of adequate funding to continue the clinical trials.

Changes in regulatory requirements and guidance also may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing and the likelihood of a successful completion of a clinical trial. If we experience delays in the completion of, or if we must terminate, any clinical trial of any product candidate, our ability to obtain regulatory approval for that product candidate will be delayed and the commercial prospects, if any, for the product candidate may suffer as a result. In addition, many of these factors may also ultimately lead to the denial of regulatory approval of a product candidate.

We rely on third parties to conduct our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves and intend to continue to rely upon such CROs, as well as medical institutions, clinical investigators and consultants, to conduct our clinical trials in accordance with our clinical protocols. Our CROs, investigators and other third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. There is no guarantee that any CROs, investigators and other third parties upon which we rely for administration and conduct of our clinical trials will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, fail to adhere to our clinical protocols or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated and may result in additional costs. If any of our clinical trial sites terminate for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be jeopardized.

If we are unable to establish sales and marketing capabilities or fail to enter into agreements with third parties to market, distribute and sell any products we may successfully develop, we may not be able to effectively market and sell any such products and generate product revenue.

We do not currently have the infrastructure for the sales, marketing and distribution of any of our product candidates, and must build this infrastructure or make arrangements with third parties to perform these functions in order to commercialize any products that we may successfully develop. The establishment and development of a sales force, either by us or jointly with a partner, or the establishment of a contract sales force to market any products we may develop, will be expensive and time-consuming and could delay any product launch. If we, or our partners, are unable to establish sales and marketing capability or any other non-technical capabilities necessary to commercialize any products we may successfully develop, we will need to contract with third parties to market and sell such products. We may not be able to establish arrangements with third-parties on acceptable terms, if at all.

We license patent rights from third party owners. If such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed.

We are party to a number of licenses that give us rights to third party intellectual property that is necessary or useful for our business. In particular, we have obtained the rights from Massachusetts General Hospital, for our composition of matter patents and some method of use patents. We may enter into additional licenses to third party intellectual property in the future. Our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents issue with respect to these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. In addition, our licensors may terminate their agreements with us in the event we breach the applicable license agreement and fail to cure the breach within a specified period of time. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. Our proprietary rights may not adequately protect our intellectual property and product candidates and if we cannot obtain adequate protection of our intellectual property and product candidates, we may not be able to successfully market our product candidates.

Our commercial success will depend in part on obtaining and maintaining intellectual property protection for our technologies and product candidates. We will only be able to protect our technologies and product candidates from unauthorized use by third parties to the extent that valid and enforceable patents cover them, or that other market exclusionary rights apply.

The patent positions of life science companies, like ours, can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Our issued patents may be subject to challenge and possibly invalidated by third parties. Changes in either the patent laws or in the interpretations of patent laws in the United States or other countries may diminish the market exclusionary ability of our intellectual property.

In addition, others may independently develop similar or alternative compounds and technologies that may be outside the scope of our intellectual property. Should third parties obtain patent rights to similar compounds or radiolabeling technology, this may have an adverse effect on our business.

To the extent that consultants or key employees apply technological information independently developed by them or by others to our product candidates, disputes may arise as to the proprietary rights of the information, which may not be resolved in our favor. Consultants and key employees that work with our confidential and proprietary technologies are required to assign all intellectual property rights in their discoveries to us. However, these consultants or key employees may terminate their relationship with us, and we cannot preclude them indefinitely from dealing with our competitors. If our trade secrets become known to competitors with greater experience and financial resources, the competitors may copy or use our trade secrets and other proprietary information in the advancement of their products, methods or technologies. If we were to prosecute a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming and the outcome would be unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets than courts in the United States. Moreover, if our competitors independently develop equivalent knowledge, we would lack any contractual claim to this information, and our business could be harmed.

Our ability to commercialize our product candidates will depend on our ability to sell such products without infringing the patent or proprietary rights of third parties. If we are sued for infringing intellectual property rights of third parties, such litigation will be costly and time consuming and an unfavorable outcome would have a significant adverse effect on our business.

Our ability to commercialize any of our product candidates that we may successfully develop will depend on our ability to sell such products without infringing the patents or other proprietary rights of third parties. Third party intellectual property in the fields of cardiology, oncology, neurology, and radiopharmaceutical technologies are complicated, and third party intellectual property rights in these fields are continuously evolving. We have not performed searches for third party intellectual property rights that may raise freedom-to-operate issues, and we have not obtained legal opinions regarding commercialization of our product candidates. As such, there may be existing patents that may affect our ability to commercialize our product candidates.

In addition, because patent applications are published 18 months after their filing, and because applications can take several years to issue, there may be currently pending third party patent applications that are unknown to us, which may later result in issued patents. If a third party claims that we infringe on its patents or other proprietary rights, we could face a number of issues that could seriously harm our competitive position, including:

- infringement claims that, with or without merit, can be costly and time consuming to litigate, can delay the regulatory approval process and can divert management's attention from our core business strategy;
- substantial damages for past infringement which we may have to pay if a court determines that our products or technologies infringe upon a competitor's patent or other proprietary rights;
- if a license is available from a holder, we may have to pay substantial royalties or grant cross licenses to our patents or other proprietary rights; and
- redesigning our process so that it does not infringe the third party intellectual property, which may not be possible, or which may require substantial time and expense including delays in bringing our own products to market.

Such actions could harm our competitive position and our ability to generate revenue and could result in increased costs.

We may incur substantial product liability or indemnification claims relating to the clinical testing of our product candidates.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and claims could be brought against us if use or misuse of one of our product candidates causes, or merely appears to have caused, personal injury or death. While we have and intend to maintain product liability insurance relating to our clinical trials, our coverage may not be sufficient to cover claims that may be made against us and we may be unable to maintain such insurance. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources or destroy the prospects for commercialization of the product which is the subject of any such claim. We are unable to predict if we will be able to obtain or maintain product liability insurance for any products that that may be approved for marketing. Additionally, we have entered into various agreements where we indemnify third parties for certain claims relating to the testing and use of our product candidates. These indemnification obligations may require us to pay significant sums of money for claims that are covered by these indemnifications.

If any product candidates that we may successfully develop do not gain market acceptance among physicians, patients and the medical community, we will be unable to generate significant revenue, if any.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payers and the medical community. Coverage and reimbursement of our product candidates by third party payers, including government payers, generally is also necessary for commercial success. The degree of market acceptance of any approved products will depend on a number of factors, including:

- limited indications of regulatory approvals;
- the establishment and demonstration in the medical community of the clinical efficacy and safety of our product candidates and their potential advantages over existing diagnostic compounds;
- the prevalence and severity of any side effects;
- our ability to offer our product candidates at an acceptable price;
- the relative convenience and ease of administration of our products;
- the strength of marketing and distribution support; and
- sufficient third party coverage or reimbursement.

The failure of any of our product candidates to gain market acceptance could impair our ability to generate revenue, which could have a material adverse effect on our future business.

We have no manufacturing capabilities and rely on third parties to manufacture our preclinical and clinical supplies and expect to continue to rely on third parties to produce commercial supplies of any approved product candidate, which reliance could adversely impact our business.

We have no commercial manufacturing facility for our product candidates and no experience in manufacturing commercial quantities of our product candidates. As such, we are dependent on third parties to supply our product candidates according to our specifications, in sufficient quantities, on time, in compliance with appropriate regulatory standards and at competitive prices. We cannot be sure that we will be able to obtain an adequate supply of our product candidates on acceptable terms, or at all. If any third party becomes unable or unwilling to deliver sufficient quantities of our product candidates to us on a timely basis and in accordance with applicable specifications and other regulatory requirements, it would materially adversely affect clinical development and potential commercialization of the product.

Third party manufacturers are required to maintain compliance with cGMPs and will be subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. In the event that the FDA or such other agencies determine that our third party suppliers have not complied with cGMP, our clinical trials could be terminated or subjected to a clinical hold until such time as we are able to obtain appropriate replacement material. Any delay, interruption or other issues that arise in the manufacture, packaging, or storage of our products as a result of a failure of the facilities or operations of our third party suppliers to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products.

We do not expect to have the resources or capacity to commercially manufacture any of our proposed products, if approved, and will likely continue to be dependent upon third party manufacturers. Our dependence on third parties to manufacture and supply us with clinical trial materials and any approved products may adversely affect our ability to develop and commercialize our products on a timely basis or at all.

Our competitors may develop products that are less expensive, deemed safer or more effective, which may diminish or eliminate the commercial success of any potential products that we may successfully develop and seek to commercialize.

If our competitors market products that are less expensive, safer or more effective than our future products developed from our product candidates, or that reach the market before our product candidates, we may not achieve commercial success. For example, if approved, 18-F FFTP's primary competition in the non-acute setting will be perfusion imaging agents, such as Sestamibi, produced by Lantheus Medical Imaging; Tetrofosmin produced by GE Healthcare; and generic thallium, the majority U.S. suppliers being Mallinckrodt and Lantheus Medical Imaging. The market may choose to continue utilizing the existing products for any number of reasons, including familiarity with or pricing of these existing products. The failure of BFPET or any of our product candidates to compete with products marketed by our competitors would impair our ability to generate revenue, which would have a material adverse effect on our future business, financial condition and results of operations.

Our competitors may:

- develop and market products that are less expensive or more effective than our future products;
- commercialize competing products before we or our partners can launch any products developed from our product candidates;
- operate larger research and development programs or have substantially greater financial resources than we do;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent;
- secure reimbursement faster; and
- take advantage of acquisition or other opportunities more readily than we can.

We expect to compete for market share against large pharmaceutical and biotechnology companies, smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research organizations.

In addition, the life sciences industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our product discovery process that we believe we derive from our research approach and proprietary technologies.

The use of hazardous materials in our operations may subject us to environmental claims or liabilities.

Our research and development activities involve the use of hazardous materials, including chemicals and biological and radioactive materials. Injury or contamination from these materials may occur and we could be held liable for any damages, which could exceed our available financial resources. This liability could materially adversely affect our business, financial condition and results of operations.

We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We may be required to incur significant costs to comply with environmental laws and regulations in the future that could materially adversely affect our business, financial condition and results of operations.

If we fail to attract and retain senior management, consultants, advisors and scientific and technical personnel, our product development and commercialization efforts could be impaired.

Our performance is substantially dependent on the performance of our senior management and key scientific and technical personnel, particularly Dr. Thomas H. Tulip, our president, chief executive officer and member of our board of directors. Although we have entered into an employment agreement with Dr. Tulip, there is no assurance that he will remain in our employ for the entire term of such employment agreement. The loss of the services of any member of our senior management or our scientific or technical staff may significantly delay or prevent the development of our product candidates and other business objectives by diverting management's attention to transition matters and identification of suitable replacements, if any, and could have a material adverse effect on our business, operating results and financial condition.

We also rely on consultants and advisors to assist us in formulating our research and development strategy. All of our consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to contribute to us.

In addition, we believe that we will need to recruit additional executive management and scientific and technical personnel. There is currently intense competition for skilled executives and employees with relevant scientific and technical expertise, and this competition is likely to continue. The inability to attract and retain sufficient scientific, technical and managerial personnel could limit or delay our product development efforts, which would adversely affect the development of our product candidates and commercialization of our potential products and growth of our business.

Healthcare reform and restrictions on reimbursement may limit our financial returns.

Our ability or the ability of our collaborators to commercialize any of our product candidates that we successfully develop may depend, in part, on the extent to which government health administration authorities, private health insurers and other organizations will reimburse consumers for the cost of these products. Significant uncertainty exists as to the reimbursement status of newly approved health care products. Each of our product candidates is intended to replace or alter existing therapies or procedures. These third party payers may conclude that our product candidates are less safe, effective or cost-effective than these existing therapies or procedures. If third party payers do not approve our product candidates for reimbursement or fail to reimburse for them adequately, sales will suffer as some physicians or their patients will opt for a competing product that is approved for reimbursement or is adequately reimbursed. Even if third party payers make reimbursement available, these payers' reimbursement policies may adversely affect our ability and the ability of our potential collaborators to sell our potential products on a profitable basis.

If we or any of our independent contractors, consultants, collaborators, manufacturers, vendors or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions, which could result in penalties and affect our ability to develop, market and sell our product candidates and may harm our reputation.

We are subject to federal, state, and foreign healthcare laws and regulations pertaining to fraud and abuse and patients' rights. These laws and regulations include:

- the U.S. federal healthcare program anti-kickback law, which prohibits, among other things, persons and entities from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for a healthcare item or service, or the purchasing or ordering of an item or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid;
- the U.S. federal false claims and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented, claims for payment by government funded programs such as Medicare or Medicaid that are false or fraudulent, and which may apply to us by virtue of statements and representations made to customers or third parties;
- the U.S. federal Health Insurance Portability and Accountability Act, or HIPAA, which prohibits, among other things, executing a scheme to defraud healthcare programs;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes requirements relating to the privacy, security, and transmission of individually identifiable health information, and requires notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members, which is published in a searchable form on an annual basis; and
- state laws comparable to each of the above federal laws, such as, for example, anti-kickback and false claims laws that may be broader in scope and also apply to commercial insurers and other non-federal payors, requirements for mandatory corporate regulatory compliance programs, and laws relating to patient data privacy and security.

If our operations are found to be in violation of any such health care laws and regulations, we may be subject to penalties, including administrative, civil and criminal penalties, monetary damages, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, or exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, any of which could adversely affect our financial results. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

In addition, legislation and regulations affecting the pricing of our product candidates may change in ways adverse to us before or after the FDA or other regulatory agencies approve any of our product candidates for marketing. While we cannot predict the likelihood of any of these legislative or regulatory proposals, if any government or regulatory agencies adopt these proposals, they could materially adversely affect our business prospects, financial condition and results of operations.

Risks Related to our Common Stock

Our stock price may be volatile.

The stock market, particularly in recent years, has experienced significant volatility particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. Factors that could cause this volatility in the market price of our common stock include:

- results from and any delays in our clinical trials;
- failure or delays in entering additional product candidates into clinical trials;
- failure or discontinuation of any of our research programs;
- delays in establishing new strategic relationships;
- delays in the development or commercialization of our potential products;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- actual and anticipated fluctuations in our financial and operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- issues in manufacturing our potential products;
- market acceptance of our potential products;
- third party healthcare reimbursement policies;
- FDA or other domestic or foreign regulatory actions affecting us or our industry;
- litigation or public concern about the safety of our product candidates; and
- additions or departures of key personnel.

These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

We have not and do not anticipate paying any dividends on our common stock.

We have paid no dividends on our common stock to date and it is not anticipated that any dividends will be paid to holders of our common stock in the foreseeable future. While our future dividend policy will be based on the operating results and capital needs of the business, it is currently anticipated that any earnings will be retained to finance our future expansion and for the implementation of our business plan. As an investor, you should take note of the fact that a lack of a dividend can further affect the market value of our stock, and could significantly affect the value of any investment in our Company.

Because we became public with a reverse merger, we may not be able to attract the attention of major brokerage firms.

There may be risks associated with us becoming public through a “reverse merger.” Securities analysts of major brokerage firms may not provide coverage of us since there is no incentive to brokerage firms to recommend the purchase of our common stock. No assurance can be given that brokerage firms will, in the future, want to conduct any secondary offerings on behalf of our post-merger company.

The limited trading market for our common stock results in limited liquidity for shares of our common stock and significant volatility in our stock price.

Although prices for our shares of common stock are quoted on the OTC.QB, there is little current trading and no assurance can be given that an active public trading market will develop or, if developed, that it will be sustained. The OTC.QB is generally regarded as a less efficient and less prestigious trading market than other national markets. There is no assurance if or when our common stock will be quoted on another more prestigious exchange or market. Active trading markets generally result in lower price volatility and more efficient execution of buy and sell orders. The absence of an active trading market reduces the liquidity of our common stock.

The market price of our stock is likely to be highly volatile because for some time there will likely be a thin trading market for the stock, which causes trades of small blocks of stock to have a significant impact on our stock price. As a result of the lack of trading activity, the quoted price for our common stock on the OTC.QB is not necessarily a reliable indicator of its fair market value. Further, if we cease to be quoted, holders of our common stock would find it more difficult to dispose of, or to obtain accurate quotations as to the market value of, our common stock, and the market value of our common stock would likely decline.

Our common stock is currently deemed a “penny stock,” which makes it more difficult for our investors to sell their shares.

Our common stock is subject to the “penny stock” rules adopted under Section 15(g) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). The penny stock rules generally apply to companies whose common stock is not listed on The NASDAQ Stock Market or other national securities exchange and trades at less than \$4.00 per share, other than companies that have had average revenue of at least \$6,000,000 for the last three years or that have tangible net worth of at least \$5,000,000 (\$2,000,000 if the company has been operating for three or more years). These rules require, among other things, that brokers who trade penny stock to persons other than “established customers” complete certain documentation, make suitability inquiries of investors and provide investors with certain information concerning trading in the security, including a risk disclosure document and quote information under certain circumstances. Many brokers have decided not to trade penny stocks because of the requirements of the penny stock rules and, as a result, the number of broker-dealers willing to act as market makers in such securities is limited. If we remain subject to the penny stock rules for any significant period, it could have an adverse effect on the market, if any, for our securities. If our securities are subject to the penny stock rules, investors will find it more difficult to dispose of our securities.

Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

If our stockholders sell substantial amounts of our common stock in the public market upon the expiration of any statutory holding period, under Rule 144, or issued upon the exercise of outstanding options or warrants, it could create a circumstance commonly referred to as an “overhang” and in anticipation of which the market price of our common stock could fall. The existence of an overhang, whether or not sales have occurred or are occurring, also could make more difficult our ability to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

Our articles of incorporation allows for our board of directors to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.

Our board of directors, or our Board, has the authority to fix and determine the relative rights and preferences of preferred stock and has designated 3,500,000 preferred shares as Series A Preferred Stock and 12,000,000 preferred shares as Series B Preferred Stock. Our Board also has the authority to issue additional shares of our preferred stock without further stockholder approval. As a result, our Board could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our Board could authorize the issuance of a series of preferred stock that has greater voting power than our common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders.

Item 1B. Unresolved Staff Comments

Not Applicable.

Item 2. Properties.

Our offices are located in Montclair, New Jersey pursuant to a lease expiring on August 1, 2017 that provides for a monthly rent of \$2,164.

Item 3. Legal Proceedings.

We are not aware of any material, active, pending or threatened legal proceeding against us nor are we, or any subsidiary, involved as a plaintiff or defendant in any other material proceeding or pending litigation.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Our common stock is quoted on the OTC.QB under the symbol “FPMI”. The following table sets forth, for the calendar periods indicated the range of the high and low last reported of the Company’s common stock, as reported by the OTC.QB. The quotations represent inter-dealer prices without retail mark-ups, mark-downs or commissions, and may not necessarily represent actual transactions. The quotations may be rounded for presentation.

| | High | Low |
|----------------|-------------|------------|
| 2016 | | |
| First Quarter | \$ 0.37 | \$ 0.21 |
| Second Quarter | \$ 0.28 | \$ 0.20 |
| Third Quarter | \$ 0.29 | \$ 0.18 |
| Fourth Quarter | \$ 0.21 | \$ 0.11 |
| 2015 | | |
| First Quarter | \$ 0.50 | \$ 0.35 |
| Second Quarter | \$ 0.45 | \$ 0.30 |
| Third Quarter | \$ 0.43 | \$ 0.24 |
| Fourth Quarter | \$ 0.37 | \$ 0.30 |

As of March 16, 2017, we had approximately 184 stockholders of record. Our transfer agent is VStock Transfer, LLC, Cedarhurst, New York.

Dividend Policy.

We have not previously paid any cash dividends on our common stock and do not anticipate or contemplate paying dividends on our common stock in the foreseeable future. We currently intend to utilize all available funds to develop our business. We can give no assurances that we will ever have excess funds available to pay dividends.

Unregistered Sales of Equity Securities

Equity Compensation Plan Information

The following table reflects, as of December 31, 2016, compensation plans pursuant to which the Company is authorized to issue options, warrants or other rights to purchase shares of its common stock, including the number of shares issuable under outstanding options, warrants and rights issued under the plans and the number of shares remaining available for issuance under the plans:

| Plan category | Number of securities to be issued upon exercise of outstanding options, warrants and rights (a) | Weighted-average price of outstanding options, warrants and rights (b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c) |
|--|---|--|---|
| Equity compensation plans approved by shareholders | 2,736,839 | \$ 0.58 | 3,577,661 |
| Equity compensation plans not approved by shareholders | -- | -- | -- |
| Total | 2,736,839 | \$ 0.58 | 3,577,661 |

Item 6. Selected Financial Data.

Not required for smaller reporting companies.

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

This report contains forward-looking statements. These forward-looking statements include, without limitation, statements containing the words "believes," "anticipates," "expects," "intends," "projects," "will," and other words of similar import or the negative of those terms or expressions. Forward-looking statements in this report include, but are not limited to, expectations of future levels of research and development spending, general and administrative spending, levels of capital expenditures and operating results, sufficiency of our capital resources, our intention to pursue and consummate strategic opportunities available to us, including sales of certain of our assets. Forward-looking statements subject to certain known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to those described in "Risk Factors" of the reports filed with the SEC.

The following discussion should be read in conjunction with our consolidated financial statements and notes thereto included elsewhere herein.

Overview

We are a biopharmaceutical company specializing in discovering, developing and commercializing molecular imaging pharmaceuticals with initial applications in the area of cardiology. Molecular imaging pharmaceuticals are radiopharmaceuticals that enable early detection of disease through the visualization of subtle changes in biochemical and biological processes. We currently have two clinical-stage molecular imaging pharmaceutical product candidates: CardioPET and BFPET.

Recent Accounting Pronouncements

In August 2014, the FASB issued ASU 2014-15 "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." The core principle of the guidance is that an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are available to be issued. When management identifies conditions or events that raise substantial doubt about an entity's ability to continue as a going concern, management should consider whether its plans that are intended to mitigate those relevant conditions or events that will alleviate the substantial doubt are adequately disclosed in the footnotes to the financial statements. This guidance will be effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. . The Company adopted ASU 2014-15 as of December 31, 2016 and updated the related disclosures. Other than the updates to going concern related disclosures, the adoption of ASU 2014-15 did not have an impact on the Company's financial statements.

In April 2015, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2015-03, 'Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs". ASU 2015-03 is intended to simplify the presentation of debt issuance costs. These amendments require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this ASU. The adoption of ASU 2015-03 resulted in the reclassification of \$17,116 and \$136,260 of unamortized debt issuance costs related to the Company's Convertible Notes (see Note 5) from prepaid expenses and other current assets to convertible notes payable within the Company's condensed consolidated balance sheets as of December 31, 2016 and December 31, 2015, respectively. Other than this reclassification, the adoption of ASU 2015-03 did not have an impact on the Company's financial statements.

In March 2016, the FASB issued ASU No. 2016-09, “Compensation – Stock Compensation”. The areas for simplification in this update involve several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. For public entities, the amendments in this update are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted in any interim or annual period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The Company is currently evaluating the impact of adopting this ASU on the financial statements.

On August 26, 2016, the FASB issued ASU No. 2016-15 “Statement of Cash Flows (Topic 230)”, a consensus of the FASB’s Emerging Issues Task Force. The new guidance is intended to reduce diversity in practice in how certain transactions are classified in the statement of cash flows. For public business entities, the standard is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. For all other entities, the standard is effective for financial statements issued for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted, provided that all of the amendments are adopted in the same period. The guidance requires application using a retrospective transition method. The Company is currently evaluating the impact of adopting this ASU on the financial statements.

Management does not expect any recently issued, but not yet effective, accounting standards to have a material effect on its results of operations or financial condition.

Critical Accounting Policies

This summary of significant accounting policies is presented to assist in understanding our consolidated financial statements. The consolidated financial statements and notes are representations of our management, which is responsible for their integrity and objectivity. These accounting policies conform to U.S. GAAP and have been consistently applied in the preparation of the financial statements.

Accounting for Share-Based Payments

We follow the provisions of ASC Topic 718, which establishes the accounting for transactions in which an entity exchanges equity securities for services and requires companies to expense the estimated fair value of these awards over the requisite service period. We use the Black-Scholes option pricing model in determining fair value. Accordingly, compensation is recognized using the fair value method and expected term accrual requirements as prescribed.

We account for share-based payments granted to non-employees in accordance with ASC Topic 505, “Equity Based Payments to Non-Employees.” The Company determines the fair value of the stock-based payment as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. If the fair value of the equity instruments issued is used, it is measured using the stock price and other measurement assumptions as of the earlier of either (1) the date at which a commitment for performance by the counterparty to earn the equity instruments is reached, or (2) the date at which the counterparty’s performance is complete.

The fair value of each share based payment is estimated on the measurement date using the Black-Scholes model with the following assumptions, which are determined at the beginning of each year and utilized in all calculations for that year:

Risk-Free Interest Rate. We utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of our awards.

Expected Volatility. We calculate the expected volatility based on a volatility index of peer companies as we did not have sufficient historical market information to estimate the volatility of our own stock.

Dividend Yield. We have not declared a dividend on its common stock since its inception and have no intentions of declaring a dividend in the foreseeable future and therefore used a dividend yield of zero.

Expected Term. The expected term of options granted represents the period of time that options are expected to be outstanding. We estimated the expected term of stock options by using the simplified method. For warrants, the expected term represents the actual term of the warrant.

Forfeitures. Estimates of option forfeitures are based on our experience. We will adjust our estimate of forfeitures over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures will be recognized through a cumulative catch-up adjustment in the period of change and will also impact the amount of compensation expense to be recognized in future periods.

Derivative Financial Instrument.

We evaluate all financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the consolidated statements of operations. For stock-based derivative financial instruments, we use a binomial pricing model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within 12 months of the balance sheet date.

At December 31, 2016, we had a derivative liability relating to certain warrants as well as embedded conversion features that contain anti-dilution provisions.

Impairments

We assess the impairment of long-lived assets, including other intangible assets, whenever events or changes in circumstances indicate that their carrying value may not be recoverable in accordance with ASC Topic 360-10-35, "Impairment or Disposal of Long-Lived Assets." The determination of related estimated useful lives and whether or not these assets are impaired involves significant judgments, related primarily to the future profitability and/or future value of the assets. We hold investments in companies having operations or technologies in areas that are within or adjacent to our strategic focus when acquired, all of which are privately held and whose values are difficult to determine. We record an investment impairment charge if it believes an investment has experienced a decline in value that is other than temporary.

Management has determined that no impairments had occurred as of December 31, 2016.

Intangible Assets

Our intangible assets consist of technology licenses and are carried at the legal cost to obtain them. Intangible assets are amortized using the straight-line method over the estimated useful life. Useful lives are as follows: technology licenses 5 to 15 years.

Research and Development Costs

Research and development costs are expensed as incurred. The cost of intellectual property purchased from others that is immediately marketable or that has an alternative future use is capitalized and amortized as intangible assets. Capitalized costs are amortized using the straight-line method over the estimated economic life of the related asset.

Use of Estimates

The accompanying consolidated financial statements are prepared in conformity with GAAP in the United States of America, and include certain estimates and assumptions which affect the reported amounts of assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Accordingly, actual results may differ from those estimates.

License Revenue Recognition

From time to time we enter into licensing agreements, the terms of which may include grants of licenses, or options to obtain licenses, to our intellectual property and research and development activities. Payments under these arrangements typically include one or more of the following: non-refundable, up-front license fees; funding of research and/or development efforts; amounts due upon the achievement of specified objectives; and/or royalties on future product sales.

We recognize milestone payments as revenue in their entirety upon the achievement of a substantive milestone if the consideration earned from the achievement of the milestone (i) is consistent with performance required to achieve the milestone or the increase in value to the delivered item, (ii) relates solely to past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement. Amounts received contractually designated to fund further research are recorded as a reduction to research and development expenses when we have satisfied all performance obligations to the licensee and expenses for specified development activities have been incurred.

RESULTS OF OPERATIONS

General

To date, we have not generated any revenues from operations and at December 31, 2016, we had an accumulated deficit of approximately \$35.2 million primarily as a result of research and development, or R&D, expenses and general and administrative, or G&A, expenses. While we may in the future generate revenue from a variety of sources, including license fees, research and development payments in connection with strategic partnerships and/or government grants, our product candidates are at an early stage of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future and there can be no assurance that we will ever generate significant revenues.

R&D Expenses

Conducting R&D is central to our business. R&D expenses consist primarily of:

- employee-related expenses, which include salaries and benefits, and rent expense;
- license fees and annual payments related to in-licensed products and intellectual property;
- expenses incurred under agreements with CROs, investigative sites and consultants that conduct or provide other services relating to our clinical trials and a substantial portion of our preclinical activities;
- the cost of acquiring clinical trial materials from third party manufacturers; and
- costs associated with non-clinical activities, patent filings and regulatory filings.

We expect to continue to incur substantial expenses related to our R&D activities for the foreseeable future as we continue product development. Since product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials, we expect that our R&D expenses will increase in the future. In addition, if our product development efforts are successful, we expect to incur substantial costs to prepare for potential commercialization of any late-stage product candidates and, in the event one or more of these product candidates receive regulatory approval, to fund the launch of the product.

G&A Expenses

G&A expenses consist principally of personnel-related costs, professional fees for legal, consulting and audit services, rent and other general operating expenses not otherwise included in R&D. We anticipate G&A expenses will increase in future periods, reflecting continued and increasing costs associated with:

- support of our expanded R&D activities;
- an expanding infrastructure and increased professional fees and other costs associated with the compliance with the Exchange Act, the Sarbanes-Oxley Act and stock exchange regulatory requirements and compliance; and
- business development and financing activities.

Comparison of Years Ended December 31, 2016 and 2015

G&A expenses were \$1,691,048 and \$2,465,478 for the years ended December 31, 2016 and 2015, respectively. The 30% decrease was due primarily to a decrease in legal costs related to litigation and financing, reduced investor relations activities, as well as a general decrease in operating expenses. We expect G&A expenses to increase going forward as we proceed to advance our product candidates through the development and regulatory process.

R&D expenses were \$511,381 and \$720,861 for the years ended December 31, 2016 and 2015, respectively. The 29% decrease was due primarily to the delay of initiation of the BFPET trial and the reimbursement of certain R&D expense as a result of the Company's license agreement with Sinotau USA, Inc. We expect R&D expenses to increase in future periods as our product candidates continue through clinical trials and we seek strategic collaborations.

Other income, net was \$152,568 and \$22,682 for the years ended December 31, 2016 and 2015, respectively. For the year ended December 31, 2016, other income, net, consisted primarily of loss on debt extinguishment of approximately \$996,000, gain on revaluation and modification of our derivative liability of approximately \$2,300,000 and interest and other expenses of approximately \$1,262,000, which primarily related to notes payable. In addition, for the year ended December 31, 2016, we recorded a gain on settlements of accounts payable of approximately \$107,000 and other income of approximately \$2,500. For the year ended December 31, 2015, other income, net, consisted primarily of realized and unrealized losses on trading securities of approximately \$4,000, gain on revaluation and modification of our derivative liability of approximately \$716,000 and interest and other expenses of \$873,000, which primarily related to notes payable. In addition, for the year ended December 31, 2015, we recorded a gain on settlements of accounts payable of approximately \$184,000.

Liquidity and Capital Resources

We have experienced net losses and negative cash flows from operations since our inception. We have sustained cumulative losses attributable to common stockholders of approximately \$35.2 million as of December 31, 2016. We have historically financed our operations through issuances of equity and the proceeds of debt instruments. We have also provided for our cash needs by issuing common stock, options and warrants for certain operating costs, including consulting and professional fees.

During the year ended December 31, 2016, we issued convertible promissory notes to certain accredited investors and received gross proceeds of \$570,000. In addition, during the year ended December 31, 2016, we received gross proceeds of \$155,000 from the issuance of short-term notes payable.

At December 31, 2016, we had cash and cash equivalents of approximately \$25,000. We continue to actively pursue various funding options, including equity offerings, to obtain additional funds to continue our product development activities beyond such date. We will seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources. Adequate additional funding may not be available to us on acceptable terms or at all. If adequate funds are not available to us, we will be required to delay, curtail or eliminate one or more of our research and development programs.

During the year ended December 31, 2015, we issued convertible promissory notes to certain accredited investors and received gross proceeds of \$2,980,005. In addition, during the year ended December 31, 2015, we received gross proceeds of \$365,000 from the issuance of short-term notes payable and \$35,970 from the sale of freely tradable securities.

Cash Flows for the Years Ended December 31, 2016 and 2015

Net cash used in operating activities for the year ended December 31, 2016 was \$880,121 which primarily reflected our net loss of \$2,049,861, including a non-cash gain on revaluation of the derivative liability of \$2,300,341 offset by non-cash expenses of \$1,938,422, and changes in the components of working capital of \$1,531,659.

Net cash used in operating activities for the year ended December 31, 2015 was \$2,676,889 which primarily reflected our net loss of \$3,163,657, including a non-cash gain on revaluation of the derivative liability of \$715,962 offset by non-cash expenses of \$623,612, and changes in the components of working capital of \$579,118.

For the year ended December 31, 2016, net cash used by investing activities was \$1,293, which reflected the purchase of the office equipment. For the year ended December 31, 2015, net cash provided by investing activities was \$29,276, which primarily reflected the proceeds from the sale of trading securities of \$35,970, offset by the purchase of office equipment.

For the year ended December 31, 2015, net cash provided by financing activities was \$615,290, which reflects net proceeds from the issuance of convertible and other notes payable. For the year ended December 31, 2015, net cash provided by financing activities was \$2,686,315, which reflects net proceeds related to the issuance of convertible notes payable.

Off-Balance Sheet Arrangements

We have no significant off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to our stockholders.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

The financial statements are included herein commencing on page F-1.

Item 9. Change in and Disagreement with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. Our management, with the participation of our CEO and our CFO, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15) and Rule 15d-15(e) of the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our CEO and our CFO concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective to ensure that information required to be disclosed is made known to management and others, as appropriate, to allow timely decision regarding required disclosure and that the information required to be disclosed by us in reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our CEO and CFO, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. A controls system cannot provide absolute assurance, however, that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Management's Annual Report on Internal Control over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Our 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 of accounting principles generally accepted in the United States.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives.

Our management evaluated the effectiveness of the Company's internal control over financial reporting as of December 31, 2016. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its updated 2013 Internal Control — Integrated Framework (2013). Based on this evaluation, our management, with the participation of the CEO and CFO, concluded that, as of December 31, 2016, our internal control over financial reporting was effective.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to rules of the SEC that permits us to provide only management's report in this annual report.

Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting that occurred during the fourth quarter of the year ended December 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 10. Directors, Executive Officers and Corporate Governance

The following persons are our executive officers and directors, and hold the positions set forth opposite their respective names.

| Name | Age | Position |
|------------------------|------------|---|
| Thomas H. Tulip, Ph.D. | 64 | Chief Executive Officer, President and Director |
| Tamara Rhein | 44 | Chief Financial Officer |
| Walter Witoshkin | 71 | Chairman of the Board |
| W. Austin Lewis, IV | 40 | Director |

Our directors hold office until the earlier of their death, resignation or removal or until their successors have been qualified.

Thomas H. Tulip, Ph.D. has served as our chief executive officer since December 28, 2015 and our president since October 5, 2015. He has also been a member of our Board since November 6, 2015. Dr. Tulip served in leadership roles at Navidea BioPharmaceuticals, Inc. (NAVBI) from June 2011 to May 2015. At Navidea, Dr. Tulip was responsible for defining the strategic direction of the company, as well as leadership of business, commercial, market, brand and product development, in addition to new product planning and project direction. Prior to joining Navidea, Dr. Tulip held senior leadership positions at Alseres Pharmaceuticals from August 2008 to May 2011 and with the succession of companies, Lantheus Medical Imaging, Bristol Myers Squibb (BMS) and DuPont, where his roles spanned product discovery and development, business and technology planning, brand and alliance management and international business management. Most recently, as President of Alseres, Molecular Imaging, Dr. Tulip led efforts to develop markets for a Phase III neuroimaging agent. While at DuPont and BMS, he was instrumental in the development, commercialization and international management of the nuclear cardiology franchise, successfully built the BMS Medical Imaging international business, and led planning activities for innovative PET tracers. Dr. Tulip earned a B.S. from the University of Vermont, and an M.S. and Ph.D. from Northwestern University. He was also a visiting scholar at Osaka University. He was Treasurer and a Board Member of the Academy of Molecular Imaging and Chairperson of its Institute for Molecular Technologies (IMT), where he held numerous leadership positions. Dr. Tulip was Chairperson of the Society of Nuclear Medicine (SNM) Corporate Advisory Board. He serves on the Board of Directors of the Medical Imaging Technology Association (MITA), leads its PET Working Group in the Molecular Imaging Section and has served as a Director for the Council on Radionuclides and Radiopharmaceuticals (CORAR). We believe that Dr. Tulip's extensive experience in advanced imaging pharmaceutical product development and commercialization provides him with the appropriate skills to serve as a member of the Board.

Tamara Rhein has been our chief financial officer since August 16, 2012 and served as our financial controller since July 2011. From November 2008 until joining us, Ms. Rhein was controller for Manhattan Pharmaceuticals, where she was responsible for a wide range of activities, including financial statement preparation, footnote disclosures for SEC filings, stock option accounting and quarterly and year-end audits. From 2005 until 2008, Ms. Rhein was with Vyteris, where her primary role was to manage the SEC accounting and reporting department. Ms. Rhein received a Bachelor's of Science degree in accounting from California State University at Northridge and is also a licensed (inactive) certified public accountant.

Walter Witoshkin has been elected interim chairman of our Board as of December 28, 2015. He has been a member of our Board since February 14, 2011. Mr. Witoshkin was the chairman and chief executive officer of QuantRx Biomedical Corporation, a medical technology company from April 2005 through August 2010. Mr. Witoshkin has held executive positions in the healthcare and pharmaceutical industries including senior financial positions at Wyeth Labs (American Cyanamide), VP Business Development and chief financial officer positions at SmithKline Beecham (now Glaxo SmithKline) and Menley & James Laboratories, Inc. He is a founding partner of the Trident Group, a global consultancy to the pharmaceutical industry. We believe that Mr. Witoshkin's industry specific extensive management experience provides him with a broad and deep understanding of our business and our competitors' efforts, which is an invaluable resource to our Board.

W. Austin Lewis, IV has been appointed a member of our Board effective November 6, 2015. Mr. Lewis serves as CEO, CFO, and a Director of PAID, Inc., a company focusing on web-development and online auctions, as well as the CEO of Lewis Asset Management Corp., an investment management company headquartered in New York City, which he founded in 2004. From 2003 to 2004, Mr. Lewis was employed at Puglisi & Company, a New York based broker-dealer registered with FINRA, where he served as a registered representative and managed individual client accounts, conducted due diligence for investment banking activities and managed his own personal account. In 2002, Mr. Lewis co-founded Thompson Davis & Company, Inc., a registered broker-dealer headquartered in Richmond, Virginia. Mr. Lewis received his Bachelor of Science degree in Finance and Financial Economics from James Madison University in 1998. Mr. Lewis is also a director on the following companies with a class of securities registered: MAM Software Group, Inc., Quest Solutions and ScripsAmerica, Inc. We believe that Mr. Lewis's management and financial industry experience, together with his understanding of our business, provides him with the appropriate skills to serve as a member of the Board.

Director Independence

Walter Witoshkin and Austin Lewis are independent directors, as the term “independent” is defined by the rules of the NASDAQ Stock Market.

Board Leadership Structure and Role in Oversight

Our Board is primarily responsible for overseeing our risk management processes. The Board receives and reviews periodic reports from management, auditors, legal counsel, and others, as considered appropriate regarding our assessment of risks. The Board focuses on the most significant risks facing our company and our general risk management strategy, and also ensures that risks undertaken by us are consistent with the Board’s appetite for risk. While the Board oversees our company, our management is responsible for day-to-day risk management processes. We believe this division of responsibilities is the most effective.

Board Committees

Audit Committee

Walter Witoshkin and Austin Lewis serve on the audit committee of the Board with Mr. Witoshkin serving as the Chairman. The audit committee operates under a charter approved by the Board. The functions of the audit committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non- audit services;
- reviewing our annual and quarterly financial statements and reports and discussing the statements and reports with our independent auditors and management;
- reviewing with our independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation, and matters concerning the scope, adequacy and effectiveness of our financial controls;
- preparing the report that the SEC will require in our annual proxy statement; and
- reviewing and providing oversight with respect to any related party transactions and monitoring compliance with our Code of Ethics; and

Our Board has determined that each member of the audit committee meets the financial literacy requirements under NASDAQ Stock Market rules and that Mr. Witoshkin’s employment experience qualifies him as an audit committee financial expert within the meaning of SEC rules and regulations.

Compensation Committee

Walter Witoshkin and Austin Lewis serve on the compensation committee of the Board, with Mr. Lewis serving as the Chairman. The compensation committee operates under a charter approved by our Board. The functions of the compensation committee include, among other things:

- reviewing our corporate goals and objectives relevant to our executives’ compensation, evaluating the executives’ performance in light of such goals and objectives and determining executive compensation levels based on such evaluations;
- reviewing and making recommendations to the Board with respect to non-executive officer compensation and independent director compensation;
- administering our incentive compensation and equity-based plans; and
- preparing the report that the SEC will require in our annual proxy statement and Form 10-K.

Nominating Committee

We do not presently have a nominating committee. Our Board currently acts as our nominating committee.

Code of Ethics

We adopted a Code of Ethics on July 22, 2011 that applies to all directors, officers and employees. Our Code of Ethics is available on our website at <http://www.fluoropharma.com>. A copy of our code of ethics will also be provided to any person without charge, upon written request sent to us at our offices located at 8 Hillside Avenue, Suite 108, Montclair, NJ 07042.

Compensation Discussion and Analysis

Overview

Dr. Tulip was appointed as our president on October 5, 2015 and our chief executive officer on December 28, 2015. We have structured our compensation packages to reflect our current level of operations and resources. This compensation discussion describes the material elements of compensation awarded to, earned by, or paid to each of our executive officers who served as named executive officers during the year ended December 31, 2016. This compensation discussion focuses on the information contained in the following tables and related footnotes and narrative for primarily the last completed fiscal year; however, we also describe compensation actions taken before or after the last completed fiscal year to the extent it enhances the understanding of our executive compensation disclosure.

Compensation Program Objectives and Philosophy

Our compensation committee currently oversees the design and administration of our executive compensation program. It reviews and approves all elements of compensation for each of our named executive officers taking into consideration recommendations from our chief executive officer (for compensation other than his own), as well as competitive market guidance. We define our competitive markets for executive talent to be the pharmaceutical and biotechnology industries in the tri-state area. To date, we have utilized Equilar Executive Compensation Survey, a third party market specific compensation survey, and, when applicable, other independent third-party compensation consultants, to benchmark our executive compensation.

The principal elements of our executive compensation program have historically been base salary, annual cash incentives, long-term equity incentives in the form of stock options, other benefits and perquisites, post-termination severance and acceleration of stock option vesting for certain named executive officers upon termination and/or a change in control. Our other benefits and perquisites have consisted of life, health and disability insurance benefits, and a qualified 401(k) savings plan. Our philosophy has been to position the aggregate of these elements at a level that is competitive within the industry and commensurate with our size and performance. During 2016, our compensation philosophy has continued to evolve to accommodate our changing circumstances, operational needs and limited financial resources during this period.

Base Salaries

For the year ended December 31, 2016, the base salary of our named executives was reflective of the availability of resources and level of continuing operations. Dr. Tulip, who was appointed as our president on October 5, 2015 and chief executive officer on December 28, 2015, receives an annual salary of \$320,000. Ms. Rhein, our chief financial officer, receives an annual salary of \$130,000. See “Employment Agreements” below.

As we continue to evaluate our future human resource requirements, our compensation committee will continue to review appropriate base salaries for our executive officers. In making its determination, the compensation committee will consider the time commitment necessary and the roles our executives will play in implementing our plans.

Long-term Equity Incentives

We provide the opportunity for our named executive officers and other executives to earn a long-term equity incentive award. Long-term incentive awards provide employees with the incentive to stay with us for longer periods of time, which in turn, provides us with greater stability. Equity awards also are less costly to us in the short term than cash compensation. We review long-term equity incentives for our named executive officers and other executives annually.

Historically, for our named executive officers, our stock option grants were of a size and term determined and approved by the compensation committee. We have traditionally used stock options as our form of equity compensation because stock options provide a relatively straightforward incentive for our executives and result in less immediate dilution of existing shareholders' interests. Generally, all grants of stock options to our employees were granted with exercise prices equal to or greater than the fair market value of our common stock on the respective grant dates. For a discussion of the determination of the fair market value of these grants, see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and the Use of Estimates."

We do not time stock option grants to executives in coordination with the release of material non-public information. Our stock option grants have a 10-year contractual exercise term. The compensation committee may provide that, in the event of a change in control, any outstanding awards that are unexercisable or otherwise unvested will become fully vested and immediately exercisable. If there is a termination of employment, the applicable termination provisions regarding exercise term will apply.

The vesting of certain of our named executive officers' stock options is accelerated pursuant to the terms of their employment agreements in certain change in control or other material events.

During 2011, Ms. Rhein was granted 10,500 common stock options with an exercise price of \$1.05 which vested equally over a three year period. During 2012, Ms. Rhein was granted 80,000 common stock options with an exercise price of \$0.83 which vest based on milestones related to the completion of our clinical trials. During 2013, Ms. Rhein was granted 100,000 common stock options with an exercise price of \$0.83. These options vest equally over a three-year period. During 2014, Ms. Rhein was granted 50,000 common stock options with an exercise price of \$0.51. These options vest based on milestones related to the completion of our clinical trials. During 2015, Dr. Tulip was granted 500,000 common stock options with an exercise price of \$0.35. These options vest equally over three years upon each anniversary of his employment.

Compensation Committee Interlocks and Insider Participation

Members of our compensation committee of the board of directors were Lawrence Atinsky, Walter Witoshkin and W. Austin Lewis. No member of our compensation committee was, or has been, our officer or employee.

No member of the compensation committee has a relationship that would constitute an interlocking relationship with our executive officers or directors or another entity.

Item 11. Executive Compensation

The following table sets forth the annual and long-term compensation paid to our chief executive officer and the other executive officers who earned more than \$100,000 per year at the end of the last three completed fiscal years. We refer to all of these officers collectively as our "named executive officers."

Summary Compensation Table

| | Year | Salary (\$) | Bonus (\$) | Stock Awards (\$) | Option Awards (\$) | Non-Equity Incentive Plan Compensation (\$) | All Other Compensation (\$) | Total (\$) |
|---------------------|------|------------------------|------------|-------------------|--------------------|---|-----------------------------|------------|
| Thomas H. Tulip | | | | | | | | |
| | 2016 | 320,000 ⁽¹⁾ | | | | | | 320,000 |
| | 2015 | 77,744 ⁽²⁾ | | | 52,204 | | | 129,948 |
| Tamara Rhein | | | | | | | | |
| | 2016 | 130,000 | | | | | | 130,000 |
| | 2015 | 130,000 | | | | | | 130,000 |
| | 2014 | 130,000 | | | 15,169 | | | 145,169 |
| Johan (Thijs) Spoor | | | | | | | | |
| | 2016 | - | - | - | - | | | - |
| | 2015 | 266,459 ⁽³⁾ | - | - | - | | | 266,459 |
| | 2014 | 305,000 ⁽⁴⁾ | - | - | - | | | 305,000 |

(1) Of this amount, \$133,333 of Mr. Tulip’s salary has been accrued for at December 31, 2016.

(2) Dr. Thomas H. Tulip joined us as president effective October 5, 2015 and chief executive officer effective December 28, 2015.

(3) Of this amount, \$25,417 of Mr. Spoor’s salary has been accrued for at December 31, 2016. Mr. Spoor resigned as our chief executive officer on December 28, 2015.

(4) Of this amount, \$63,542 of Mr. Spoor’s salary has been accrued for at December 31, 2016.

Outstanding Equity Awards at Fiscal Year End

The following table sets forth information with respect to grants of options to purchase our common stock to the named executive officers at December 31, 2016.

| Name | Options awards | | | | | Stock awards | | | |
|-----------------|---|---|---|----------------------------|------------------------|---|--|---|---|
| | Number of securities underlying unexercised options (#) exercisable | Number of securities underlying unexercised options (#) unexercisable | Equity incentive plan awards: Number of securities underlying unexercised options (#) | Option exercise price (\$) | Option expiration date | Number of shares or units of stock that have not vested (#) | Market value of shares or units of stock that have not vested (\$) | Equity incentive awards: Number of shares, units or other rights that have not vested (#) | Equity incentive awards: Market or payout value of unearned shares, units or other rights that have not vested (\$) |
| Thomas H. Tulip | | | | | | | | | |
| | 166,667 | 333,333 | | \$ 0.35 | 10/05/2025 | - | - | - | - |
| Tamara Rhein | | | | | | | | | |
| | 10,500 | | | \$ 1.05 | 12/05/2021 | - | - | - | - |
| | 40,000 | 40,000 | | \$ 0.83 | 06/25/2022 | - | - | - | - |
| | 100,000 | | | \$ 0.83 | 01/02/2023 | - | - | - | - |
| | 25,000 | 25,000 | | \$ 0.51 | 02/13/2024 | - | - | - | - |

Employment Agreements with Executive Officers

Thomas H. Tulip, Ph.D.:

On October 5, 2015, we entered into a three-year employment agreement with Dr. Tulip to join the Company as president. The employment agreement provides for a base salary of \$320,000, which amount shall increase to \$375,000 per year upon the completion of a bona fide firm commitment underwritten public offering in which we raise gross proceeds of at least \$12,000,000. Dr. Tulip is entitled to an annual bonus in such amount and based upon such criteria as the Board of Directors or Compensation Committee shall determine. For the calendar year ending December 31, 2016, the maximum bonus payable to Dr. Tulip will be \$125,000, which bonus will be primarily based upon successfully achieving the financial business and clinical milestones as set forth in the agreement. In addition, Dr. Tulip is eligible for grants of awards under the Company's 2011 Equity Incentive Plan as the Board of Directors or Compensation Committee may from time to time determine. Dr. Tulip shall initially be granted 500,000 stock options pursuant to the terms of the 2011 Equity Incentive Plan, which options shall vest equally over three years upon each anniversary of his employment.

Upon termination of Dr. Tulip's employment without Cause (as defined in the agreement) or his resignation for Good Reason (as defined in the agreement) prior to expiration of his employment period, he shall be entitled to receive \$550,000 payable in either 12 equal monthly installment payments or in a single lump sum, at the Company's discretion, together with the value of any accrued but unused vacation time, the amount of all accrued but previously unpaid base salary through the date of such termination, and reimbursement of any expenses incurred. In addition, the Company shall provide him with all benefits to which he is entitled for 18 months or the full unexpired term of the agreement, whichever is longer, unless Dr. Tulip's employment is terminated for Cause. Additionally, in the event the Company complete a Sales Transaction (as defined in the agreement), Dr. Tulip shall be entitled to a bonus as set forth in the agreement and 100% of Dr. Tulip's then outstanding options will vest immediately. This agreement contains standard non-competition, non-solicitation, and confidentiality clauses.

Tamara Rhein:

We are party to an employment agreement with Ms. Rhein pursuant to which Ms. Rhein serves as our chief financial officer. The agreement is for an initial one year term that shall automatically renew for successive one year increments unless otherwise terminated. Under the agreement, Ms. Rhein will receive a base salary at an annual rate of \$130,000, and is entitled to an annual bonus as determined by our Board or compensation committee. Ms. Rhein is also eligible for grants of awards under our 2011 Incentive Plan as the compensation committee may determine from time to time. Upon termination of Ms. Rhein's employment prior to expiration of her employment period without cause Ms. Rhein shall be entitled to receive (i) all unpaid but due base salary, unpaid bonus and unused vacation days, (ii) benefits received immediately prior to termination for an additional period of six months following termination, (iii) reimbursement of expenses, and (iv) base salary immediately prior to termination for an additional period of six months following termination. In the event that her employment is terminated within 30 days prior to, or is terminated or she resigns for Good Reason (as defined in the agreement) within 12 months following a Change of Control (as defined in the agreement), she will be entitled to her base salary and benefits for a period of 12 months following such termination or resignation. The employment agreement contains standard non-competition, non-solicitation, and confidentiality clauses.

Director Compensation

The following table sets forth certain information concerning compensation paid or accrued to our non-executive directors during the year ended December 31, 2016.

| Name | Fees Earned or Paid in Cash (\$) | Stock Awards (\$) | Option Awards (\$) | Non- Equity Incentive Plan Compensation (\$) | Change in Pension Value and Nonqualified Deferred Compensation Earnings | All Other Compensation (\$) | Total (\$) |
|---------------------------------|---|-------------------------|--------------------------|---|---|-----------------------------------|------------|
| | | | | | | | |
| Walter Witoshkin | \$ - | - | \$ 3,480 | - | - | \$ 80,000 | \$ 83,480 |
| Lawrence Atinsky ⁽¹⁾ | \$ - | - | \$ 3,480 | - | - | \$ - | \$ 3,480 |
| W. Austin Lewis, IV | \$ - | - | \$ 534 | - | - | \$ - | \$ 534 |
| Peter Conti ⁽²⁾ | \$ - | - | \$ 3,480 | - | - | \$ - | 3,480 |

(1) Mr. Lawrence Atinsky resigned as a director in February 2017

(2) Mr. Peter Conti resigned as a director in January 2017

Equity Incentive Plan

On February 14, 2011, our Board and stockholders adopted the 2011 Equity Incentive Plan (the “Plan”). Under the Plan, awards may take the form of options intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code of 1986 (the “Code”), non-statutory options or restricted stock. The purpose of the Plan is to attract and retain the best available personnel in order to promote the success of our business and to encourage the sense of proprietorship and to stimulate the active interest of such persons in our development and financial success.

The Plan initially reserved 6,475,750 shares of common stock for issuance, of which a maximum of 161,250 could be issued as restricted stock. The 2011 Plan provides that on January 1 of each year, commencing on January 1, 2013, the aggregate number of shares available for issuance under the Plan shall be automatically increased so that the number of shares then available for issuance under the Plan will equal the greater of (i) the aggregate number of shares subject to the Plan as of the preceding December 31 and (ii) seven percent (7%) of our total outstanding shares. There are currently 3,577,661 shares reserved for issuance under the Plan. As of December 31, 2016, there were outstanding under the Plan options to purchase 2,736,839 shares and 161,250 shares of restricted stock.

Administration

The Plan is administered by our Board or a committee designated by our Board. With respect to grants of awards to our officers or directors, the Plan is administered by our Board or a committee in a manner that permits such grants to be exempt from Section 16(b) of the Exchange Act. Grants of awards to covered employees as defined under Section 162(m) of the Code, will be made only by a committee comprised solely of two or more directors eligible to serve on a committee making awards. The Board or the committee has the full authority to select recipients of the grants, determine the terms and conditions of any awards, interpret the Plan, and to take any other action deemed appropriate, consistent with the terms of the Plan.

Eligibility

Under the Plan, awards may be granted to employees, officers and directors of, and consultants and advisors to, our company and any subsidiary.

Terms of Options

The term of each option granted under the Plan shall be contained in a stock option agreement with the optionee and such terms shall be determined by the administrator consistent with the provisions of the Plan, including the following:

Purchase Price. The purchase price of the common stock subject to each incentive stock option shall not be less than the fair market value (as set forth in the Plan), or in the case of the grant of an incentive stock option to a principal stockholder, not less than 110% of fair market value of such common stock at the time such option is granted.

Vesting. The dates on which each option (or portion thereof) shall be exercisable and the conditions precedent to such exercise, if any, shall be fixed by the administrator, in its discretion, at the time such option is granted. Unless otherwise provided in the grant agreement, in the event of a change of control (as set forth in the Plan) the administrator may, in its sole discretion, accelerate the vesting of outstanding options, in whole or in part.

Expiration. Any option granted to an employee shall become exercisable over a period of no longer than five years. No option shall in any event be exercisable after 10 years from, and no incentive stock option granted to a 10% stockholder shall become exercisable after the expiration of five years from, the date of the option.

Transferability. Options are not transferable and may be exercised solely by the optionee during his or her lifetime or, following death, by the person entitled by will or the laws of descent and distribution; provided, however, that the administrator may, in its sole discretion, permit limited transfers of non-statutory options.

Terms of Restricted Stock

A stock award consists of the transfer by us to a participant of shares of common stock. The consideration for the shares to be issued shall be determined by the administrator. Shares of restricted stock are forfeitable until the terms of grant are satisfied and are not transferable until all restrictions have lapsed. Unless otherwise provided by the administrator, any distributions in respect of a restricted stock award will be subject to the same restrictions as the award.

Termination, Modification and Amendment

The Board may, in so far as permitted by law, from time to time, suspend or terminate the Plan or revise or amend it in any respect whatsoever, except that without the approval of our stockholders, no such revision or amendment shall (i) materially increase the number of shares subject to the Plan, (ii) decrease the price at which grants may be granted, (iii) materially increase the benefits to participants, (iv) materially modify the eligibility requirements for participation in the Plan, (v) effect a repricing, including through cancellations and regrants of awards, or (v) alter or impair the rights and obligations under any outstanding award without the written consent of the participant thereunder.

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

The following tables set forth certain information as of March 15, 2017 regarding the beneficial ownership of our common stock, by (i) each person or entity who, to our knowledge, owns more than 5% of our common stock; (ii) our executive officers; (iii) each director; and (iv) all of our executive officers and directors as a group. Unless otherwise indicated in the footnotes to the following table, each person named in the table has sole voting and investment power and that person's address is c/o FluoroPharma Medical, Inc., 8 Hillside Avenue, Suite 108, Montclair, N.J. 07042. Shares of common stock subject to options, warrants, or other rights currently exercisable or exercisable within 60 days of March 15, 2017, are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the stockholder holding such options, warrants or other rights, but are not deemed outstanding for computing the percentage of any other stockholder.

| Name and Address of Beneficial Owner ⁽¹⁾ | Number of Shares Beneficially Owned | Percentage Beneficially Owned ⁽²⁾ |
|---|--|--|
| Thomas H. Tulip ⁽³⁾ | 166,667 | 0.5% |
| Tamara Rhein ⁽⁴⁾ | 219,202 | 0.6% |
| Johan (Thijs) Spoor ⁽⁵⁾ | 288,925 | 0.8% |
| Walter Witoshkin ⁽⁶⁾ | 230,845 | 0.7% |
| Peter S. Conti ⁽⁷⁾ | 514,083 | 1.5% |
| Lawrence Atinsky ⁽⁸⁾ | 307,587 | 0.9% |
| W. Austin Lewis, IV ⁽⁹⁾ | 10,871,693 | 31.7% |
| Platinum Long Term Growth VII LLC ⁽¹⁰⁾ | 1,815,193 | 5.3% |
| All executive officers and directors as a group (7 persons) | 12,599,002 | 36.8% |

- (1) Unless otherwise indicated in the footnotes to the following table, each person named in the table has sole voting and investment power and that person's address is c/o FluoroPharma Medical, Inc., 8 Hillside Avenue, Suite 108, Montclair, N.J. 07042.
- (2) Based upon 34,262,264 shares of our common stock issued and outstanding.
- (3) Represents 166,667 shares of common stock issuable upon exercise of options at \$0.35 per share. Does not include 333,333 shares of common stock issuable upon exercise of options at \$0.35 per share which are held by Dr. Tulip but not currently exercisable nor exercisable within 60 days of March 15, 2017.
- (4) Includes 10,000 shares of common stock, 22,991 shares of common stock issuable upon conversion of Series B Preferred Stock, 10,711 shares of common stock underlying warrants, 10,500 shares of common stock issuable upon exercise of options at \$1.05 per share, 140,000 shares of common stock issuable upon exercise of options at \$0.83 per share and 25,000 shares of common stock issuable upon exercise of options at \$0.51. Does not include 40,000 shares of common stock issuable upon exercise of options at \$0.83 per share and 25,000 shares of common stock issuable upon exercise of options at \$0.51 per share which are held by Ms. Rhein but not currently exercisable nor exercisable within 60 days of March 15, 2017.
- (5) Includes 200,398 shares of common stock, 53,571 shares of common stock issuable upon conversion of Series B Preferred Stock, and 34,956 shares of common stock underlying warrants.
- (6) Does not include 161,250 restricted shares that vest upon the earlier of (i) the occurrence of a Change of Control, as defined in the 2011 Equity Incentive Plan; (ii) the successful completion of a Phase II clinical trial for any of the Company's products; or (ii) the determination by the Board to provide for immediate vesting. Does include 37,500 shares of common stock issuable upon exercise of options at \$0.95 per share, 17,857 shares of common stock issuable upon exercise of options at \$1.40 per share, 125,488 shares of common stock issuable upon exercise of options at \$0.83 per share, 25,000 shares of common stock issuable upon exercise of options at \$0.53 per share and 25,000 shares of common stock issuable upon exercise of options at \$0.35 per share.

- (7) Includes 35,738 shares of common stock, 285,000 shares of common stock issuable upon exercise of options at \$0.16 per share, 17,857 shares of common stock issuable upon exercise of options at \$1.40 per share, 125,488 shares of common stock issuable upon exercise of options at \$0.83 per share, 25,000 shares of common stock issuable upon exercise of options at \$0.53 per share and 25,000 shares of common stock issuable upon exercise of options at \$0.35 per share.
- (8) Includes 53,571 shares of common stock issuable upon conversion of Series B Preferred Stock, 24,956 shares of common stock underlying warrants, 125,488 shares of common stock issuable upon exercise of options at \$0.83 per share, 25,000 shares of common stock issuable upon exercise of options at \$0.53 per share, 25,000 shares of common stock issuable upon exercise of options at \$0.35 per share and 53,571 shares of common stock issuable upon conversion of outstanding convertible notes. Does not include any shares of common stock issued or issuable as accrued interest pursuant to the convertible notes.
- (9) Includes 100,000 shares of common stock, 3,836 shares of common stock issuable upon exercise of options at \$0.35 per share and 178,571 shares of common stock issuable upon conversion of outstanding convertible notes. Also includes, 7,732,143 shares of common stock issuable upon conversion of the convertible notes at \$0.28 per share and 2,857,143 shares of common stock issuable upon exercise of the warrants at \$0.50 per share held by Lewis Opportunity Fund. Does not include any shares of common stock issued or issuable as accrued interest pursuant to the convertible notes. W. Austin Lewis, IV is an affiliate of Lewis Opportunity Fund and has voting and dispositive power with respect to such shares.
- (10) Includes 1,815,193 shares of common stock. The number of shares beneficially owned by Platinum Long Term Growth VII LLC does not include 4,523,076 shares of common stock underlying 4,523,076 shares of Series B Preferred Stock and 6,020,214 shares of common stock underlying warrants, exercisable at \$0.28 per share, beneficially owned by Platinum-Montaur Life Sciences, LLC. The terms of such Series B Preferred Stock and warrants provide that the holder may not convert or exercise such securities to the extent such conversion or exercise could result in the holder beneficially owning more than 4.99% of our outstanding common stock, unless waived by the holder on at least 61 days' notice and subject to the terms of such securities. Assuming such blocker provisions were waived and the full conversion and exercise of the Series B Preferred Stock and warrants held by Platinum-Montaur Life Sciences, LLC, such holder would beneficially own, together with Platinum Long Term Growth Fund VII LLC, approximately 47% of our issued and outstanding common stock. Michael Goldberg has the voting and dispositive power over the securities held for the account of this beneficial owner. The address of Platinum Long Term Growth VII LLC is 152 West 57th Street, 4th Floor, New York, NY 10019.

The information regarding the Company's "Equity Compensation Plan Information" is incorporated herein by reference in Part II, Item 5 of this Annual Report on Form 10-K.

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

Lewis Opportunity Fund, an affiliate of W. Austin Lewis, IV, a member of our Board, participated as an investor in the private placement of convertible notes in 2015 and was issued 12% convertible notes in an aggregate principal amount of \$2,000,000 and warrants to purchase an aggregate of 2,857,143 shares of common stock. In addition, W. Austin Lewis Defined Benefit Plan participated in the private placement of convertible notes in 2016 and was issued 12% convertible notes in the aggregate principal amount of \$160,000.

Director independence

Walter Witoshkin and Austin Lewis are independent directors, as the term "independent" is defined by the rules of the NASDAQ Stock Market.

Item 14. Principal Accounting Fees and Services

The following table sets forth fees billed to us by our independent auditors for the years ended 2016 and 2015 for (i) services rendered for the audit of our annual financial statements and the review of our quarterly financial statements, (ii) services rendered that are reasonably related to the performance of the audit or review of our financial statements that are not reported as Audit Fees, and (iii) services rendered in connection with tax preparation, compliance, advice and assistance.

| SERVICES | 2016 | 2015 |
|--------------------|------------------|------------------|
| Audit fees | \$ 81,000 | \$ 75,500 |
| Audit-related fees | 12,000 | 14,000 |
| Tax fees | - | - |
| All other fees | - | - |
| Total fees | \$ 93,000 | \$ 89,500 |

Our audit committee is responsible for the pre-approval of all audit and permissible non-audit services provided by our principal accountants on a case-by-case basis. Our audit committee has established a policy regarding approval of all audit and permissible non-audit services provided by our principal accountants. Our audit committee pre-approves these services by category and service. Our audit committee has pre-approved all of the services provided by our principal accountants.

Item 15. Exhibits, Financial Statement Schedules

Exhibit No. Description

| | |
|------|---|
| 2.1 | Agreement and Plan of Merger, dated as of May 16, 2011, by and among FluoroPharma Medical, Inc., FPI Merger Corporation and FluoroPharma, Inc. (Incorporated by reference to the Company's Current Report on Form 8-K/A filed with the Securities and Exchange Commission on July 12, 2011). |
| 2.2 | Certificate of Merger, dated May 16, 2011 merging FPI Merger Corporation with and into FluoroPharma, Inc. (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 16, 2011). |
| 3.1 | Articles of Incorporation (Incorporated by reference to the Company's Registration Statement on Form SB-2 filed on November 7, 2007). |
| 3.2 | Bylaws (Incorporated by reference to the Company's Registration Statement on Form SB-2 filed on November 7, 2007). |
| 3.3 | Certificate of Designation of the Relative Rights and Preferences of the Series A Preferred Stock, filed with the Secretary of State of Nevada on May 13, 2011 (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 16, 2011). |
| 3.4 | Certificate of Designation of the Relative Rights and Preferences of the Series B Preferred Stock, filed with the Secretary of State of Nevada on September 18, 2013 (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 19, 2013). |
| 3.5 | Certificate of Amendment to Articles of Incorporation (incorporated by reference to the Company's Current Report on Form 10-K filed with the Securities and Exchange Commission on August 18, 2016). |
| 4.1 | Form of 2012 Warrant (Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on November 21, 2012). |
| 4.2 | Form of 2011 Warrant (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 16, 2011). |
| 4.3 | Form of Warrant (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 19, 2013). |
| 4.4 | Form of Warrant (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 7, 2014). |
| 4.5 | Form of 2014 Promissory Note (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 25, 2014). |
| 4.6 | Form of Amendments to 2014 Promissory Note (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 22, 2016). |
| 4.7 | Form of 2015 Convertible Note (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 3, 2015). |
| 4.8 | Form of 2015 Warrant (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 3, 2015). |
| 4.9 | Form of Amendment to 2015 Promissory Note (incorporated by reference to the Company's Report on Form 8-K filed with the Securities and Exchange Commission on May 31, 2013). |
| 4.10 | Form of 2016 Convertible Note (incorporated by reference to the Company's Report Fom 8-K filed with the Securities and Exchange Commission on March 23, 2016). |
| 10.1 | Exclusive License Agreement with Massachusetts General Hospital dated as of April 27, 2009, as amended.** + |
| 10.2 | Securities Purchase Agreement dated November 19, 2012 (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 21, 2012). |
| 10.3 | Registration Rights Agreement dated November 19, 2012 (Incorporated by reference to the Company's Current Report on |

Form 8-K filed with the Securities and Exchange Commission on November 21, 2012).

- 10.4 Form of 2011 Subscription Agreement - Lead Investor (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 16, 2011).
- 10.5 Form of 2011 Registration Rights Agreement (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 16, 2011).
- 10.6 Form of Securities Purchase Agreement dated September 18, 2013 (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 19, 2013).
- 10.7 Form of Registration Rights Agreement dated September 18, 2013 (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 19, 2013).
- 10.8 Form of Securities Purchase Agreement dated December 31, 2013 (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 7, 2014).

| | |
|----------|--|
| 10.9 | Form of Registration Rights Agreement dated December 31, 2013 (Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on January 7, 2014). |
| 10.10 | FluoroPharma Medical, Inc. 2011 Incentive Plan (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 16, 2011). |
| 10.11 | Lease Agreement between Hillside Square, LLC and FluoroPharma Medical, Inc. dated as of September 8, 2011 (Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 14, 2011). |
| 10.12 | Second Amendment to Lease Agreement between Hillside Square, LLC and FluoroPharma Medical, Inc. dated as of February 2015 (Incorporated by reference to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2015). |
| 10.13 | Employment Agreement dated August 22, 2012 between the Company and Tamara Rhein (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 22, 2012). |
| 10.14 | Amendment to Employment Agreement dated October 5, 2015 between the Company and Tamara Rhein (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 8, 2015). |
| 10.15 | Employment Agreement dated October 5, 2015 between the Company and Thomas H. Tulip (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 8, 2015). |
| 10.16 | Note Purchase Agreement dated July 22, 2014 (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 25, 2014). |
| 10.17 | Note and Warrant Purchase Agreement dated May 28, 2015 (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 3, 2015). |
| 10.18 | Note Purchase Agreement dated March 23, 2016 (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 23, 2016). |
| 10.19 | License Agreement dated as of June 3, 2016 between the Company and Sinatau USA, Inc. (CardioPet license) (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 9, 2016). |
| 10.20 | License Agreement dated as of June 3, 2016 between the Company and Sinatau USA, Inc. (BFPet license), (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 9, 2016). |
| 14.1 | Code of Ethics adopted by the Board of Directors (Incorporated by reference to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2012). |
| 21 | List of Subsidiaries (Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 16, 2011). |
| 23.1* | Consent of Wolf & Company, P.C. |
| 31.1* | Certification of Chief Executive Officer pursuant to Rule 13a-14 of the Securities Exchange Act of 1934. |
| 31.2* | Certification of Chief Financial Officer pursuant to Rule 13a-14 of the Securities Exchange Act of 1934. |
| 32.1* | Certification of Chief Executive Officer pursuant to Section 1350. |
| 32.2* | Certification of Chief Financial Officer pursuant to Section 1350. |
| 101.INS* | XBRL Instance Document. |
| 101.SCH* | XBRL Schema Document. |
| 101.CAL* | XBRL Calculation Linkbase Document. |
| 101.LAB* | XBRL Label Linkbase Document. |
| 101.PRE* | XBRL Presentation Linkbase Document. |
| 101.DEF* | XBRL Definition Linkbase Document. |

+ Confidential treatment has been granted with respect to portions of this exhibit.

++ The XBRL-related information in Exhibit 101 to this Registration Statement on Form S-1 shall not be deemed "filed" or a part of this registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, and is not filed for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of those sections.^[1]_[SEP]

Item 16. Form 10-K Summary

No Disclosure.

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.

FluoroPharma Medical, Inc.

March 31, 2017

By: /s/ Thomas H. Tulip
Thomas H. Tulip, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

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

/s/ Thomas H. Tulip March 31, 2017
Thomas H. Tulip, Ph.D.
President, Chief Executive Officer & Director
(Principal Executive Officer)

/s/ Tamara Rhein March 31, 2017
Tamara Rhein
Chief Financial and Accounting Officer
(Principal Accounting Officer)

/s/ Walter Witoshkin March 31, 2017
Walter Witoshkin
Director

/s/ W. Austin Lewis March 31, 2017
W. Austin Lewis
Director

FluoroPharma Medical, Inc.

Index to Financial Statements

| | <u>Page Number</u> |
|---|--------------------|
| Report of Independent Registered Public Accounting Firm | F-2 |
| Consolidated Balance Sheets at December 31, 2016 and 2015 | F-3 |
| Consolidated Statements of Operations for the years ended December 31, 2016 and 2015 | F-4 |
| Consolidated Statements of Stockholders' Deficit for the years ended December 31, 2016 and 2015 | F-5 |
| Consolidated Statements of Cash Flows for the years ended December 31, 2016 and 2015 | F-6 |
| Notes to Consolidated Financial Statements | F-7 |

Report of Independent Registered Public Accounting Firm

To the Board of Directors of FluoroPharma Medical, Inc. and Subsidiary

We have audited the accompanying consolidated balance sheets of FluoroPharma Medical, Inc. and Subsidiary as of December 31, 2016 and 2015 and the related consolidated statements of operations, stockholders' deficit, and cash flows for the years then ended. 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 audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated 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 audits 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 consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of FluoroPharma Medical, Inc. and Subsidiary as of December 31, 2016 and 2015, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations, has a significant accumulated deficit and, at December 31, 2016, the Company did not have sufficient capital to fund its operations. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regards to these matters are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Wolf & Company, P.C.

Boston, Massachusetts

March 31, 2017

FLUOROPHARMA MEDICAL, INC. and Subsidiary
CONSOLIDATED BALANCE SHEETS

| | <u>December 31,</u> <u>2016</u> | <u>December 31,</u> <u>2015</u> |
|--|------------------------------------|------------------------------------|
| ASSETS | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 24,723 | \$ 290,847 |
| Prepaid expenses and other | 23,060 | 218,155 |
| Total Current Assets | <u>47,783</u> | <u>509,002</u> |
| Property and equipment, net | 7,424 | 11,049 |
| Intangible assets, net | 279,553 | 318,547 |
| Total Assets | <u>\$ 334,760</u> | <u>\$ 838,598</u> |
| LIABILITIES AND STOCKHOLDERS' DEFICIT | | |
| Current Liabilities: | | |
| Convertible notes payable - short term, net (see Note 5) | \$ 5,769,558 | \$ 4,349,449 |
| Notes payable - short term | 55,000 | - |
| Accounts payable | 1,413,874 | 1,219,867 |
| Derivative liabilities | 251,806 | 1,526,060 |
| Deferred revenue | 408,333 | - |
| Accrued expenses and other | 2,615,481 | 1,603,605 |
| Total Current Liabilities | <u>10,514,052</u> | <u>8,698,981</u> |
| Commitments & Contingencies | | |
| Stockholders' Deficit: | | |
| Preferred stock Series A; \$0.001 par value, 3,500,000 shares designated 9,370 and 150,611 shares issued and outstanding at December 31, 2016 and 2015, respectively (preference in liquidation of \$7,777 at December 31, 2016) | 11 | 152 |
| Preferred stock Series B; \$0.001 par value, 12,000,000 shares designated 5,382,071 shares issued and outstanding at December 31, 2016 and 2015 (preference in liquidation of \$5,860,248 at December 31, 2016) | 5,382 | 5,382 |
| Common stock - Class A - \$0.001 par value, 200,000,000 shares authorized, 34,074,284 and 32,908,503 shares issued and outstanding at December 31, 2016 and 2015, respectively | 34,075 | 32,910 |
| Additional paid-in capital | 24,958,880 | 24,705,547 |
| Accumulated deficit | (35,177,640) | (32,604,374) |
| Total Stockholders' Deficit | <u>(10,179,292)</u> | <u>(7,860,383)</u> |
| Total Liabilities and Stockholders' Deficit | <u>\$ 334,760</u> | <u>\$ 838,598</u> |

See the report of independent registered public accounting firm and the accompanying notes to these consolidated financial statements

**FLUOROPHARMA MEDICAL, INC. and Subsidiary
CONSOLIDATED STATEMENTS OF OPERATIONS**

| | For the Years Ended December 31, | |
|---|---|-----------------------|
| | 2016 | 2015 |
| Operating Expenses: | | |
| General and administrative | \$ 1,691,048 | \$ 2,465,478 |
| Research and development | 511,381 | 720,861 |
| Total Operating Expenses | <u>2,202,429</u> | <u>3,186,339</u> |
| Loss from Operations | <u>(2,202,429)</u> | <u>(3,186,339)</u> |
| Other Income (Expense): | | |
| Other income | 2,485 | - |
| Loss on debt extinguishment | (995,735) | - |
| Gain on settlement of accounts payable | 107,451 | 184,039 |
| Loss on sale of trading securities | - | (11,946) |
| Unrealized gain on trading securities | - | 7,986 |
| Gain on revaluation of derivative liabilities | 2,300,341 | 715,962 |
| Interest and other expense | (1,261,974) | (873,359) |
| Total Other Income, net | <u>152,568</u> | <u>22,682</u> |
| Net Loss | \$ (2,049,861) | \$ (3,163,657) |
| Preferred Stock Dividends | <u>(523,405)</u> | <u>(574,034)</u> |
| Net Loss Attributable to Common Stockholders | <u>\$ (2,573,266)</u> | <u>\$ (3,737,691)</u> |
| Net Loss per Common Share - Basic and Diluted | <u>\$ (0.08)</u> | <u>\$ (0.12)</u> |
| Weighted Average Shares Used in per Share Calculation - Basic and Diluted: | <u>33,556,201</u> | <u>30,038,240</u> |

See the report of independent registered public accounting firm and the accompanying notes to these consolidated financial statements

FLUOROPHARMA MEDICAL, INC. and Subsidiary
CONSOLIDATED STATEMENTS OF STOCKHOLDERS'
DEFICIT

| | Preferred Stock - Series A | | Preferred Stock - Series B | | Common Stock | | Additional | | Total Stockholders' |
|---|----------------------------|---------------|----------------------------|-----------------|-------------------|------------------|---------------------|---------------------|----------------------|
| | Number of shares | Amount | Number of shares | Amount | Number of shares | Amount | Paid-In Capital | Accumulated Deficit | Equity (Deficit) |
| BALANCE, December 31, 2014 | <u>949,477</u> | <u>\$ 951</u> | <u>5,694,571</u> | <u>\$ 5,695</u> | <u>29,197,497</u> | <u>\$ 29,199</u> | <u>\$24,034,203</u> | <u>\$28,866,683</u> | <u>\$(4,796,635)</u> |
| Share Based Compensation | | | | | | | 135,492 | | 135,492 |
| Fair value of warrants issued | | | | | | | 80,472 | | 80,472 |
| Common stock issued in settlement of accounts payable | | | | | 738,572 | 739 | 276,511 | | 277,250 |
| Common stock issued for consulting services | | | | | 128,571 | 129 | 59,871 | | 60,000 |
| Preferred Stock Dividend - Series A | 57,353 | 57 | | | 45,987 | 46 | 64,532 | (64,635) | - |
| Common Stock issued for cash, net of offering costs of \$31,445 | | | | | | | | | - |
| Conversion of Series A Preferred to Common Stock | (856,219) | (856) | | | 1,923,324 | 1,923 | (1,067) | | - |
| Conversion of Series B Preferred to Common Stock | | | (312,500) | (313) | 714,285 | 714 | (401) | | - |
| Preferred Stock Dividend Accrued - Series B | | | | | | | | (509,399) | (509,399) |
| Warrant modification and reclassification to derivative liability | | | | | | | | | - |
| Common Stock issued in lieu of accumulated dividend on Series B | | | | | 160,267 | 160 | 55,934 | | 56,094 |
| Exercise of Warrants | | | | | | | | | - |
| Net loss | | | | | | | | (3,163,657) | (3,163,657) |
| BALANCE, December 31, 2015 | <u>150,611</u> | <u>\$ 152</u> | <u>5,382,071</u> | <u>\$ 5,382</u> | <u>32,908,503</u> | <u>\$ 32,910</u> | <u>\$24,705,547</u> | <u>\$32,604,374</u> | <u>\$(7,860,383)</u> |
| Share Based Compensation | | | | | | | 32,451 | | 32,451 |
| Fair value of warrants issued | | | | | | | 22,576 | | 22,576 |
| Common stock issued in settlement of accounts payable | | | | | 61,159 | 61 | 21,345 | | 21,406 |
| Preferred Stock Dividend - Series A | 9,370 | 10 | | | 10,432 | 10 | 10,688 | (10,708) | - |
| Conversion of Series A Preferred to Common Stock | (150,611) | (151) | | | 440,202 | 440 | (289) | | - |

| | | | | | | | | | |
|---|--------------|--------------|------------------|-----------------|-------------------|------------------|---------------------|---------------------|---------------------|
| Preferred Stock | | | | | | | | (512,697) | (512,697) |
| Dividend Accrued - Series B | | | | | | | | | |
| Conversion of Convertible Notes Payable to Common Stock | | | | | 653,988 | 654 | 166,562 | | 167,216 |
| Net loss | | | | | | | | (2,049,861) | (2,049,861) |
| BALANCE, December 31, 2016 | <u>9,370</u> | <u>\$ 11</u> | <u>5,382,071</u> | <u>\$ 5,382</u> | <u>34,074,284</u> | <u>\$ 34,075</u> | <u>\$24,958,880</u> | <u>\$35,177,640</u> | <u>\$10,179,292</u> |

See the report of independent registered public accounting firm and the accompanying notes to these consolidated financial statements

FLUOROPHARMA MEDICAL, INC. and Subsidiary
CONSOLIDATED STATEMENTS OF CASH FLOWS

| | For the Years Ended | |
|--|----------------------------|--------------------|
| | December 31, | |
| | 2016 | 2015 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | \$ (2,049,861) | \$ (3,163,657) |
| Adjustments to reconcile net loss to net cash used by operating activities | | |
| Depreciation and amortization | 43,912 | 46,365 |
| Amortization of issuance costs and discounts on convertible notes | 751,684 | 511,362 |
| Accretion of interests related to convertible notes | 199,515 | - |
| Share-based compensation related to stock options | 32,451 | 135,492 |
| Fair value of warrants | 22,576 | 80,472 |
| Fair value of stock issued for consulting | - | 30,000 |
| Gain on accounts payable settlement | (107,451) | (184,039) |
| Loss on debt extinguishment | 995,735 | - |
| Net loss on sale of trading securities | - | 11,946 |
| Change in unrealized loss on trading securities | - | (7,986) |
| Gain on revaluation of derivative liabilities | (2,300,341) | (715,962) |
| (Increase) decrease in: | | |
| Prepaid expenses and other | 77,878 | (113,247) |
| Increase (decrease) in: | | |
| Accounts payable | 322,864 | 616,676 |
| Deferred revenue | 408,333 | - |
| Accrued expenses and other | 722,584 | 75,689 |
| Net Cash Used by Operating Activities | <u>(880,121)</u> | <u>(2,676,889)</u> |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Proceeds from sale of investments | - | 35,970 |
| Purchase of equipment | (1,293) | (6,694) |
| Net Cash Provided (Used) by Investing Activities | <u>(1,293)</u> | <u>29,276</u> |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from other short - term financing | 155,000 | 365,000 |
| Proceeds from issuance of convertible notes payable – short term | 570,000 | 2,980,005 |
| Notes payable issuance costs | (9,710) | (168,690) |
| Repayment of notes payable | (100,000) | (490,000) |
| Net Cash Provided by Financing Activities | <u>615,290</u> | <u>2,686,315</u> |
| Net change in Cash and Cash Equivalents | (266,124) | 38,702 |
| Cash and Cash Equivalents, Beginning of Period | 290,847 | 252,145 |
| Cash and Cash Equivalents, End of Period | <u>\$ 24,723</u> | <u>\$ 290,847</u> |
| Supplemental Cash Flow Disclosures: | | |
| Interest expense paid in cash | \$ 472 | \$ 3,543 |
| Tax paid | \$ 1,662 | \$ 1,912 |
| Supplemental Non-Cash Disclosure: | | |
| Series B Preferred Stock dividends | \$ 512,697 | \$ 453,305 |
| Series A Preferred Stock dividends | \$ 7,777 | \$ 47,602 |
| Accounts payable settled in Common Stock | \$ 21,406 | \$ 277,250 |
| Series A Preferred Stock dividend issued upon conversion to Common Stock | \$ 2,931 | \$ 17,033 |
| Prepaid consulting settled in Common Stock | \$ - | \$ 30,000 |

| | | |
|---|------------|------------|
| Conversion of Series A Preferred Stock to Common Stock | \$ 440 | \$ 1,923 |
| Conversion of Series B Preferred Stock dividend to Common Stock | \$ - | \$ 56,094 |
| Conversion of Series B preferred shares to Common Stock | \$ - | \$ 313 |
| Conversion of Convertible Notes plus accreted interests | \$ 178,731 | \$ - |
| Fair value of warrants issued as covenant settlement | \$ - | \$ 80,472 |
| Fair value of warrants issued with Convertible Notes | \$ - | \$ 358,255 |
| Fair value of warrants issued to Convertible Notes placement agents | \$ - | \$ 39,108 |
| Fair value of embedded derivative liability in 2016 Convertible Notes | \$ 95,407 | \$ - |
| Fair value of embedded derivative liability in 2015 Convertible Notes | \$ - | \$ 490,340 |
| Fair value of embedded derivative liability in 2014 Convertible Notes | \$ 945,951 | \$ - |
| Embedded conversion feature -Amended 2014 Notes Converted | \$ 15,271 | \$ - |

See the report of independent registered public accounting firm and the accompanying notes to these consolidated financial statements

FLUOROPHARMA MEDICAL, INC. and Subsidiary
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION AND GOING CONCERN

FluoroPharma Medical, Inc. (the “Company”) was organized on January 25, 2007 under the laws of the State of Nevada. The Company’s subsidiary, FluoroPharma Inc. (“FPI” or “the Subsidiary”), a Delaware corporation, is a molecular imaging company headquartered in Montclair, NJ. FPI was founded in 2003 to engage in the discovery, development and commercialization of proprietary products for the positron emission tomography (PET) market. The Company’s initial focus has been on the development of novel cardiovascular imaging agents that can more efficiently and effectively detect and assess acute and chronic forms of coronary artery disease (CAD). Molecular imaging pharmaceuticals are radiopharmaceuticals that enable early detection of disease through the visualization of subtle changes in biochemical and biological processes.

Going concern

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has experienced net losses and negative cash flows from operations since its inception. The Company has sustained cumulative losses attributable to common stockholders of \$35,217,640 as of December 31, 2016. The Company has historically financed its operations through issuances of equity and the proceeds of debt instruments. In the past, the Company has also provided for its cash needs by issuing common stock, options and warrants for certain operating costs, including consulting and professional fees. During the year ended December 31, 2016, the Company raised net cash proceeds of \$615,290 through the issuance of notes payable. In addition, during the year ended December 31, 2016, the Company received payments of \$775,000 in accordance with two exclusive license agreements.

The Company continues to actively pursue various funding options, including equity offerings, to obtain additional funds to continue the development of its products and bring them to commercial markets. Management continues to assess fund raising opportunities to ensure minimal dilution to its existing shareholder base and to obtain the best price for its securities. Management is optimistic based upon its ability to raise funds in prior years, through private placement offerings (see Note 5), that it will be able to raise additional funds in the future. If the Company is unable to raise additional capital as may be needed to meet its projections for operating expenses, it could have a material adverse effect on liquidity or require the Company to cease or significantly delay some of its clinical trials. The outcome of these matters cannot be predicted at this time. The Company is uncertain whether it can obtain financing to complete its clinical trials. These uncertainties cast significant doubt upon the Company’s ability to continue as a going concern. These financial statements do not include any adjustments relating to the recoverability of recorded asset amounts that might be necessary as a result of the above uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less from date of purchase to be cash equivalents. All cash balances were highly liquid at December 31, 2016 and 2015.

Use of Estimates

The accompanying consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America, and include certain estimates and assumptions which affect the reported amounts of assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period, including contingencies. Accordingly, actual results may differ from those estimates.

Concentration of Risks

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company primarily maintains its cash balances with financial institutions in federally insured accounts. The Company may from time to time have cash in banks in excess of FDIC insurance limits. The Company has not experienced any losses to date resulting from this practice.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, FluoroPharma, Inc. Intercompany transactions and balances have been eliminated upon consolidation.

Property and Equipment

Property and equipment are stated at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. The Company's property and equipment at December 31, 2016 and 2015 consisted of computer and office equipment and machinery and equipment with estimated useful lives of three to five years. Depreciation was \$4,918 and \$7,372 in the years ended December 31, 2016 and 2015, respectively.

Intangible Assets

The Company's intangible assets consist of technology licenses and are carried at the legal cost to obtain them. Intangible assets are amortized using the straight-line method over the estimated useful life. Useful lives on technology licenses are 5 to 15 years.

Impairments

The Company assesses the impairment of long-lived assets, including other intangible assets, whenever events or changes in circumstances indicate that their carrying value may not be recoverable in accordance with ASC Topic 360-10-35, "Impairment or Disposal of Long-Lived Assets." The determination of related estimated useful lives and whether or not these assets are impaired involves significant judgments, related primarily to the future profitability and/or future value of the assets. The Company records an impairment charge if it believes an investment has experienced a decline in value that is other than temporary.

Management has determined that no impairments were required as of December 31, 2016 and 2015, respectively.

Derivative financial instruments

The Company evaluates all of its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the consolidated statements of operations. For stock-based derivative financial instruments, the Company uses a binomial pricing model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within 12 months of the balance sheet date.

The Company has derivative liabilities at December 31, 2016 and 2015 relating to certain warrants and embedded conversion features that contain anti-dilution provisions.

Fair Value of Financial Instruments

The Company's financial instruments primarily consist of cash, trading securities, accounts payable, notes payable and derivative liabilities. The fair value of these instruments is calculated using current market prices, or on a historical cost basis, which, due to the short maturity of these financial instruments, approximates the fair value at the reporting dates of these financial statements.

The Company groups its assets and liabilities measured at fair value, in three levels based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (an exit price).

Financial instruments with readily available active quoted prices or for which fair value can be measured from actively quoted prices generally will have a higher degree of market price observability and a lesser degree of judgment used in measuring fair value.

The three levels of the fair value hierarchy are as follows:

Level 1 – Valuation is based on quoted prices in active markets for identical assets or liabilities. Valuations are obtained from readily available pricing sources for market transactions involving identical assets or liabilities.

Level 2 – Valuation is based on observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Valuation is based on unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation.

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, an instrument's level within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the financial instrument.

The Company recognizes transfers between levels at the end of the reporting period as if the transfers occurred on the last day of the reporting period.

Assets and liabilities measured at fair value on a recurring basis are summarized below:

| | December 31, 2016 | | | |
|------------------------|--------------------------|----------------|----------------|-------------------|
| | Level 1 | Level 2 | Level 3 | Fair Value |
| Current Liabilities: | | | | |
| Derivative liabilities | \$ - | \$ -- | \$ 251,806 | \$ 251,806 |

| | December 31, 2015 | | | |
|------------------------|--------------------------|----------------|----------------|-------------------|
| | Level 1 | Level 2 | Level 3 | Fair Value |
| Current Liabilities: | | | | |
| Derivative liabilities | \$ - | \$ -- | \$ 1,526,060 | \$ 1,526,060 |

The following table sets forth the changes in the estimated fair value for our Level 3 classified derivative liabilities:

| | Year Ended December 31, 2016 | Year Ended December 31, 2015 |
|--|---|---|
| Fair value at beginning of the year | \$ 1,526,060 | \$ 1,354,319 |
| Issuance of warrants – 2015 Notes | - | 397,363 |
| Embedded conversion feature – 2015 Notes | - | 490,340 |
| Embedded conversion feature – Amended 2014 Notes | 945,951 | - |
| Embedded conversion feature – 2016 Notes | 95,407 | - |
| Embedded conversion feature – Amended 2014 Notes converted | (15,271) | - |
| Change in fair value | (2,300,341) | (715,962) |
| Fair value at end of the year | <u>\$ 251,806</u> | <u>\$ 1,526,060</u> |

Revenue Recognition

From time to time the Company enters into licensing agreements, the terms of which may include grants of licenses, or options to obtain licenses, to our intellectual property and research and development activities. Payments under these arrangements typically include one or more of the following: non-refundable, up-front license fees; funding of research and/or development efforts; amounts due upon the achievement of specified objectives; and/or royalties on future product sales.

The Company recognizes milestone payments as revenue in their entirety upon the achievement of a substantive milestone if the consideration earned from the achievement of the milestone (i) is consistent with performance required to achieve the milestone or the increase in value to the delivered item, (ii) relates solely to past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement. Amounts received contractually designated to fund further research are recorded as a reduction to research and development expenses when the Company has satisfied all performance obligations to the licensee and expenses for specified development activities have been incurred.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to the differences between the financial statement carrying amounts of the existing assets and liabilities and the respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be realized or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in results of operations in the period that the tax rate change occurs. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company accounts for uncertain tax positions in accordance with FASB ASC Topic 740-10, *Accounting for Uncertainty in Income Taxes*. Income tax positions must meet a more-likely-than-not threshold in order to be recognized in the financial statements. There were no recognized uncertain tax positions at December 31, 2016 and 2015. The Company recognizes potential accrued interest and penalties related to unrecognized tax benefits within operations as income tax expense. As new information becomes available, the assessment of the recognition threshold and the measurement of the associated tax benefit of uncertain tax positions may result in financial statement recognition or de-recognition. The Company had no accrual for interest or penalties on its balance sheets at December 31, 2016 or 2015, and has not recognized interest and/or penalties in the statement of operations for the years ended December 31, 2016 and 2015. Further, the Company currently has no open tax years, subject to audit prior to December 31, 2013.

Accounting for Share-Based Payments

The Company follows the provisions of ASC Topic 718, which establishes the accounting for transactions in which an entity exchanges equity securities for services and requires companies to expense the estimated fair value of these awards over the requisite service period. The Company uses the Black-Scholes option pricing model in determining fair value. Accordingly, compensation cost has been recognized using the fair value method and expected term accrual requirements as prescribed, which resulted in stock-based compensation expense for the years ended December 31, 2016 and 2015 of \$32,451 and \$135,492, respectively.

The Company accounts for share-based payments granted to non-employees in accordance with ASC Topic 505, “Equity Based Payments to Non-Employees.” The Company determines the fair value of the stock-based payment as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. If the fair value of the equity instruments issued is used, it is measured using the stock price and other measurement assumptions as of the earlier of either (1) the date at which a commitment for performance by the counterparty to earn the equity instruments is reached, or (2) the date at which the counterparty’s performance is complete.

To compute compensation expense, the Company estimated the fair value of each option award on the date of grant using the Black-Scholes-Merton option pricing model for employees, and calculated the fair value of each option award at the end of the period for non-employees. The Company based the expected volatility assumption on a volatility index of peer companies as the Company did not have sufficient historical market information to estimate the volatility of its own stock. The expected term of options granted represents the period of time that options are expected to be outstanding. The Company estimated the expected term of stock options by using the simplified method. The expected forfeiture rates are based on the historical employee forfeiture experiences. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company’s awards. The Company has not declared a dividend on its common stock since its inception and has no intentions of declaring a dividend in the foreseeable future and therefore used a dividend yield of zero.

The fair value of each share-based payment is estimated on the measurement date using the Black-Scholes model with the following assumptions:

| | <u>2016</u> | <u>2015</u> |
|-------------------------|-------------|-------------|
| Risk-free interest rate | 1.83% | 2.07% |
| Expected volatility | 68.09% | 49.42% |
| Dividend yield | none | none |
| Expected term | 5 years | 6.5 years |

Net Loss per Common Share

The Company computes net loss per common share in accordance with ASC Topic 260. Net loss per share is based upon the weighted average number of outstanding common shares and the dilutive effect of common share equivalents, such as options and warrants to purchase common stock, and convertible notes, if applicable, that are outstanding each year.

Basic and diluted earnings per share were the same for all periods presented as including common stock equivalents in the calculation of diluted earnings per share would have been antidilutive. As of December 31, 2016, the Company had outstanding options exercisable for 2,736,839 shares of its common stock, warrants exercisable for 16,137,761 shares of its common stock, series A preferred stock (the “Series A Preferred Stock”) convertible into 27,775 shares of common stock, and series B preferred stock (the “Series B Preferred Stock”) convertible into 20,929,456 shares of common stock. As of December 31, 2015, the Company had outstanding options exercisable for 4,996,095 shares of its common stock, warrants exercisable for 16,281,164 shares of its common stock, series A preferred stock (the “Series A Preferred Stock”) convertible into 357,163 shares of common stock, and series B preferred stock (the “Series B Preferred Stock”) convertible into 15,278,717 shares of common stock.

Research and Development Costs

Research and development costs are expensed as incurred.

Segment Reporting

The Company has determined that it operates in only one segment currently, which is biopharmaceutical research and development.

Recent Accounting Pronouncements

In August 2014, the FASB issued ASU 2014-15 “Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern.” The core principle of the guidance is that an entity’s management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are available to be issued. When management identifies conditions or events that raise substantial doubt about an entity’s ability to continue as a going concern, management should consider whether its plans that are intended to mitigate those relevant conditions or events that will alleviate the substantial doubt are adequately disclosed in the footnotes to the financial statements. This guidance will be effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. The Company adopted ASU 2014-15 as of December 31, 2016 and updated the related disclosures. Other than the updates to going concern related disclosures, the adoption of ASU 2014-15 did not have an impact on the Company’s financial statements.

In April 2015, the FASB issued ASU 2015-03, 'Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs'. ASU 2015-03 is intended to simplify the presentation of debt issuance costs. These amendments require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this ASU. The Company adopted ASU 2015-03 on January 1, 2016 and applied the standard retrospectively. The adoption of ASU 2015-03 resulted in the reclassification of \$17,116 and \$136,260 of unamortized debt issuance costs related to the Company's Convertible Notes (see Note 5) from prepaid expenses and other current assets to convertible notes payable within the Company’s condensed consolidated balance sheets as of December 31, 2016 and December 31, 2015, respectively. Other than this reclassification, the adoption of ASU 2015-03 did not have an impact on the Company's financial statements.

In March 2016, the FASB issued ASU No. 2016-09, “Compensation – Stock Compensation”. The areas for simplification in this update involve several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. For public entities, the amendments in this update are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted in any interim or annual period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The Company is currently evaluating the impact of adopting this ASU on the financial statements.

On August 26, 2016, the FASB issued ASU No. 2016-15 “Statement of Cash Flows (Topic 230)”, a consensus of the FASB’s Emerging Issues Task Force. The new guidance is intended to reduce diversity in practice in how certain transactions are classified in the statement of cash flows. For public business entities, the standard is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. For all other entities, the standard is effective for financial statements issued for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted, provided that all of the amendments are adopted in the same period. The guidance requires application using a retrospective transition method. The Company is currently evaluating the impact of adopting this ASU on the financial statements.

Management does not expect the above recently issued, but not yet effective, accounting standards to have a material effect on the accompanying financial statements.

3. OTHER BALANCE SHEET INFORMATION

Components of selected captions in the accompanying balance sheets as of December 31, 2016 and 2015 consist of:

| | December 31, 2016 | December 31, 2015 |
|--|------------------------------|------------------------------|
| Prepaid expenses and other: | | |
| Prepaid insurance | \$ 20,038 | \$ 39,756 |
| Annual license fee | - | 104,167 |
| Other | 3,022 | 74,232 |
| Prepaid expenses and other | <u>\$ 23,060</u> | <u>\$ 218,155</u> |
| Property and equipment: | | |
| Computers and office equipment | \$ 75,204 | \$ 73,911 |
| Machinery and equipment | 112,421 | 112,421 |
| Less: accumulated depreciation | <u>(180,201)</u> | <u>(175,283)</u> |
| Property and equipment, net | <u>\$ 7,424</u> | <u>\$ 11,049</u> |
| Accrued expenses and other: | | |
| Professional fees | \$ 32,000 | \$ 49,703 |
| Accrued dividends Series B Preferred Stock | 1,554,591 | 1,041,894 |
| Deferred salary | 237,293 | 88,958 |
| Accrued interest on Notes Payable | 523,360 | 327,203 |
| Accrued research and development | 53,995 | 39,268 |
| Funded research | 77,316 | - |
| Other | 136,926 | 56,579 |
| Accrued expenses and other | <u>\$ 2,615,481</u> | <u>\$ 1,603,605</u> |

4. INTANGIBLE ASSETS

Intangible assets as of December 31, 2016 and 2015 consist of the following:

| | December 31, 2016 | December 31, 2015 |
|--------------------------------|----------------------------------|----------------------------------|
| Technology license | \$ 413,398 | \$ 413,398 |
| Less: accumulated amortization | (133,845) | (94,851) |
| Intangibles, net | <u>\$ 279,553</u> | <u>\$ 318,547</u> |

Amortization expense relating to intangible assets was \$38,994 during the years ended December 31, 2016 and 2015.

On June 26, 2014, the Company and The General Hospital Corporation, d/b/a Massachusetts General Hospital (“MGH”) entered into two license agreements, which replaced the single license agreement dated April 27, 2009. The Company paid to MGH an initial license fee of \$175,000 for each license.

The assumptions and estimates used to determine future values and remaining useful lives of our intangible and other long-lived assets are complex and subjective. They can be affected by various factors, including external factors such as industry and economic trends, and internal factors such as changes in our business strategy. Based on our assessment, we did not recognize any impairment as of December 31, 2016 and 2015.

Future amortization will approximate \$39,000 for each of the next five years.

See Note 12 for commitments and contingencies associated with the Company's technology licenses.

5. CONVERTIBLE NOTES PAYABLE - SHORT TERM

2014 Convertible Notes Payable

During 2014 and 2015, the Company issued promissory notes (the "2014 Notes") pursuant to a Note Purchase Agreement entered into with certain accredited investors for an aggregate principal amount of \$2,198,416. The 2014 Notes mature one year from the date of issuance and bear interest at the rate of 8% per annum. All principal and accrued interest under the 2014 Notes will automatically convert into the Company's next equity or equity-linked financing (a "Subsequent Financing") in accordance with the following formula: (outstanding balance of the Notes as of the closing of the Subsequent Financing) x (1.15) / (the per security price of the securities sold in the Subsequent Financing). The investors shall be considered to be purchasers in the Subsequent Financing by way of their converted 2014 Notes. In addition, upon the closing of a Subsequent Financing, each of the investors shall be issued, in addition to any warrants issued in connection with a Subsequent Financing, an additional warrant to purchase a number of shares of common stock equal to fifty percent (50%) of the number of shares of common stock purchased by such investor in the Subsequent Financing assuming a per share purchase price of the securities to be issued in the Subsequent Financing.

In May 2015, in connection with the issuance of the Convertible Notes (as defined and discussed below), the holders of the 2014 Notes, in the outstanding principal amount of \$2,198,416, amended their 2014 Notes to (i) extend the maturity date an additional six months, (ii) change the terms of the conversion premium from 1.15 to 1.25 to be consistent with conversion terms of the Convertible Notes, and (iii) provide that the issuance of promissory notes by the Company in a transaction with a substantially similar structure to the transactions contemplated by the 2014 Notes shall not be deemed a Subsequent Financing.

On January 20, 2016, the Company further amended the 2014 Notes (the "Amended 2014 Notes"), in order to (i) extend the maturity date for an additional six months, (ii) retroactively increase the interest rate to 12%, (iii) provide the ability to voluntarily convert the notes, including principal and interest multiplied by 1.25, at a conversion price of \$0.35 per share (which results in an effective conversion price of \$0.28 per share), (iv) provide resale registration rights, and (v) provide "full-ratchet" anti-dilutive protection. As a result of this amendment, the conversion price of each of the Company's existing Series A Preferred Stock, Series B Preferred Stock, the Convertible Notes and certain related warrants, has been adjusted to \$0.28 per share.

The Company applied guidance in FASB ASC 470-50, "Debt Modifications and Extinguishments," (ASC 470-50) and determined that the amendment qualified as a debt extinguishment (the "Debt Extinguishment"). This determination was made after calculating that the newly amended terms increased the fair value of the embedded conversion feature in excess of 10 percent.

In order to account for the Debt Extinguishment, the Company recorded the Amended 2014 Notes and the embedded conversion feature at their then fair values of \$2,495,582 and \$945,951, respectively. The embedded conversion feature was recorded as a derivative liability after determining the requirements for equity classification, in accordance with ASC Topic 815-40, were not met. The difference between the carrying value of the 2014 Notes, including all principal, accrued interest and deferred financing costs and the fair value of the Amended 2014 Notes and embedded conversion feature was recorded as a loss on debt extinguishment of \$1,022,520 in the statement of operations. The difference between the principal amount of the Amended 2014 Notes and the fair value of the Amended 2014 Notes of \$238,515 will be amortized to interest expense over the term of the notes. During the year ended December 31, 2016, the Company amortized interest of \$199,515 on the Amended 2014 Notes.

On July 22, 2016, the Company entered into a further amendment to the 2014 Notes to extend the maturity date of the Notes for an additional ninety days. On November 2, 2016, the Company obtained majority approval to further amend the 2014 Notes to extend the maturity date of the Notes for an additional ninety days, with an effective date of October 22, 2016. On March 13, 2017, the Company obtained majority approval to further amend the 2014 Notes to extend the maturity date of the Notes to June 22, 2017, with an effective date of January 22, 2017.

During the year ended December 31, 2016, the Company issued 653,988 shares of common stock pursuant to the conversion of Amended 2014 Notes. The carrying value of the converted Amended 2014 Notes plus accreted interest was approximately \$178,731 and the fair value of the derivative related to the embedded conversion feature was \$15,271. The Company recorded a gain on extinguishment related to these conversions totaling \$26,785.

The calculation of the net loss on extinguishment is as follows:

| | December 31, 2016 |
|--|------------------------------|
| Fair value – Amended 2014 Notes | \$ 2,495,582 |
| Fair value – embedded conversion feature | 945,951 |
| Total Amended 2014 Notes | <u>3,441,533</u> |
| Principal – 2014 Notes | 2,198,416 |
| Accrued interest – 2014 Notes | 232,235 |
| Deferred financing costs – 2014 Notes | (11,638) |
| Total 2014 Notes | <u>2,419,013</u> |
| Loss on Extinguishment from 2014 Note Amendment | <u>1,022,520</u> |
| Carrying value – Amended 2014 Notes converted | 175,922 |
| Value of interest accretion – Amended 2014 Notes converted | 2,809 |
| Fair value of embedded conversion feature – Amended 2014 Notes converted | 15,271 |
| Fair value – common stock issued upon conversion | (167,217) |
| Gain on Extinguishment from Amended 2014 Note Conversions | <u>26,785</u> |
| Loss on Extinguishment, net | <u>\$ 995,735</u> |

The derivative liability related to the embedded conversion feature is being re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value is being recorded in the Company's consolidated statement of operations.

Upon conversion, the notes and embedded derivatives are removed at their carrying value, after a final mark-to-market of the embedded derivative's fair value. Common stock issued upon conversion is measured at its current fair value, with any difference recorded as a gain or loss on extinguishment.

2015 Convertible Notes Payable

On May 28, 2015, the Company accepted subscriptions pursuant to a new Note and Warrant Purchase Agreement, as amended on August 6, 2015, for the issuance and sale in a private placement of up to \$3,000,000 of convertible promissory notes (the “Convertible Notes”). The Convertible Notes mature one year from the date of issuance and bear interest at the rate of 8% per annum. All principal and accrued interest under the Convertible Notes will, at the sole option of the investor (i) convert into the Company’s next equity or equity-linked financing in which the Company raises gross proceeds of at least \$3,600,000 (the “Subsequent Financing”), into such securities, including warrants of the Company as are issued in the Subsequent Financing, the amount of which shall be determined in accordance with the following formula: (the outstanding balance of the Convertible Notes plus accrued interest as of the closing of the Subsequent Financing) x (1.25) / (the per security price of the securities sold in the Subsequent Financing), or (ii) convert into a new financing in which the Company shall issue to the investor one share of common stock and one-half of one warrant at a purchase price no greater than \$0.35 per share. The per security price of the securities sold in the Subsequent Financing shall not exceed \$0.35. In addition, the holders of the Convertible Notes shall have the option, at any time, to convert all principal and accrued interest into common stock at price per share of \$0.35. In the event that the Company shall, at any time, issue or sell additional shares of common stock or common stock equivalents, as defined, at a price per share less than \$0.35, then the conversion price of the Convertible Notes shall be reduced to a price equal to the consideration paid for these additional shares of common stock. As a result of the 2016 amendment to the 2014 Notes, the conversion price of the Convertible Notes was adjusted to \$0.28 per share.

Pursuant to the Note and Warrant Purchase Agreement, the Company issued warrants at an initial exercise price per share of \$0.50 to purchase a number of shares of common stock equal to fifty percent of the number of shares of common stock such investor would receive upon full conversion of the Convertible Notes at a conversion price of \$0.35 per share. As a result of the 2016 amendment to the 2014 Notes, the exercise price of the warrants was adjusted to \$0.28 per share.

From May through September 2015, the Company issued Convertible Notes in the aggregate principal amount of \$2,780,005 and warrants to purchase 3,971,436 shares of common stock at \$0.50 per share. In connection with the issuance of the Convertible Notes, the Company paid to placement agents a cash fee of \$142,400 and issued 406,859 five-year warrants to purchase shares of common stock at an exercise price of \$0.50 per share. On the issuance date, the fair value of the placement agent warrants was \$39,108 which was recorded as a deferred offering cost and as a derivative warrant liability.

Based upon the Company’s analysis of the criteria contained in ASC Topic 815-40, “Derivatives and Hedging—Contracts in Entity’s Own Equity” (“ASC Topic 815-40”), the Company has determined that since the exercise price of the warrants may be reduced if the Company issues shares at a price below the then-current exercise price, the warrants issued in connection with the Convertible Notes must be classified as derivative instruments. In accordance with ASC Topic 815-40, these warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value is being recorded in the Company’s consolidated statement of operations.

In order to account for the issuance of the Convertible Notes and warrants, the Company allocated the total gross proceeds of \$2,780,005 between the Convertible Notes and the warrants. The warrants were allocated their full fair value as of the respective grant dates totaling \$358,255 and the residual net proceeds of \$2,421,750 were allocated to the Convertible Notes. The conversion feature of the Convertible Notes was then analyzed. The Company determined that the embedded conversion feature did not meet the requirements for equity classification in accordance with ASC Topic 815-40. Therefore, the conversion feature fair value of \$490,340 was bifurcated from the host contract, the Convertible Notes, and recorded as a derivative liability, thereby creating a further discount on the Convertible Notes. The conversion feature is also being re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value is being recorded in the Company’s consolidated statement of operations.

On May 26, 2016, the 2015 Notes were amended to (i) extend the maturity date an additional six months and (ii) increase the interest rate, from 8% to 12%, applied retroactively from the initial issuance date of the Notes. The Company applied guidance in ASC 470-50 and determined that the amendment did not qualify as a debt extinguishment. This determination was made after calculating that the present value of the cash flows under the modified debt instrument is less than a 10 percent change from the present value of the remaining cash flows under the original debt. On December 5, 2016, the Company obtained majority approval to further amend the 2015 Notes to extend the maturity date of the 2015 Notes for additional six months, with an effective date November 28, 2016.

Lewis Opportunity Fund, an affiliate of W. Austin Lewis, IV, a member of the Company's Board of Directors, participated as an investor in the Convertible Notes in 2015 in an aggregate principal amount of \$2,000,000 and was issued warrants to purchase an aggregate of 2,857,143 shares of common stock.

2016 Convertible Notes Payable

During 2016, the Company issued convertible promissory notes (the "2016 Convertible Notes") in the principal amount of \$570,000 under the terms of a new Note Purchase Agreement. The Company's Chief Executive Officer and the W. Austin Lewis Defined Benefit Plan, an affiliate of W. Austin Lewis, IV, a member of the Company's Board of Directors, participated as an investor in the Convertible Notes in 2016 in an aggregate principal amounts of \$150,000 and \$160,000, respectively.

The 2016 Convertible Notes mature one year from the date of issuance and bear interest at the rate of 12% per annum payable upon the earlier of (i) exchange or voluntary conversion of the 2016 Convertible Notes in accordance with the terms thereof and (ii) the maturity date. All principal and accrued interest under the 2016 Convertible Notes (the "Outstanding Balance") will automatically convert into the Company's next equity or equity-linked financing (the "Subsequent Financing"), without any action on the part of the investor, into such securities, including warrants of the Company that are issued in the Subsequent Financing, the amount of which shall be determined in accordance with the following formula: (the Outstanding Balance as of the closing of the Subsequent Financing) x (1.25) / (the per security price of the securities sold in the Subsequent Financing). For the purpose of calculating the formula above, the per security price of the securities sold in the Subsequent Financing shall not exceed \$0.35. The issuance of promissory notes by the Company in a transaction with a substantially similar structure to the 2016 Convertible Notes (as determined in good faith by the Company's board of directors) shall not be deemed a Subsequent Financing.

Each investor also has the right, at its option at any time, to convert the Outstanding Balance into shares of common stock as is obtained by dividing (i) the Outstanding Balance to be converted multiplied by 1.25, by (ii) a conversion price, \$0.35 per share; provided, however, if an event of default has occurred and is continuing, the conversion price shall be adjusted to \$0.15 per share. The 2016 Convertible Notes are subject to customary adjustments for issuances of shares of common stock as a dividend or distribution on shares of the common stock, or mergers or reorganizations, as well as "full-ratchet" anti-dilution adjustments for future issuances of other Company securities (subject to certain standard carve-outs).

Upon the closing of a Subsequent Financing, each of the investors shall be issued, in addition to any warrants issued in connection with a Subsequent Financing, an additional warrant (the "Additional Warrant"), to purchase a number of shares of common stock equal to fifty percent (50%) of the number of shares of common stock purchased by such investor in the Subsequent Financing assuming a per share purchase price of the securities to be issued in the Subsequent Financing. The terms of the Additional Warrants shall be substantially identical to the terms of the warrants issued in the Subsequent Financing, except the exercise price per share of the Additional Warrants shall be equal to the per share purchase price of the securities issued in the Subsequent Financing. In the event no warrants are issued in the Subsequent Financing, each of the investors shall nonetheless be entitled to an Additional Warrant, which Additional Warrant shall be non-callable, exercised on a cash only basis and have a term of five (5) years following the closing date of the Subsequent Financing.

The conversion feature of the 2016 Convertible Notes was analyzed. The Company determined that the embedded conversion feature did not meet the requirements for equity classification in accordance with ASC Topic 815-40. Therefore, the conversion feature with a fair value of \$95,407 was bifurcated from the host contract, the 2016 Convertible Notes, and recorded as a derivative liability, thereby creating a discount on the 2016 Convertible Notes. The conversion feature is also being re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value is being recorded in the Company's consolidated statement of operations.

On July 22, 2016, the 2016 Convertible Notes were amended to change the final closing date from 120 days to 240 days after the initial closing of March 23, 2016.

A reconciliation of the Company’s Convertible Notes Payable – Short Term, as of December 31, 2016, is as follows:

| | <u>2014 Amended Notes</u> | <u>2015 Convertible Notes</u> | <u>2016 Convertible Notes</u> | <u>Total</u> |
|---|-----------------------------------|---------------------------------------|---------------------------------------|---------------------|
| Principal | \$ 2,198,416 | \$ 2,780,005 | \$ 570,000 | \$ 5,548,421 |
| Adjustments to fair value, net of accretion | 496,681 | - | - | 496,681 |
| Conversions | (175,922) | - | - | (175,922) |
| Debt discount | - | (44,268) | (38,238) | (82,506) |
| Deferred financing costs | - | (13,404) | (3,712) | (17,116) |
| | <u>\$ 2,519,175</u> | <u>\$ 2,722,333</u> | <u>\$ 528,050</u> | <u>\$ 5,769,558</u> |

In connection with the private placement of the Convertible Notes, the Company entered into a registration rights agreement with the investors, in which the Company agreed to file a registration statement with the SEC to register for resale the shares underlying the Convertible Notes and the warrants within 90 calendar days of the final closing date of the Convertible Notes and to have the registration statement declared effective within 120 calendar days after the filing date.

For embedded conversion features that are accounted for as a derivative liability, the Company used a Binomial Options Pricing model. The primary assumptions used to determine the fair values of these embedded conversion features were: risk free interest rate with a range 0.35% - 1.14%, volatility of 68.09%, and actual term of the related convertible notes.

Other Notes Payable

On September 27, 2016, the Company borrowed \$100,000 in the form of a short term promissory note (the “Note”). The Note matures on October 31, 2016 and bears interest at the rate of 5% per annum if the Note is repaid on or prior to the maturity date and 15% if the Note is not repaid by the maturity date. On November 2, 2016, the Company repaid the Note and accumulated interest in the aggregate amount of \$100,472.

On October 25, 2016, the Company borrowed \$5,000 in the form of a promissory note (the “Note”), from a former Director of the Company, which matured on November 25, 2016. The Note has been amended to extend the maturity date to June 30, 2017.

On December 22, 2016, the Company borrowed \$50,000 in the form of a promissory note (the “Note”). The Note matures on January 31, 2017 and bears interest at the rate of 10% per annum if the Note is repaid on or prior to the maturity date and 15% if the Note is not repaid by the maturity date.

In connection with the issuance of the other notes payable and the convertible notes in 2014, 2015 and 2016, the Company incurred \$345,836 in issuance costs. These costs are recorded as deferred issuance costs, which are offset against the proceeds from the convertible notes on the Company’s balance sheet and amortized to interest expense over the term of such convertible notes. For the period ended December 31, 2016 and 2015, the Company has amortized \$117,217 and \$155,479, respectively, of issuance costs to expense. For the period ended December 31, 2016 and 2015, the Company recorded non-cash interest expense related to the amortization of the discount on the convertible notes of \$505,613 and \$355,883, respectively.

Interest expense, including accretion of the 2014 Amended Notes to fair value, amortization of deferred issuance costs and debt discounts related to the warrants and beneficial conversion feature, totaled \$1,261,974 and \$873,359 for the year ended December 31, 2016 and 2015, respectively.

6. LICENSE AGREEMENT

On June 3, 2016, the Company entered into two exclusive license agreements (the “Licenses”) with Sinotau USA, Inc., a wholly-owned subsidiary of Hainan Sinotau Pharmaceutical Co., Ltd. (“Sinotau”), a pharmaceutical organization. Sinotau is responsible for developing and commercializing the Company’s proprietary cardiac PET imaging assets, CardioPET and BFPET, in China and Canada. Sinotau also retains a first right of refusal to license the technology for development in Australia and Singapore. In accordance with the Licenses, the Company is entitled to upfront payments of \$550,000, milestone payments totaling \$1,450,000 upon the completion of certain development activities and royalties on future sales made by Sinotau. As of December 31, 2016, the Company has received payments of \$775,000 under the terms of the License.

As of December 31, 2016, the transfer of technology specified in the Sinotau agreement has not been completed and therefore a portion of the payments received totaling \$408,333 has been recorded as deferred revenue. The remaining portion of the payments received, totaling \$366,667, is to be used in order to further fund the Company’s research and development activities and is included in accrued expenses and other liabilities until such research and development costs are incurred. As of December 31, 2016, the Company has incurred \$289,351 of research and development costs and recorded these amounts as a reduction in research and development expenses. The unused portion of funded research totaling \$77,316 remains in accrued expenses and other liabilities as of December 31, 2016.

License payments, excluding payments to fund further research, are subject to the Company’s license agreement with MGH (see Note 12). Upon receiving the upfront payment from Sinotau, the Company recorded a royalty expense of \$88,750, payable to MGH, within research and development expenses.

7. CAPITAL STOCK

SERIES A PREFERRED STOCK

The Company is authorized to issue 100,000,000 shares of preferred stock, \$0.001 par value, of which 3,500,000 shares have been designated Series A Preferred Stock. At December 31, 2016 and 2015, 9,370 and 150,611 shares of Series A Preferred Stock, respectively, were issued and outstanding.

The material terms of the Series A Preferred Stock, as specified in the Certificate of Designation for the Series A Preferred Stock, are as follows:

Conversion

Each share of Series A Preferred Stock may, at the holder’s option, convert into common stock. The conversion rate is equal to the sum of the stated value of the Series A Preferred Stock, which is \$0.83 per share, plus all accrued and unpaid dividends, divided by the conversion price. As of December 31, 2016, the conversion price was \$0.28.

During the year ended December 31, 2016, 150,611 shares of Series A Preferred Stock were converted into 440,202 shares of the Company’s common stock. In addition, the Company issued 10,432 shares of the Company’s common stock in satisfaction of \$2,931 dividend accrued on the shares of Series A Preferred Stock that were converted. During the year ended December 31, 2015, 856,219 shares of Series A Preferred Stock were converted into 1,923,324 shares of the Company’s common stock. In addition, the Company issued 45,987 shares of the Company’s common stock in satisfaction of \$17,033 dividend accrued on the shares of Series A Preferred Stock that were converted.

Subject to the specified provisions, the Series A Preferred Stock will automatically convert into common stock at the conversion price on the mandatory conversion date, which is defined as the first date at least six (6) months after the issuance of the Series A Preferred Stock on which each of the following conditions shall have been satisfied: (i) the Company shall have consummated, a qualified financing for aggregate gross proceeds to the Company of \$7,000,000, (ii) the volume weighted average trading price for the Company’s common stock for each day on thirty (30) consecutive trading days immediately preceding such date, must be above \$1.50 and the trading volume over that period must exceed 1,500,000 shares, and (iii) as of such date, all shares of common stock issuable upon conversion of the Series A Preferred Stock are registered under the Securities Act of 1933, as amended (the “Act”) pursuant to an effective registration statement or are otherwise eligible for sale under Rule 144 under the Act. As of December 31, 2016, no mandatory conversion has taken place as all of the conditions required for such mandatory conversion have not occurred.

Dividends

(a) **Cumulative Preferred Dividends.** Each holder of the Series A Preferred Stock shall be entitled to receive cash dividends payable on the stated value of the Series A Preferred Stock at a rate of 10% per annum which shall be cumulative and accrue daily from the original issuance date.

(b) **Payment of Dividends.** The Company shall be required to pay all accrued and unpaid dividends (whether or not declared) in respect of the Series A Preferred Stock semi-annually on each June 30 and December 31 of each calendar year. All such dividends shall be paid in cash; provided, that, at the option of the Company, the Company may pay any accrued and unpaid dividends on the Series A Preferred Stock in the form of additional shares of Series A Preferred Stock, with each share of Series A Preferred Stock being valued for this purpose at the stated value in effect on the date of payment.

For the year ended December 31, 2016, the Company accrued a preferred stock dividend of \$10,708 and issued 9,370 shares of Series A Preferred Stock in payment of such dividend. In addition, during the year ended December 31, 2016, the Company issued 10,432 shares of common stock in payment of such dividend as related to the shares of Series A Preferred Stock converted into common stock. For the year ended December 31, 2015, the Company accrued a preferred stock dividend of \$64,635 and issued 57,353 shares of Series A Preferred Stock in payment of such dividend. In addition, during the year ended December 31, 2015, the Company issued 45,987 shares of common stock in payment of such dividend as related to the shares of Series A Preferred Stock converted into common stock.

Liquidation preference

In the event of liquidation, dissolution or winding up of the business of the Company, whether voluntary or involuntary, each holder of Series A Preferred Stock shall be entitled to receive, for each share thereof, out of assets of the Company legally available therefor, a preferential amount in cash, per share of Series A Preferred Stock, equal to (and not more than) the sum of the (x) stated value, plus (y) all accrued and unpaid dividends thereon. All preferential amounts to be paid to the holders of Series A Preferred Stock in connection with such liquidation, dissolution or winding up shall be paid before the payment or setting apart for payment of any amount for, or the distribution of any assets of the Company to the holders of the Company's common stock. If upon any such distribution the assets of the Company shall be insufficient to pay the holders of the outstanding shares of Series A Preferred Stock the full amounts to which they shall be entitled, such holders shall share ratably in any distribution of assets in accordance with the sums which would be payable on such distribution if all sums payable thereon were paid in full.

Voting

The holders of the Series A Preferred Stock have the right to one vote for each share of common stock into which such Series A Preferred Stock could then convert.

SERIES B PREFERRED STOCK

The Company is authorized to issue 100,000,000 shares of preferred stock, \$0.001 par value, of which 12,000,000 shares have been designated Series B Preferred Stock. At December 31, 2016 and 2015, 5,382,071 shares of Series B Preferred Stock were issued and outstanding.

The material terms of the Series B Preferred Stock, as specified in the Certificate of Designation for the Series B Preferred Stock, are as follows:

Ranking

The Series B Preferred Stock ranks junior to the Company's Series A Preferred Stock and senior to the Company's common stock with respect to distributions of assets upon the liquidation, dissolution or winding up of the Company.

Stated Value

Each share of Series B Preferred Stock will have a stated value of \$0.80, subject to adjustment for stock splits, combinations and similar events.

Dividends

Cumulative dividends on the Series B Preferred Stock accrue at the rate of 10% of the stated value per annum, compounded annually, from and after the date of the initial issuance through the third anniversary of the issuance date; provided, however, that any holder of at least 4,500,000 shares of Series B Preferred Stock after the issuance date and prior to October 1, 2013 (a “Major Holder”) will be entitled to accrued dividends through the fourth anniversary of the issuance date (as applicable, the “Accrual Period”). Accrued dividends are payable upon the earliest to occur of (i) the third anniversary of the issuance date (or, with respect to the Major Holder, the fourth anniversary of the issuance date), (ii) mandatory conversion (as described below) and (iii) an automatic conversion upon a fundamental transaction (as such term is defined in the Certificate of Designation) or triggering event (as described below). Dividends are payable in Series B Preferred Stock valued at the stated value, or in cash upon the mutual agreement of the Company and the holder.

For the year ended December 31, 2016, the Company accrued a Series B Preferred Stock dividend of \$512,697 which is included in accrued expenses in the Company’s consolidated balance sheet. As of December 31, 2016, no voluntary conversion has taken place. For the year ended December 31, 2015, the Company accrued a Series B Preferred Stock dividend of \$509,399 which is included in accrued expenses in the Company’s consolidated balance sheet. In addition, the Company issued 160,267 shares of common stock in payment of such dividend as related to the 312,500 shares of Series B Preferred Stock converted to common stock during the year ended December 31, 2015.

Liquidation Preference

If the Company voluntarily or involuntarily liquidates, dissolves or winds up its affairs, each holder of the Series B Preferred Stock will be entitled to receive out of the Company’s assets available for distribution to stockholders, after satisfaction of liabilities to creditors, if any, and payments due to holders of the Series A Preferred Stock but before any distribution of assets is made on the Company’s common stock or any of our other shares of stock ranking junior as to such a distribution to the Series B Preferred Stock, a liquidating distribution in the amount in the amount of the stated value of all such holder’s Series B Preferred Stock plus all accrued and unpaid dividends thereon.

Voluntary Conversion

Each share of Series B Preferred Stock is convertible at the holder’s option into the Company’s common stock in an amount equal to the stated value plus accrued and unpaid dividends thereon through the conversion date divided by the then applicable conversion price. The initial conversion price was \$0.80 per share and is subject to customary adjustments for issuances of shares of common stock as a dividend or distribution on shares of the common stock, or mergers or reorganizations, as well as “full-ratchet” anti-dilution adjustments for future issuances of other Company securities. At December 31, 2016, the conversion price was \$0.28 per share.

During the year ended December 31, 2016, no voluntary conversions have taken place. During the year ended December 31, 2015, 312,500 shares of Series B Preferred Stock were converted into 714,285 shares of the Company’s common stock.

Holder also have the option to convert their Series B Preferred Stock upon the occurrence of a fundamental transaction or one of the following triggering events: Johan (Thijs) Spoor ceases to be the chief executive officer of the Company; or there is a change in three of the five current members of the Company’s board of directors, such conversion will be on the same terms as a mandatory conversion.

Mandatory Conversion

The Series B Preferred Stock is subject to mandatory conversion at such time as the volume weighted average price of the Company's common stock is at least \$1.20 (subject to adjustments for stock splits and similar events) provided, that, on the mandatory conversion date, (A) a registration statement providing for the resale of the shares underlying the Series B Preferred Stock is effective, or such shares may be offered for sale to the public without limitations pursuant to Rule 144, (B) trading in the common stock shall not have been suspended by the SEC or exchange or market on which the common stock is trading), (C) the daily volume of the common stock is at least 50,000 shares per day for the applicable ten (10) consecutive trading days, and (D) the Company is in material compliance with the terms and conditions of the transaction documents. In the event of mandatory conversion, each share of Series B Preferred Stock will convert into the number of shares of common stock equal to the stated value plus accrued and unpaid dividends for the Accrual Period divided by the conversion price.

Voting Rights

The holders of the Series B Preferred Stock will be entitled to vote upon all matters upon which holders of common stock have the right to vote, such votes to be counted together with all other shares of capital stock having general voting powers and not separately as a class. The holders of the Series B Preferred Stock will be entitled to the number of votes equal to the number of common stock into which the Series B Preferred Stock are then convertible.

In addition, as long as at least 25% of the Series B Preferred Stock remains outstanding, the Company will not, without the affirmative vote or consent of the holders of at least a majority of the outstanding Series B Preferred Stock, voting as a separate class, (i) amend, waive or repeal (including through a merger, consolidation or similar event) any provision of the Company's articles of incorporation or by-laws in any manner that adversely affects the rights of the holders of the Series B Preferred Stock; (ii) alter or change adversely the preferences, rights, privileges, or restrictions of the Series B Preferred Stock; (iii) authorize or create any class or series of stock having rights, preferences or privileges in any respect senior to the Series B Preferred Stock; or (iv) reclassify, alter or amend any existing class or series of stock, if such reclassification, alteration or amendment would render such other class or series of stock as having rights, preferences or privileges in any respect senior to the Series B Preferred Stock.

COMMON STOCK

The Company has authorized 200,000,000 shares of its common stock, \$0.001 par value, At December 31, 2016 and 2015, the Company had issued and outstanding 34,074,284 and 32,908,503, respectively, shares of its common stock.

In January 2016, the Company issued an aggregate of 61,159 shares of common stock with fair value of \$21,406 in settlement of certain outstanding liabilities to third parties.

In December 2015, the Company issued an aggregate of 867,143 shares of common stock, with a total fair value of \$337,250, for consulting services and in settlement of certain outstanding liabilities to third parties. As of December 31, 2015, \$30,000 of this settlement, relates to services to be performed in 2016 and is included in prepaid expense in the consolidated balance sheet. In addition, certain settlement agreements included a provision to issue, upon a Subsequent Financing as defined, an amount of warrants equal to fifty percent of the number of shares of common stock issued by the Company in the Subsequent Financing.

8. STOCK PURCHASE WARRANTS

Common Stock Warrants

During the year ended December 31, 2016, the Company issued 200,000 common stock warrants at an exercise price of \$0.28 per share with a five-year term to a consultant. The fair value of these warrants of \$22,576 was recorded as expense in the year ended December 31, 2016.

During the year ended December 31, 2016, 343,403 stock purchase warrants expired with a weighted average exercise price of \$0.88.

As a result of the amendment to the 2014 Notes entered into with existing convertible note holders on January 20, 2016, the conversion price of certain related warrants has been adjusted to \$0.28 per share.

During the year ended December 31, 2015, the Company issued 3,971,436 common stock warrants to investors and 406,859 common stock warrants to the placement agents in connection with issuance of the 2015 Convertible Notes (see Note 5). These warrants are recorded as a derivative liability.

In addition, during the year ended December 31, 2015, the Company issued 607,229 common stock warrants at an exercise price of \$0.50 per share with a five-year term. These warrants were issued in consideration of the warrant holder waiving its rights with respect to indebtedness incurred by the Company in excess of the amount permitted pursuant to the Certificate of Designation of Relative Rights and Preferences of the Company's Series A Preferred Stock. The warrants had a fair value of \$80,472 and are included in interest and other expense in the consolidated statement of operations.

During the year ended December 31, 2015, 3,558,395 stock purchase warrants expired with a weighted average exercise price of \$1.29.

As a result of the issuance of the 2015 Convertible Notes, the exercise price of the 8,676,408 common stock warrants, which were issued in connection with the Company's Series B Preferred Stock in 2013 and 2014, was reduced to \$0.35 per share.

The following is a summary of all common stock warrant activity during the year ended December 31, 2016:

| | Number of Shares Under Warrants | Exercise Price Per Share | Weighted Average Exercise Price |
|--|--|---|--|
| Warrants issued and exercisable at December 31, 2015 | 16,281,164 | \$ 0.35 - 1.33 | \$ 0.48 |
| Warrants Issued/Exchanged | 200,000 | \$ 0.28 | \$ 0.28 |
| Warrants Expired/Forfeited | (343,403) | \$ 0.83 - 1.33 | \$ 0.88 |
| Warrants issued and exercisable at December 31, 2016 | <u>16,137,761</u> | <u>\$ 0.28 - 1.33</u> | <u>\$ 0.37</u> |

The following represents additional information related to common stock warrants outstanding and exercisable at December 31, 2016:

| Exercise Price | Number of Shares Under Warrants | Weighted Average Remaining Contract Life in Years | Weighted Average Exercise Price |
|--|--|--|--|
| \$ 0.28 | 13,054,703 | 2.42 | \$ 0.28 |
| Total warrants accounted for as derivative liability | | | |
| | <u>13,054,703</u> | <u>2.42</u> | <u>\$ 0.28</u> |
| \$ 0.28 | 200,000 | 4.30 | \$ 0.28 |
| \$ 0.50 | 607,229 | 3.79 | \$ 0.50 |
| \$ 0.83 | 1,928,500 | 2.01 | \$ 0.83 |
| \$ 0.85 | 181,912 | 0.88 | \$ 0.85 |
| \$ 1.00 | 165,417 | 2.13 | \$ 1.00 |
| Total warrants accounted for as equity | | | |
| | <u>3,083,058</u> | <u>2.45</u> | <u>\$ 0.79</u> |
| Total for all warrants outstanding | | | |
| | <u>16,137,761</u> | <u>2.42</u> | <u>\$ 0.37</u> |

The Company used the Black-Scholes option price calculation to value the warrants granted in 2016 using the following assumptions: risk-free rate of 1.24%, volatility of 68.09%, actual term and exercise price of warrants granted. For warrants granted that are accounted for as a derivative liability, the Company used a Binomial Options Pricing model. The primary assumptions used to determine the grant date fair value of these warrants were: a risk free interest rate with the range from 1.01% - 1.93%, volatility of 68.89%, actual term and exercise price of the warrants granted. There were no material changes to the primary assumptions, as noted above, used to determine the fair value of the warrants as of December 31, 2016.

The Company used the Black-Scholes option price calculation to value the warrants granted in 2015 using the following assumptions: risk-free rate of 1.76%, volatility of 49.42%, actual term and exercise price of warrants granted. For warrants granted that are accounted for as a derivative liability, the Company used a Binomial Options Pricing model. The primary assumptions used to determine the grant date fair value of these warrants were: a risk free interest rate with the range from 1.37% - 1.76%, volatility of 49.42%, actual term and exercise price of the warrants granted. There were no material changes to the primary assumptions, as noted above, used to determine the fair value of the warrants as of December 31, 2015.

9. COMMON STOCK OPTIONS

On February 11, 2011, the Company adopted its 2011 Equity Incentive Plan (the “Plan”) under which 6,475,750 shares of common stock were reserved for issuance under options or other equity interests as set forth in the Plan. Under the Plan, options are available for issuance to employees, officers, directors, consultants and advisors. The Plan provides that the board of directors will determine the exercise price and vesting terms of each option on the date of grant. Options granted under the Plan generally expire ten years from the date of grant. As of December 31, 2016, there were 3,577,661 shares available for issuance under the Plan.

Under the Plan, the Company has issued 161,250 shares of fully paid and non-assessable restricted common stock to a director of the Company. These shares of restricted stock are subject to the terms of the Plan and are unvested and outstanding as of December 31, 2015. The shares shall vest upon the earlier of (i) the occurrence of a Change of Control, as defined in the Plan, (ii) the successful completion of a Phase II clinical trial for any of the Company’s products, or (iii) the determination by the board of directors to provide for immediate vesting. The weighted average grant-date fair value is \$1.07 per share.

The following is a summary of all common stock option activity for the year ended December 31, 2016:

| | Options Outstanding | Weighted Average Exercise Price |
|----------------------------------|--------------------------------|--|
| Outstanding at December 31, 2015 | 4,996,095 | \$ 0.65 |
| Options granted | 125,411 | \$ 0.35 |
| Options forfeited | (2,384,667) | \$ 0.70 |
| Options exercised | - | \$ - |
| Outstanding at December 31, 2016 | <u>2,736,839</u> | <u>\$ 0.58</u> |

| | Options Exercisable | Weighted Average Exercise Price per Share |
|----------------------------------|--------------------------------|--|
| Exercisable at December 31, 2015 | 4,312,762 | \$ 0.68 |
| Exercisable at December 31, 2016 | 2,283,506 | \$ 0.62 |

The weighted average fair value of options granted during the year ended December 31, 2016 was \$0.14.

The weighted average remaining contractual term for exercisable and outstanding options is 4.55 and 5.15 years, respectively. The aggregate intrinsic value of all of the Company's exercisable and outstanding options is approximately \$0 and \$0, respectively.

As of December 31, 2016, there was approximately \$31,906 of unrecognized compensation cost related to non-vested options. The unrecognized compensation expense is estimated to be recognized over a period of 1.7 years at December 31, 2016.

The Company used the Black-Scholes option pricing model to value all option grants (see Note 2, Summary of Significant Accounting Policies, "Accounting for Share Based Payments").

10. RETIREMENT PLAN

In 2011, the Company adopted a defined contribution plan intended to qualify under Section 401(k) of the Internal Revenue Code covering all eligible employees of the Company. All employees are eligible to become participants of the plan upon reaching age 21 on the first day of the month following the hire date. Each employee may elect, voluntarily, to contribute a percentage of their compensation to the plan each year, subject to certain limitations. The Company reserves the right to make additional contributions to the plan. The Company has elected to make "safe harbor" contributions equal to 100% of the first 6% of participants' elective deferrals. In the years ended December 31, 2016 and 2015, the Company recognized expense related to its contributions of \$31,300 and \$37,175, respectively.

11. INCOME TAXES

The Company is subject to taxation in the U.S. and the State of New Jersey. At December 31, 2016 and 2015, the Company had gross deferred tax assets calculated at an expected blended rate of 39.94% of approximately \$12,267,597 and \$11,149,349, respectively. As the Company cannot determine that it is more likely than not that the Company will realize the benefit of the deferred tax asset, a valuation allowance of approximately \$12,266,000 and \$11,149,000 has been established at December 31, 2016 and 2015, respectively.

The significant components of the Company's net deferred tax assets (liabilities) at December 31, 2016 and 2015 are as follows:

| | December 31, 2016 | December 31, 2015 |
|--|----------------------------------|----------------------------------|
| Gross deferred tax assets: | | |
| Net operating loss carry-forwards | \$ 10,144,390 | \$ 9,099,986 |
| Stock based expenses | 1,108,677 | 1,094,424 |
| Tax credit carry-forwards | 361,758 | 363,607 |
| Capital loss carry-forwards | 462,566 | 462,128 |
| Long lived assets | 190,206 | 129,204 |
| | <u>12,267,597</u> | <u>11,149,349</u> |
| Deferred tax asset valuation allowance | (12,267,597) | (11,149,349) |
| Net deferred tax asset | <u>\$ -</u> | <u>\$ -</u> |

Income taxes computed using the federal statutory income tax rate differs from the Company's effective tax rate primarily due to the following:

| | December 31, 2016 | December 31, 2015 |
|--|------------------------------|------------------------------|
| Income taxes benefit (expense) at statutory rate | 34.00% | 34.00% |
| State income tax, net of federal benefit | (5.94)% | (5.94)% |
| Permanent differences | | |
| Meals & entertainment | (0.16)% | (0.01)% |
| Share-based compensation & warrant adjustments | 14.00% | 2.56% |
| Change in valuation allowance | (41.90)% | (30.62)% |
| | <u>0%</u> | <u>0%</u> |

At December 31, 2016, the Company has gross net operating loss carry-forwards for federal income tax purposes of approximately \$26,800,000 which expire in the years 2023 through 2036. The Company has gross state net operating loss carryforwards of approximately \$22,800,000 which expire in the years 2030 through 2035. The Company also has federal research and development carryforwards of approximately \$362,000 which expire twenty years from the date of inception. The net increase in the valuation allowance in the years ended December 31, 2016 and 2015 was approximately \$1,000,000 and \$1,500,000, respectively.

The Company is subject to the net operating loss utilization provisions of Section 382 of the Internal Revenue Code. Due to the reverse merger/recapitalization, the Company is restricted in the future use of net operating loss and tax credit carry-forwards generated by the Company before the effective date of the merger. Other ownership changes may cause the net operating losses to further be limited. Both of the separate loss years' net operating losses will be subject to possible limitations concerning changes of control and other limitations under the Internal Revenue Code. The effect of an ownership change would be the imposition of an annual limitation on the use of NOL carryforwards attributable to periods before the change. The amount of the annual limitation depends upon the value of the Company immediately before the change, changes to the Company's capital during a specified period prior to the change, and the federal published interest rate.

Topic 740 in the Accounting Standards Codification (ASC 740) prescribes recognition threshold and measurement attributes for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in a tax return. ASC 740 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. At December 31, 2016, the Company had taken no uncertain tax positions that would require disclosure under ASC 740.

12. COMMITMENTS AND CONTINGENCIES

License Agreements

On June 26, 2014, the Company and The General Hospital Corporation, d/b/a Massachusetts General Hospital ("MGH") entered into two license agreements (the "Agreements"), which Agreements replace the single license agreement between the Company and MGH dated April 27, 2009, as amended by letter dated June 21, 2011 and agreement dated October 31, 2011 (the "Original Agreement"). The Agreements provide exclusive licenses for the Company's two lead product candidates, BFPET and CardioPET, two of the three cardiac imaging technologies covered by the Original Agreement. The Agreements were entered into primarily for the purpose of separating the Company's rights and obligations with respect to its different product development programs. Each of the Agreements requires the Company to pay MGH an initial license fee of \$175,000 and annual license maintenance fees of \$125,000 each. The Agreements require the Company to meet certain obligations, including, but not limited to, meeting certain development milestones relating to clinical trials and filings with the United States Food and Drug Administration. MGH has the right to cancel or make non-exclusive certain licenses on certain patents should the Company fail to meet stipulated obligations and milestones. Additionally, upon commercialization, the Company is required to make specified milestone payments and royalties on commercial sales. The Company is amortizing the cost of these intangible assets over the remaining useful life of the Agreements of 10 years.

The Company pays annual maintenance fees of \$125,000 for each of its license agreements. For the years ended December 31, 2016 and 2015, the Company has recorded license fee expenses of \$250,000 and \$153,332, respectively.

On August 10, 2016, the Company entered into agreements with MGH to amend the Agreements to include the potential to license technical information in addition to intellectual property.

The Company is current with all stipulated obligations and milestones under the Agreements and the Agreements remain in full force and effect. The Company believes that it maintains a good relationship with MGH and will be able to obtain waivers or extension of its obligations under the Agreement, should the need arise. If MGH were to refuse to provide the Company with a waiver or extension of any of its obligations or were to cancel or make the license non-exclusive, this would have a material adverse impact on the Company as it may be unable to commercialize products without exclusivity and would lose its competitive edge for portions of the patent portfolio.

Executive Employment Contracts

The Company maintains employment contracts with key Company executives that provide for the continuation of salary and the grant of certain options to the executives if terminated for reasons other than cause, as defined within the agreements. One contract also provides for a \$1 million bonus should the Company execute transactions as specified in the contract, including the sale of substantially all of the Company's assets or a stock, or merger transaction, any of which resulting in compensation to the Company's stockholders aggregating in excess of \$50 million for such transaction.

Operating Lease Commitment

Effective July 31, 2016, the Company terminated its existing lease agreement. Then on August 1, 2016, the Company entered into a new one year lease agreement. The annual minimum lease payments for this space are \$25,966, payable in equal installments of \$2,164 per month.

The future minimum lease payments remaining through August 1, 2017 amount to \$17,312.

Rent expense, net of sublease income, was \$37,551 and \$76,975 for the years ended December 31, 2016 and 2015, respectively.

Legal Contingencies

The Company is not aware of any material, active, pending or threatened proceeding, nor is the Company, or any subsidiary, involved as a plaintiff or defendant in any other material proceeding or pending litigation.

13. SUBSEQUENT EVENTS

In 2017, Dr. Peter Conti, Mr. Johan (Thijs) Spoor, and Mr. Lawrence Atinsky resigned as directors. The resignations are not due to any disagreements on any matter relating to the Company's operations, policies and practices.

On March 13, 2017, the Company obtained majority approval to further amend the 2014 Notes to extend the maturity date of the Notes to June 22, 2017, with an effective date of January 22, 2017.

In February 2017, the Company issued 187,980 shares of common stock pursuant to the conversion of 2014 Convertible Notes.

During 2017, the Company issued promissory secured notes for the aggregate amount of \$155,000 with terms substantially similar to the 2016 Convertible Notes (see Note 5).

Effective as of February 24, 2017, Platinum Montaur, on behalf of itself and each of its successors and assigns, waived its Preferred Ratchet Rights and Warrant Ratchet Rights with respect to the Subsequent Financing, as defined, provided, however, that such waiver shall be automatically revoked and of no further force and effect if the Subsequent Financing is not completed by August 10, 2017.

On March 30, 2017, the Company obtained majority approval to amend the 2016 Notes to September 23, 2017, with an effective date of March 23, 2017.