

INNOVUS PHARMACEUTICALS, INC.

Form 10-K

March 09, 2017

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2016

Commission file number: 000-52991

INNOVUS PHARMACEUTICALS, INC.

(Name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation or organization)

90-0814124

(IRS Employer Identification No.)

9171 Towne Centre Drive, Suite 440, San Diego, CA

(Address of principal executive offices)

92122

(Zip code)

Registrant's telephone number: 858-964-5123

Securities registered under Section 12(b) of the Act: None.

Securities registered under Section 12 (g) of the Act:

Common Stock \$0.001 par value

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 15(d) of the Exchange Act.

Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, 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 for 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 registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the 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

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

As of June 30, 2016, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$11.2 million, based on the closing price of \$0.21 for the registrant's common stock as quoted on the OTCQB Market on that date. For purposes of this calculation, it has been assumed that shares of common stock held by each director, each officer and each person who owns 10% or more of the outstanding common stock of the registrant are held by affiliates of the registrant. The treatment of these persons as affiliates for purposes of this calculation is not conclusive as to whether such persons are, affiliates of the registrant for any other purpose.

As of March 3, 2017, the registrant had 124,810,756 shares of common stock outstanding.

Portions of the registrant's definitive proxy statement for its 2016 Annual Meeting of Stockholders (Proxy Statement) are incorporated by reference in Part III of this annual report on Form 10-K (Annual Report), to the extent stated herein.

TABLE OF CONTENTS

	Page
<u>PART I</u>	
<u>FORWARD LOOKING STATEMENTS</u>	1
<u>Item 1. Business.</u>	1
<u>Item 1A. Risk Factors.</u>	10
<u>Item 1B. Unresolved Staff Comments.</u>	20
<u>Item 2. Properties.</u>	20
<u>Item 3. Legal Proceedings.</u>	20
<u>Item 4. Mine Safety Disclosures.</u>	20
<u>PART II</u>	
<u>Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters, and Issuer Purchase of Equity Securities.</u>	21
<u>Item 6. Selected Financial Data.</u>	21
<u>Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.</u>	22
<u>Item 7A. Quantitative and Qualitative Disclosures about Market Risk.</u>	32
<u>Item 8. Financial Statements and Supplementary Data.</u>	32
<u>Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.</u>	32
<u>Item 9A. Controls and Procedures.</u>	32
<u>Item 9B. Other Information.</u>	33
<u>PART III</u>	
<u>Item 10. Directors, Executive Officers and Corporate Governance.</u>	34
<u>Item 11. Executive Compensation.</u>	34
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.</u>	34
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence.</u>	34
<u>Item 14. Principal Accountant Fees and Services.</u>	34
<u>PART IV</u>	
<u>Item 15. Exhibits and Financial Statement Schedules.</u>	35

Table of Contents

PART I

This Annual Report on Form 10-K includes the accounts of Innovus Pharmaceuticals, Inc., a Nevada corporation (“Innovus Pharma”), together with its wholly-owned subsidiaries, as follows (collectively referred to as “Innovus”, “we”, “our”, “us” or the “Company”): Semprae Laboratories, Inc., a Delaware corporation (“Semprae”), FasTrack Pharmaceuticals, Inc., a Delaware corporation (“FasTrack”) and Novalere, Inc., a Delaware corporation (“Novalere”).

“Zestra®”, “Zestra Glide®”, “EjectDelay®”, “Sensum+®”, “Vesele®”, “Beyond Human®”, “Androferti®”, “RecalMax™”, “FlutiCare™”, “Xyralid™”, “AllerVarx™”, “Urocis™ XR”, “AndroVit™” and other trademarks and intellectual property of others mentioned in this report are our property. This report contains additional trade names and trademarks of other companies. We do not intend our use or display of other companies’ trade names or trademarks to imply an endorsement or sponsorship of us by such companies, or any relationship with any of these companies.

FORWARD LOOKING STATEMENTS

Certain statements in this report, including information incorporated by reference, are “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements reflect current views about future events and financial performance based on certain assumptions. They include opinions, forecasts, intentions, plans, goals, projections, guidance, expectations, beliefs or other statements that are not statements of historical fact. Words such as “will,” “may,” “should,” “could,” “would,” “expects,” “plans,” “believes,” “anticipates,” “intends,” “estimates,” “approximates,” “predicts,” “forecasts,” “potential,” “continue,” or “projects,” or the negative or other variation of such words, and similar expressions may identify a statement as a forward-looking statement. Any statements that refer to projections of our future financial performance, our anticipated growth and trends in our business, our goals, strategies, focus and plans, and other characterizations of future events or circumstances, including statements expressing general optimism about future operating results and the development of our products, 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 Securities and Exchange Commission (“SEC”). You can 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. Readers are urged to carefully review and consider the various disclosures made throughout the entirety of this Annual Report on Form 10-K, which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

Item 1. Business

Overview

We are an emerging over-the-counter (“OTC”) consumer goods and specialty pharmaceutical company engaged in the commercialization, licensing and development of safe and effective non-prescription medicine and consumer care products to improve men’s and women’s health and vitality and respiratory diseases. We deliver innovative and uniquely presented and packaged health solutions through our (a) OTC medicines and consumer and health products, which we market directly, (b) commercial partners to primary care physicians, urologists, gynecologists and therapists, and (c) directly to consumers through our on-line channels, retailers and wholesalers. We are dedicated to being a leader in developing and marketing new OTC and branded Abbreviated New Drug Application (“ANDA”) products. We are actively pursuing opportunities where existing prescription drugs have recently, or are expected to, change from prescription (or Rx) to OTC. These “Rx-to-OTC switches” require Food and Drug Administration (“FDA”) approval through a process initiated by the New Drug Application (“NDA”) holder.

Our business model leverages our ability to (a) develop and build our current pipeline of products, and (b) to also acquire outright or in-license commercial products that are supported by scientific and/or clinical evidence, place them through our existing supply chain, retail and on-line (including Amazon®-based business platform) channels to tap new markets and drive demand for such products and to establish physician relationships. We currently have 17 products marketed in the United States with six of those being marketed and sold in multiple countries around the world through some of our 14 commercial partners. We currently expect to launch an additional five products in the U.S. in 2017 and we currently have approvals to launch certain of our already marketed products in 31 additional countries.

Table of Contents

Corporate Structure

We incorporated in the State of Nevada. In December 2011, we merged with FasTrack Pharmaceuticals, Inc. and changed our name to Innovus Pharmaceuticals, Inc.

In December 2013, we acquired Semprae Laboratories, Inc., which had two commercial products in the U.S. and one in Canada. As a result, Semprae became our wholly-owned subsidiary.

In February 2015, we entered into a merger agreement, whereby we acquired Novalere, Inc. and its worldwide rights to the Fluticare™ brand (fluticasone propionate nasal spray). We expect that the ANDA filed in November 2014 with the FDA may be approved in 2017, which will allow us to market and sell Fluticare™ over the counter in the U.S in the second half of 2017.

Our Strategy

Our corporate strategy focuses on two primary objectives:

1. Developing a diversified product portfolio of exclusive, unique and patented non-prescription OTC and branded ANDA drugs and consumer health products through: (a) the introduction of line extensions and reformulations of either our or third-party currently marketed products; and (b) the acquisition of products or obtaining exclusive licensing rights to market such products; and
2. Building an innovative, U.S. and global sales and marketing model through direct to consumer approaches such as our proprietary Beyond Human® Sales and Marketing platform, the addition of new online platforms such as Amazon® and commercial partnerships with established international complimentary partners that: (a) generates revenue, and (b) requires a lower cost structure compared to traditional pharmaceutical companies thereby increasing our gross margins.

We believe that our proven ability to market, license, acquire and develop brand name non-prescription pharmaceutical and consumer health products uniquely positions us to commercialize our products and grow in this market in a differentiated way. The following are additional details about our strategy:

Focusing on acquisition and licensing of commercial, non-prescription pharmaceutical and consumer health products that are well aligned with current therapeutic areas of male and female sexual health, pain, vitality and respiratory diseases . In general, we seek non-prescription pharmaceutical (OTC monograph, Rx to OTC ANDA switched drugs) and consumer health products that are already marketed with scientific and/or clinical data and evidence that are aligned with our therapeutic areas, which we then can grow through promotion to physicians and expanding sales through our existing retail and online channels and commercial partners on a worldwide basis. We have done this through our acquisitions and licensing of (1) Sensum+® from Centric Research Institute or CRI, (2) Zestra® and Zestra Glide® from Semprae, (3) Vesele® from Trōphikōs, LLC, (4) U.S. and Canada rights to Androferti® from Laboratorios Q Pharma (Spain), (5) FlutiCare™ from Novalere, and (6) UriVarx™ from Seipel Group;

Increasing the number of U.S. non-exclusive distribution channel partners for direct and online sales and also open more channels directly to physicians, urologists, gynecologists and therapists . One of our goals is to increase the

number of U.S. distribution channel partners that sell our products. To do this, we have devised a three-pronged approach. First, we are seeking to expand the number of OTC direct selling partners, such as the larger in-store distributors for selected products, and to expand sales to the more regional, statewide and local distributors, such as regional pharmacy chains, large grocery stores and supplement and health stores for selected products. Second, we are working to expand our online presence through relationships with well-known online sellers and the acquisition of additional platforms such as established Amazon® stores. Third, we are seeking to expand sales of our OTC products directly through sampling programs and detailing to physicians, urologists, gynecologists, therapists and to other healthcare providers who generally are used to recommending to their patients products that are supported by strong scientific and/or clinical data and evidence;

Seeking commercial partnerships outside the U.S. and developing consistent international commercial and distribution systems. We seek to develop a strong network of international distribution partners outside of the U.S. To do so, we are relying in part on past relationships that Dr. Bassam Damaj, our President and Chief Executive Officer, has had with certain commercial partners globally. In addition, we believe we have the ability to develop new relationships with commercial distributors who can demonstrate they have leading positions in their regions and can provide us with effective marketing and sales efforts and teams to detail our products to physicians and therapists. Our commercial partners outside the U.S. are responsible for storing, distributing and promoting our products to physicians, urologists, gynecologists, therapists and to other healthcare providers. We have already entered into 14 commercial partnerships covering our products in 65 countries outside the U.S.;

Table of Contents

Developing a proprietary patent portfolio to protect the therapeutic products and categories we desire to enter. We have filed and are working to secure patent claims in the U.S. and abroad covering product inventions and innovations that we believe are valuable. These patents, if issued and ultimately found to be valid, may enable us to create a barrier to entry for competitors on a worldwide basis; and

Achieving cost economies of scale from lower cost manufacturing, integrated distribution channels and multiple product discounts. We believe that we can achieve higher gross margins per product by shifting manufacturing to lower cost manufacturers. We also feel that we can acquire other OTC and consumer healthcare products and reintroduce them into our networks and sales and marketing platforms utilizing our integrated distribution and direct to consumer channels, thus receiving multiple product economies of scale from our distribution partners.

Our Products

Marketed Products

We currently market 17 products in the U.S. and six in multiple countries around the world through our commercial partners:

1.
Vesele® for promoting sexual and health (U.S. and U.K.);
2.
Zestra® for female arousal (U.S., U.K., Denmark, Canada, Morocco, the UAE and South Korea);
3.
Zestra Glide® (U.S, Canada and the MENA countries);
4.
EjectDelay® indicated for the treatment of premature ejaculation (U.S. and Canada);
5.
Sensum+® to alleviate reduced penile sensitivity (U.S., U.K. and Morocco);
6.
Beyond Human® Testosterone Booster;
7.
Beyond Human® Ketones;
8.
Beyond Human® Krill Oil;
9.
Beyond Human® Omega 3 Fish Oil;
- 10.

Beyond Human® Vision Formula;

11.

Beyond Human® Blood Sugar;

12.

Beyond Human® Colon Cleanse;

13.

Beyond Human® Green Coffee Extract;

14.

Beyond Human® Growth Agent;

15.

RecalMax™ for brain health;

16.

Androferti® (U.S. and Canada) supports overall male reproductive health and sperm quality; and

17.

UriVarx™ for overactive bladder and urinary incontinence.

Below is a more detailed description of each of our main products that we currently market and sell:

Vesele®

Vesele® is a proprietary oral supplement of Arginine with high absorption backed with clinical use data in men and women for sexual dysfunction. Vesele® contains a patented formulation of L-Arginine and L-Citrulline in combination with the natural absorption enhancer Bioperine®. The beneficial effects of Vesele® on sexual and cognitive functions were confirmed in a four month US clinical survey study involving 152 patients (69 men and 83 women). Results from the clinical survey have indicated (1) improvement of erectile hardness and maintenance in men and increased sexual intercourse frequency with their partners, and (2) lubrication in women, when taken separately by each.

Table of Contents

Sensum+®

Sensum+® is a non-medicated cream which moisturizes the head and shaft of the penis for enhanced feelings of sensation and greater sexual satisfaction. It is a patent-pending blend of essential oils and ingredients generally recognized as safe that recently commenced marketing in the U.S. We acquired the global ex-U.S. distribution rights to Sensum+® from CRI. The safety and efficacy of Sensum+® was evaluated in two post-marketing survey studies in circumcised and non-circumcised men. A total of 382 men used Sensum+® twice daily for 14 consecutive days followed by once daily for eight weeks and as needed thereafter. Study participants reported a ~50% increase in penile sensitivity with the use of Sensum+®.

Beyond Human® Testosterone Booster (BHT)

BHT is a proprietary oral supplement containing clinically tested ingredients to increase libido, vitality and sexual health endpoints in combination with the natural absorption enhancer Bioperine®.

Zestra®

Zestra® is our proprietary blend of essential oils proven in two peer-reviewed and published U.S. placebo controlled clinical trials in 276 women to increase desire, arousal and satisfaction. Zestra® is commercialized in the U.S. and Canada through major retailers, drug wholesalers such as McKesson and Cardinal Health and online.

Female Sexual Arousal Disorder, or FSAD, is a disorder part of the Female Sexual Dysfunction, or FSD, and is characterized by the persistent or recurrent inability to attain sexual arousal or to maintain arousal until completion of sexual activity. 43% of women age 18-59 experience some sort of sexual difficulties with one approved prescription product (Laumann, E.O. et al. Sexual Dysfunction in the United States: Prevalence and Predictors. JAMA, Feb. 10, 1999. vol. 281, No. 6.537-542). The U.S. arousal liquid market is estimated to be around \$500.0 million.

RecalMax™

RecalMax™ is a proprietary, novel oral dietary supplement to maximize nitric oxide's beneficial effects on brain health. RecalMax™ contains a patented formulation of low dose L-Arginine and L-Citrulline, in combination with the natural absorption enhancer Bioperine®. The beneficial effects of RecalMax™ on cognitive functions were confirmed in a four month U.S. clinical survey study involving 152 patients (69 men and 83 women). Results from the clinical survey have indicated improvement in multiple brain functions including word recall and focus.

UriVarx™

UriVarx™ is proprietary supplement clinically proven and to reduce urinary urgency, accidents and both day and night frequency in Overactive Bladder ("OAB") and Urinary Incontinence ("UI") patients. UriVarx™ was tested in OAB and UI patients in a 152 double blind placebo patient study over a period of eight weeks yielding up to 60% in reduction of urinary urgency and nocturia.

EjectDelay®

EjectDelay® is our proprietary, clinical proven OTC monograph compliant 7.5% benzocaine gel for premature ejaculation. Benzocaine acts to inhibit the voltage-dependent sodium channels on the nerve membrane, stopping the propagation of the action potential and resulting in temporary numbing of the application site. EjectDelay® is applied to the head of the penis ten minutes before intercourse. Premature Ejaculation, or PE, is the absence of

voluntary control over ejaculation resulting in ejaculation either preceding vaginal entry or occurring immediately upon vaginal entry and is defined as an ejaculation latency time of less than one minute. It is estimated that over 30% of males suffer from PE with a market size of \$1.0 billion with a 10.3% annual growth rate. Topical anesthetics make up 14% of the total PE market (The Journal of Sexual Medicine in 2007 Sex Med 2007).

Zestra Glide®

Zestra Glide® is a clinically tested water-based longer lasting lubricant. We acquired Zestra Glide® in our acquisition of Sempra in December 2013. In a 57 patient safety clinical study, Zestra Glide® proved to be safe and caused no irritation or skin side effects during the six week trial. To our knowledge, Zestra Glide® is the only water-based lubricant clinically tested for safety and has a viscosity of over 16000cps on the market. Increased viscosity usually translates into longer effects. The lubricant market is estimated to be around \$200.0 million in the U.S. (Symphony IRI Group Study, 2012).

Androferti®

Androferti® is a patented natural supplement that supports overall male reproductive health and sperm quality. Androferti®, has been shown in over five published clinical trials to statistically increase seminal quality (concentration, motility, morphology and vitality) and enhances spermatozoa quality (decreases of vacuoles in the sperm nucleus), decreases DNA fragmentation, decreases the dynamics of sperm DNA fragmentation and improvement on the inventory of mobile sperms.

Table of Contents

Pipeline Products

Fluticare™ (Fluticasone propionate nasal spray)

We expect that the ANDA filed in November 2014 with the FDA to be approved in 2017, which will allow us to market and sell Fluticare™ over the counter in the second half of 2017. FlutiCare™ is a nasal spray in the form of fluticasone propionate that has been the most prescribed nasal spray to patients in the U.S. for more than five consecutive years. The nasal steroid market is over \$1.0 billion annually in the U.S. (Reed, Lee and McCrory, "The Economic Burden of Allergic Rhinitis, Pharmacoeconomics 2004, 22 (6) 345-361).

Xyralid™

Xyralid™ is a lidocaine based cream for the relief of pain and symptoms caused by hemorrhoids. We expect to launch Xyralid™ in the first half of 2017 under our Beyond Human® sales and marketing platform.

AllerVarx™

AllerVarx™ is a patented formulation produced in bilayer tablets with a technology that allows a controlled release of the ingredients. The fast-release layer allows the rapid antihistaminic activity of perilla. The sustained-release layer enhances quercetin and vitamin D3 bioavailability, thanks to its lipidic matrix, and exerts antiallergic activity spread over time. AllerVarx™ was studied in a clinical trial assessing the reduction of both nasal and ocular symptoms in allergic patients, and daily consumption of anti-allergic drugs, over a period of 30 days. AllerVarx™ showed a reduction of approximately 70% in total symptom scores and a reduction of approximately 73% in the use of anti-allergic drugs. There were no side effects noted during the administration of AllerVarx™ and all the patients enrolled finished the study with good compliance. We expect to launch this product in the first half of 2017.

Urocis™ XR

Urocis™ XR, a proprietary 24-hour extended release of vaccinium marccarpon for urinary tract infections in women shown to provide 24-hour coverage in the body to increase compliance of the use of the product to get full benefit. According to Business Insights in their "The Antibacterials Market Outlook to 2016" report, urinary tract infections are very common, with an estimated incidence of 9.6%, or 7.0 million people in the U.S. Urinary tract infections typically affect post-pubescent females and the elderly. We expect to launch this product in the second half of 2017.

AndroVit™

AndroVit™ is a proprietary supplement to support overall prostate and male sexual health currently marketed in Europe. AndroVit™ was specifically formulated with ingredients known to support the normal prostate health and vitality and male sexual health. We expect to launch this product in the second half of 2017.

Sales and Marketing Strategy U.S. and Internationally

Our sales and marketing strategy is based on (a) the use of direct to consumer advertisements in print and online media through our proprietary Beyond Human® sales and marketing platform acquired in March 2016, (b) working with direct commercial channel partners in the U.S. and also directly marketing the products ourselves to physicians, urologists, gynecologists and therapists and to other healthcare providers, and (c) working with exclusive commercial partners outside of the U.S. that would be responsible for sales and marketing in those territories. We have now fully integrated most of our existing line of products such as Vesele®, Sensum+®, UriVarx™, Zestra®, and RecalMax™ into

the Beyond Human® sales and marketing platform. We plan to integrate Xyralid™, AllerVarx™, AndroVit™, Urocis™ XR; and FlutiCare™, subject to regulatory approvals, upon their commercial launches in 2017. We also market and distribute our products in the U.S. through retailers, wholesalers and other online channels. Our strategy outside the U.S. is to partner with companies who can effectively market and sell our products in their countries through their direct marketing and sales teams. The strategy of using our partners to commercialize our products is designed to limit our expenses and fix our cost structure, enabling us to increase our reach while minimizing our incremental spending.

Our current OTC, Rx-to-OTC ANDA switch drugs and consumer care products marketing strategy is to focus on four main U.S. markets which we all believe to be each in excess of \$1.0 billion: (1) Sexual health (female and male sexual dysfunction and health); (2) Urology (bladder and prostate health); (3) Respiratory disease; and (4) Brain health. We will focus our current efforts on these four markets and will seek to develop, acquire or license products that we can sell through our sales channels in these fields.

-5-

Table of Contents

Manufacturers and Single Source Suppliers

We use third-party manufacturers for the production of our products for development and commercial purposes. We believe there is currently excess capacity for manufacturing in the marketplace and opportunities to lower manufacturing cost through outsourcing to regions and countries that can do it in a more cost-effective basis. Some of our products are currently available only from sole or limited suppliers. We currently have multiple contract manufacturers for our multiple products and we issue purchase orders to these suppliers each time we require replenishment of our product inventory. All of our current manufacturers are based in the U.S. except for two based in Italy and we are looking to establish contract manufacturing for certain of our products in Europe and the Middle East and Northern Africa regions to reduce the cost and risk of supply chain to our current and potential commercial partners in their territories.

Government Regulation

Our products are normally subject to regulatory approval or must comply with various U.S. and international regulatory requirements. Unlike pharmaceutical companies who primarily sell prescription products, we currently sell drug or health products into the OTC market. While prescription products normally must progress from pre-clinical to clinical to FDA approval and then can be marketed and sold, our products are normally subject to conformity to FDA monograph requirements and similar requirements in other countries, which requires a shorter time frame for us to satisfy regulatory requirements and permits us to begin commercialization.

Below is a brief description of the FDA regulatory process for our products in the U.S.

U.S. Food and Drug Administration

The FDA and other federal, state, local and foreign regulatory agencies impose substantial requirements upon the clinical development, approval, labeling, manufacture, marketing and distribution of drug products. These agencies regulate, among other things, research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, advertising and promotion of our product candidates. The regulatory approval process is generally lengthy and expensive, with no guarantee of a positive result. Moreover, failure to comply with applicable FDA or other requirements may result in civil or criminal penalties, recall or seizure of products, injunctive relief including partial or total suspension of production, or withdrawal of a product from the market.

The FDA regulates, among other things, the research, manufacture, promotion and distribution of drugs in the U.S. under the Federal Food, Drug and Cosmetic Act, or the ("FFDCA"), and other statutes and implementing regulations. The process required by the FDA before prescription drug product candidates may be marketed in the U.S. generally involves the following:

Completion of extensive nonclinical laboratory tests, animal studies and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice regulations;

Submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;

For some products, performance of adequate and well-controlled human clinical trials in accordance with the FDA's regulations, including Good Clinical Practices, to establish the safety and efficacy of the product candidate for each proposed indication;

Submission to the FDA of a new drug application, or NDA;

Submission to the FDA of an abbreviated new drug application, or ANDA;

Satisfactory completion of an FDA preapproval inspection of the manufacturing facilities at which the product is produced to assess compliance with current Good Manufacturing Practice, or cGMP, regulations; and

FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Table of Contents

Nonclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals and other animal studies. The results of nonclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND to the FDA. Some nonclinical testing may continue even after an IND is submitted. The IND also includes one or more protocols for the initial clinical trial or trials and an investigator's brochure. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to the proposed clinical trials as outlined in the IND and places the clinical trial on a clinical hold. In such cases, the IND sponsor and the FDA must resolve any outstanding concerns or questions before any clinical trials can begin. Clinical trial holds also may be imposed at any time before or during studies due to safety concerns or non-compliance with regulatory requirements. An independent institutional review board, or IRB, at each of the clinical centers proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the consent form signed by the trial participants and must monitor the study until completed.

Abbreviated New Drug Application

An ANDA contains data which when submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the public than a bioequivalent prescription product.

A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. Generic drug applications are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug). One way scientists demonstrate bioequivalence is to measure the time it takes the generic drug to reach the bloodstream in 24 to 36 healthy, volunteers. This gives them the rate of absorption, or bioavailability, of the generic drug, which they can then compare to that of the innovator drug. The generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as the innovator drug.

Using bioequivalence as the basis for approving generic copies of drug products was established by the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Waxman-Hatch Act. This Act expedites the availability of less costly generic drugs by permitting FDA to approve applications to market generic versions of brand-name drugs without conducting costly and duplicative clinical trials. At the same time, the Act granted companies the ability to apply for up to five additional years of patent protection for the innovator drugs developed to make up for time lost while their products were going through the FDA's approval process. Brand-name drugs are subject to the same bioequivalence tests as generics upon reformulation.

BioEquivalency Studies

Studies to measure bioavailability and/or establish bioequivalence of a product are important elements in support of investigational new drug applications, or INDs, new drug applications, or NDAs, ANDAs and their supplements. As part of INDs and NDAs for orally administered drug products, bioavailability studies focus on determining the process by which a drug is released from the oral dosage form and moves to the site of action. Bioavailability data provide an estimate of the fraction of the drug absorbed, as well as its subsequent distribution and elimination. Bioavailability can be generally documented by a systemic exposure profile obtained by measuring drug and/or metabolite concentration in the systemic circulation over time. The systemic exposure profile determined during clinical trials in the IND

period can serve as a benchmark for subsequent bioequivalence studies. Studies to establish bioequivalence between two products are important for certain changes before approval for a pioneer product in NDA and ANDA submissions and in the presence of certain post-approval changes in NDAs and ANDAs. In bioequivalence studies, an applicant compares the systemic exposure profile of a test drug product to that of a reference drug product. For two orally or intra-nasally administered drug products to be bioequivalent, the active drug ingredient or active moiety in the test product must exhibit the same rate.

OTC Monograph Process

The FDA regulates certain non-prescription drugs using an OTC Monograph product designation which, when final, is published in the Code of Federal Regulations at 21 C.F.R. Parts 330-358. Such products that meet each of the conditions established in the OTC Monograph regulations, as well as all other applicable regulations, may be marketed without prior approval by the FDA.

The general conditions set forth for OTC Monograph products include, among other things:

The product is manufactured at FDA registered establishments and in accordance with cGMPs;

The product label meets applicable format and content requirements including permissible "Indications" and all required dosing instructions and limitations, warnings, precautions and contraindications that have been established in an applicable OTC Monograph;

Table of Contents

The product contains only permissible active ingredients in permissible strengths and dosage forms;

The product contains only suitable inactive ingredients which are safe in the amounts administered and do not interfere with the effectiveness of the preparation; and

The product container and container components meet FDA's requirements.

The advertising for OTC drug products is regulated by the Federal Trade Commission, or FTC, which generally requires that advertising claims be truthful, not misleading, and substantiated by adequate and reliable scientific evidence. False, misleading or unsubstantiated OTC drug advertising may be subject to FTC enforcement action and may also be challenged in court by competitors or others under the federal Lanham Act or similar state laws. Penalties for false or misleading advertising may include monetary fines or judgments as well as injunctions against further dissemination of such advertising claims.

A product marketed pursuant to an OTC Monograph must be listed with the FDA's Drug Regulation and Listing System and have a National Drug Code listing which is required for all marketed drug products. After marketing, the FDA may test the product or otherwise investigate the manufacturing and development of the product to ensure compliance with the OTC Monograph. Should the FDA determine that a product is not marketed in compliance with the OTC Monograph or is advertised outside of its regulations, the FDA may require corrective action up to and including market withdrawal and recall.

Other Regulatory Requirements

Maintaining substantial compliance with appropriate federal, state, local and international statutes and regulations requires the expenditure of substantial time and financial resources. Drug manufacturers are required to register their establishments with the FDA and certain state agencies and, after approval, the FDA and these state agencies conduct periodic unannounced inspections to ensure continued compliance with ongoing regulatory requirements, including cGMPs. In addition, after approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. The FDA may require post-approval testing and surveillance programs to monitor safety and the effectiveness of approved products that have been commercialized. Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including:

Meeting record-keeping requirements;

Reporting of adverse experiences with the drug;

Providing the FDA with updated safety and efficacy information;

Reporting on advertisements and promotional labeling;

Drug sampling and distribution requirements; and

Complying with electronic record and signature requirements.

In addition, the FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. There are numerous regulations and policies that govern various means for disseminating information to health-care professionals as well as consumers, including to industry sponsored scientific and educational activities, information provided to the media and information provided over the Internet. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

The FDA has very broad enforcement authority and the failure to comply with applicable regulatory requirements can result in administrative or judicial sanctions being imposed on us or on the manufacturers and distributors of our approved products, including warning letters, refusals of government contracts, clinical holds, civil penalties, injunctions, restitution and disgorgement of profit, recall or seizure of products, total or partial suspension of production or distribution, withdrawal of approvals, refusal to approve pending applications and criminal prosecution resulting in fines and incarceration. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label or unapproved uses may be subject to significant liability. In addition, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

-8-

Table of Contents

Competition

The OTC pharmaceutical market is highly competitive with many established manufacturers, suppliers and distributors that are actively engaged in all phases of the business. We believe that competition in the sale of our products will be based primarily on efficacy, regulatory compliance, brand awareness, availability, product safety and price. Our brand name OTC pharmaceutical products may be subject to competition from alternate therapies during the period of patent protection and thereafter from generic or other competitive products. All of our existing products, and products we have agreements to acquire, compete with generic and other competitive products in the marketplace.

Competing in the branded product business requires us to identify and quickly bring to market new products embodying technological innovations. Successful marketing of branded products depends primarily on the ability to communicate the efficacy, safety and value to healthcare professionals in private practice, group practices and managed care organizations. We anticipate that our branded product offerings will support our existing lines of therapeutic focus. Based upon business conditions and other factors, we regularly reexamine our business strategies and may from time to time reallocate our resources from one therapeutic area to another, withdraw from a therapeutic area or add an additional therapeutic area in order to maximize our overall growth opportunities.

Some of our existing products, and products we have agreements to acquire, compete with one or more products marketed by very large pharmaceutical companies that have much greater financial resources for marketing, selling and developing their products. These competitors, as well as others, have been in business for a longer period of time, have a greater number of products on the market and have greater financial and other resources than we do. If we directly compete with them for the same markets and/or products, their financial and market strength could prevent us from capturing a meaningful share of those markets.

We also compete with other OTC pharmaceutical companies for product line acquisitions as well as for new products and acquisitions of other companies.

Research and Development

We have used outside contract research organizations to carry out our research and development activities. During the years ended December 31, 2016 and 2015, we incurred research and development costs totaling \$77,804, and \$0, respectively. This increase was a result of the cost of salary and the related health benefits for an employee, conclusion of testing, non-human primate safety studies, clinical studies for our products Zestra®, Zestra Glide®, EjectDelay® and Sensum+®, as well as the fair value of the shares of common stock issued to CRI totaling \$23,000 for the settlement of certain clinical and regulatory milestone payments due under the in-license agreement for Sensum+®.

Employees

We currently have five full-time employees, including Dr. Bassam Damaj, who serves as our President and Chief Executive Officer. We also rely on a number of consultants. Our employees are not represented by a labor union or by a collective bargaining agreement. Subject to the availability of financing, we intend to expand our staff to implement our growth strategy.

Intellectual Property Protection

Our ability to protect our intellectual property, including our technology, will be an important factor in the success and continued growth of our business. We protect our intellectual property through trade secrets law, patents, copyrights,

trademarks and contracts. Some of our technology relies upon third-party licensed intellectual property.

We currently hold four patents in the U.S. and six patents registered outside the U.S. We currently have no patent applications pending in the U.S. and 11 patent applications pending in countries other than the U.S. We also have exclusive U.S. rights to multiple patents in the U.S. and Europe licensed under the product license agreements we have with NTC Pharma and Q Pharma.

We own nine trademark registrations and have four trademark applications pending in the U.S. We also own 19 trademarks registered outside of the U.S., with no applications currently pending.

We have established business procedures designed to maintain the confidentiality of our proprietary information, including the use of confidentiality agreements and assignment-of-inventions agreements with employees, independent contractors, consultants and companies with which we conduct business.

Company Information

Our executive offices are located at 9171 Towne Centre Drive, Suite 440, San Diego, California 92122 and our telephone number at such office is (858) 964-5123. Our website address is innovuspharma.com. Information contained on our website is not deemed part of this Annual Report.

Table of Contents

Item 1A. Risk Factors.

Our business endeavors and our common stock involve a high degree of risk. You should carefully consider the risks described below with all of the other information included in this report. If any of the following risks actually occur, they may materially harm our business and our financial condition and results of operations. In that event, the market price of our common stock could decline, and investors could lose part or all of their investment.

Risks Associated with Our Financial Condition

We have a history of significant recurring losses and these losses may continue in the future, therefore negatively impacting our ability to achieve our business objectives.

As of December 31, 2016, we had an accumulated deficit of approximately \$29.1 million. In addition, we incurred net losses of approximately \$13.7 million and \$4.2 million for the years ended December 31, 2016 and 2015, respectively. These losses may continue in the future. We expect to continue to incur significant sales and marketing, research and development, and general and administrative expense. As a result, we will need to generate significant revenue to achieve profitability, and we may never achieve profitability. Revenue and profit, if any, will depend upon various factors, including (1) growing the current sales of our products, (2) the successful acquisition of additional commercial products, (3) raising capital to implement our growth strategy, (4) obtaining any applicable regulatory approvals of our proposed product candidates, (5) the successful licensing and commercialization of our proposed product candidates, and (6) growth and development of our operations. We may not achieve our business objectives and the failure to achieve such goals would have an adverse impact on us.

We may require additional financing to satisfy our current contractual obligations and execute our business plan.

We have not been profitable since inception. As of December 31, 2016, we had approximately \$0.8 million in cash. We had a net loss of approximately \$13.7 million and \$4.2 million for the years ended December 31, 2016 and 2015, respectively. Additionally, sales of our existing products are significantly below the levels necessary to achieve positive cash flow. Although we expect that our existing capital resources, revenue from sales of our products will be sufficient to allow us to continue our operations, commence the product development process and launch selected products through at least January 1, 2018, no assurances can be given that we will not need to raise additional capital to fund our business plan. Although no assurances can be given, we currently plan to raise additional capital through the sale of equity or debt securities. If we are not able to raise sufficient capital, our continued operations may be in jeopardy and we may be forced to cease operations and sell or otherwise transfer all or substantially all of our remaining assets.

If we issue additional shares of common stock in the future, it will result in the dilution of our existing shareholders.

Our Amended and Restated Articles of Incorporation authorize the issuance of up to 292.5 million shares of common stock and up to 7.5 million shares of preferred stock. The issuance of any such shares of common stock may result in a decrease in value of your investment. If we do issue any such additional shares of common stock, such issuance also will cause a reduction in the proportionate ownership and voting power of all other shareholders. Further, any such issuance may result in a change of control of our corporation.

If we issue additional debt securities, our operations could be materially and negatively affected.

We have historically funded our operations partly through the issuance of debt securities. If we obtain additional debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest

on such indebtedness, thus limiting funds available for our business activities. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or curtail our operations. In addition, we may be required to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to technologies or products that we would otherwise seek to develop or commercialize ourselves or license rights to technologies or products on terms that are less favorable to us than might otherwise be available.

Our ability to use our net operating loss carry-forwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carry-forwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carry-forwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Table of Contents

Risks Associated with Our Business Model

We have a short operating history and have not produced significant revenue over a period of time. This makes it difficult to evaluate our future prospects and increases the risk that we will not be successful.

We have a short operating history with our current business model, which involves the commercialization, licensing and development of over-the-counter healthcare products. While we have been in existence for years, we only began our current business model in 2013 and have only generated approximately \$1.0 million in net revenue in 2014, approximately \$736,000 in 2015 and approximately \$4.8 million in net revenue for the year ended December 31, 2016, and our operations have not yet been profitable. No assurances can be given that we will generate any significant revenue in the future. As a result, we have a very limited operating history for you to evaluate in assessing our future prospects. Our operations have not produced significant revenue over a period of time, and may not produce significant revenue in the near term, which may harm our ability to obtain additional financing and may require us to reduce or discontinue our operations. You must consider our business and prospects in light of the risks and difficulties we will encounter as an early-stage company. We may not be able to successfully address these risks and difficulties, which could significantly harm our business, operating results and financial condition.

The success of our business currently depends on the successful continuous commercialization of our main products and these products may not be successfully grown beyond their current levels.

We currently have a limited number of products for sale. The success of our business currently depends on our ability, directly or through a commercial partner, to successfully market and sell those limited products outside the U.S. and to expand our retail and online channels in the U.S.

Although we have commercial products that we can currently market and sell, we will continue to seek to acquire or license other products and we may not be successful in doing so.

We currently have a limited number of products. We may not be successful in marketing and commercializing these products to the extent necessary to sustain our operations. In addition, we will continue to seek to acquire or license non-prescription pharmaceutical and consumer health products. The successful consummation of these types of acquisitions and licensing arrangements is subject to the negotiation of complex agreements and contractual relationships and we may be unable to negotiate such agreements or relationships on a timely basis, if at all, or on terms acceptable to us.

If we fail to successfully introduce new products, we may lose market position.

New products, product improvements, line extensions and new packaging will be an important factor in our sales growth. If we fail to identify emerging consumer trends, to maintain and improve the competitiveness of our existing products or to successfully introduce new products on a timely basis, we may lose market position. Continued product development and marketing efforts have all the risks inherent in the development of new products and line extensions, including development delays, the failure of new products and line extensions to achieve anticipated levels of market acceptance and the cost of failed product introductions.

Our sales and marketing function is currently very limited and we currently rely on third parties to help us promote our products to physicians in the U.S. and rely on our partners outside the U.S. We will need to maintain the commercial partners we currently have and attract others or be in a position to afford qualified or experienced marketing and sales personnel for our products.

We have had only approximately \$736,000 in net revenue in 2015, and approximately \$4.8 million during the year ended December 31, 2016. We will need to continue to develop strategies, partners and distribution channels to promote and sell our products.

We have no commercial manufacturing capacity and rely on third-party contract manufacturers to produce commercial quantities of our products.

We do not have the facilities, equipment or personnel to manufacture commercial quantities of our products and therefore must rely on qualified third-party contract manufactures with appropriate facilities and equipment to contract manufacture commercial quantities of products. These third-party contract manufacturers are also subject to current good manufacturing practice, or cGMP regulations, which impose extensive procedural and documentation requirements. Any performance failure on the part of our contract manufacturers could delay commercialization of any approved products, depriving us of potential product revenue.

Table of Contents

Failure by our contract manufacturers to achieve and maintain high manufacturing standards could result in patient injury or death, product recalls or withdrawals, delays or failures in testing or delivery, cost overruns or other problems that could materially adversely affect our business. Contract manufacturers may encounter difficulties involving production yields, quality control and quality assurance. These manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state and foreign agencies to ensure strict compliance with cGMP and other applicable government regulations; however, beyond contractual remedies that may be available to us, we do not have control over third-party manufacturers' compliance with these regulations and standards.

If for some reason our contract manufacturers cannot perform as agreed, we may be required to replace them. Although we believe there are a number of potential replacements, we may incur added costs and delays in identifying and qualifying any such replacements.

The inability of a manufacturer to ship orders of our products in a timely manner or to meet quality standards could cause us to miss the delivery date requirements of our customers for those items, which could result in cancellation of orders, refusal to accept deliveries or a reduction in purchase prices, any of which could have a material adverse effect as our revenue would decrease and we would incur net losses as a result of sales of the product, if any sales could be made.

We are also dependent on certain third parties for the supply of the raw materials necessary to develop and manufacture our products, including the active and inactive pharmaceutical ingredients used in our products. We are required to identify the supplier of all the raw materials for our products in any drug applications that we file with the FDA and all FDA-approved products that we acquire from others. If raw materials for a particular product become unavailable from an approved supplier specified in a drug application, we would be required to qualify a substitute supplier with the FDA, which would likely delay or interrupt manufacturing of the affected product. To the extent practicable, we attempt to identify more than one supplier in each drug application. However, some raw materials are available only from a single source and, in some of our drug applications, only one supplier of raw materials has been identified, even in instances where multiple sources exist.

In addition, we obtain some of our raw materials and products from foreign suppliers. Arrangements with international raw material suppliers are subject to, among other things, FDA regulation, various import duties, foreign currency risk and other government clearances. Acts of governments outside the U.S. may affect the price or availability of raw materials needed for the development or manufacture of our products. In addition, any changes in patent laws in jurisdictions outside the U.S. may make it increasingly difficult to obtain raw materials for research and development prior to the expiration of the applicable U.S. or foreign patents.

Our U.S. business could be adversely affected by changes in the U.S. presidential administration.

A new U.S. presidential administration came to power in January 2017 and President Trump has publicly stated that he will take certain efforts to impose importation tariffs from certain countries such as China and Mexico which could affect the cost of certain of our product components. In addition, the Trump Administration has and will appoint and employ many new secretaries, directors and the like into positions of authority in the U.S. Federal government dealing with the pharmaceutical and healthcare industries that may potentially have a negative impact on the prices and the regulatory pathways for certain pharmaceuticals, nutritional supplements and health care products such as those developed, marketed and sold by us. Such changes in the regulatory pathways could adversely affect and or delay our ability to market and sell our products in the U.S.

The business that we conduct outside the U.S. may be adversely affected by international risk and uncertainties.

Although our operations are based in the U.S., we conduct business outside the U.S and expect to continue to do so in the future. In addition, we plan to seek approvals to sell our products in foreign countries. Any business that we conduct outside the U.S. will be subject to additional risks that may materially adversely affect our ability to conduct business in international markets, including:

Potentially reduced protection for intellectual property rights;

Unexpected changes in tariffs, trade barriers and regulatory requirements;

Economic weakness, including inflation or political instability in particular foreign economies and markets;

Workforce uncertainty in countries where labor unrest is more common than in the United States;

Production shortages resulting from any events affecting a product candidate and/or finished drug product supply or manufacturing capabilities abroad;

Table of Contents

Business interruptions resulting from geo-political actions, including war and terrorism or natural disasters, including earthquakes, hurricanes, typhoons, floods and fires; and

Failure to comply with Office of Foreign Asset Control rules and regulations and the Foreign Corrupt Practices Act, or FCPA.

These factors or any combination of these factors may adversely affect our revenue or our overall financial performance.

Acquisitions involve risks that could result in a reduction of our operating results, cash flows and liquidity.

We have made and in the future may, continue to make strategic acquisitions including licenses of third-party products. However, we may not be able to identify suitable acquisition and licensing opportunities. We may pay for acquisitions and licenses with our common stock or with convertible securities, which may dilute your investment in our common stock, or we may decide to pursue acquisitions and licenses that investors may not agree with. In connection with one of our latest acquisitions, we have also agreed to substantial earn-out arrangements. To the extent we defer the payment of the purchase price for any acquisition or license through a cash earn-out arrangement, it will reduce our cash flows in subsequent periods. In addition, acquisitions or licenses may expose us to operational challenges and risks, including:

The ability to profitably manage acquired businesses or successfully integrate the acquired business' operations and financial reporting and accounting control systems into our business;

Increased indebtedness and contingent purchase price obligations associated with an acquisition;

The ability to fund cash flow shortages that may occur if anticipated revenue is not realized or is delayed, whether by general economic or market conditions or unforeseen internal difficulties;

The availability of funding sufficient to meet increased capital needs;

Diversion of management's attention; and

The ability to retain or hire qualified personnel required for expanded operations.

Completing acquisitions may require significant management time and financial resources. In addition, acquired companies may have liabilities that we failed, or were unable, to discover in the course of performing due diligence investigations. We cannot assure you that the indemnification granted to us by sellers of acquired companies will be sufficient in amount, scope or duration to fully offset the possible liabilities associated with businesses or properties we assume upon consummation of an acquisition. We may learn additional information about our acquired businesses

that materially adversely affect us, such as unknown or contingent liabilities and liabilities related to compliance with applicable laws. Any such liabilities, individually or in the aggregate, could have a material adverse effect on our business.

Failure to successfully manage the operational challenges and risks associated with, or resulting from, acquisitions could adversely affect our results of operations, cash flows and liquidity. Borrowings or issuances of convertible securities associated with these acquisitions may also result in higher levels of indebtedness, which could impact our ability to service our debt within the scheduled repayment terms.

We will need to expand our operations and increase our size, and we may experience difficulties in managing growth.

As we increase the number of products we own or have the right to sell, we will need to increase our sales, marketing, product development and scientific and administrative headcount to manage these programs. In addition, to meet our obligations as a public company, we will need to increase our general and administrative capabilities. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

Successfully attract and recruit new employees with the expertise and experience we will require;

Successfully grow our marketing, distribution and sales infrastructure; and

Table of Contents

Continue to improve our operational, manufacturing, financial and management controls, reporting systems and procedures.

If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully operate our business.

Our success depends to a significant extent upon the continued services of Dr. Bassam Damaj, our President and Chief Executive Officer. Dr. Damaj has overseen our current business strategy since inception and provides leadership for our growth and operations strategy as well as being our sole employee with any significant scientific or pharmaceutical experience. Loss of the services of Dr. Damaj would have a material adverse effect on our growth, revenue and prospective business. The loss of any of our key personnel, or the inability to attract and retain qualified personnel, may significantly delay or prevent the achievement of our research, development or business objectives and could materially adversely affect our business, financial condition and results of operations.

Any employment agreement we enter into will not ensure the retention of the employee who is a party to the agreement. In addition, we have only limited ability to prevent former employees from competing with us. Furthermore, our future success will also depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire and retain additional personnel. We experience intense competition for qualified personnel and may be unable to attract and retain the personnel necessary for the development of our business. Moreover, competition for personnel with the scientific and technical skills that we seek is extremely high and is likely to remain high. Because of this competition, our compensation costs may increase significantly. We presently have no scientific employees.

We may not be able to continue to pay consultants, vendors and independent contractors through the issuance of equity instruments in order to conserve cash.

We have paid numerous consultants and vendor fees through the issuance of equity instruments in order to conserve our cash, however there can be no assurance that we, our vendors, consultants or independent contractors, current or future, will continue to agree to this arrangement. As a result, we may be asked to spend more cash for the same services, or we may not be able to retain the same consultants, vendors, etc.

We face significant competition and have limited resources compared to our competitors.

We are engaged in a highly competitive industry. We can expect competition from numerous companies, including large international enterprises and others entering the market for products similar to ours. Most of these companies have greater research and development, manufacturing, patent, legal, marketing, financial, technological, personnel and managerial resources. Acquisitions of competing companies by large pharmaceutical or healthcare companies could further enhance such competitors' financial, marketing and other resources. Competitors may complete clinical trials, obtain regulatory approvals and commence commercial sales of their products before we could enjoy a significant competitive advantage. Products developed by our competitors may be more effective than our product candidates.

Competition and technological change may make our product candidates and technologies less attractive or obsolete.

We compete with established pharmaceutical and biotechnology companies that are pursuing other products for the same markets we are pursuing and that have greater financial and other resources. Other companies may succeed in developing or acquiring products earlier than us, developing products that are more effective than our products or achieve greater market acceptance. As these companies develop their products, they may develop competitive positions that may prevent, make futile, or limit our product commercialization efforts, which would result in a decrease in the revenue we would be able to derive from the sale of any products.

Risks Relating to Intellectual Property

If we fail to protect our intellectual property rights, our ability to pursue the development of our technologies and products would be negatively affected.

Our success will depend in part on our ability to obtain patents and maintain adequate protection of our technologies and products. If we do not adequately protect our intellectual property, competitors may be able to use our technologies to produce and market products in direct competition with us and erode our competitive advantage. Some foreign countries lack rules and methods for defending intellectual property rights and do not protect proprietary rights to the same extent as the U.S. Many companies have had difficulty protecting their proprietary rights in these foreign countries. We may not be able to prevent misappropriation of our proprietary rights.

Table of Contents

We have received, and are currently seeking, patent protection for numerous compounds and methods of use. However, the patent process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our products by obtaining and defending patents. These risks and uncertainties include the following: patents that may be issued or licensed may be challenged, invalidated or circumvented, or otherwise may not provide any competitive advantage; our competitors, many of which have substantially greater resources than us and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with or eliminate our ability to make, use and sell our potential products either in the U.S. or in international markets and countries other than the U.S. may have less restrictive patent laws than those upheld by U.S. courts, allowing foreign competitors the ability to exploit these laws to create, develop and market competing products.

Moreover, any patents issued to us may not provide us with meaningful protection or others may challenge, circumvent or narrow our patents. Third parties may also independently develop products similar to our products, duplicate our unpatented products or design around any patents on products we develop. Additionally, extensive time is required for development, testing and regulatory review of a potential product. While extensions of patent term due to regulatory delays may be available, it is possible that, before any of our products candidates can be commercialized, any related patent, even with an extension, may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent.

In addition, the U.S. Patent and Trademark Office (the "PTO") and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the patents may be substantially narrower than anticipated.

Our success depends on our patents, patent applications that may be licensed exclusively to us and other patents to which we may obtain assignment or licenses. We may not be aware, however, of all patents, published applications or published literature that may affect our business either by blocking our ability to commercialize our products, by preventing the patentability of our products to us or our licensors or by covering the same or similar technologies that may invalidate our patents, limit the scope of our future patent claims or adversely affect our ability to market our products.

In addition to patents, we rely on a combination of trade secrets, confidentiality, nondisclosure and other contractual provisions and security measures to protect our confidential and proprietary information. These measures may not adequately protect our trade secrets or other proprietary information. If they do not adequately protect our rights, third parties could use our technology and we could lose any competitive advantage we may have. In addition, others may independently develop similar proprietary information or techniques or otherwise gain access to our trade secrets, which could impair any competitive advantage we may have.

Patent protection and other intellectual property protection are crucial to the success of our business and prospects, and there is a substantial risk that such protections will prove inadequate.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive and time consuming.

The pharmaceutical industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may become subject to infringement claims or litigation arising out of patents and pending applications of our

competitors or additional interference proceedings declared by the PTO to determine the priority of inventions. The defense and prosecution of intellectual property suits, PTO proceedings and related legal and administrative proceedings are costly and time-consuming to pursue and their outcome is uncertain. Litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope and validity of the proprietary rights of others. An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties or restrict or prevent us from selling our products in certain markets. Although patent and intellectual property disputes might be settled through licensing or similar arrangements, the costs associated with such arrangements may be substantial and could include our paying large fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all.

Competitors may infringe our patents and we may file infringement claims to counter infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly.

Table of Contents

Also, a third party may assert that our patents are invalid and/or unenforceable. There are no unresolved communications, allegations, complaints or threats of litigation related to the possibility that our patents are invalid or unenforceable. Any litigation or claims against us, whether merited or not, may result in substantial costs, place a significant strain on our financial resources, divert the attention of management and harm our reputation. An adverse decision in litigation could result in inadequate protection for our product candidates and/or reduce the value of any license agreements we have with third parties.

Interference proceedings brought before the PTO may be necessary to determine priority of invention with respect to our patents or patent applications. During an interference proceeding, it may be determined that we do not have priority of invention for one or more aspects in our patents or patent applications and could result in the invalidation in part or whole of a patent or could put a patent application at risk of not issuing. Even if successful, an interference proceeding may result in substantial costs and distraction to our management.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or interference proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the price of our common stock could be adversely affected.

If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages and defend against litigation.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to: obtain licenses, which may not be available on commercially reasonable terms, if at all; abandon an infringing product candidate; redesign our products or processes to avoid infringement; stop using the subject matter claimed in the patents held by others; pay damages; and/or defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

We may be subject to potential product liability and other claims, creating risks and expense.

We are also exposed to potential product liability risks inherent in the development, testing, manufacturing, marketing and sale of human therapeutic products. Product liability insurance for the pharmaceutical industry is extremely expensive, difficult to obtain and may not be available on acceptable terms, if at all. We have no guarantee that the coverage limits of such insurance policies will be adequate. A successful claim against us, which is in excess of our insurance coverage, could have a material adverse effect upon us and on our financial condition.

Changes in trends in the pharmaceutical and biotechnology industries, including difficult market conditions, could adversely affect our operating results.

The biotechnology, pharmaceutical and medical device industries generally, and drug discovery and development companies more specifically, are subject to increasingly rapid technological changes. Our competitors and others might develop technologies or products that are more effective or commercially attractive than our current or future technologies or products or that render our technologies or products less competitive or obsolete. If competitors introduce superior technologies or products and we cannot make enhancements to our technologies or products to remain competitive, our competitive position and, in turn, our business, revenue and financial condition, would be materially and adversely affected.

We may encounter new FDA rules, regulations and laws that could impede our ability to sell our OTC products

The FDA regulates most of our OTC or non-prescription drugs using its OTC Monograph, which when final, is published in the Code of Federal Regulations at 21 CFR Parts 330-358. Such of our products that meet each of these conditions established in the OTC Monograph regulations, as well as all other regulations, may be marketed without prior approval by the FDA. If the FDA changes its OTC Monograph regulatory process, it may subject us to additional FDA rules, regulations and laws that may be more time consuming and costly to us and could negatively affect our business.

We may never receive ANDA approval for our product Fluticare™, which we are relying upon to generate a significant amount of future revenue.

Because of the unpredictability of the FDA review process for generic drugs, the ANDA filed for our product Fluticare™ may never be approved by the FDA for a variety of reasons. If such ANDA is not approved, we will not be able to realize revenue from the sale of this drug and our revenue will not grow as quickly as we anticipate.

Table of Contents

If the Fluticare™ ANDA is approved, we have no assurances as to the additional costs associated with launching our new product, and may need to raise additional capital in the future to fund such efforts.

Since approval is dependent upon a complex FDA review and regulatory process, should we receive approval for our product Fluticare™, it is unclear the extent of the additional work and costs associated with launching the new product. There can be no assurances to the time frame in which we could get approval, and so no assurances as to the timing and extent of the possible additional expenses. As a result, additional funding may be required to cover such expenses.

Risks Related to Ownership of our Common Stock

Sales of additional shares of our common stock could cause the price of our common stock to decline.

As of December 31, 2016, we had 121,694,293 shares of common stock outstanding. A substantial number of those shares are restricted securities and such shares may be sold under Rule 144 of the Securities Act of 1933, as amended ("Securities Act"), subject to any applicable holding period. As such, sales of the above shares or other substantial amounts of our common stock in the public or private markets, or the availability of such shares for sale by us, including the issuance of common stock upon conversion and/or exercise of outstanding convertible securities, warrants and options, could adversely affect the price of our common stock. We may sell additional shares or securities convertible into shares of common stock, which could adversely affect the market price of shares of our common stock. In addition, the sale of a substantial number of shares of our common stock, or anticipation of such sales, could make it more difficult for us to obtain future financing. To the extent the trading price of our common stock at the time of exercise of any of our outstanding options or warrants exceeds their exercise price, such exercise will have a dilutive effect on our stockholders.

If we default on our Convertible Notes, or if such Convertible Notes are voluntarily converted, it could result in a significant dilution of stockholders' position.

As of December 31, 2016, we have issued and outstanding convertible promissory notes in the aggregate principal amount of approximately \$1.6 million (the "Convertible Notes"). Upon the occurrence of an Event of Default, as such term is defined in the Convertible Notes, a "Default Amount" equal to the sum of (i) the outstanding principal amount, together with accrued interest due thereon through the date of payment, and (ii) an additional amount equal to the outstanding principal amount is payable, either in cash or shares of common stock. Assuming the Convertible Notes are in default on their maturity date, we may be required to issue up to 16,027,339 shares of our common stock to the holders of the Convertible Notes.

The holders of our Convertible Notes also have the right to convert such Convertible Notes into common stock at \$0.25 per share. In the event the holders of such Convertible Notes elect to convert their Convertible Notes into common stock, an additional 6,414,132 shares of our common stock will be issued, resulting in substantial dilution to existing stockholders. In the event such holders elect to sell their common stock issued upon conversion of such Convertible Notes, the price of our common stock may be negatively and materially impacted.

The market price for our common stock may be volatile and your investment in our common stock could decline in value.

The stock market in general has experienced extreme price and volume fluctuations. The market prices of the securities of biotechnology and specialty pharmaceutical companies, particularly companies like ours with limited product revenue, have been highly volatile and may continue to be highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies. The following factors, in addition to other

risk factors described in this section, may have a significant impact on the market price of our common stock:

Announcements of technological innovations or new products by us or our competitors;

Announcement of FDA approval or disapproval of our product candidates or other product-related actions;

Developments involving our discovery efforts and clinical trials;

Developments or disputes concerning patents or proprietary rights, including announcements of infringement, interference or other litigation against us or our potential licensees;

-17-

Table of Contents

Developments involving our efforts to commercialize our products, including developments impacting the timing of commercialization;

Announcements concerning our competitors or the biotechnology, pharmaceutical or drug delivery industry in general;

Public concerns as to the safety or efficacy of our products or our competitors' products;

Changes in government regulation of the pharmaceutical or medical industry;

Actual or anticipated fluctuations in our operating results;

Changes in financial estimates or recommendations by securities analysts;

Developments involving corporate collaborators, if any;

Changes in accounting principles; and

The loss of any of our key management personnel.

In the past, securities class action litigation has often been brought against companies that experience volatility in the market price of their securities. Whether meritorious or not, litigation brought against us could result in substantial costs and a diversion of management's attention and resources, which could adversely affect our business, operating results and financial condition.

We do not anticipate paying dividends on our common stock and, accordingly, shareholders must rely on stock appreciation for any return on their investment.

We have never declared or paid cash dividends on our common stock and do not expect to do so in the foreseeable future. The declaration of dividends is subject to the discretion of our board of directors and will depend on various factors, including our operating results, financial condition, future prospects and any other factors deemed relevant by our board of directors. You should not rely on an investment in our Company if you require dividend income from your investment in our Company. The success of your investment will likely depend entirely upon any future appreciation of the market price of our common stock, which is uncertain and unpredictable. There is no guarantee that our common stock will appreciate in value.

Nevada law and provisions in our charter documents may delay or prevent a potential takeover bid that would be beneficial to common stockholders.

Our articles of incorporation and our bylaws contain provisions that may enable our board of directors to discourage, delay or prevent a change in our ownership or in our management. In addition, these provisions could limit the price that investors would be willing to pay in the future for shares of our common stock. These provisions include the following:

Our board of directors may increase the size of the board of directors up to nine directors and fill vacancies on the board of directors; and

Our board of directors is expressly authorized to make, alter or repeal our bylaws.

In addition, Chapter 78 of the Nevada Revised Statutes also contains provisions that may enable our board of directors to discourage, delay or prevent a change in our ownership or in our management. The combinations with interested stockholders provisions of the Nevada Revised Statutes, subject to certain exceptions, restrict our ability to engage in any combination with an interested stockholder for three years after the date a stockholder becomes an interested stockholder, unless, prior to the stockholder becoming an interested stockholder, our board of directors gave approval for the combination or the acquisition of shares which caused the stockholder to become an interested stockholder. If the combination or acquisition was not so approved prior to the stockholder becoming an interested stockholder, the interested stockholder may effect a combination after the three-year period only if either the stockholder receives approval from a majority of the outstanding voting shares, excluding shares beneficially owned by the interested stockholder or its affiliates or associates, or the consideration to be paid by the interested stockholder exceeds certain thresholds set forth in the statute. For purposes of the foregoing provisions, "interested stockholder" means either a person, other than us or our subsidiaries, who directly or indirectly beneficially owns 10% or more of the voting power of our outstanding voting shares, or one of our affiliates or associates which at any time within three years immediately before the date in question directly or indirectly beneficially owned 10% or more of the voting power of our outstanding shares.

Table of Contents

In addition, the acquisition of controlling interest provisions of the Nevada Revised Statutes provide that a stockholder acquiring a controlling interest in our Company, and those acting in association with that stockholder, obtain no voting rights in the control shares unless voting rights are conferred by stockholders holding a majority of our voting power (exclusive of the control shares). For purposes of these provisions, "controlling interest" means the ownership of outstanding voting shares enabling the acquiring person to exercise (either directly or indirectly or in association with others) one-fifth or more but less than one-third, one-third or more but less than a majority, or a majority or more of the voting power in the election of our directors, and "control shares" means those shares the stockholder acquired on the date it obtained a controlling interest or in the 90-day period preceding that date.

Accordingly, the provisions could require multiple votes with respect to voting rights in share acquisitions effected in separate stages, and the effect of these provisions may be to discourage, delay or prevent a change in control of our Company.

The rights of the holders of common stock may be impaired by the potential issuance of preferred stock.

Our articles of incorporation give our board of directors the right to create new series of preferred stock. As a result, the board of directors may, without stockholder approval, issue preferred stock with voting, dividend, conversion, liquidation or other rights, which could adversely affect the voting power and equity interest of the holders of common stock. Preferred stock, which could be issued with the right to more than one vote per share, could be utilized as a method of discouraging, delaying or preventing a change of control. The possible impact on takeover attempts could adversely affect the price of our common stock. Although we have no present intention to issue any shares of preferred stock or to create a series of preferred stock, we may issue such shares in the future.

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

The SEC has adopted Rule 15c-9 which establishes the definition of a "penny stock," for the purposes relevant to us, as any equity security that has a market price of less than \$5.00 per share or with an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require:

That a broker or dealer approve a person's account for transactions in penny stocks; and

The broker or dealer receives from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must:

Obtain financial information and investment experience objectives of the person; and

Make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form:

Sets forth the basis on which the broker or dealer made the suitability determination; and

That the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

Table of Contents

FINRA sales practice requirements may also limit a shareholder's ability to buy and sell our stock.

In addition to the "penny stock" rules described above, the Financial Industry Regulatory Authority ("FINRA") has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low priced securities will not be suitable for at least some customers. The FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our stock and have an adverse effect on the market for our shares.

Item 1B. Unresolved Staff Comments.

There are no unresolved staff comments at December 31, 2016.

Item 2. Properties.

We lease 2,578 square feet of office space in San Diego, California that commenced on December 10, 2013 and continues until January 31, 2019. This facility serves as our corporate headquarters. Monthly rent at December 31, 2016 is in the amount of \$7,347, with an approximate 4% increase in the base rent amount on an annual basis.

We believe that our existing facilities are suitable and adequate to meet our current business requirements, but we will require a larger, more permanent space as we add personnel consistent with our business plan. We anticipate we will be able to acquire additional facilities as needed on terms consistent with our current lease.

Item 3. Legal Proceedings.

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

Item 4. Mine Safety Disclosures.

Not applicable.

Table of Contents

PART II

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

Market Information

Our common stock is available for quotation on the OTCQB Marketplace under the trading symbol “INN.V.” The market for our common stock is limited. The prices at which our common stock may trade may be volatile and subject to broad price movements.

The following table sets forth the high and low bid prices per share of our common stock for the periods indicated as reported on the OTCQB Marketplace. The quotes represent inter-dealer prices, without adjustment for retail mark-up, markdown or commission and may not represent actual transactions. The trading volume of our securities fluctuates and may be limited during certain periods. As a result of these volume fluctuations, the liquidity of an investment in our securities may be adversely affected.

	2016		2015	
	High	Low	High	Low
First Quarter	\$0.10	\$0.03	\$0.28	\$0.13
Second Quarter	\$0.37	\$0.05	\$0.19	\$0.11
Third Quarter	\$0.66	\$0.21	\$0.16	\$0.05
Fourth Quarter	\$0.33	\$0.16	\$0.12	\$0.05

As of March 3, 2017, we had 544 record holders of our common stock. The number of record holders does not include holders who hold their stock in “street name” or “nominee name” inside bank or brokerage accounts.

Dividend Policy

We have never declared or paid any cash dividends on our common stock and do not anticipate declaring or paying any cash dividends on our common stock in the foreseeable future. We expect to retain all available funds and any future earnings to support operations and fund the development and growth of our business. Our board of directors will determine whether we pay and the amount of future dividends (including cash dividends), if any.

Recent Sales of Unregistered Securities

In the fourth quarter of 2016, we issued 2,206,786 restricted shares of common stock valued at \$641,783 in exchange for services under our existing consulting and service agreements with third parties.

In the fourth quarter of 2016, certain 2016 Notes holders elected to convert \$328,805 in principal and interest into 1,315,220 shares of common stock.

In January and February 2017, we issued 1,159,023 shares of common stock to various consultants for services rendered. The fair value of the common stock issued was approximately \$321,000.

On January 1, 2017, we issued restricted shares of common stock totaling 225,000 to Centric Research Institute as a prepayment of royalties due on net profits of Sensum+® in the U.S. in 2017. The royalty prepayment amount is \$45,000.

In March 2017, certain 2016 Notes holders elected to convert \$350,610 in principal and interest into 1,402,440 shares of common stock.

In November 2016, we issued 12,808,796 shares of common stock to Novalere Holdings, LLC in connection with the Amendment and Supplement to a Registration Rights and Stock Restriction Agreement and \$2,971,641 of the acquisition contingent consideration was reclassified from liabilities to stockholders' equity.

We entered into a private financing for \$550,000 on December 5, 2016 with three institutional investors and for \$165,000 with one institutional investor on January 19, 2017. We issued 1,441,111 restricted shares of common stock to the investors in connection with the notes payable. Each of the securities were offered and sold in transactions exempt from registration under the Securities Act, in reliance on Section 4(a)(2) thereof and Rule 506 of Regulation D thereunder and/or Section 3(a)(9) of the Securities Act. Each of the investors represented that it was an "accredited investor" as defined in Regulation D under the Securities Act.

There were no issuances of unregistered securities to report which were sold or issued by us without the registration of these securities under the Securities Act of 1933 in reliance on exemptions from such registration requirements, within the period covered by this report, which have not been previously included in an Annual Report on Form 10-K, a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

Item 6. Selected Financial Data.

Under SEC rules and regulations, because of the aggregate worldwide market value of our common stock held by non-affiliates as of the last business day of our most recently completed second fiscal quarter, we are considered to be a "smaller reporting company." Accordingly, we are not required to provide the information required by this item in this report.

Table of Contents

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and the related notes contained in this annual report on Form 10-K (Annual Report). Our consolidated financial statements have been prepared and, unless otherwise stated, the information derived therefrom as presented in this discussion and analysis is presented, in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP). In addition to historical information, the following discussion contains forward-looking statements based upon our current views, expectations and assumptions that are subject to risks and uncertainties. Actual results may differ substantially from those expressed or implied by any forward-looking statements due to a number of factors, including, among others, the risks described in the "Risk Factors" section and elsewhere in this Annual Report.

As used in this discussion and analysis, unless the context indicates otherwise, the terms the "Company", "Innovus" "we", "us" and "our" refer to Innovus Pharmaceuticals, Inc. and its consolidated subsidiaries, consisting of FasTrack Pharmaceuticals, Inc. (FasTrack), Semprae Laboratories, Inc. (Semprae), and Novalere, Inc. (Novalere).

Overview

We are an emerging over-the-counter ("OTC") consumer goods and specialty pharmaceutical company engaged in the commercialization, licensing and development of safe and effective non-prescription medicine and consumer care products to improve men's and women's health and vitality and respiratory diseases. We deliver innovative and uniquely presented and packaged health solutions through our (a) OTC medicines and consumer and health products, which we market directly, (b) commercial partners to primary care physicians, urologists, gynecologists and therapists, and (c) directly to consumers through our on-line channels, retailers and wholesalers. We are dedicated to being a leader in developing and marketing new OTC and branded Abbreviated New Drug Application ("ANDA") products. We are actively pursuing opportunities where existing prescription drugs have recently, or are expected to, change from prescription (or Rx) to OTC. These "Rx-to-OTC switches" require Food and Drug Administration ("FDA") approval through a process initiated by the New Drug Application ("NDA") holder.

Our business model leverages our ability to (a) develop and build our current pipeline of products and (b) to also acquire outright or in-license commercial products that are supported by scientific and/or clinical evidence, place them through our existing supply chain, retail and on-line (including Amazon®-based business platform) channels to tap new markets and drive demand for such products and to establish physician relationships. We currently have 17 products marketed in the U.S. with six of those being marketed and sold in multiple countries around the world through some of our 14 commercial partners. We currently expect to launch an additional five products in the U.S. in 2017 and we currently have approvals to launch certain of our already marketed products in 31 additional countries.

Our Strategy

Our corporate strategy focuses on two primary objectives:

1. Developing a diversified product portfolio of exclusive, unique and patented non-prescription OTC and branded ANDA drugs and consumer health products through: (a) the introduction of line extensions and reformulations of either our or third-party currently marketed products; and (b) the acquisition of products or obtaining exclusive licensing rights to market such products; and

2.

Building an innovative, U.S. and global sales and marketing model through direct to consumer approaches such as our proprietary Beyond Human® Sales and Marketing platform, the addition of new online platforms such as Amazon® and commercial partnerships with established international complimentary partners that: (a) generates revenue, and (b) requires a lower cost structure compared to traditional pharmaceutical companies thereby increasing our gross margins.

Our Products

We currently generate revenue from 17 products in the U.S. and six in international countries, as follows:

1.

Vesele® for promoting sexual and health (U.S. and U.K.);

2.

Zestra® for female arousal (U.S., U.K., Denmark, Canada, Morocco, the UAE and South Korea);

3.

Zestra Glide® (U.S, Canada and the MENA countries);

4.

EjectDelay® indicated for the treatment of premature ejaculation (U.S. and Canada);

5.

Sensum+® to alleviate reduced penile sensitivity (U.S., U.K. and Morocco);

6.

Beyond Human® Testosterone Booster;

-22-

Table of Contents

7.
Beyond Human® Ketones;
8.
Beyond Human® Krill Oil;
9.
Beyond Human® Omega 3 Fish Oil;
10.
Beyond Human® Vision Formula;
11.
Beyond Human® Blood Sugar;
12.
Beyond Human® Colon Cleanse;
13.
Beyond Human® Green Coffee Extract;
14.
Beyond Human® Growth Agent;
15.
RecalMax™ for brain health;
16.
Androferti® (U.S. and Canada) for the support of overall male reproductive health and sperm quality; and
17.
UriVarx™ for overactive bladder and urinary incontinence.

In addition, we currently expect to launch in the U.S. the following products in 2017, subject to the applicable regulatory approvals, if required:

1.
Xyralid™ for the relief of the pain and symptoms caused by hemorrhoids (first half of 2017);
2.
AllerVarx™ for allergic rhinitis symptoms (first half of 2017);
3.
AndroVit™ for prostate and sexual health (second half of 2017);
4.
Urocis™ XR for urinary tract infections (second half of 2017); and
5.
FlutiCare™ for allergic rhinitis subject to FDA ANDA approval (second half of 2017).

Sales and Marketing Strategy U.S. and Internationally

Our sales and marketing strategy is based on (a) the use of direct to consumer advertisements in print and online media through our proprietary Beyond Human® sales and marketing infrastructure acquired in March 2016, (b) working with direct commercial channel partners in the U.S. and also directly marketing the products ourselves to physicians, urologists, gynecologists and therapists and to other healthcare providers, and (c) working with exclusive commercial partners outside of the U.S. that would be responsible for sales and marketing in those territories. We have now fully integrated most of our existing line of products such as Vesele®, Sensum+®, UriVarx™, Zestra®, and RecalMax™ into the Beyond Human® sales and marketing platform. We plan to integrate Xyralid™, AllerVarx™, AndroVit™, Urocis™ XR; and FlutiCare™, subject to regulatory approvals, upon their commercial launches in 2017. We also market and distribute our products in the U.S. through retailers, wholesalers and other online channels. Our strategy outside the U.S. is to partner with companies who can effectively market and sell our products in their countries through their direct marketing and sales teams. The strategy of using our partners to commercialize our products is designed to limit our expenses and fix our cost structure, enabling us to increase our reach while minimizing our incremental spending.

Our current OTC monograph, Rx-to-OTC ANDA switch drugs and consumer care products marketing strategy is to focus on four main U.S. markets which we believe each to be in excess of \$1.0 billion: (1) Sexual health (female and male sexual dysfunction and health); (2) Urology (bladder and prostate health); (3) Respiratory disease; and (4) Brain health. We will focus our current efforts on these four markets and will seek to develop, acquire or license products that we can sell through our sales channels in these fields.

Recent Developments

Acquisition of Assets of Beyond Human®

On February 8, 2016 we entered into an Asset Purchase Agreement (“APA”), pursuant to which Innovus agreed to purchase substantially all of the assets of Beyond Human® (the “Acquisition”) for a total cash payment of \$630,000 (the “Purchase Price”). The Purchase Price was paid in the following manner: (1) \$300,000 in cash at the closing of the Acquisition (the “Initial Payment”), (2) \$100,000 in cash four months from the closing upon the occurrence of certain milestones as described in the APA, (3) \$100,000 in cash eight months from the closing upon the occurrence of certain milestones as described in the APA, and (4) \$130,000 in cash in twelve months from the closing upon the occurrence of certain milestones as described in the APA. On September 6, 2016, the Company and the sellers entered into an agreement in which we agreed to pay the sellers \$150,000 to settle all of the contingent consideration payments under the APA.

2016 and 2017 Notes Payable Financing

On December 5, 2016 and January 19, 2017, we entered into securities purchase agreements with three unrelated third party investors in which the investors loaned us gross proceeds of \$650,000 pursuant to 5% promissory notes. The notes have an OID of \$65,000 and requires payment of \$715,000 in principal upon maturity. The notes bear interest at the rate of 5% per annum and the principal amount and interest are payable at maturity on October 4, 2017 and November 18, 2017.

Table of Contents

Zestra® and Zestra Glide® License Agreement

On November 9, 2016, we entered into an exclusive ten-year license agreement with J&H Co. LTD, a South Korea company (“J&H”), under which Innovus granted to J&H an exclusive license to market and sell Zestra® and Zestra Glide® in South Korea. Under the agreement, J&H is obligated to order minimum annual quantities of Zestra® and Zestra Glide® totaling \$2,000,000 at a pre-negotiated transfer price per unit. On February 3, 2017, we announced that J&H received approval from the South Korean government to market and sell the two products in South Korea.

Product In-License Agreements

On December 15, 2016, we entered into a license and distribution agreement with NTC S.r.l (“NTC”) pursuant to which we acquired the rights to use, market and sell NTC’s proprietary modified release bilayer tablet formerly known as LERTAL® for the management of allergic rhinitis in the U.S. and Canada. Under this agreement, we are obligated to pay a non-refundable upfront license fee of €15,000 (\$15,806 USD based on December 31, 2016 exchange rate) and cash payments of up to €120,000 (\$126,448 USD based on December 31, 2016 exchange rate) upon the achievement of certain sales milestones. Such licensed product will be sold by us under the name AllerVarx™ in the U.S. and Canada and is expected to launch in the first of 2017.

On September 29, 2016, we entered into a license and purchase agreement with Seipel Group Pty Ltd. (“SG”) pursuant to which we acquired the rights to use, market and sell SG’s proprietary dietary supplement formula known as Urox® for bladder support in the U.S. and worldwide. Under this agreement, we have agreed to minimum purchase order requirements to retain our exclusivity of 25,000 units per calendar quarter beginning 12 months after our initial order and paid a brokerage fee of \$200,000. We launched this product in the U.S. under the name UriVarx™ in December 2016.

Results of Operations

Year Ended December 31, 2016 Compared to Year Ended December 31, 2015

	Year Ended December 31, 2016	Year Ended December 31, 2015	\$ Change	% Change
NET REVENUE:				
Product sales, net	\$4,817,603	\$730,717	\$4,086,886	\$559.3%
License revenue	1,000	5,000	(4,000)	(80.0)%
Net revenue	4,818,603	735,717	4,082,886	555.0%
OPERATING EXPENSE:				
Cost of product sales	1,083,094	340,713	742,381	217.9%
Research and development	77,804	-	77,804	100.0%
Sales and marketing	3,621,045	82,079	3,538,966	4,311.7%
General and administrative	5,870,572	3,828,113	2,042,459	53.4%
Impairment of goodwill	-	759,428	(759,428)	(100.0)%

Edgar Filing: INNOVUS PHARMACEUTICALS, INC. - Form 10-K

Total operating expense	10,652,515	5,010,333	5,642,182	112.6%
LOSS FROM OPERATIONS	(5,833,912)	(4,274,616)	(1,559,296)	36.5%
OTHER INCOME (EXPENSE):				
Interest expense	(6,661,694)	(1,153,376)	(5,508,318)	477.6%
Loss on extinguishment of debt	-	(32,500)	32,500	(100.0)%
Other income (expense), net	1,649	(8,495)	10,144	(119.4)%
Change in fair value of contingent consideration	(1,269,857)	115,822	(1,385,679)	(1,196.4)%
Change in fair value of derivative liabilities	65,060	393,509	(328,449)	(83.5)%
LOSS BEFORE PROVISION FOR (BENEFIT FROM)	(13,698,754)	(4,959,656)	(8,739,098)	176.2%
INCOME TAXES				
Provision for (benefit from) income taxes	2,400	(757,028)	759,428	(100.3)%
NET LOSS	\$(13,701,154)	\$(4,202,628)	\$(9,498,526)	226.0%

-24-

Table of Contents

Net Revenue

We recognized net revenue of approximately \$4.8 million for the year ended December 31, 2016 compared to \$0.7 million for the year ended December 31, 2015. The increase in revenue in 2016 was primarily the result of the product sales generated through the sales and marketing platform acquired in the Beyond Human® asset acquisition. The increase was also due to an increase in sales of Vesele® and Sensum+® which generated net revenue of approximately \$2.2 million and \$0.4 million during the year ended December 31, 2016, respectively, compared to approximately \$7,000 and less than \$1,000 during the year ended December 31, 2015, respectively. We generated additional net revenue of approximately \$0.8 million and \$0.2 million when selling Vesele® and Sensum+® with other Beyond Human® products during the year ended December 31, 2016, respectively. The increase in net revenue from the sale of products through the Beyond Human® sales and marketing platform was offset by decreases in our other existing product sales channels to major retailers and wholesalers as we concentrated our sales efforts and resources on integrating our existing products into the Beyond Human® sales and marketing platform. The decreases in existing product sales channels resulted in net revenue from the Zestra® products decreasing approximately \$0.3 million during the year ended December 31, 2016 when compared to the same period in 2015. We signed an exclusive licensed and distribution agreement in November 2016 which is expected to lead to an increase in product sales of Zestra® and Zestra Glide® through that sales channel in 2017.

Cost of Product Sales

We recognized cost of product sales of approximately \$1.1 million for the year ended December 31, 2016 compared to \$0.3 million for the year ended December 31, 2015. The cost of product sales includes the cost of inventory, shipping and royalties. The increase in cost of product sales is a result of higher shipping costs due to an increase in the number of units shipped. The increase in the gross margin to 78% in 2016 compared to 54% in 2015 is due to the higher margins earned on the increased volume of our product sales through the Beyond Human® sales and marketing platform. The increased margin in 2016 is also due to fewer sales when compared to 2015 through our retail and wholesale sales channels which have lower margins.

Research and Development

We recognized research and development expense of approximately \$78,000 for the year ended December 31, 2016 compared to no expense for the year ended December 31, 2015. The research and development expense includes salary and the related health benefits for an employee, the fair value of the shares of common stock issued to CRI totaling \$23,000 for the settlement of certain clinical and regulatory milestone payments due under the in-license agreement for Sensum+®, as well as, clinical costs incurred related to post marketing studies for Vesele® and Beyond Human® Testosterone Booster.

Sales and Marketing

We recognized sales and marketing expense of approximately \$3.6 million for the year ended December 31, 2016 compared to \$82,000 for the year ended December 31, 2015. Sales and marketing expense of \$3.6 million during the year ended December 31, 2016 consist primarily of print advertisements and sales and marketing support. The increase in sales and marketing expense during the year ended December 31, 2016 when compared to the same period in 2015 is due to the costs of integration of our existing products into the Beyond Human® sales and marketing platform and the increase in the number of print and online media advertisements of our existing products through the Beyond Human® platform. The increase is also attributable to increased costs in sales and marketing support services due to the higher volume of sales orders received as a result of the Beyond Human® asset acquisition and the integration of more products into this platform.

General and Administrative

We recognized general and administrative expense of approximately \$5.9 million for the year ended December 31, 2016 compared to \$3.8 million for the year ended December 31, 2015. General and administrative expense consists primarily of investor relation expense, legal, accounting, public reporting costs and other infrastructure expense related to the launch of our products. Additionally, our general and administrative expense includes professional fees, insurance premiums and general corporate expense. The increase is primarily due to the increase in non-cash stock-based compensation to consultants for services rendered, an increase in merchant processing fees due to increased credit card sales volume, an increase in the amortization of intangible assets as a result of the acquisitions in 2016 and 2015 and increased payroll and related costs due to the increase in headcount when compared to 2015.

Other Income and Expense

We recognized interest expense of approximately \$6.7 million for the year ended December 31, 2016 compared to \$1.2 million for the year ended December 31, 2015. Interest expense primarily includes interest related to our debt, amortization of debt discounts and the fair value of the embedded conversion feature derivative liability in excess of the proceeds allocated to the debt (see Notes 5, 6 and 9 to the accompanying consolidated financial statements included elsewhere in this Annual Report). Due to the shares, warrants and cash discounts provided to our lenders, the effective interest rate is significantly higher than the coupon rate. The increase in interest expense reflects the larger amount of debt discount amortization of approximately \$2.7 million when compared to 2015 due to the convertible debt and note payable financings completed in 2016 and 2015 and the increase in the fair value in excess of the allocated proceeds of the embedded conversion feature in the convertible debt financings in June and July of 2016 of approximately \$2.7 million.

Table of Contents

We recognized a loss from the change in fair value of contingent consideration of approximately \$1.3 million for the year ended December 31, 2016 compared to a gain from the change in fair value of consideration of \$0.1 million for the year ended December 31, 2015. Change in fair value of contingent consideration consists primarily of the increase in the fair value of the contingent ANDA shares of common stock issuable to Novalere Holdings, LLC in connection with our acquisition in 2015 totaling approximately \$1.4 million and the increase in the royalty contingent consideration to Semprae of approximately \$103,000 (see Note 3 to the accompanying consolidated financial statements included elsewhere in this Annual Report). Such amount was offset with the gain on contingent consideration of \$180,000 as a result of the settlement agreement entered into with the sellers of the Beyond Human® assets in September 2016 (see Note 3 to the accompanying consolidated financial statements included elsewhere in this Annual Report).

We recognized a gain from the change in fair value of derivative liabilities of approximately \$65,000 for the year ended December 31, 2016 compared a gain from the change in fair value of derivative liabilities of \$0.4 million for the year ended December 31, 2015. Change in fair value of derivative liabilities primarily includes the change in the fair value of the warrants and embedded conversion features classified as derivative liabilities. The decrease in the gain on change in fair value of derivative liabilities during the year ended December 31, 2016 is due to the increase in our stock price during that period when compared to 2015.

Income Taxes

We recognized a provision for income taxes of \$2,400 for the year ended December 31, 2016 compared to a benefit from income taxes of approximately \$0.8 million for the year ended December 31, 2015. The benefit from income taxes during the year ended December 31, 2015 is due to the release of a portion of the deferred tax valuation allowance as a result of the Novalere acquisition.

Net Loss

Net loss for the year ended December 31, 2016 was approximately \$(13.7 million), or \$(0.15) basic and diluted net loss per share, compared to a net loss for the same period in 2015 of \$(4.2 million), or \$(0.08) basic and diluted net loss per share.

Liquidity and Capital Resources

Historically, we have funded losses from operations through the sale of equity and issuance of debt instruments. Combined with revenue, these funds have provided us with the resources to operate our business, to sell and support our products, attract and retain key personnel, and add new products to our portfolio. To date, we have experienced net losses each year since our inception. As of December 31, 2016, we had an accumulated deficit of \$29.1 million and a working capital deficit of \$1.7 million.

As of February 28, 2017, we had approximately \$0.7 million in cash and \$150,000 of cash collections held by our third-party merchant service provider, which is expected to be remitted to us by April 2017. Although no assurances can be given, we currently plan to raise additional capital through the sale of equity or debt securities. We expect, however, that our existing capital resources, revenue from sales of our products and upcoming new product launches and sales milestone payments from the commercial partners signed for our products, and equity instruments available to pay certain vendors and consultants, will be sufficient to allow us to continue our operations, commence the product development process and launch selected products through at least the next 12 months. In addition, our Chief Executive Officer, who is also a significant shareholder, has deferred the payment of his salary earned thru June 30, 2016 for at least the next 12 months.

Our principle debt instruments include the following:

February 2016 Note Payable

On February 24, 2016, the Company and SBI Investments, LLC, 2014-1 (“SBI”) entered into an agreement in which SBI loaned us gross proceeds of \$550,000 pursuant to a purchase agreement, 20% secured promissory note and security agreement (“February 2016 Note Payable”), all dated February 19, 2016 (collectively, the “Finance Agreements”), to purchase substantially all of the assets of Beyond Human®. Of the \$550,000 gross proceeds, \$300,000 was paid into an escrow account held by a third-party bank and was released to Beyond Human® upon closing of the transaction, \$242,500 was provided directly to us for use in building the Beyond Human® business and \$7,500 was provided for attorneys’ fees.

-26-

Table of Contents

Pursuant to the Finance Agreements, the principal amount of the February 2016 Note Payable is \$550,000 and the interest rate thereon is 20% per annum. We began to pay principal and interest on the February 2016 Note Payable on a monthly basis beginning on March 19, 2016 for a period of 24 months and the monthly mandatory principal and interest payment amount thereunder is \$28,209. The monthly amount shall be paid by us through a deposit account control agreement with a third-party bank in which SBI shall be permitted to take the monthly mandatory payment amount from all revenue received by us from the Beyond Human® assets in the transaction. The maturity date for the February 2016 Note Payable is February 19, 2018. The February 2016 Note Payable is secured by SBI through a first priority secured interest in all of the Beyond Human® assets acquired by us in the transaction including all revenue received by us from these assets.

Convertible Debentures - 2016 Financing

In the second and third quarter of 2016, we entered into Securities Purchase Agreements with eight accredited investors (the “Investors”), pursuant to which we received aggregate gross proceeds of \$3,000,000 (net of OID). We sold nine convertible promissory notes totaling \$3,303,889 (each a “2016 Note” and collectively the “2016 Notes”) (the 2016 Notes were sold at a 10% OID and we received an aggregate total of \$2,657,500 in funds thereunder after debt issuance costs of \$342,500). The 2016 Notes and accrued interest are convertible into shares of our common stock at a conversion price of \$0.25 per share, with certain adjustment provisions noted below. The maturity date of the 2016 Notes issued on June 30, 2016 and July 15, 2016 is July 30, 2017 and the maturity date of the 2016 Notes issued on July 25, 2016 is August 25, 2017. The 2016 Notes bear interest on the unpaid principal amount at the rate of 5% per annum from the date of issuance until the same becomes due and payable, whether at maturity or upon acceleration or by prepayment or otherwise.

Notwithstanding the foregoing, upon the occurrence of an Event of Default as defined in such 2016 Notes, a Default Amount is equal to the sum of (i) the principal amount, together with accrued interest due thereon through the date of payment payable at the holder’s option in cash or common stock and (ii) an additional amount equal to the principal amount payable at our option in cash or common stock. For purposes of payments in common stock, the following conversion formula shall apply: the conversion price shall be the lower of: (i) the fixed conversion price (\$0.25) or (ii) 75% multiplied by the volume weighted average price of our common stock during the ten consecutive trading days immediately prior to the later of the Event of Default or the end of the applicable cure period. For purposes of the Investors request of repayment in cash but we are unable to do so, the following conversion formula shall apply: the conversion price shall be the lower of: (i) the fixed conversion price (\$0.25) or (ii) 60% multiplied by the lowest daily volume weighted average price of our common stock during the ten consecutive trading days immediately prior to the conversion. Certain other conversion rates apply in the event of our sale or merger, default and other defined events.

We may prepay the 2016 Notes at any time on the terms set forth in the 2016 Notes at the rate of 110% of the then outstanding balance of the 2016 Notes. Under the terms of the 2016 Notes, we shall not effect certain corporate and business actions during the term of the 2016 Notes, although some may be done with proper notice. Pursuant to the Securities Purchase Agreements, with certain exceptions, the Investors have a right of participation during the term of the 2016 Notes; additionally, we granted the 2016 Note holders registration rights for the shares of common stock underlying the 2016 Notes up to \$1,000,000 pursuant to Registration Rights Agreements.

December 2016 and January 2017 Notes Payable

On December 5, 2016 and January 19, 2017, we entered into a securities purchase agreement with three unrelated third-party investors in which the investors loaned us gross proceeds of \$650,000 pursuant to 5% promissory notes. The notes have an OID of \$65,000 and requires payment of \$715,000 in principal upon maturity. The notes bear interest at the rate of 5% per annum and the principal amount and interest are payable at maturity on October 4,

Edgar Filing: INNOVUS PHARMACEUTICALS, INC. - Form 10-K

2017 and November 18, 2017. In connection with the notes, we issued the investors restricted shares of common stock totaling 1,441,111. The fair value of the restricted shares of common stock issued was based on the market price of our common stock on the date of issuance of the notes.

Net Cash Flows

For the Year Ended December 31, 2016 For the Year Ended December 31, 2015

Net cash used in operating activities	\$(1,784,258)	\$(1,031,727)
Net cash used in investing activities	(172,103)	(12,816)
Net cash provided by financing activities	2,730,393	1,092,965
Net change in cash	774,032	48,422
Cash at beginning of the year	55,901	7,479
Cash at the end of the year	\$829,933	\$55,901

-27-

Table of Contents

Operating Activities

For the year ended December 31, 2016, cash used in operating activities was approximately \$1.8 million, consisting primarily of the net loss for the period of approximately \$13.7 million, which was primarily offset by non-cash common stock, restricted stock units and stock options issued for services and compensation of approximately \$2.7 million, amortization of debt discount of \$3.6 million, fair value of the embedded conversion feature in excess of allocated proceeds of \$2.8 million, change in fair value of contingent consideration of \$1.4 million and amortization of intangible assets of \$0.6 million. The non-cash expense was offset with the non-cash gain on contingent consideration of \$0.2 million and change in fair value of derivative liabilities of \$65,000. Additionally, working capital changes consisted of cash increases of approximately \$1.0 million related to a decrease in accounts receivable from cash collections from customers of approximately \$48,000, \$0.9 million related to an increase in accrued compensation, and \$0.7 million related to an increase in accounts payable and accrued expense, partially offset by a cash decrease related to the increase in prepaid expense and other current assets of \$0.3 million and inventories of \$0.3 million. The increase in net cash used in operating activities from 2015 was mainly due to expanding our operations, including hiring additional personnel, commercialization and marketing activities related to our existing products and those acquired in 2016, as well as, purchasing more finished goods inventory to fulfill the forecasted increase in revenue in 2017.

Investing Activities

For the year ended December 31, 2016, cash used in investing activities was approximately \$0.2 million which consisted of the contingent consideration payment of approximately \$0.2 million made to the seller of the Beyond Human® assets, as well as, a contingent royalty payment to Semprae for Zestra® product sales in 2015. Cash used in investing activities in 2015 was primarily related to the purchase of property and equipment.

Financing Activities

For the year ended December 31, 2016, cash provided by financing activities was approximately \$2.7 million, consisting primarily of the net proceeds from notes payable and convertible debentures of approximately \$3.6 million and proceeds from warrant exercises of \$0.3 million, offset by the repayment of short-term loans payable of \$0.3 million, notes payable of \$0.4 million and the related party line of credit convertible debenture of \$0.4 million. Cash provided by financing activities in 2015 was primarily related to net proceeds from notes payable and convertible debentures of approximately \$1.5 million and proceeds from short-term loans payable of \$0.3 million, offset by the repayment of notes payable of \$0.4 million and related party non-convertible debentures of \$0.1 million.

Sources of Capital

Our operations have been financed primarily through the sale of equity and issuance of debt instruments and revenue generated from the launch of our products and commercial partnerships signed for the sale and distribution of our products domestic and internationally. These funds have provided us with the resources to operate our business, sell and support our products, attract and retain key personnel and add new products to our portfolio. We have experienced net losses and negative cash flows from operations each year since our inception. As of December 31, 2016, we had an accumulated deficit of approximately \$29.1 million and a working capital deficit of \$1.7 million.

We have raised funds through the issuance of debt and the sale of common stock. We have also issued equity instruments in certain circumstances to pay for services from vendors and consultants. For the year ended December 31, 2016, we raised approximately \$3.6 million in funds, which included net proceeds of \$2.7 million from the issuance of convertible debentures (with warrants and common stock) and \$0.9 million from the issuance of notes

payable. The funds raised through the issuance of the convertible debentures were used to pay off other debt instruments and accounts payable, to increase inventory and for the expanded operations in 2016. In the event we do not pay the convertible debentures upon their maturity, or after the remedy period, the note holder has the right to convert the principal amount and accrued interest into shares of common stock at the lower of \$0.25 per share or 60% multiplied by the lowest daily volume weighted average price of our shares of common stock. The outstanding convertible debentures principal and interest balance at December 31, 2016 was approximately \$1.6 million.

Our actual needs will depend on numerous factors, including timing of introducing our products to the marketplace, our ability to attract additional Ex-U.S. distributors for our products and our ability to in-license in non-partnered territories and/or develop new product candidates. In addition, we continue to seek new licensing agreements from third-party vendors to commercialize our products in territories outside the U.S., which could result in upfront, milestone, royalty and/or other payments.

We currently intend to raise additional capital through the sale of debt or equity securities to provide additional working capital, for further expansion and development of our business, and to meet current obligations, although no assurances can be given. If we issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience substantial dilution, and the newly issued equity or debt securities may have more favorable terms or rights, preferences and privileges senior to those of our existing stockholders. If we raise funds by incurring additional debt, we may be required to pay significant interest expense and our leverage relative to our earnings or to our equity capitalization may increase. Obtaining commercial loans, assuming they would be available, would increase our liabilities and future cash commitments and may impose restrictions on our activities, such as financial and operating covenants. Further, we may incur substantial costs in pursuing future capital and/or financing transactions, including investment banking fees, legal fees, accounting fees, printing and distribution expense and other costs. We may also be required to recognize non-cash expense in connection with certain securities we may issue, such as convertible notes and warrants, which would adversely impact our financial results. We may be unable to obtain financing when necessary as a result of, among other things, our performance, general economic conditions, conditions in the pharmaceuticals industries, or our operating history. In addition, the fact that we are not and have never been profitable could further impact the availability or cost to us of future financings. As a result, sufficient funds may not be available when needed from any source or, if available, such funds may not be available on terms that are acceptable to us. If we are unable to raise funds to satisfy our capital needs when needed, then we may need to forego pursuit of potentially valuable development or acquisition opportunities, we may not be able to continue to operate our business pursuant to our business plan, which would require us to modify our operations to reduce spending to a sustainable level by, among other things, delaying, scaling back or eliminating some or all of our ongoing or planned investments in corporate infrastructure, business development, sales and marketing and other activities, or we may be forced to discontinue our operations entirely.

Table of Contents

Critical Accounting Policies and Management Estimates

The SEC defines critical accounting policies as those that are, in management's view, important to the portrayal of our financial condition and results of operations and demanding of management's judgment. Our discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expense and related disclosures. We base our estimates on historical experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from those estimates.

While our significant accounting policies are described in more detail in Note 1 to our consolidated financial statements, we believe that the accounting policies described below are critical to understanding our business, results of operations and financial condition because they involve the use of more significant judgments and estimates in the preparation of our consolidated financial statements. An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and any changes in the assumptions used in making the accounting estimates that are reasonably likely to occur could materially impact our consolidated financial statements.

Revenue Recognition and Deferred Revenue

We generate revenue from product sales and the licensing of the rights to market and commercialize its products.

We recognize revenue in accordance with FASB Accounting Standards Codification ("ASC") 605, Revenue Recognition. Revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) title to the product has passed or services have been rendered; (3) price to the buyer is fixed or determinable and (4) collectability is reasonably assured.

Product Sales: We ship product directly to consumers pursuant to phone or online orders and to our wholesale and retail customers pursuant to purchase agreements or sales orders. Revenue from sales transactions where the buyer has the right to return the product is recognized at the time of sale only if (1) the seller's price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product, (3) the buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product, (4) the buyer acquiring the product for resale has economic substance apart from that provided by the seller, (5) the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer and (6) the amount of future returns can be reasonably estimated.

License Revenue: The license agreements we enter into normally generate three separate components of revenue: 1) an initial payment due on signing or when certain specific conditions are met; 2) royalties that are earned on an ongoing basis as sales are made or a pre-agreed transfer price and 3) sales-based milestone payments that are earned when cumulative sales reach certain levels. Revenue from the initial payments or licensing fee is recognized when all required conditions are met. Royalties are recognized as earned based on the licensee's sales. Revenue from the sales-based milestone payments is recognized when the cumulative revenue levels are reached. The achievement of the sales-based milestone underlying the payment to be received predominantly relates to the licensee's performance of future commercial activities. FASB ASC 605-28, Milestone Method, ("ASC 605-28") is not used by us as these milestones do not meet the definition of a milestone under ASC 605-28 as they are sales-based and similar to a royalty

and the achievement of the sales levels is neither based, in whole or in part, on our performance, a specific outcome resulting from our performance, nor is it a research or development deliverable.

Table of Contents

Sales Allowances

We accrue for product returns, volume rebates and promotional discounts in the same period the related sale is recognized.

Our product returns accrual is primarily based on estimates of future product returns over the period customers have a right of return, which is in turn based in part on estimates of the remaining shelf-life of products when sold to customers. Future product returns are estimated primarily based on historical sales and return rates. We estimate our volume rebates and promotional discounts accrual based on our estimates of the level of inventory of our products in the distribution channel that remain subject to these discounts. The estimate of the level of products in the distribution channel is based primarily on data provided by our customers.

In all cases, judgment is required in estimating these reserves. Actual claims for rebates and returns and promotional discounts could be materially different from the estimates.

We provide a customer satisfaction warranty on all of our products to customers for a specified amount of time after product delivery. Estimated return costs are based on historical experience and estimated and recorded when the related sales are recognized. Any additional costs are recorded when incurred or when they can reasonably be estimated.

Stock-Based Compensation

We account for stock-based compensation in accordance with FASB ASC 718, Stock Based Compensation. All stock-based payments to employees and directors, including grants of stock options, warrants, restricted stock units (“RSUs”) and restricted stock, are recognized in the consolidated financial statements based upon their estimated fair values. We use Black-Scholes to estimate the fair value of stock-based awards. The estimated fair value is determined at the date of grant. FASB ASC 718 requires that stock-based compensation expense be based on awards that are ultimately expected to vest. Stock-based compensation for the years ended December 31, 2016 and 2015 have been reduced for estimated forfeitures. When estimating forfeitures, voluntary termination behaviors, as well as trends of actual option forfeitures, are considered. To the extent actual forfeitures differ from our current estimates, cumulative adjustments to stock-based compensation expense are recorded.

Except for transactions with employees and directors that are within the scope of FASB ASC 718, all transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable.

Equity Instruments Issued to Non-Employees for Services

Our accounting policy for equity instruments issued to consultants and vendors in exchange for goods and services follows FASB guidance. As such, the value of the applicable stock-based compensation is periodically remeasured and income or expense is recognized during the vesting terms of the equity instruments. The measurement date for the estimated fair value of the equity instruments issued is the earlier of (i) the date at which a commitment for performance by the consultant or vendor is reached or (ii) the date at which the consultant or vendor’s performance is complete. In the case of equity instruments issued to consultants, the estimated fair value of the equity instrument is primarily recognized over the term of the consulting agreement. According to FASB guidance, an asset acquired in exchange for the issuance of fully vested, nonforfeitable equity instruments should not be presented or classified as an offset to equity on the grantor’s balance sheet once the equity instrument is granted for accounting purposes.

Accordingly, we record the estimated fair value of nonforfeitable equity instruments issued for future consulting services as prepaid expense and other current assets in its consolidated balance sheets.

Business Combinations

We account for business combinations by recognizing the assets acquired, liabilities assumed, contractual contingencies, and contingent consideration at their fair values on the acquisition date. The final purchase price may be adjusted up to one year from the date of the acquisition. Identifying the fair value of the tangible and intangible assets and liabilities acquired requires the use of estimates by management and was based upon currently available data. Examples of critical estimates in valuing certain of the intangible assets we have acquired or may acquire in the future include but are not limited to future expected cash flows from product sales, support agreements, consulting contracts, other customer contracts, and acquired developed technologies and patents and discount rates utilized in valuation estimates.

Unanticipated events and circumstances may occur that may affect the accuracy or validity of such assumptions, estimates or actual results. Additionally, any change in the fair value of the acquisition-related contingent consideration subsequent to the acquisition date, including changes from events after the acquisition date, such as changes in our estimate of relevant revenue or other targets, will be recognized in earnings in the period of the estimated fair value change. A change in fair value of the acquisition-related contingent consideration or the occurrence of events that cause results to differ from our estimates or assumptions could have a material effect on the consolidated statements of operations, financial position and cash flows in the period of the change in the estimate.

Table of Contents

Goodwill and Intangible Assets

We test our goodwill for impairment annually, or whenever events or changes in circumstances indicates an impairment may have occurred, by comparing our reporting unit's carrying value to its implied fair value. The goodwill impairment test consists of a two-step process as follows:

Step 1. We compare the fair value of each reporting unit to its carrying amount, including the existing goodwill. The fair value of each reporting unit is determined using a discounted cash flow valuation analysis. The carrying amount of each reporting unit is determined by specifically identifying and allocating the assets and liabilities to each reporting unit based on headcount, relative revenue or other methods as deemed appropriate by management. If the carrying amount of a reporting unit exceeds its fair value, an indication exists that the reporting unit's goodwill may be impaired and we then perform the second step of the impairment test. If the fair value of a reporting unit exceeds its carrying amount, no further analysis is required.

Step 2. If further analysis is required, we compare the implied fair value of the reporting unit's goodwill, determined by allocating the reporting unit's fair value to all of its assets and its liabilities in a manner similar to a purchase price allocation, to its carrying amount. If the carrying amount of the reporting unit's goodwill exceeds its fair value, an impairment loss will be recognized in an amount equal to the excess.

Impairment may result from, among other things, deterioration in the performance of the acquired business, adverse market conditions, adverse changes in applicable laws or regulations and a variety of other circumstances. If we determine that an impairment has occurred, it is required to record a write-down of the carrying value and charge the impairment as an operating expense in the period the determination is made. In evaluating the recoverability of the carrying value of goodwill, we must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the acquired assets. Changes in strategy or market conditions could significantly impact those judgments in the future and require an adjustment to the recorded balances.

Intangible assets with finite lives are amortized on a straight-line basis over their estimated useful lives, which range from one to fifteen years. The useful life of the intangible asset is evaluated each reporting period to determine whether events and circumstances warrant a revision to the remaining useful life.

Long-Lived Assets

We review our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. We evaluate assets for potential impairment by comparing estimated future undiscounted net cash flows to the carrying amount of the assets. If the carrying amount of the assets exceeds the estimated future undiscounted cash flows, impairment is measured based on the difference between the carrying amount of the assets and fair value. Assets to be disposed of would be separately presented in the consolidated balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and are no longer depreciated. The assets and liabilities of a disposal group classified as held-for-sale would be presented separately in the appropriate asset and liability sections of the consolidated balance sheet, if material.

Derivative Liabilities

Certain of our embedded conversion features on debt and issued and outstanding common stock purchase warrants, which have exercise price reset features and other anti-dilution protection clauses, are treated as derivatives for accounting purposes. The common stock purchase warrants were not issued with the intent of effectively hedging any future cash flow, fair value of any asset, liability or any net investment in a foreign operation. The warrants do not

qualify for hedge accounting, and as such, all future changes in the fair value of these warrants are recognized currently in earnings until such time as the warrants are exercised, expire or the related rights have been waived. These common stock purchase warrants do not trade in an active securities market, and as such, we estimate the fair value of these warrants using a Probability Weighted Black-Scholes Model and the embedded conversion features using a Path-Dependent Monte Carlo Simulation Model.

Recent Accounting Pronouncements

See Note 1 to our consolidated financial statements for the years ended December 31, 2016 and 2015 included elsewhere in this Annual Report.

Off-Balance Sheet Arrangements

Since our inception, except for standard operating leases, we have not engaged in any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K, including the use of structured finance, special purpose entities or variable interest entities. We have no 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, revenue or expense, results of operations, liquidity, capital expenditures or capital resources that is material to stockholders.

Table of Contents

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Not required under Regulation S-K for “smaller reporting companies.”

Item 8. Financial Statements and Supplementary Data.

The consolidated financial statements and supplementary data required by this item are included in this Annual Report beginning on page F-1 immediately following the Exhibits Index and are incorporated herein by reference.

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

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer (“CEO”), our principal executive officer, and our Chief Financial Officer (“CFO”), our principal financial and accounting officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2016, the end of the period covered by this Annual Report, pursuant to Rules 13a-15(b) and 15d-15(b) under the Securities Exchange Act of 1934, as amended (“Exchange Act”).

In connection with that evaluation, our CEO and CFO concluded that, as of December 31, 2016, our disclosure controls and procedures were effective. For the purpose of this review, disclosure controls and procedures means controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms. These disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal accounting and financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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 Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, our CEO and CFO and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with accepted accounting principles generally accepted in the United States of America. Our management, under the supervision and with the participation of our CEO and CFO, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations (“COSO”). Based on such evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2016.

This Annual Report does not include an attestation report by our independent registered public accounting firm regarding internal control over financial reporting. As a smaller reporting company, our management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit 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 (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the year ended December 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. During 2016, we have expanded our financial and accounting department with the employment of a new CFO and a vice president of finance to maintain the effectiveness of our internal controls.

Table of Contents

Inherent Limitations on Effectiveness of Controls

Our management, including our CEO and CFO, do not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Item 9B. Other Information.

None.

Table of Contents

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

The information required by this item is incorporated by reference to information contained in the Proxy Statement or an amendment to this Annual Report, in either case to be filed with the Securities and Exchange Commission on or before the 120th day after the end of the fiscal year covered by this Annual Report.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to information contained in the Proxy Statement or an amendment to this Annual Report, in either case to be filed with the Securities and Exchange Commission on or before the 120th day after the end of the fiscal year covered by this Annual Report.

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

The information required by this item is incorporated by reference to information contained in the Proxy Statement or an amendment to this Annual Report, in either case to be filed with the Securities and Exchange Commission on or before the 120th day after the end of the fiscal year covered by this Annual Report.

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

The information required by this item is incorporated by reference to information contained in the Proxy Statement or an amendment to this Annual Report, in either case to be filed with the Securities and Exchange Commission on or before the 120th day after the end of the fiscal year covered by this Annual Report.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference to information contained in the Proxy Statement or an amendment to this Annual Report, in either case to be filed with the Securities and Exchange Commission on or before the 120th day after the end of the fiscal year covered by this Annual Report.

Table of Contents

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Documents Filed. The following documents are filed as part of this report:

(1) Consolidated Financial Statements:

Report of Hall and Company, Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2016 and 2015

Consolidated Statements of Operations for the Years Ended December 31, 2016 and 2015

Consolidated Statements of Stockholders' Equity (Deficit) for the Years Ended December 31, 2016 and 2015

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

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules. See subsection (c) below.

(3) Exhibits. See subsection (b) below.

(b) Exhibits. The exhibits filed or furnished with this report are set forth on the Exhibit Index immediately following the signature page of this report, which Exhibit Index is incorporated herein by reference.

(c) Financial Statement Schedules. All schedules are omitted because they are not applicable, the amounts involved are not significant or the required information is shown in the financial statements or notes thereto.

Table of Contents

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:

Date: March 9, 2017 Innovus Pharmaceuticals, Inc.

By: /s/ Bassam Damaj
 Bassam Damaj, Ph.D.
 President and Chief Executive Officer
 (Principal Executive Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Bassam Damaj and Robert E. Hoffman, and each of them individually, as his true and lawful attorneys-in-fact and agents, with full powers of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents or any of them the full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his substitutes or resubstitutes, may lawfully do or cause to be done by virtue hereof.

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.

Signature	Title	Date
/s/ Bassam Damaj Bassam Damaj, Ph.D.	Director, President and Chief Executive Officer (Principal Executive Officer)	March 9, 2017
/s/ Robert E. Hoffman Robert E. Hoffman	Executive Vice President and Chief Financial Officer (Principal Accounting and Financial Officer)	March 9, 2017
/s/ Henry Esber Henry Esber, Ph.D.	Chairman of the Board of Directors	March 9, 2017
/s/ Ziad Mirza Ziad Mirza, M.D.	Director	March 9, 2017
/s/ Vivian Liu Vivian Liu	Director	March 9, 2017

Table of Contents

INDEX TO EXHIBITS

Exhibit No. Description

2.1 Merger Agreement and Plan of Merger, dated as of July 13, 2011, by and among FasTrack, Inc., a Delaware corporation, North Horizon, Inc., a Nevada corporation and North First General, Inc., a Utah corporation, a wholly-owned subsidiary of North Horizon, Inc. filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on July 20, 2011 and incorporated herein by reference.

2.2 Asset Purchase Agreement dated April 19, 2013, between Innovus Pharmaceuticals, Inc. and Centric Research Institute, Inc. filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on April 24, 2013 and incorporated herein by

reference.

2.3 Agreement and Plan of Merger, made as of December 24, 2013, by and among Innovus Pharmaceuticals, Inc., Innovus Acquisition Corporation, Semprae Laboratories, Inc., the major stockholders of Semprae Laboratories, Inc. party thereto and Quaker Bioventures II, L.P., as principal stockholder of Semprae Laboratories, Inc., filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on December 30, 2013 and incorporated herein by reference.

2.4 Agreement and Plan of Merger, dated February 4, 2015, by and among Innovus Pharmaceuticals, Inc., Innovus Pharma Acquisition Corporation, Innovus Pharma Acquisition Corporation II, Novalere FP, Inc. and Novalere Holdings, LLC,

- filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on February 5, 2015 and incorporated herein by reference.
- 2.5 Asset Purchase Agreement, dated February 8, 2016, by and between Innvovs Pharmaceuticals, Inc. and Beyond Human LLC, filed as an exhibit to the Registrant's current report on Form 8-k, filed with the SEC on February 11, 2016, and incorporated herein by reference.
- 3.1 Amended and Restated Articles of Incorporation of the Registrant as filed with the Office of the Secretary of State of the State of Nevada on October 10, 2016, filed as an exhibit to the Registrant's registration statement on Form S-8, filed with the SEC on November 28, 2016, and incorporated herein by reference.
- 3.2 Amended and Restated Bylaws

of the Registrant,
filed as an exhibit
to the Registrant's
registration
statement on
Form S-8, filed
with the SEC on
November 28,
2016, and
incorporated
herein by
reference.

Certificate of
Amendment to
Articles of
Incorporation of
the Registrant as
filed with the
Office of the
Secretary of State
of the State of
Nevada on
October 13, 2011
changing the
Registrant's name
from North

3.3

Horizon, Inc., a
Nevada
corporation to
Innovus
Pharmaceuticals,
Inc., a Nevada
corporation, filed
as an exhibit to
the Registrant's
current report on
Form 8-K, filed
with the SEC on
December 12,
2011 and
incorporated
herein by
reference.

3.4

Certificate of
Correction to the
Company's
Articles of
Incorporation,
dated July 30,
2013, filed with
the Secretary of

- State for the State of Nevada, filed as an exhibit to the Registrant's annual report on Form 10-K, filed with the SEC on March 28, 2014 and incorporated herein by reference.
- 10.1# Employment Agreement, dated January 22, 2013, between Innovus Pharmaceuticals, Inc. and Bassam Damaj, Ph.D., filed as an exhibit to the Registrant's annual report on Form 10-K, filed with the SEC on March 19, 2013, and incorporated herein by reference.
- 10.2# 2013 Equity Incentive Plan of the Registrant, effective February 15, 2013, filed as an exhibit to the Registrant's registration statement on Form S-8, filed with the SEC on February 15, 2013, and incorporated herein by reference.
- 10.3# Form of Restricted Stock Agreement under the Registrant's 2013 Equity Incentive Plan, effective February

- 15, 2013, filed as an exhibit to the Registrant's registration statement on Form S-8, filed with the SEC on February 15, 2013, and incorporated herein by reference.
- 10.4# Form of Stock Unit Agreement under the Registrant's 2013 Equity Incentive Plan, effective February 15, 2013, filed as an exhibit to the Registrant's registration statement on Form S-8, filed with the SEC on February 15, 2013, and incorporated herein by reference.
- 10.5# Form of Nonstatutory Stock Option Agreement under the Registrant's 2013 Equity Incentive Plan, effective February 15, 2013, filed as an exhibit to the Registrant's registration statement on Form S-8, filed with the SEC on February 15, 2013, and incorporated herein by reference.

- 10.6# Form of Incentive Stock Option Agreement under the Registrant's 2013 Equity Incentive Plan, effective February 15, 2013, filed as an exhibit to the Registrant's registration statement on Form S-8, filed with the SEC on February 15, 2013, and incorporated herein by reference.
- 10.7 Form of Officer and Director Indemnification Agreement, dated June 2013, filed as an exhibit to the Registrant's quarterly report on Form 10-Q, filed with the SEC on August 13, 2013, and incorporated herein by reference.
- 10.8# Amended and Restated Innovus Pharmaceuticals, Inc. Non-Employee Director Compensation Plan, dated October 1, 2013, filed as an exhibit to the Registrant's quarterly report on Form 10-Q, filed with the SEC on

November 14,
2013, and
incorporated
herein by
reference.

10.9#

Innovus
Pharmaceuticals,
Inc. 2014 Equity
Incentive Plan,
filed as an exhibit
to the registration
statement on
Form S-8, filed
with the SEC on
January 2, 2015,
and incorporated
herein by
reference.

-37-

Table of Contents

- Form of Warrant
between the
Company and
Lynnette Dillen,
dated January 21,
2015, filed as an
exhibit to the
- 10.10 Registrant's
current report on
Form 8-K, filed
with the SEC on
January 23, 2015,
and incorporated
herein by
reference.
- Form of Warrant
Amendment
between the
Company and
Lynnette Dillen,
dated January 21,
2015, filed as an
exhibit to the
- 10.11 Registrant's
current report on
Form 8-K, filed
with the SEC on
January 23, 2015,
and incorporated
herein by
reference.
- 10.12# Employment
Agreement
Amendment,
between Innovus
Pharmaceuticals,
Inc. and Bassam
Damaj, dated
January 21, 2015,
filed as an exhibit
to the Registrant's
current report on
Form 8-K, filed
with the SEC on
January 23, 2015,
and incorporated
herein by

- reference.
- 10.13 Registration
Rights and Stock
Restriction
Agreement, dated
February 4, 2015,
by and between
Innovus
Pharmaceuticals,
Inc., and
Novalere
Holdings, LLC,
filed as an exhibit
to the Registrant's
current report on
Form 8-K, filed
with the SEC on
February 5, 2015,
and incorporated
herein by
reference.
- 10.14 Voting
Agreement, dated
February 4, 2015,
by and between
Innovus
Pharmaceuticals,
Inc., and
Novalere
Holdings, LLC,
filed as an exhibit
to the Registrant's
current report on
Form 8-K, filed
with the SEC on
February 5, 2015,
and incorporated
herein by
reference.
- 10.15 Form of
Securities
Purchase
Agreement, dated
July 15, 2015,
filed as an exhibit
to the
Registrant's
current report on
Form 8-K, filed
with the SEC on
August 3, 2015,

- and incorporated herein by reference.
- Form of Securities Purchase Agreement, dated August 25, 2015, filed as an exhibit to the
- 10.16 Registrant's current report on Form 8-K, filed with the SEC on September 2, 2015, and incorporated herein by reference.
- Form of Common Stock Purchase Warrant Agreement, dated August 25, 2015, filed as an exhibit to the
- 10.17 Registrant's current report on Form 8-K, filed with the SEC on September 2, 2015, and incorporated herein by reference.
- Form of Registration Rights Agreement, dated August 25, 2015, filed as an exhibit to the
- 10.18 Registrant's current report on Form 8-K, filed with the SEC on September 2, 2015, and incorporated herein by reference.

- Form of Share
Issuance
Agreement, dated
August 27, 2015,
filed as an exhibit
to the
Registrant's
10.19 current report on
Form 8-K, filed
with the SEC on
September 2,
2015, and
incorporated
herein by
reference.
Form of Purchase
Agreement, dated
February 19,
2016, by and
among the
Company and
SBI Investments,
LLC 2014-1,
10.20 filed as an exhibit
to the Registrant's
report on Form
8-K with the SEC
on March 1,
2016, and
incorporated
herein by
reference.
20% Secured
Promissory Note,
dated February
19, 2016 by and
among the
Company ad SGI
Investments,
LLC 2014-1,
10.21 filed as an exhibit
to the Registrant's
report on Form
8-K with the SEC
on March 1,
2016, and
incorporated
herein by
reference.
10.22 Security
Agreement, dated

February 19, 2016 by and among the Company and SGU Investments, LLC 2014-1, filed as an exhibit to the Registrant's report on Form 8-K with the SEC on March 1, 2016, and incorporated herein by reference. Form of Securities Purchase Agreement, dated June 30, 2016, filed as an exhibit to the

10.23 Registrant's current report on Form 8-K, filed with the SEC on July 6, 2016, and incorporated herein by reference.

Form of Convertible Promissory Note, dated June 30, 2016, filed as an exhibit to the

10.24 Registrant's current report on Form 8-K, filed with the SEC on July 6, 2016, and incorporated herein by reference.

10.25 Form of Common Stock Purchase Warrant Agreement, dated June 30, 2016, filed as an exhibit

- to the Registrant's current report on Form 8-K, filed with the SEC on July 6, 2016, and incorporated herein by reference.
- 10.26 Form of Registration Rights Agreement, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on July 6, 2016, and incorporated herein by reference.
- 10.27 Garden State Securities Engagement Agreement, filed as an exhibit to the Registrant's Registration Statement on Form S-1, filed with the SEC on August 9, 2016, and incorporated herein by reference.
- 10.28 H.C. Wainwright and Co., LLC Engagement Agreement filed as an exhibit to the Registrant's Registration Statement on Form S-1, filed with the SEC on August 9, 2016, and incorporated herein by reference.
- 10.29

- First Amendment
to the Securities
Purchase
Agreement filed
as an exhibit to
the Registrant's
Registration
Statement on
Form S-1, filed
with the SEC on
August 9, 2016,
and incorporated
herein by
reference.
- 10.30 10% Debenture,
filed as an exhibit
to the
Registrant's
Current Report
on Form 8-K,
filed with the
SEC on August
15, 2016, and
incorporated
herein by
reference.
- 10.31 Securities
Purchase
Agreement, filed
as an exhibit to
the Registrant's
Current Report
on Form 8-K,
filed with the
SEC on August
15, 2016, and
incorporated
herein by
reference.
- 10.32 Promissory Note,
filed as an exhibit
to the
Registrant's
Current Report
on Form 8-K,
filed with the
SEC on August
15, 2016, and
incorporated
herein by
reference.

- Employment Agreement, between Innovus Pharmaceuticals, Inc. and Robert Hoffman, dated September 6, 2016, filed as an
- 10.33# exhibit to the Registrant's current report on Form 8-K, filed with the SEC on August 29, 2016 and incorporated herein by reference.
- Employment Agreement, between Innovus Pharmaceuticals, Inc. and Randy Berholtz, dated January 9, 2017, filed as an exhibit
- 10.34# to the Registrant's current report on Form 8-K, filed with the SEC on January 6, 2017, and incorporated herein by reference.
- Innovus Pharmaceuticals, Inc. 2014 Equity Incentive Plan, filed as an exhibit
- 10.35# to the registration statement on Form S-8, filed with the SEC on January 2, 2015, and incorporated herein by reference.
- 10.36# Amended and Restated 2016 Equity Incentive Plan of the Registrant, filed

as an exhibit to
the Registrant's
registration
statement on
Form S-8, filed
with the SEC on
November 28,
2016, and
incorporated
herein by
reference.

Table of Contents

14.1*	Code of Ethics
21.1*	List of Subsidiaries
23.1*	Consent of Hall and Company, Independent Registered Public Accounting Firm Power of Attorney, included as part of signature page to this Annual Report.
24.1*	Certification of the Registrant's Principal Executive Officer pursuant to Securities Exchange Act
31.1*	Rules 13a-14(a) and 15(d)-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Certification of the Registrant's Principal Financial Officer pursuant to Securities Exchange Act
31.2*	Rules 13a-14(a) and 15(d)-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	

Certification of
 the Registrant's
 Principal
 Executive
 Officer pursuant
 to 18 U.S.C. SS.
 1350, as
 adopted
 pursuant to
 Section. 906 of
 the
 Sarbanes-Oxley
 Act of 2002.
 Certification of
 the Registrant's
 Principal
 Financial
 Officer pursuant
 to 18 U.S.C. SS.
 1350, as
 adopted
 pursuant to
 Section. 906 of
 the
 Sarbanes-Oxley
 Act of 2002.
 XBRL Instance
 Document
 XBRL
 Taxonomy
 Extension
 Schema
 Document
 XBRL
 Taxonomy
 Extension
 Calculation
 Linkbase
 Document
 XBRL
 Taxonomy
 Extension
 Definition
 Linkbase
 Document
 XBRL
 Taxonomy
 Extension Label
 Linkbase
 Document
 101.PRE*

XBRL
Taxonomy
Extension
Presentation
Linkbase
Document

*

Filed herewith

**

Furnished herewith

#

Management contract or compensatory plan or arrangement

-39-

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Innovus Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Innovus Pharmaceuticals, Inc. and subsidiaries (the “Company”) as of December 31, 2016 and 2015, and the related consolidated statements of operations, stockholders’ equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2016. These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these consolidated 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. 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 the Company as of December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America.

/s/ Hall & Company Certified Public Accountants & Consultants, Inc.
Hall & Company Certified Public Accountants & Consultants, Inc.

Irvine, CA
March 9, 2017

Table of ContentsINNOVUS PHARMACEUTICALS, INC.
Consolidated Balance Sheets

	As of December 31,	
	2016	2015
ASSETS		
CURRENT ASSETS		
Cash	\$829,933	\$55,901
Accounts receivable, net	33,575	83,097
Prepaid expense and other current assets	863,664	53,278
Inventories	599,856	254,443
Total current assets	2,327,028	446,719
PROPERTY AND EQUIPMENT, NET	29,569	35,101
OTHER ASSETS		
Deposits	14,958	14,958
Goodwill	952,576	549,368
Intangible assets, net	4,903,247	5,300,859
TOTAL ASSETS	\$8,227,378	\$6,347,005
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued expense	\$1,210,050	\$155,503
Accrued compensation	767,689	535,862
Deferred revenue and customer deposits	11,000	24,079
Accrued interest payable	47,782	79,113
Short-term loans payable	-	230,351
Derivative liabilities – embedded conversion features	319,674	301,779
Derivative liabilities – warrants	164,070	432,793
Contingent consideration	170,015	-
Current portion of notes payable and non-convertible debenture, net of debt discount of \$216,403 and \$0, respectively	626,610	73,200
Line of credit convertible debenture and non-convertible debenture – related parties, net of debt discount of \$0 and \$17,720, respectively	-	391,472
Convertible debentures, net of debt discount of \$845,730 and \$1,050,041, respectively	714,192	407,459
Total current liabilities	4,031,082	2,631,611

NON-CURRENT LIABILITIES

Accrued compensation – less current portion	1,531,904	906,928
Notes payable and non-convertible debenture, net of current portion and debt discount of \$468 and \$0, respectively	54,517	-
Line of credit convertible debenture and non-convertible debenture – related parties, net of current portion	-	25,000
Contingent consideration – less current portion	1,515,902	3,229,804
Total non-current liabilities	3,102,323	4,161,732
TOTAL LIABILITIES	7,133,405	6,793,343

COMMITMENTS AND CONTINGENCIES

STOCKHOLDERS' EQUITY (DEFICIT)

Preferred stock: 7,500,000 shares authorized, at \$0.001 par value, no shares issued and outstanding at December 31, 2016 and 2015, respectively	-	-
Common stock: 292,500,000 shares authorized, at \$0.001 par value, 121,694,293 and 47,141,230 shares issued and outstanding at December 31, 2016 and 2015, respectively	121,694	47,141
Additional paid-in capital	30,108,028	14,941,116
Accumulated deficit	(29,135,749)	(15,434,595)
Total stockholders' equity (deficit)	1,093,973	(446,338)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	\$8,227,378	\$6,347,005

See accompanying notes to these consolidated financial statements.

Table of ContentsINNOVUS PHARMACEUTICALS, INC.
Consolidated Statements of Operations

	For the Year Ended December 31,	
	2016	2015
NET REVENUE:		
Product sales, net	\$4,817,603	\$730,717
License revenue	1,000	5,000
Net revenue	4,818,603	735,717
OPERATING EXPENSE:		
Cost of product sales	1,083,094	340,713
Research and development	77,804	-
Sales and marketing	3,621,045	82,079
General and administrative	5,870,572	3,828,113
Impairment of goodwill	-	759,428
Total operating expense	10,652,515	5,010,333
LOSS FROM OPERATIONS	(5,833,912)	(4,274,616)
OTHER INCOME AND (EXPENSE):		
Interest expense	(6,661,694)	(1,153,376)
Change in fair value of derivative liabilities	65,060	393,509
Other income (expense), net	1,649	(8,495)
Fair value adjustment for contingent consideration	(1,269,857)	115,822
Loss on extinguishment of debt	-	(32,500)
Total other expense, net	(7,864,842)	(685,040)
LOSS BEFORE PROVISION FOR (BENEFIT FROM) INCOME TAXES	(13,698,754)	(4,959,656)
Provision for (benefit from) income taxes	2,400	(757,028)
NET LOSS	\$(13,701,154)	\$(4,202,628)
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	\$(0.15)	\$(0.08)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK OUTSTANDING – BASIC AND DILUTED	94,106,382	52,517,530

See accompanying notes to these consolidated financial statements.

F-3

Table of ContentsINNOVUS PHARMACEUTICALS, INC.
Consolidated Statements of Cash Flows

	For the Year Ended December 31,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES		
NET LOSS	\$(13,701,154)	\$(4,202,628)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	5,532	28,950
Allowance for doubtful accounts	2,066	5,892
Common stock, restricted stock units and stock options issued to employees, board of directors and consultants for compensation and services	2,684,602	1,508,769
Gain on purchase price adjustment to goodwill	-	(759,428)
Impairment of goodwill	-	759,428
Loss on extinguishment of debt	-	32,500
Change in fair value of contingent consideration	1,449,857	(115,822)
Non-cash gain on settlement of contingent consideration	(180,000)	-
Change in fair value of derivative liabilities	(65,060)	(393,509)
Shares of common stock issued for debt amendment	-	15,500
Fair value of embedded conversion feature in convertible debentures in excess of allocated proceeds	2,756,899	71,224
Amortization of debt discount	3,646,161	960,061
Amortization of intangible assets	624,404	550,789
Changes in operating assets and liabilities, net of acquisition amounts:		
Accounts receivable	47,456	102,612
Prepaid expense and other current assets	(279,786)	27,653
Deposits	-	6,961
Inventories	(345,413)	11,516
Accounts payable and accrued expense	694,547	(206,657)
Accrued compensation	856,803	535,862
Accrued interest payable	31,907	29,745
Deferred revenue and customer deposits	(13,079)	(1,145)
Net cash used in operating activities	(1,784,258)	(1,031,727)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	-	(9,540)
Purchase of intangible assets	-	(3,276)
Payments on contingent consideration	(172,103)	-

Edgar Filing: INNOVUS PHARMACEUTICALS, INC. - Form 10-K

Net cash used in investing activities	(172,103)	(12,816)
CASH FLOWS FROM FINANCING ACTIVITIES		
Repayments of line of credit convertible debenture – related party	(409,192)	(14,886)
Financing costs in connection with issuance of convertible debentures	(40,000)	(82,500)
Proceeds from short-term loans payable	21,800	258,278
Payments on short-term loans payable	(252,151)	(27,927)
Proceeds from notes payable and convertible debentures	3,574,000	1,455,000
Payments on notes payable	(449,204)	(440,000)
Proceeds from warrant exercises	310,140	-
Proceeds from non-convertible debentures – related party	-	50,000
Payments on non-convertible debentures – related party	(25,000)	(105,000)
Net cash provided by financing activities	2,730,393	1,092,965
NET CHANGE IN CASH	774,032	48,422
CASH AT BEGINNING OF YEAR	55,901	7,479
CASH AT END OF YEAR	\$829,933	\$55,901

F-4

Table of Contents

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION :

Cash paid for income taxes	\$-	\$2,400
Cash paid for interest	\$229,046	\$107,764

SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:

Common stock issued for conversion of notes payable, convertible debentures and accrued interest	\$3,264,705	\$167,000
Reclassification of the fair value of the embedded conversion features from derivative liability to additional paid-in capital upon conversion	\$3,111,828	\$-
Cashless exercise of warrants	\$3,385	\$-
Reclassification of the fair value of the warrants from derivative liability to additional paid-in capital upon cashless exercise	\$518,224	\$-
Common stock issued for acquisition	\$-	\$2,071,625
Relative fair value of common stock issued in connection with notes payable recorded as debt discount	\$276,167	\$-
Relative fair value of warrants issued in connection with convertible debentures recorded as debt discount	\$445,603	\$89,551
Relative fair value of common stock issued in connection with convertible debentures recorded as debt discount	\$1,127,225	\$374,474
Fair value of embedded conversion feature derivative liabilities recorded as debt discount	\$687,385	\$830,560
Fair value of warrants issued to placement agents in connection with convertible debentures recorded as debt discount	\$357,286	\$68,419
Fair value of the contingent consideration for acquisition	\$330,000	\$2,905,425
Fair value of warrant derivative liabilities recorded as debt discount	\$-	\$226,297
Proceeds from note payable paid to seller in connection with acquisition	\$300,000	\$-
Financing costs paid with proceeds from note payable	\$7,500	\$-
Common stock issued to Novalere Holdings for payment of the acquisition contingent consideration as a result of an amendment and supplement to the registration rights and stock restriction agreement	\$2,971,641	\$-
Fair value of unamortized non-forfeitable common stock issued to consultant included in prepaid expense and other current assets	\$170,600	\$-
Fair value of non-forfeitable common stock to be issued to consultant included in prepaid expense and other current assets and accounts payable and accrued expense	\$360,000	\$-
Issuance of shares of common stock for vested restricted stock units	\$19,316	\$500
Return of shares of common stock related to license agreement	\$-	\$38,000
Accrued interest added to principal in connection with amendment of notes payable	\$-	\$3,200
Fair value of beneficial conversion feature on line of credit convertible debenture – related party	\$3,444	\$8,321

See accompanying notes to these consolidated financial statements.

Table of Contents

INNOVUS PHARMACEUTICALS, INC.
 Consolidated Statements of Stockholders' Equity (Deficit)
 For the Years Ended December 31, 2016 and 2015

	Common Stock		Additional Paid-in	Accumulated	Stockholders' Equity
	Shares	Amount	Capital	Deficit	(Deficit)
Balance at January 1, 2015	27,112,263	\$27,113	\$10,778,807	\$(11,231,967)	\$(426,047)
Common stock issued for services	1,780,625	1,780	208,749	-	210,529
Stock compensation expense	-	-	1,298,240	-	1,298,240
Common stock issued for product acquisition	12,947,657	12,948	2,058,677	-	2,071,625
Common stock issued upon conversion of convertible debentures, note payable and debentures – related party	699,260	699	166,301	-	167,000
Common stock issued for vested restricted stock units	500,000	500	(500)	-	-
Return of shares of common stock from CRI license transaction	(200,000)	(200)	(37,800)	-	(38,000)
Return of shares of common stock from Semprae merger transaction	(386,075)	(386)	(115,436)	-	(115,822)
Fair value of beneficial conversion feature on line of credit convertible debenture – related party	-	-	8,321	-	8,321
Shares of common stock issued for extension of February 2014 convertible debentures	250,000	250	32,250	-	32,500
Shares of common stock issued for amendment of January 2015 convertible debentures	100,000	100	15,400	-	15,500
Relative fair value of shares of common stock issued in connection with convertible debentures	4,337,500	4,337	370,137	-	374,474
Relative fair value of warrants issued in connection with convertible debentures	-	-	89,551	-	89,551
Fair value of warrants issued to placement agents in connection with convertible debentures	-	-	68,419	-	68,419
Net loss for year ended December 31, 2015	-	-	-	(4,202,628)	(4,202,268)
Balances at December 31, 2015	47,141,230	47,141	14,941,116	(15,434,595)	(446,338)
Common stock issued for services	10,732,500	10,733	1,802,216	-	1,812,949
Stock-based compensation	-	-	954,753	-	954,753
	12,808,796	12,809	2,958,832	-	2,971,641

Edgar Filing: INNOVUS PHARMACEUTICALS, INC. - Form 10-K

Common stock issued to Novalere Holdings, LLC for payment of contingent consideration					
Common stock issued upon conversion of convertible debentures and accrued interest	17,100,508	17,100	3,247,605	-	3,264,705
Common stock issued for vested restricted stock units	19,315,994	19,316	(19,316)	-	-
Fair value of beneficial conversion feature on line of credit convertible debenture – related-party	-	-	3,444	-	3,444
Relative fair value of shares of common stock issued in connection with notes payable and convertible debentures	9,861,111	9,861	1,393,531	-	1,403,392
Relative fair value of warrants issued in connection with convertible debentures	-	-	445,603	-	445,603
Fair value of warrants issued to placement agents in connection with convertible debentures	-	-	357,286	-	357,286
Common stock issued for legal costs from Sempra merger transaction	215,000	215	64,285	-	64,500
Common stock issued in connection with license agreement	100,000	100	22,900	-	23,000
Common stock issued upon cashless exercise of warrants	3,385,354	3,385	(3,385)	-	-
Common stock issued upon exercise of warrants	1,033,800	1,034	309,106	-	310,140
Reclassification of embedded conversion feature derivative liability upon conversion of convertible debentures	-	-	3,111,828	-	3,111,828
Reclassification of warrant derivative liability upon cashless exercise of warrants	-	-	518,224	-	518,224
Net loss for year ended December 31, 2016	-	-	-	(13,701,154)	(13,701,154)
Balances at December 31, 2016	121,694,293	\$121,694	\$30,108,028	\$(29,135,749)	\$1,093,973

See accompanying notes to these consolidated financial statements.

Table of Contents

INNOVUS PHARMACEUTICALS, INC.

Notes to the Consolidated Financial Statements

December 31, 2016 and 2015

NOTE 1 – ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Innovus Pharmaceuticals, Inc., together with its subsidiaries (collectively referred to as “Innovus”, “we”, “our”, “us” or the “Company”) is a Nevada formed, San Diego, California-based emerging commercial stage pharmaceutical company delivering over-the-counter medicines and consumer care products for men’s and women’s health and respiratory diseases.

We generate revenue from 17 commercial products in the United States, including six of these commercial products in multiple countries around the world through our commercial partners. Our commercial product portfolio includes (a) Beyond Human® Testosterone Booster, (b) Beyond Human® Growth Agent, (c) Zestra® for female arousal, (d) EjectDelay® for premature ejaculation, (e) Sensum+® for reduced penile sensitivity, (f) Zestra Glide®, (g) Vesele® for promoting sexual health, (h) Androferti® to support overall male reproductive health and sperm quality, (i) RecalMax™ for cognitive brain health (j) Beyond Human® Green Coffee Extract (k) Beyond Human® Vision Formula, (l) Beyond Human® Blood Sugar, (m) Beyond Human® Colon Cleans, (n) Beyond Human® Ketones, (o) Beyond Human® Krill Oil (p) Beyond Human® Omega 3 Fish Oil and (q) Urivarx™ for overactive bladder and urinary incontinence. While we generate revenue from the sale of our commercial products, most revenue is currently generated by Vesele®, Zestra®, Zestra® Glide, RecalMax™, Sensum +®, Urivarx™ and Beyond Human® Testosterone Booster.

Pipeline Products

Fluticare™ (fluticasone propionate nasal spray). Innovus acquired the worldwide rights to market and sell the Fluticare™ brand (fluticasone propionate nasal spray) and the related manufacturing agreement from Novalere FP in February 2015. The Over-the-Counter (“OTC”) Abbreviated New Drug Application (“ANDA”) filed at the end of 2014 by the manufacturer with the U.S. Food and Drug Administration (“FDA”), subject to FDA approval, may allow us to market and sell Fluticare™ OTC. An ANDA is an application for a U.S. generic drug approval for an existing licensed medication or approved drug.

AllerVarx™. On December 15, 2016, we entered into an exclusive license and distribution agreement with NTC S.r.l (Italy) to distribute and commercialize AllerVarx™ in the U.S. and Canada. AllerVarx™ is a proprietary modified release bilayer tablet for the management of allergic rhinitis. We expect to launch this product in the first half of 2017.

Xyralid™. Xyralid™ is an OTC FDA monograph compliant drug containing the active drug ingredient lidocaine and indicated for the relief of the pain and symptoms caused by hemorrhoids. We expect to launch this product in the first half of 2017.

Urocis™ XR. On October 27, 2015, we entered into an exclusive distribution agreement with Laboratorios Q Pharma (Spain) to distribute and commercialize Urocis™ XR in the U.S. and Canada. Urocis™ XR is a proprietary extended release of Vaccinium Marcocarpon (cranberry) shown to provide 24-hour coverage in the body in connection with urinary tract infections in women. We expect to launch this product in the second half of 2017.

AndroVit™. On October 27, 2015, we entered into an exclusive distribution agreement with Laboratorios Q Pharma (Spain) to distribute and commercialize AndroVit™ in the U.S. and Canada. AndroVit™ is a proprietary supplement to support overall prostate and male sexual health currently marketed in Europe. AndroVit™ was specifically formulated with ingredients known to support normal prostate health and vitality and male sexual health. We expect to launch this product in the second half of 2017.

Change in Accounting Principle

On January 1, 2016, we retrospectively adopted Financial Accounting Standards Board (“FASB”) Accounting Standards Update (“ASU”) No. 2015-03, Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. This ASU requires that debt issuance costs be presented as a direct reduction from the carrying amount of debt. As a result of the adoption of this ASU, the consolidated balance sheet at December 31, 2015 was adjusted to reflect the reclassification of \$97,577 from deferred financing costs, net to convertible debentures, net. The adoption of this ASU did not have an impact on our consolidated results of operations.

Basis of Presentation and Principles of Consolidation

These consolidated financial statements have been prepared by management in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and include all assets, liabilities, revenue and expense of us and our wholly-owned subsidiaries: FasTrack Pharmaceuticals, Inc., Semprae Laboratories, Inc. (“Semprae”) and Novalere, Inc. (“Novalere”). All material intercompany transactions and balances have been eliminated. Certain items have been reclassified to conform to the current year presentation.

Table of Contents

Use of Estimates

The preparation of these consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the consolidated financial statements and the reported amounts of revenue and expense during the reporting periods. Such management estimates include the allowance for doubtful accounts, sales returns and chargebacks, realizability of inventories, valuation of deferred tax assets, goodwill and intangible assets, valuation of contingent acquisition consideration, recoverability of long-lived assets and goodwill, fair value of derivative liabilities and the valuation of equity-based instruments and beneficial conversion features. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from these estimates under different assumptions or conditions.

Liquidity

Our operations have been financed primarily through proceeds from convertible debentures and notes payable and revenue generated from our products domestically and internationally by our partners. These funds have provided us with the resources to operate our business, sell and support our products, attract and retain key personnel and add new products to our portfolio. We have experienced net losses and negative cash flows from operations each year since our inception. As of December 31, 2016, we had an accumulated deficit of \$29,135,749 and a working capital deficit of \$1,704,054.

We have raised funds through the issuance of debt and the sale of common stock. We have also issued equity instruments in certain circumstances to pay for services from vendors and consultants. In December 2016, we raised \$500,000 in gross proceeds from the issuance of notes payable to three investors and in June and July 2016, we raised \$3,000,000 in gross proceeds from the issuance of convertible debentures to eight investors (see Note 5). In the event we do not pay the convertible debentures upon their maturity, or after the remedy period, the principal amount and accrued interest on the convertible debentures is convertible at our option to common stock at the lower of the fixed conversion price or 60% of the volume weighted average price ("VWAP") during the ten consecutive trading day period preceding the date of conversion. In February 2016, we also raised \$550,000 in funds from a note payable with net proceeds of \$242,500 to us, which was used to pay for the asset acquisition of Beyond Human, LLC (see Note 5), a Texas limited liability company ("Beyond Human®") and for working capital purposes.

As of December 31, 2016, we had \$829,933 in cash and \$221,243 of cash collections held by our third-party merchant service provider, which is included in prepaid expense and other current assets in the accompanying consolidated balance sheet. During the year ended December 31, 2016, we had net cash used in operating activities of \$1,784,258 primarily from purchasing inventory to support our growing revenue and certain prepayments of annual expenses. We expect that our existing capital resources, revenue from sales of our products and upcoming sales milestone payments from the commercial partners signed for our products, and equity instruments available to pay certain vendors and consultants, will be sufficient to allow us to continue our operations, commence the product development process and launch selected products through at least the next 12 months. In addition, our CEO, who is also a significant shareholder, has deferred the payment of his salary earned thru June 30, 2016 for at least the next 12 months. Our actual needs will depend on numerous factors, including timing of introducing our products to the marketplace, our ability to attract additional Ex-U.S. distributors for our products and our ability to in-license in non-partnered territories and/or develop new product candidates. Although no assurances can be given, we currently intend to raise additional capital through the sale of debt or equity securities to provide additional working capital, pay for further expansion and development of our business, and to meet current obligations. Such capital may not be available to us when we need it or on terms acceptable to us, if at all.

Fair Value Measurement

Our financial instruments are cash, accounts receivable, accounts payable, accrued liabilities, derivative liabilities, contingent consideration and debt. The recorded values of cash, accounts receivable, accounts payable and accrued liabilities approximate their fair values based on their short-term nature. The recorded fair value of the convertible debentures, net of debt discount, is based upon the relative fair value calculation of the common stock and warrants issued in connection with the convertible debentures and the fair value of the embedded conversion feature. The fair values of the warrant derivative liabilities and embedded conversion feature derivative liabilities are based upon the Black Scholes Option Pricing Model (“Black-Scholes”) and the Path-Dependent Monte Carlo simulation model calculations, respectively, and are a Level 3 measurement (see Note 9). The fair value of the contingent acquisition consideration is based upon the discounted future payments due under the terms of the agreements and is a Level 3 measurement (see Note 3). Based on borrowing rates currently available to us, the carrying values of the notes payable and convertible debentures approximate their respective fair values.

F-8

Table of Contents

We follow a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets and liabilities (Level 1) and the lowest priority to measurements involving significant unobservable inputs (Level 3). The three levels of the fair value hierarchy are as follows:

Level 1 measurements are quoted prices (unadjusted) in active markets for identical assets or liabilities that we have the ability to access at the measurement date.

Level 2 measurements are inputs other than quoted prices included in Level 1 that are observable either directly or indirectly.

Level 3 measurements are unobservable inputs.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and highly liquid investments with remaining maturities of three months or less when purchased.

Concentration of Credit Risk, Major Customers and Segment Information

Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash and accounts receivable. Cash held with financial institutions may exceed the amount of insurance provided by the Federal Deposit Insurance Corporation on such deposits. Accounts receivable consist primarily of sales of Zestra® to U.S. based retailers and Ex-U.S. partners. We also require a percentage of payment in advance for product orders with our larger partners. We perform ongoing credit evaluations of our customers and generally do not require collateral.

Revenue consists primarily of product sales and licensing rights to market and commercialize our products. We had no customers that accounted for 10% or greater of our total net revenue during the year ended December 31, 2016. Three customers accounted for 62% of total net accounts receivable as of December 31, 2016. We had three customers that accounted for 43% of our total net revenue during the year ended December 31, 2015 and two customers accounted for 73% of net accounts receivable as of December 31, 2015.

We categorize revenue by geographic area based on selling location. All operations are currently located in the U.S.; therefore, over 90% of our sales are currently within the U.S. The balance of the sales are to various other countries. All long-lived assets at December 31, 2016 and 2015 are located in the U.S.

We operate our business on the basis of a single reportable segment, which is the business of delivering over-the-counter medicines and consumer care products for men's and women's health and respiratory diseases. Our chief operating decision-maker is the Chief Executive Officer, who evaluates us as a single operating segment.

Concentration of Suppliers

We have manufacturing relationships with a number of vendors or manufacturers for our products including: Sensum+®, EjectDelay®, Vesele®, RecalMax™, UriVarx™, Androferti®, the Zestra® line of products and Beyond Human® line of products. Pursuant to these relationships, we purchase products through purchase orders with our manufacturers.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined on a first-in, first-out basis. We evaluate the carrying value of inventories on a regular basis, based on the price expected to be obtained for products in their respective markets compared with historical cost. Write-downs of inventories are considered to be permanent reductions in the cost basis of inventories.

We also regularly evaluate our inventories for excess quantities and obsolescence (expiration), taking into account such factors as historical and anticipated future sales or use in production compared to quantities on hand and the remaining shelf life of products and raw materials on hand. We establish reserves for excess and obsolete inventories as required based on our analyses.

Property and Equipment

Property and equipment, including software, are recorded at historical cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets which range from three to ten years. The initial cost of property and equipment and software consists of its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

F-9

Table of Contents

Business Combinations

We account for business combinations by recognizing the assets acquired, liabilities assumed, contractual contingencies, and contingent consideration at their fair values on the acquisition date. The final purchase price may be adjusted up to one year from the date of the acquisition. Identifying the fair value of the tangible and intangible assets and liabilities acquired requires the use of estimates by management and was based upon currently available data. Examples of critical estimates in valuing certain of the intangible assets we have acquired or may acquire in the future include but are not limited to future expected cash flows from product sales, support agreements, consulting contracts, other customer contracts, and acquired developed technologies and patents and discount rates utilized in valuation estimates.

Unanticipated events and circumstances may occur that may affect the accuracy or validity of such assumptions, estimates or actual results. Additionally, any change in the fair value of the acquisition-related contingent consideration subsequent to the acquisition date, including changes from events after the acquisition date, such as changes in our estimate of relevant revenue or other targets, will be recognized in earnings in the period of the estimated fair value change. A change in fair value of the acquisition-related contingent consideration or the occurrence of events that cause results to differ from our estimates or assumptions could have a material effect on the consolidated statements of operations, financial position and cash flows in the period of the change in the estimate.

Goodwill and Intangible Assets

We test our goodwill for impairment annually, or whenever events or changes in circumstances indicates an impairment may have occurred, by comparing our reporting unit's carrying value to its implied fair value. The goodwill impairment test consists of a two-step process as follows:

Step 1. We compare the fair value of each reporting unit to its carrying amount, including the existing goodwill. The fair value of each reporting unit is determined using a discounted cash flow valuation analysis. The carrying amount of each reporting unit is determined by specifically identifying and allocating the assets and liabilities to each reporting unit based on headcount, relative revenue or other methods as deemed appropriate by management. If the carrying amount of a reporting unit exceeds its fair value, an indication exists that the reporting unit's goodwill may be impaired and we then perform the second step of the impairment test. If the fair value of a reporting unit exceeds its carrying amount, no further analysis is required.

Step 2. If further analysis is required, we compare the implied fair value of the reporting unit's goodwill, determined by allocating the reporting unit's fair value to all of its assets and its liabilities in a manner similar to a purchase price allocation, to its carrying amount. If the carrying amount of the reporting unit's goodwill exceeds its fair value, an impairment loss will be recognized in an amount equal to the excess.

Impairment may result from, among other things, deterioration in the performance of the acquired business, adverse market conditions, adverse changes in applicable laws or regulations and a variety of other circumstances. If we determine that an impairment has occurred, it is required to record a write-down of the carrying value and charge the impairment as an operating expense in the period the determination is made. In evaluating the recoverability of the carrying value of goodwill, we must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the acquired assets. Changes in strategy or market conditions could significantly impact those judgments in the future and require an adjustment to the recorded balances.

The goodwill was recorded as part of the acquisition of Semprae that occurred on December 24, 2013, the acquisition of Novalere that occurred on February 5, 2015 and the asset acquisition of Beyond Human® that closed on March 1,

2016. During the year ended December 31, 2015, we recorded \$759,428 of goodwill related to the acquisition of Novalere as an income tax benefit and also recorded an impairment of \$759,428 against this benefit. There was no impairment of goodwill for the year ended December 31, 2016.

Intangible assets with finite lives are amortized on a straight-line basis over their estimated useful lives, which range from one to fifteen years. The useful life of the intangible asset is evaluated each reporting period to determine whether events and circumstances warrant a revision to the remaining useful life.

Long-Lived Assets

We review our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. We evaluate assets for potential impairment by comparing estimated future undiscounted net cash flows to the carrying amount of the assets. If the carrying amount of the assets exceeds the estimated future undiscounted cash flows, impairment is measured based on the difference between the carrying amount of the assets and fair value. Assets to be disposed of would be separately presented in the consolidated balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and are no longer depreciated. The assets and liabilities of a disposal group classified as held-for-sale would be presented separately in the appropriate asset and liability sections of the consolidated balance sheet, if material. During the years ended December 31, 2016 and 2015, we did not recognize any impairment of our long-lived assets.

Table of Contents

Debt Issuance Costs

Debt issuance costs represent costs incurred in connection with the issuance of the convertible debentures during the third quarter of 2015 and the note payable and convertible debentures during the year ended December 31, 2016. Debt issuance costs related to the issuance of the convertible debentures and note payable are recorded as a reduction to the debt balances in the accompanying consolidated balance sheets. The debt issuance costs are being amortized to interest expense over the term of the financing instruments using the effective interest method.

Beneficial Conversion Feature

If a conversion feature of convertible debt is not accounted for separately as a derivative instrument and provides for a rate of conversion that is below market value, this feature is characterized as a beneficial conversion feature ("BCF"). A BCF is recorded by us as a debt discount. We amortize the discount to interest expense over the life of the debt using the effective interest rate method.

Derivative Liabilities

Certain of our embedded conversion features on debt and issued and outstanding common stock purchase warrants, which have exercise price reset features and other anti-dilution protection clauses, are treated as derivatives for accounting purposes. The common stock purchase warrants were not issued with the intent of effectively hedging any future cash flow, fair value of any asset, liability or any net investment in a foreign operation. The warrants do not qualify for hedge accounting, and as such, all future changes in the fair value of these warrants are recognized currently in earnings until such time as the warrants are exercised, expire or the related rights have been waived. These common stock purchase warrants do not trade in an active securities market, and as such, we estimate the fair value of these warrants using a Probability Weighted Black-Scholes Model and the embedded conversion features using a Path-Dependent Monte Carlo Simulation Model (see Note 9).

Debt Extinguishment

Any gain or loss associated with debt extinguishment is recorded in the period in which the debt is considered extinguished. Third party fees incurred in connection with a debt restructuring accounted for as an extinguishment are capitalized. Fees paid to third parties associated with a term debt restructuring accounted for as a modification are expensed as incurred. Third party and creditor fees incurred in connection with a modification to a line of credit or revolving debt arrangements are considered to be associated with the new arrangement and are capitalized.

Income Taxes

Income taxes are provided for using the asset and liability method whereby deferred tax assets and liabilities are recognized using current tax rates on the difference between the financial statement carrying amounts and the respective tax basis of the assets and liabilities. We provide a valuation allowance on deferred tax assets when it is more likely than not that such assets will not be realized.

We recognize the benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting this standard, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the relevant tax authority. There were no uncertain tax positions at December 31, 2016 and 2015.

Revenue Recognition and Deferred Revenue

We generate revenue from product sales and the licensing of the rights to market and commercialize our products.

We recognize revenue in accordance with FASB Accounting Standards Codification (“ASC”) 605, Revenue Recognition. Revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) title to the product has passed or services have been rendered; (3) price to the buyer is fixed or determinable and (4) collectability is reasonably assured.

Product Sales: We ship products directly to consumers pursuant to phone or online orders and to our wholesale and retail customers pursuant to purchase agreements or sales orders. Revenue from sales transactions where the buyer has the right to return the product is recognized at the time of sale only if (1) the seller’s price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product, (3) the buyer’s obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product, (4) the buyer acquiring the product for resale has economic substance apart from that provided by the seller, (5) the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer and (6) the amount of future returns can be reasonably estimated.

Table of Contents

License Revenue: The license agreements we enter into normally generate three separate components of revenue: 1) an initial payment due on signing or when certain specific conditions are met; 2) royalties that are earned on an ongoing basis as sales are made or a pre-agreed transfer price and 3) sales-based milestone payments that are earned when cumulative sales reach certain levels. Revenue from the initial payments or licensing fee is recognized when all required conditions are met. Royalties are recognized as earned based on the licensee's sales. Revenue from the sales-based milestone payments is recognized when the cumulative revenue levels are reached. The achievement of the sales-based milestone underlying the payment to be received predominantly relates to the licensee's performance of future commercial activities. FASB ASC 605-28, Milestone Method, ("ASC 605-28") is not used by us as these milestones do not meet the definition of a milestone under ASC 605-28 as they are sales-based and similar to a royalty and the achievement of the sales levels is neither based, in whole or in part, on our performance, a specific outcome resulting from our performance, nor is it a research or development deliverable.

Sales Allowances

We accrue for product returns, volume rebates and promotional discounts in the same period the related sale is recognized.

Our product returns accrual is primarily based on estimates of future product returns over the period customers have a right of return, which is in turn based in part on estimates of the remaining shelf-life of products when sold to customers. Future product returns are estimated primarily based on historical sales and return rates. We estimate our volume rebates and promotional discounts accrual based on its estimates of the level of inventory of our products in the distribution channel that remain subject to these discounts. The estimate of the level of products in the distribution channel is based primarily on data provided by our customers.

In all cases, judgment is required in estimating these reserves. Actual claims for rebates and returns and promotional discounts could be materially different from the estimates.

We provide a customer satisfaction warranty on all of our products to customers for a specified amount of time after product delivery. Estimated return costs are based on historical experience and estimated and recorded when the related sales are recognized. Any additional costs are recorded when incurred or when they can reasonably be estimated.

The estimated reserve for sales returns and allowances, which is included in accounts payable and accrued expense, was approximately \$61,000 and \$5,000 at December 31, 2016 and 2015, respectively.

Cost of Product Sales

Cost of product sales includes the cost of inventory, royalties and inventory reserves. We are required to make royalty payments based upon the net sales of three of our marketed products, Zestra®, Sensum+® and Vesele®.

Advertising Expense

Advertising costs, which primarily includes print and online media advertisements, are expensed as incurred and are included in sales and marketing expense in the accompanying consolidated statements of operations. Advertising costs were approximately \$2.7 million and \$3,000 for the years ended December 31, 2016 and 2015, respectively.

Research and Development Costs

Research and development (“R&D”) costs, including research performed under contract by third parties, are expensed as incurred. Major components of R&D expense consists of salaries and benefits, testing, post marketing clinical trials, material purchases and regulatory affairs.

Stock-Based Compensation

We account for stock-based compensation in accordance with FASB ASC 718, Stock Based Compensation. All stock-based payments to employees and directors, including grants of stock options, warrants, restricted stock units (“RSUs”) and restricted stock, are recognized in the consolidated financial statements based upon their estimated fair values. We use Black-Scholes to estimate the fair value of stock-based awards. The estimated fair value is determined at the date of grant. FASB ASC 718 requires that stock-based compensation expense be based on awards that are ultimately expected to vest. Stock-based compensation for the years ended December 31, 2016 and 2015 have been reduced for estimated forfeitures. When estimating forfeitures, voluntary termination behaviors, as well as trends of actual option forfeitures, are considered. To the extent actual forfeitures differ from our current estimates, cumulative adjustments to stock-based compensation expense are recorded.

Except for transactions with employees and directors that are within the scope of FASB ASC 718, all transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable.

Table of Contents

Equity Instruments Issued to Non-Employees for Services

Our accounting policy for equity instruments issued to consultants and vendors in exchange for goods and services follows FASB guidance. As such, the value of the applicable stock-based compensation is periodically remeasured and income or expense is recognized during the vesting terms of the equity instruments. The measurement date for the estimated fair value of the equity instruments issued is the earlier of (i) the date at which a commitment for performance by the consultant or vendor is reached or (ii) the date at which the consultant or vendor's performance is complete. In the case of equity instruments issued to consultants, the estimated fair value of the equity instrument is primarily recognized over the term of the consulting agreement. According to FASB guidance, an asset acquired in exchange for the issuance of fully vested, nonforfeitable equity instruments should not be presented or classified as an offset to equity on the grantor's balance sheet once the equity instrument is granted for accounting purposes. Accordingly, we record the estimated fair value of nonforfeitable equity instruments issued for future consulting services as prepaid expense and other current assets in our consolidated balance sheets.

Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding and vested but deferred RSUs during the period presented. Diluted net loss per share is computed using the weighted average number of common shares outstanding and vested but deferred RSUs during the periods plus the effect of dilutive securities outstanding during the periods. For the years ended December 31, 2016 and 2015, basic net loss per share is the same as diluted net loss per share as a result of our common stock equivalents being anti-dilutive. See Note 8 for more details.

Recent Accounting Pronouncements

In January 2017, the FASB issued ASU 2017-04, Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. The update simplifies how an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount. This update is effective for annual and interim periods beginning after December 15, 2019, and interim periods within that reporting period. While we are still in the process of completing our analysis on the impact this guidance will have on the consolidated financial statements and related disclosures, we do not expect the impact to be material.

In January 2017, the FASB issued ASU 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business. The update provides that when substantially all the fair value of the assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This update is effective for annual and interim periods beginning after December 15, 2017, and interim periods within that reporting period. While we are still in the process of completing our analysis on the impact this guidance will have on the consolidated financial statements and related disclosures, we do not expect the impact to be material.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230) – Classification of Certain Cash Receipts and Cash Payments. This ASU provides clarification regarding how certain cash receipts and cash payments are presented and classified in the statement of cash flows. This ASU addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. The issues addressed in this ASU that will affect us is classifying debt prepayments or debt extinguishment costs and contingent consideration payments made after a business combination. This update is effective for annual and interim periods beginning after December 15, 2017, and interim periods within that reporting period. Early adoption is permitted. While we are still in the process of completing our analysis on the impact this guidance will have on the consolidated financial statements and related

disclosures, we do not expect the impact to be material.

In March 2016, the FASB issued ASU No. 2016-09, Improvements to Employee Share-Based Payment Accounting, which amends ASC Topic 718, Compensation - Stock Compensation. The ASU includes provisions intended to simplify various aspects related to how share-based payments are accounted for and presented in the financial statements. ASU 2016-09 is effective for public business entities for annual reporting periods beginning after December 15, 2016, and interim periods within that reporting period. Early adoption will be permitted in any interim or annual period, with any adjustments reflected as of the beginning of the fiscal year of adoption. While we are still in the process of completing our analysis on the impact this guidance will have on the consolidated financial statements and related disclosures, we do not expect the impact to be material.

In February 2016, the FASB issued its new lease accounting guidance in Accounting Standards Update (“ASU”) No. 2016-02, Leases (Topic 842). Under the new guidance, lessees will be required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: A lease liability, which is a lessee’s obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee’s right to use, or control the use of, a specified asset for the lease term. Under the new guidance, lessor accounting is largely unchanged. Certain targeted improvements were made to align, where necessary, lessor accounting with the lessee accounting model and ASC 606, Revenue from Contracts with Customers. The new lease guidance simplified the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities. Lessees will no longer be provided with a source of off-balance sheet financing. Public business entities should apply the amendments in ASU 2016-02 for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. Lessees (for capital and operating leases) must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the consolidated financial statements. The modified retrospective approach would not require any transition accounting for leases that expired before the earliest comparative period presented. Lessees may not apply a full retrospective transition approach. While we are currently assessing the impact ASU 2016-02 will have on the consolidated financial statements, we expect the primary impact to the consolidated financial position upon adoption will be the recognition, on a discounted basis, of the minimum commitments on the consolidated balance sheet under our sole noncancelable operating lease for our facility in San Diego resulting in the recording of a right of use asset and lease obligation. The current minimum commitment under the noncancelable operating lease is disclosed in Note 11.

Table of Contents

In November 2015, the FASB issued Accounting Standards Update (ASU) No. 2015-17, Balance Sheet Classification of Deferred Taxes. Current U.S. GAAP requires an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. To simplify the presentation of deferred income taxes, the amendments in this update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The amendments in this update apply to all entities that present a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments in this update. The amendments in this update will align the presentation of deferred income tax assets and liabilities with International Financial Reporting Standards (IFRS) and are effective for fiscal years after December 15, 2016, including interim periods within those annual periods. While we are still in the process of completing our analysis on the impact this guidance will have on the consolidated financial statements and related disclosures, we do not expect the impact to be material.

In September 2015, the FASB issued ASU 2015-16, Simplifying the Accounting for Measurement-Period Adjustments, which eliminates the requirement to retrospectively adjust the consolidated financial statements for measurement-period adjustments that occur in periods after a business combination is consummated. Measurement period adjustments are calculated as if they were known at the acquisition date, but are recognized in the reporting period in which they are determined. Additional disclosures are required about the impact on current-period income statement line items of adjustments that would have been recognized in prior periods if prior-period information had been revised. The guidance is effective for annual periods beginning after December 15, 2015 and is to be applied prospectively to adjustments of provisional amounts that occur after the effective date. Early application is permitted. The adoption of this ASU during the year ended December 31, 2016 did not have a material impact on our consolidated financial position and results of operations.

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. Topic 330. Inventory, currently requires an entity to measure inventory at the lower of cost or market. Market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. The amendments apply to all other inventory, which includes inventory that is measured using first-in, first-out (FIFO) or average cost. An entity should measure in scope inventory at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The amendments in this Update more closely align the measurement of inventory in U.S. GAAP with the measurement of inventory in IFRS. For public business entities, the amendments are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The amendments should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. While we are still in the process of completing our analysis on the impact this guidance will have on the consolidated financial statements and related disclosures, we do not expect the impact to be material.

In August 2014, the FASB issued ASU 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. This ASU 2014-15 describes how an entity should assess its ability to meet obligations and sets rules for how this information should be disclosed in the consolidated financial statements. The standard provides accounting guidance that will be used along with existing auditing standards. The ASU 2014-15 is effective for the annual period ending after December 15, 2016. Early application is permitted. While we are still in the process of completing our analysis on the impact this guidance will have on the consolidated financial statements and related disclosures, we do not expect the impact to be material.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers. This updated guidance supersedes the current revenue recognition guidance, including industry-specific guidance. The updated guidance introduces a five-step model to achieve its core principal of the entity recognizing revenue to depict the transfer of

goods or services to customers at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In August 2015, the FASB issued ASU 2015-14 which deferred the effective date by one year for public entities and others. The amendments in this ASU are effective for interim and annual periods beginning after December 15, 2017 for public business entities, certain not-for-profit entities, and certain employee benefit plans. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. In March 2016, the FASB issued ASU 2016-08 which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU 2016-10 which clarifies the principle for determining whether a good or service is “separately identifiable” and, therefore, should be accounted for separately. In May 2016 the FASB issued ASU 2016-12 which clarifies the objective of the collectability criterion. A separate update issued in May 2016 clarifies the accounting for shipping and handling fees and costs as well as accounting for consideration given by a vendor to a customer. The guidance includes indicators to assist an entity in determining whether it controls a specified good or service before it is transferred to the customers. We have not yet determined whether we will adopt the provisions of ASU 2014-09 on a retrospective basis or through a cumulative adjustment to equity. While we are still in the process of completing our analysis on the impact this guidance will have on the consolidated financial statements and related disclosures, we do not expect the impact to be material.

F-14

Table of Contents

NOTE 2 – LICENSE AGREEMENTS

NTC S.r.l. In-License Agreement

On December 15, 2016, the Company and NTC S.r.l (“NTC”) entered into a license and distribution agreement (“NTC License Agreement”) pursuant to which we acquired the rights to use, market and sell NTC’s proprietary modified release bilayer tablet formerly known as LERTAL® for the management of allergic rhinitis in the U.S. and Canada. Such licensed product will be sold by us under the name AllerVarx™ in the U.S. and Canada. Under this agreement, we are obligated to pay a non-refundable upfront license fee of €15,000 (\$15,806 USD based on December 31, 2016 exchange rate) and cash payments of up to €120,000 (\$126,448 USD based on December 31, 2016 exchange rate) upon the achievement of certain sales milestones. The non-refundable upfront license is included in sales and marketing expense in the accompanying consolidated statement of operations for the year ended December 31, 2016 and accounts payable and accrued expense in the accompanying consolidated balance sheet at December 31, 2016.

Seipel Group Pty Ltd. In-License Agreement

On September 29, 2016, the Company and Seipel Group Pty Ltd. (“SG”) entered into a license and purchase agreement (“SG License Purchase Agreement”) pursuant to which we acquired the exclusive rights to use, market and sell SG’s proprietary dietary supplement formula known as Urox® for bladder support in the U.S. and worldwide. Under this agreement, we have agreed to minimum purchase order requirements of 25,000 units per calendar quarter beginning 12 months after our initial order to retain our exclusivity (see Note 11) and paid a brokerage fee of \$200,000 which is included in sales and marketing expense in the accompanying consolidated statement of operations for the year ended December 31, 2016.

CRI In-License Agreement

On April 19, 2013, the Company and Centric Research Institute (“CRI”) entered into an asset purchase agreement (the “CRI Asset Purchase Agreement”) pursuant to which we acquired:

All of CRI’s rights in past, present and future Sensum+® product formulations and presentations, and

An exclusive, perpetual license to commercialize Sensum+® products in all territories except for the United States.

On June 9, 2016, the Company and CRI amended the CRI Asset Purchase Agreement (“Amended CRI Asset Purchase Agreement”) to provide us commercialization rights for Sensum+® in the U.S. through our Beyond Human® marketing platform through December 31, 2016. On January 1, 2017, the Company and CRI agreed to extend the term of the Amended CRI Asset Purchase Agreement to December 31, 2017, subject to an automatic one-year extension to December 31, 2018 upon certain conditions (see Note 12).

In consideration for the CRI Asset Purchase Agreement, we issued 631,313 shares of common stock to CRI in 2013. We recorded an asset totaling \$250,000 related to the CRI Asset Purchase Agreement and are amortizing this amount over its estimated useful life of 10 years. Under the CRI Asset Purchase Agreement, we were required to issue to CRI shares of our common stock valued at an aggregate of \$200,000 for milestones relating to additional clinical data to be received. As a result of the Amended CRI Asset Purchase Agreement, the Company and CRI agreed to settle the clinical milestone payments with a payment of 100,000 shares of restricted common stock. The fair value of the restricted shares of common stock of \$23,000 was based on the market price of our common stock on the date of

issuance and is included in research and development expense in the accompanying consolidated statement of operations for the year ended December 31, 2016.

The CRI Asset Purchase Agreement also requires us to pay to CRI up to \$7 million in cash milestone payments based on first achievement of annual Ex-U.S. net sales targets plus a royalty based on annual Ex-U.S. net sales. The obligation for these payments expires on April 19, 2023 or the expiration of the last of CRI's patent claims covering the product or its use outside the U.S., whichever is sooner. No sales milestone obligations have been met and no royalties are owed to CRI under this agreement during the years ended December 31, 2016 and 2015.

Table of Contents

In consideration for the Amended CRI Asset Purchase Agreement, we are required to pay CRI a percentage of the monthly net profit, as defined in the agreement, from our sales of Sensum+® in the U.S. through our Beyond Human® marketing platform. During the year ended December 31, 2016, no amounts have been earned by CRI under the Amended CRI Asset Purchase Agreement.

J&H Co. LTD Agreement

On November 9, 2016, we entered into an exclusive ten-year license agreement with J&H Co. LTD, a South Korea company (“J&H”), under which we granted to J&H an exclusive license to market and sell our topical treatment for Female Sexual Interest/Arousal Disorder (“FSI/AD”) Zestra® and Zestra Glide® in South Korea. Under the agreement, J&H is obligated to order minimum annual quantities of Zestra® and Zestra Glide® totaling \$2,000,000 at a pre-negotiated transfer price per unit. The minimum annual order quantities by J&H are to be made over a 12-month period beginning upon the completion of the first shipment of product in 2017. During the year ended December 31, 2016, no revenue was recognized related to this agreement.

Sothema Laboratories Agreement

On September 23, 2014, we entered into an exclusive license agreement with Sothema Laboratories, SARL, a Moroccan publicly traded company (“Sothema”), under which we granted to Sothema an exclusive license to market and sell Zestra® (based on the latest Canadian approval of the indication) and Zestra Glide® in several Middle Eastern and African countries (collectively the “Territory”).

Under the agreement, we received an upfront payment of \$200,000 and are eligible to receive up to approximately \$171 million upon and subject to the achievement of sales milestones based on cumulative supplied units of the licensed products in the Territory, plus a pre-negotiated transfer price per unit. We believe the amount of the upfront payment received is reasonable compared to the amounts to be received upon obtainment of future sales-based milestones.

As the sales-based milestones do not meet the definition of a milestone under ASC 605-28, we will recognize the revenue from the milestone payments when the cumulative supplied units’ volume is met. During the years ended December 31, 2016 and 2015, we recognized \$16,056 and \$56,487, respectively, in net revenue for the sales of products related to this agreement, and no revenue was recognized for the sales-based milestones of the agreement.

Orimed Pharma Agreement

On September 18, 2014, we entered into a twenty year exclusive license agreement with Orimed Pharma (“Orimed”), an affiliate of JAMP Pharma, under which we granted to Orimed an exclusive license to market and sell in Canada Zestra®, Zestra Glide®, our topical treatment for premature ejaculation EjectDelay® and our product Sensum+® to increase penile sensitivity.

Under the agreement, we received an upfront payment of \$100,000 and are eligible to receive up to approximately CN \$94.5 million (\$70.2 million USD based on December 31, 2016 exchange rate) upon and subject to the achievement of sales milestones based on cumulative gross sales in Canada by Orimed plus double-digit tiered royalties based on Orimed’s cumulative net sales in Canada. We believe the amount of the upfront payment received is reasonable compared to the amounts to be received upon obtainment of future sales-based milestones.

As the sales-based milestones do not meet the definition of a milestone under ASC 605-28, we will recognize the revenue from the milestone payments when the cumulative gross sales volume is met. We will recognize the revenue

from the royalty payments on a quarterly basis when the cumulative net sales have been met. During the years ended December 31, 2016 and 2015, under this agreement we recognized \$42,153 and \$108,988, respectively, in net revenue for the sales of products and no revenue was recognized for the sales-based milestones. During the years ended December 31, 2016 and 2015, we recognized royalty payments of \$1,252 and \$0, respectively.

Elis Pharmaceuticals Agreements

On July 4, 2015, we announced that we had entered into an exclusive license and distribution agreement with Elis Pharmaceuticals, an emirates company (“Elis”), under which we granted to Elis an exclusive ten-year distribution right to market and sell Zestra® EjectDelay®, Sensum+® and Zestra Glide® in Turkey and select African and gulf countries. If Elis exceeds its minimum yearly orders, the agreement has a ten-year term extension. Under the agreement, we are eligible to receive up to \$35.5 million in sales milestone payments plus an agreed-upon transfer price upon sale of products. We had preliminary listed Syria, Yemen and Somalia as countries in the definition of licensed territories, but these countries were removed by the agreement of both parties from the agreement effective the date of signing of the agreement. As the sales-based milestones are not considered a milestone under ASC 605-28, we will recognize the revenue from the milestone payments when the cumulative gross sales volume is met. We did not recognize any revenue from this agreement during the years ended December 31, 2016 and 2015.

On October 31, 2016, we entered into another exclusive license and distribution agreement with Elis under which we granted to Elis an exclusive ten-year distribution right to market and sell Zestra® in Lebanon. Under the agreement, we are eligible to receive up to \$2.35 million in sales milestone payments plus an agreed-upon transfer price upon sale of products. As the sales-based milestones are not considered a milestone under ASC 605-28, we will recognize the revenue from the milestone payments when the cumulative gross sales volume is met. During the year ended December 31, 2016, no revenue was recognized related to this agreement.

Table of Contents

Khandelwal Laboratories Agreement

On September 9, 2015, we entered into an exclusive license and distribution agreement with Khandelwal Laboratories, an Indian company (“KLabs”) under which we have granted to KLabs an exclusive ten-year distribution right to market and sell in the Indian Subcontinent, which is defined as India, Nepal, Bhutan, Bangladesh and Sri Lanka our products including Zestra®, EjectDelay®, Sensum+® and Zestra Glide®. If KLabs exceeds its minimum yearly orders, the agreement has two five-year term extensions. Under the agreement the minimum orders for the first ten-year term of the agreement are approximately \$2.6 million. We did not recognize any revenue from this agreement during the years ended December 31, 2016 and 2015.

NOTE 3 – BUSINESS AND ASSET ACQUISITIONS

Acquisition of Assets of Beyond Human® in 2016

On February 8, 2016, we entered into an Asset Purchase Agreement (“APA”), pursuant to which we agreed to purchase substantially all of the assets of Beyond Human® (the “Acquisition”) for a total cash payment of up to \$662,500 (the “Purchase Price”). The Purchase Price was payable in the following manner: (1) \$300,000 in cash at the closing of the Acquisition (the “Initial Payment”), (2) \$100,000 in cash four months from the closing upon the occurrence of certain milestones as described in the APA, (3) \$100,000 in cash eight months from the closing upon the occurrence of certain milestones as described in the APA, and (4) \$130,000 in cash in twelve months from the closing upon the occurrence of certain milestones as described in the APA. An additional \$32,500 in cash is due if certain milestones occur twelve months from closing. The transaction closed on March 1, 2016.

The fair value of the contingent consideration is based on cash flow projections and other assumptions for the milestone payments and future changes in the estimate of such contingent consideration will be recognized as a charge to fair value adjustment for contingent consideration.

The total purchase price is summarized as follows:

Cash consideration	\$300,000
Fair value of future earn out payments	330,000
Total	\$630,000

We accounted for such asset acquisition as a business combination under ASC 805, Business Combinations. We did not acquire any identifiable tangible assets and did not assume any liabilities as a result of the asset acquisition. The excess of the acquisition date fair value of consideration transferred of \$630,000 over the estimated fair value of the intangible assets acquired was recorded as goodwill. The establishment of the fair value of the contingent consideration, and the allocation to identifiable intangible assets requires the extensive use of accounting estimates and management judgment. The fair values assigned to the assets acquired are based on estimates and assumptions from data currently available.

In determining the fair value of the intangible assets, we considered, among other factors, the best use of acquired assets such as the Beyond Human® website, analyses of historical financial performance of the Beyond Human® products and estimates of future performance of the Beyond Human® products and website acquired. The fair values of the identified intangible assets related to Beyond Human®’s website, trade name, non-competition covenant and customer list. The fair value of the website, customer list and the non-competition covenant were calculated using an income approach. The fair value of the trade name was calculated using a cost approach. The following table sets forth the components of identified intangible assets associated with the Acquisition and their estimated useful lives:

	Fair Value	Useful Life
Website	\$171,788	5 years
Trade name	50,274	10 years
Non-competition covenant	3,230	3 years
Customer list	1,500	1 year
Total	\$226,792	

We determined the useful lives of intangible assets based on the expected future cash flows and contractual lives associated with the respective asset. Website represents the fair value of the expected benefit from revenue to be generated from the Beyond Human® website and domain name for both Beyond Human® products as well as our existing products. Trade name represents the fair value of the brand and name recognition associated with the marketing of Beyond Human®'s products. Customer list represents the expected benefit from customer contracts that, at the date of acquisition, were reasonably anticipated to continue given the history and operating practices of Beyond Human®. The non-competition covenant represents the contractual period and expected degree of adverse economic impact that would exist in its absence.

Table of Contents

Of the total estimated purchase price, \$403,208 was allocated to goodwill and is attributable to expected synergies the acquired assets will bring to our existing business, including access for us to market and sell our existing products through Beyond Human®'s sales and marketing platform. Goodwill represents the excess of the purchase price of the acquired business over the estimated fair value of the underlying intangible assets acquired. Goodwill resulting from the Acquisition will be tested for impairment at least annually and more frequently if certain indicators of impairment are present. In the event we determine that the value of goodwill has become impaired, we will incur an accounting charge for the amount of the impairment during the fiscal quarter in which the determination is made. All of the goodwill is expected to be deductible for income tax purposes. As a result of completing our final valuation, the total purchase price increased by \$15,521 and goodwill increased by \$403,208 compared to the initial allocation of the purchase price during the first quarter of 2016.

On September 6, 2016, the Company and the sellers entered into an agreement in which we agreed to pay the sellers \$150,000 to settle the contingent consideration payments totaling up to \$362,500 under the APA. The settlement agreement was not contemplated at the time of the acquisition and the fair value of the contingent consideration on the date of settlement was \$330,000. As a result, we recorded a non-cash gain on contingent consideration of \$180,000, which is included in change in fair value of contingent consideration in the accompanying consolidated statement of operations for the year ended December 31, 2016.

Supplemental Pro Forma Information for Acquisition of Assets of Beyond Human® (unaudited)

The following unaudited supplemental pro forma information for the years ended December 31, 2016 and 2015, assumes the asset acquisition of Beyond Human® had occurred as of January 1, 2016 and 2015, giving effect to purchase accounting adjustments such as amortization of intangible assets. The pro forma data is for informational purposes only and may not necessarily reflect the actual results of operations had the assets of Beyond Human® been operated as part of the Company since January 1, 2016 and 2015.

	Year Ended December 31, 2016		Year Ended December 31, 2015	
	As Reported	Pro Forma (unaudited)	As Reported	Pro Forma (unaudited)
Net revenue	\$4,818,603	\$4,868,241	\$735,717	\$2,947,694
Net loss	\$(13,701,154)	\$(13,700,702)	\$(4,202,628)	\$(3,901,770)
Net loss per share of common stock – basic and diluted	\$(0.15)	\$(0.15)	\$(0.08)	\$(0.07)
Weighted average number of shares outstanding – basic and diluted	94,106,382	94,106,382	52,517,530	52,517,530

We incurred approximately \$70,000 in expense related to the Acquisition.

Acquisition of Novalere

On February 5, 2015 (the “Closing Date”), Innovus, Innovus Pharma Acquisition Corporation, a Delaware corporation and a wholly-owned subsidiary of Innovus (“Merger Subsidiary I”), Innovus Pharma Acquisition Corporation II, a Delaware corporation and a wholly-owned subsidiary of Innovus (“Merger Subsidiary II”), Novalere FP, Inc., a

Delaware corporation (“Novalere FP”) and Novalere Holdings, LLC, a Delaware limited liability company (“Novalere Holdings”), as representative of the shareholders of Novalere (the “Novalere Stockholders”), entered into an Agreement and Plan of Merger (the “Merger Agreement”), pursuant to which Merger Subsidiary I merged into Novalere and then Novalere merged with and into Merger Subsidiary II (the “Merger”), with Merger Subsidiary II surviving as a wholly-owned subsidiary of Innovus. Pursuant to the articles of merger effectuating the Merger, Merger Subsidiary II changed its name to Novalere, Inc.

With the Merger, we acquired the worldwide rights to market and sell the Fluticare™ brand (Fluticasone propionate nasal spray) and the related manufacturing agreement from Novalere FP. We currently anticipate that the Abbreviated New Drug Application (“ANDA”) filed in November 2014 by the manufacturer with the U.S. Food and Drug Administration (“FDA”) may be approved in 2017, which, when and if approved, may allow us to market and sell Fluticare™ over the counter in the second half of 2017. An ANDA is an application for a U.S. generic drug approval for an existing licensed medication or approved drug.

Under the terms of the Merger Agreement, at the Closing Date, the Novalere Stockholders received 50% of the Consideration Shares (the “Closing Consideration Shares”) and the remaining 50% of the Consideration Shares (the “ANDA Consideration Shares”) were to be delivered only if an ANDA of Fluticasone Propionate Nasal Spray of Novalere Manufacturing Partners (the “Target Product”) was approved by the FDA (the “ANDA Approval”). A portion of the Closing Consideration Shares and, if ANDA Approval was obtained prior to the 18 month anniversary of the Closing Date, a portion of the ANDA Consideration Shares, would have been held in escrow for a period of 18 months from the Closing Date to be applied towards any indemnification claims by us pursuant to the Merger Agreement.

Table of Contents

In addition, the Novalere Stockholders are entitled to receive, if and when earned, earn-out payments (the “Earn-Out Payments”). For every \$5 million in Net Revenue (as defined in the Merger Agreement) realized from the sales of Fluticare™, the Novalere Stockholders will be entitled to receive, on a pro rata basis, \$500,000, subject to cumulative maximum Earn-Out Payments of \$2.5 million.

The closing price of our common stock on the Closing Date was \$0.20 per share. We issued 12,947,657 Closing Consideration Shares of our common stock at the Closing Date, the fair market value, (“FMV”) of the Closing Consideration Shares was \$2,071,625 as of the Closing Date.

The fair value of the contingent consideration is based on preliminary cash flow projections and other assumptions for the ANDA Consideration shares and the Earn-Out Payments and future changes in the estimate of such contingent consideration will be recognized as a charge to other expense.

Issuance of the 12,947,655 ANDA Consideration Shares was subject to milestones, achievement of which was uncertain at the time of acquisition. The FMV of the ANDA Consideration Shares was established to account for the uncertainty in the future value of the shares. The value of the shares as derived using the options pricing model was then weighted based on the probability of achieving the milestones to determine the FMV of the ANDA Consideration Shares and estimated potential share prices at such dates. Due to certain restrictions on the shares of common stock to be issued, we applied a 20% discount for lack of marketability to the FMV of the ANDA Consideration Shares. Based on the aforementioned calculation the fair market value of the ANDA Consideration shares was determined to be \$1,657,300.

The total fair market value of the considerations issued and to be issued for the transaction are as follows:

	Shares	FMV
Closing Consideration Shares	12,947,657	\$2,071,625
ANDA Consideration Shares	12,947,655	1,657,300
Total	25,895,312	\$3,728,925

Based on the assumptions, the fair market value of the Earn-Out Payments was determined to be \$1,205,000. The preliminary fair values of the future earn out payments was determined by applying the income approach, using several significant unobservable inputs for projected cash flows and a discount rate. These inputs are considered Level 3 inputs under the fair value measurements and disclosure guidance.

The total purchase price is summarized as follows:

Cash consideration	\$43,124
Fair value of common stock issued at closing	2,071,625
Fair value of ANDA consideration shares	1,657,300
Fair value of future earn out payments	1,205,000
Total	\$4,977,049

The fair values of acquired assets and liabilities are based on cash flow projections and other assumptions. The fair values of acquired intangible assets were determined using several significant unobservable inputs for projected cash flows and a discount rate. These inputs are considered Level 3 inputs under the fair value measurements and disclosure guidance. The transaction has been accounted for as a business combination under the acquisition method

of accounting. Accordingly, the tangible assets and identifiable intangible assets acquired and liabilities assumed have been recorded at fair value, with the remaining purchase price recorded as goodwill.

The fair values of assets acquired and liabilities assumed at the transaction date are summarized below:

Cash	\$43,124
Prepaid expense	25,907
Total tangible assets	69,031
Product rights and related manufacturing agreement	4,681,000
Trademarks	150,000
Total identifiable intangible assets	4,831,000
Goodwill	120,143
Total acquired assets	5,020,174
Other current liabilities	(43,125)
Total assumed liabilities	(43,125)
Acquired assets net of assumed liabilities	\$4,977,049

Table of Contents

We recorded \$759,428 of goodwill related to the acquisition of Novalere as an income tax benefit and also recorded an impairment of \$759,428 against this benefit during the year ended December 31, 2015.

The carrying value of current assets and liabilities in Novalere's financial statements are considered to be a proxy for the fair value of those assets and liabilities. Novalere is a pre-commercial organization specializing in selling and marketing nasal steroid products; most of the value in Novalere is applicable to the product rights and related manufacturing agreement. Novalere holds a non-exclusive, worldwide, royalty-free license to market, promote, sell, offer for sale, import and distribute the product. This business relationship is contractual in nature and meets the separability criterion and as a result is considered an identifiable intangible asset recognized separately from goodwill. The value of the business relationship is included in goodwill under U.S. GAAP. Goodwill is calculated as the difference between the fair value of the consideration transferred and the values assigned to the identifiable tangible assets acquired and liabilities assumed. The acquired goodwill presented in the above table reflects the estimated goodwill from the preliminary purchase price allocation. The cash acquired was used to pay amounts due to shareholders and thus was received by us.

The establishment of the fair value of the consideration for a Merger, and the allocation to identifiable tangible and intangible assets and liabilities, requires the extensive use of accounting estimates and management judgment. The fair values assigned to the assets acquired and liabilities assumed were based on estimates and assumptions. During the year ended December 31, 2016, there was an increase in the estimated fair value of the ANDA consideration shares of \$1,346,556 due to the amended agreement entered into with Novalere Holdings (see below) which is included in change in fair value of contingent consideration in the accompanying consolidated statement of operations. There was no change to the estimated fair value of the future earn-out payments of \$1,248,125 during the year ended December 31, 2016 and there was no change to the estimate fair value of the contingent consideration during the year ended December 31, 2015.

On November 12, 2016, we entered into an Amendment and Supplement to a Registration Rights and Stock Restriction Agreement (the "Agreement") with Novalere Holdings pursuant to which we agreed to issue 12,808,796 shares of our common stock (the "Novalere Shares") that were issuable pursuant to agreement upon the approval of Fluticare™ by the FDA. Management agreed to issue the Novalere Shares due to its confidence that FlutiCare™ would be approved by the FDA in the near future and the obligation of us to issue and register for resale the Novalere Shares and all other shares of our common stock held by Novalere Holdings. In connection with the issuance of the Novalere Shares, Novalere Holdings also agreed to certain restrictions, and to an extension in the date to register the Novalere Shares and all other shares of our common stock held by Novalere Holdings until the second quarter of 2017. In the event a registration statement to register the Novalere Shares is not filed by February 1, 2017, and does not become effective by May 15, 2017, the Company will be required to issue additional shares of common stock as a penalty to Novalere Holdings equal to 10% of the total shares to be registered of 25,617,592. We filed a Registration Statement on Form S-1 on February 1, 2017 to register the 25,617,592 shares of common stock issued to Novalere Holdings. Management believed that the issuance of the Novalere Shares at that time was in our and our stockholders best interest as it results in a restriction on the resale of all shares of our common stock held by Novalere Holdings, including the Novalere Shares, until after we have achieved certain milestones. As a result of the issuance of the Novalere Shares, the fair value of Novalere Shares on the date of issuance of \$2,971,641 was reclassified from liabilities to equity. The remaining 138,859 ANDA consideration shares not issuable yet will be issued upon FDA approval of Fluticare™ and the estimated fair value of such remaining shares of \$32,215 is included in contingent consideration in the accompanying consolidated balance sheet at December 31, 2016.

Supplemental Pro Forma Information for Acquisition of Novalere (unaudited)

Edgar Filing: INNOVUS PHARMACEUTICALS, INC. - Form 10-K

The following unaudited supplemental pro forma information for the year ended December 31, 2015, assumes the acquisition of Novalere had occurred as of January 1, 2015, giving effect to purchase accounting adjustments such as amortization of intangible assets. The pro forma data is for informational purposes only and may not necessarily reflect the actual results of operations had Novalere been operated as part of the Company since January 1, 2015.

	Year Ended December 31, 2015	
	As Reported	Pro Forma (unaudited)
Net revenue	\$735,717	\$735,717
Net loss	\$(4,202,628)	\$(4,578,521)
Net loss per share of common stock – basic and diluted	\$(0.08)	\$(0.09)
Weighted average number of shares outstanding – basic and diluted	52,517,530	53,794,559

F-20

Table of Contents

Purchase of Semprae Laboratories, Inc. in 2013

On December 24, 2013 (the “Semprae Closing Date”), we, through Merger Sub, obtained 100% of the outstanding shares of Semprae in exchange for the issuance of 3,201,776 shares of our common stock, which shares represented fifteen percent (15%) of our total issued and outstanding shares as of the close of business on the Closing Date, whereupon Merger Sub was renamed Semprae Laboratories, Inc. Also, we agreed to pay \$343,500 to the New Jersey Economic Development Authority (“NJEDA”) as settlement-in full for an outstanding loan of approximately \$640,000 owed by the former stockholder’s of Semprae, in full satisfaction of the obligation to the NJEDA. In addition, we agreed to pay the former shareholders an annual royalty (“Royalty”) equal to 5% of the net sales from Zestra® and Zestra Glide® and any second generation products derived primarily therefrom (“Target Products”) up until the time that a generic version of such Target Product is introduced worldwide by a third party.

The fair market value of our common stock issued on the Closing Date was \$0.30 per share, which resulted in a fair market value of \$960,530 for the common stock issued to the shareholders of Semprae. The fair value of the shares of common stock issued were determined by quoted market prices that are considered to be Level 1 inputs under the fair value measurements and disclosure guidance. A portion of the shares issued were held in escrow pending reconciliation of assets received and liabilities assumed at the acquisition date and were released on September 10, 2015. 386,075 shares of common stock were canceled based on the terms of the agreement, reducing the total number of shares issued to 2,815,701. We recorded income on the cancellation of shares of \$115,822, which is included in the change in fair value of contingent consideration in the accompanying consolidated statement of operations for the year ended December 31, 2015.

The agreement to pay the annual Royalty resulted in the recognition of a contingent consideration, which is recognized at the inception of the transaction, and subsequent changes to estimate of the amounts of contingent consideration to be paid will be recognized as charges or credits in the consolidated statement of operations. The fair value of the contingent consideration is based on preliminary cash flow projections, growth in expected product sales and other assumptions. Based on the assumptions, the fair value of the Royalty was determined to be \$308,273 at the date of acquisition. The fair value of the Royalty was determined by applying the income approach, using several significant unobservable inputs for projected cash flows and a discount rate of approximately 22% commensurate with our cost of capital and expectation of the revenue growth for products at their life cycle stage. These inputs are considered Level 3 inputs under the fair value measurements and disclosure guidance. During 2016 and 2015, \$22,103 and \$0, respectively, was paid under this arrangement. The fair value of the expected royalties to be paid was increased by \$103,301 and \$0 during the years ended December 31, 2016 and 2015, respectively, which is included in the change in fair value of contingent consideration in the accompanying consolidated statements of operations. The fair value of the contingent consideration was \$405,577 and \$324,379 at December 31, 2016 and 2015, based on the new estimated fair value of the consideration, net of the amounts to be returned to us as discussed above.

NOTE 4 – ASSETS AND LIABILITIES

Inventories

Inventories consist of the following:

December 31,

2016 2015

Raw materials and supplies	\$85,816	\$77,649
Work in process	48,530	90,540
Finished goods	465,510	86,254
Total	\$599,856	\$254,443

Property and Equipment

Property and equipment consists of the following:

December 31,

	2016	2015
Computer equipment	\$5,254	\$5,254
Office furniture and fixtures	33,376	33,376
Production equipment	276,479	276,479
Software	338,976	338,976
Total cost	654,085	654,085
Less accumulated depreciation	(624,516)	(618,984)
Property and equipment, net	\$29,569	\$35,101

Table of Contents

Depreciation expense for the years ended December 31, 2016 and 2015 was \$5,532 and \$28,950, respectively.

Intangible Assets

Amortizable intangible assets consist of the following:

At December 31, 2016

	Amount	Accumulated Amortization	Net Amount	Useful Lives (years)
Patent & Trademarks	\$417,597	\$(91,201)	\$326,396	7 – 15
Customer Contracts	611,119	(188,428)	422,691	10
Sensum+® License (from CRI)	234,545	(84,009)	150,536	10
Vesele® Trademark	25,287	(7,047)	18,240	8
Beyond Human® Website and Trade Name	222,062	(32,821)	189,241	5 – 10
Novalere Mfg. Contract	4,681,000	(887,440)	3,793,560	10
Other Beyond Human® Intangible Assets	4,730	(2,147)	2,583	1 – 3
Total	\$6,196,340	\$(1,293,093)	\$4,903,247	

At December 31, 2015

	Amount	Accumulated Amortization	Net Amount	Useful Lives (years)
Patent & Trademarks	\$417,597	\$(57,593)	\$360,004	7 – 15
Customer Contracts	611,119	(127,316)	483,803	10
Sensum+® License (from CRI)	234,545	(60,554)	173,991	10
Vesele® Trademark	25,287	(3,886)	21,401	8
Novalere Mfg. Contract	4,681,000	(419,340)	4,261,660	10
Total	\$5,969,548	\$(668,689)	\$5,300,859	

Amortization expense for the years ended December 31, 2016 and 2015 was \$624,404 and \$550,789, respectively. The following table summarizes the approximate expected future amortization expense as of December 31, 2016 for intangible assets:

2017	\$630,000
2018	630,000
2019	629,000
2020	629,000
2021	600,000

Thereafter 1,785,000
 Total \$4,903,000

Prepaid Expense and Other Current Assets

Prepaid expense and other current assets consist of the following:

	December 31,	
	2016	2015
Prepaid insurance	\$69,976	\$27,816
Prepaid inventory	20,750	-
Merchant net settlement reserve receivable (see Note 1)	221,243	-
Prepaid consulting and other expense	21,094	25,462
Prepaid consulting and other service stock-based compensation expense (see Note 8)	530,601	-
Total	\$863,664	\$53,278

Table of Contents

Accounts Payable and Accrued Expense

Accounts payable and accrued expense consists of the following:

	December 31,	
	2016	2015
Accounts payable	\$647,083	\$63,826
Accrued credit card balances	31,654	91,037
Accrued royalties	73,675	-
Sales returns and allowances	60,853	-
Accrual for stock to be issued to consultants (see Note 8)	360,000	-
Accrued other	36,785	640
Total	\$1,210,050	\$155,503

Goodwill

The changes in the carrying value of our goodwill for the years ended December 31, 2016 and 2015 is as follows:

Beginning balance December 31, 2014	\$429,225
Acquisition of Novalere (see Note 3)	120,143
Release of valuation allowance in connection with acquisition of Novalere (see Note 10)	759,428
Impairment of valuation allowance in connection with acquisition of Novalere (see Note 10)	(759,428)
Ending balance December 31, 2015	549,368
Asset acquisition of Beyond Human® (see Note 3)	403,208
Ending balance December 31, 2016	\$952,576

NOTE 5 – NOTES PAYABLE AND DEBENTURES – NON-RELATED PARTIES

Short-Term Loans Payable

The short-term non-convertible financings were from three funding sources and all balances were guaranteed by our CEO. We repaid these amounts in full in July 2016.

Notes Payable and Non-Convertible Debenture

The following table summarizes the outstanding notes payable and non-convertible debenture at December 31, 2016 and 2015:

	2016	2015
--	------	------

Notes payable and non-convertible debenture:

Edgar Filing: INNOVUS PHARMACEUTICALS, INC. - Form 10-K

February 2016 Note Payable	\$347,998	\$-
December 2016 Notes Payable	550,000	-
July 2015 Debenture (Amended August 2014 Debenture)	-	73,200
Total notes payable and non-convertible debenture	897,998	73,200
Less: Debt discount	(216,871)	-
Carrying value	681,127	73,200
Less: Current portion	(626,610)	(73,200)
Notes payable and non-convertible debenture, net of current portion	\$54,517	\$-

F-23

Table of Contents

The following table summarizes the future minimum payments as of December 31, 2016 for the notes payable and non-convertible debenture:

2017	\$843,013
2018	54,985
Total	\$897,998

July 2015 Debenture (Amended August 2014 Debenture)

On August 30, 2014, we issued an 8% debenture to an unrelated third party investor in the principal amount of \$40,000 (the “August 2014 Debenture”). The August 2014 Debenture bore interest at the rate of 8% per annum. The principal amount and interest were payable on August 29, 2015. On July 21, 2015, we received an additional \$30,000 from the investor and amended and restated this agreement to a new principal balance of \$73,200 (including accrued interest of \$3,200 added to principal) and a new maturity date of July 21, 2016. The note was repaid in full in July 2016.

February 2016 Note Payable

On February 24, 2016, the Company and SBI Investments, LLC, 2014-1 (“SBI”) entered into an agreement in which SBI loaned us gross proceeds of \$550,000 pursuant to a purchase agreement, 20% secured promissory note and security agreement (“February 2016 Note Payable”), all dated February 19, 2016 (collectively, the “Finance Agreements”), to purchase substantially all of the assets of Beyond Human® (see Note 3). Of the \$550,000 gross proceeds, \$300,000 was paid into an escrow account held by a third party bank and was released to Beyond Human® upon closing of the transaction, \$242,500 was provided directly to us for use in building the Beyond Human® business and \$7,500 was provided for attorneys’ fees. The attorneys’ fees were recorded as a discount to the carrying value of the February 2016 Note Payable in accordance with ASU 2015-03.

Pursuant to the Finance Agreements, the principal amount of the February 2016 Note Payable is \$550,000 and the interest rate thereon is 20% per annum. We began to pay principal and interest on the February 2016 Note Payable on a monthly basis beginning on March 19, 2016 for a period of 24 months and the monthly mandatory principal and interest payment amount thereunder is \$28,209. The monthly amount shall be paid by us through a deposit account control agreement with a third-party bank in which SBI shall be permitted to take the monthly mandatory payment amount from all revenue received by us from the Beyond Human® assets in the transaction. The maturity date for the February 2016 Note Payable is February 19, 2018.

The February 2016 Note Payable is secured by SBI through a first priority secured interest in all of the Beyond Human® assets acquired by us in the transaction including all revenue received by us from these assets.

May 2016 Debenture

On May 4, 2016, we issued a 10% non-convertible debenture to an unrelated third party investor in the principal amount of \$24,000 (the “May 2016 Debenture”). The May 2016 Debenture bore interest at the rate of 10% per annum. The principal amount and interest were payable on May 4, 2017. The note was repaid in full in July 2016.

May 2016 Notes Payable

On May 6, 2016, we entered into a securities purchase agreement with an unrelated third party investor in which the investor loaned us gross proceeds of \$50,000 pursuant to a 3% promissory note (“May 6, 2016 Note Payable”). The

May 6, 2016 Note Payable bore interest at the rate of 3% per annum. The principal amount and interest were payable on November 6, 2016. The note was repaid in full in June 2016.

In connection with the May 6, 2016 Note Payable, we issued the investor restricted shares of common stock totaling 500,000. The fair value of the restricted shares of common stock issued was based on the market price of our common stock on the date of issuance of the May 6, 2016 Note Payable. The allocation of the proceeds received to the restricted shares of common stock based on their relative fair value resulted in us recording a debt discount of \$23,684. The discount was amortized in full to interest expense during the year ended December 31, 2016.

On May 20, 2016, we entered into a securities purchase agreement with an unrelated third party investor in which the investor loaned us gross proceeds of \$100,000 pursuant to a 3% promissory note ("May 20, 2016 Note Payable"). The May 20, 2016 Note Payable bore interest at the rate of 3% per annum. The principal amount and interest were payable on February 21, 2017. The note was repaid in full in June 2016.

In connection with the May 20, 2016 Note Payable, we issued the investor restricted shares of common stock totaling 750,000. The fair value of the restricted shares of common stock issued was based on the market price of our common stock on the date of issuance of the May 20, 2016 Note Payable. The allocation of the proceeds received to the restricted shares of common stock based on their relative fair value resulted in us recording a debt discount of \$70,280. The discount was amortized in full to interest expense during the year ended December 31, 2016.

Table of Contents

December 2016 Notes Payable

On December 5, 2016, we entered into a securities purchase agreement with three unrelated third party investors in which the investors loaned us gross proceeds of \$500,000 pursuant to a 5% promissory note (“December 5, 2016 Notes Payable”). The notes have an Original Issue Discount (“OID”) of \$50,000 and requires payment of \$550,000 in principal upon maturity. The December 5, 2016 Notes Payable bear interest at the rate of 5% per annum and the principal amount and interest are payable at maturity on October 4, 2017.

In connection with the December 5, 2016 Notes Payable, we issued the investors restricted shares of common stock totaling 1,111,111. The fair value of the restricted shares of common stock issued was based on the market price of our common stock on the date of issuance of the December 5, 2016 Notes Payable. The allocation of the proceeds received to the restricted shares of common stock based on their relative fair value resulted in us recording a debt discount of \$182,203. The discount is being amortized to interest expense using the effective interest method over the term of the December 5, 2016 Notes Payable.

September 2014 Convertible Debenture

On September 29, 2014, we issued a convertible promissory note (the “Note”) to an unrelated third party accredited investor for \$50,000. The Note had a principal face amount of \$92,000, did not accrue interest and was due on March 28, 2016 (the “Maturity Date”). The Note was converted into 230,000 shares common stock according to the terms of the note, by the investor on March 30, 2015. As such, we recorded the conversion of the note and the remaining debt discount was charged to interest expense during the year ended December 31, 2015.

January 2015 Non-Convertible Debenture

On January 21, 2015, we entered into securities purchase agreements with Vista Capital Investments, LLC (“Vista”) whereby we issued and sold to the Vista promissory notes (“January 2015 Non-Convertible Debenture”) and warrants (the “Vista Warrants”) to purchase up to 500,000 shares of the our common stock for gross proceeds of \$100,000. The note has an OID of \$10,000 and requires payment of \$110,000 in principal upon maturity. On July 30, 2015, the Company and Vista entered into an amendment to the \$110,000 Promissory Note dated January 21, 2015 (“Vista Note Amendment”). In consideration for the Vista Note Amendment, we issued 100,000 restricted shares of common stock to Vista. The fair value of such shares totaling \$15,500 was recognized as interest expense during the year ended December 31, 2015. The principal note balance totaling \$110,000 was paid off on November 2, 2015.

The Vista Warrants were exercisable for five years from the closing date at an exercise price of \$0.30 (see Note 8) per share of common stock. The warrants contained anti-dilution protection, including protection upon dilutive issuances.

The Vista Warrants were measured at fair value and classified as a liability because these warrants contained anti-dilution protection and therefore could not be considered indexed to the our own stock which was a requirement for the scope exception as outlined under FASB ASC 815. The estimated fair value of the Vista Warrants was determined using the Probability Weighted Black-Scholes Model, resulting in a fair value of \$99,999 on the date they were issued. The allocation of the proceeds of the debt was initially recorded using the residual method, at \$1, net of a debt discount of \$109,999 for the fair value of the Vista Warrants and the OID. The discount was being accreted as non-cash interest expense over the expected term of the January 2015 Non-Convertible Debenture using the effective interest method. During the year ended December 31, 2015, the full amount of debt discount has been accreted to interest expense. The fair value of the Vista Warrants was affected by changes in inputs to that model including our stock price, expected stock price volatility, the contractual term and the risk-free interest rate. We continued to classify the fair value of the Vista Warrants as a liability until the warrants were exercised in full during the year ended

December 31, 2016 (see Notes 8 and 9).

February 2014 Convertible Debenture

On February 13, 2014, we entered into a securities purchase agreement with an unrelated third party accredited investor pursuant to which we issued a convertible debenture in the aggregate principal amount of \$330,000 (issued at an OID of 10%) (“February 2014 Convertible Debenture”) and a warrant to purchase 250,000 shares of our common stock (“Warrant Agreement”).

The February 2014 Convertible Debenture bore interest at the rate of 10% per annum and the principal amount and interest were payable on March 13, 2015. The Warrant Agreement provided the holder with the right to acquire up to 250,000 shares of common stock at an exercise price of \$0.50 per share, subject to standard certain adjustments as described in the Warrant Agreement, at any time through the fifth anniversary of its issuance date.

On March 12, 2015, we issued 250,000 shares of our common stock and 250,000 warrants to the holder of the February 2014 Convertible Debenture to extend the maturity date to September 13, 2015 which resulted in a debt extinguishment. The fair value of the 250,000 shares of common stock issued totaled \$32,500 computed based on the stock price on the date of issuance. The terms of the warrants issued to the holder were amended to reduce the exercise price of the total warrants outstanding to \$0.30 per share (see Note 8) and included certain anti-dilution protection, including protection upon dilutive issuances. The warrants were measured at fair value and classified as a liability because these warrants contained anti-dilution protection and therefore could not be considered indexed to our own stock which was a requirement for the scope exception as outlined under FASB ASC 815. The estimated fair value of the warrants was determined using the Probability Weighted Black-Scholes Model, resulting in a fair value of \$76,299 on the date they were issued. The allocation of the proceeds of the debt after modification which resulted in a debt extinguishment was initially recorded using the residual method, at \$253,701, net of a debt discount of \$76,299 for the fair value of the warrants. The discount was being accreted as non-cash interest expense over the expected term of the February 2014 Convertible Debenture using the effective interest method. During the year ended December 31, 2015, the full amount of debt discount has been accreted to interest expense. The fair value of the common stock issued of \$32,500 was recorded as a loss on debt extinguishment, based on the estimated fair value of the stock on date of issuance, in the accompanying consolidated statement of operations during the year ended December 31, 2015. This convertible debenture was repaid in September 2015 and we continued to classify the fair value of the warrants as a liability until the warrants were exercised in full during the year ended December 31, 2016 (see Notes 8 and 9).

Table of Contents

Interest Expense

We recognized interest expense on the short-term loans payable and non-related party notes payable and non-convertible debentures of \$151,924 and \$102,105 for the years ended December 31, 2016 and 2015, respectively. Amortization of the debt discount to interest expense during the years ended December 31, 2016 and 2015 totaled \$116,798 and \$310,006, respectively.

Convertible Debentures

Third Quarter 2015 Financing

The following table summarizes the outstanding Third Quarter 2015 Convertible Debentures at December 31, 2016 and 2015:

	2016	2015
Convertible debentures	\$-	\$1,457,500
Less: Debt discount	-	(1,050,041)
Carrying value	-	407,459
Less: Current portion	-	(407,459)
Convertible debentures – long-term	\$-	\$-

In the third quarter of 2015, we entered into Securities Purchase Agreements with three accredited investors (the “Buyers”), pursuant to which we received aggregate gross proceeds of \$1,325,000 (net of OID) pursuant to which we sold:

Six convertible promissory notes of the Company totaling \$1,457,500 (each a “Q3 2015 Note” and collectively the “Q3 2015 Notes”) (the Q3 2015 Notes were sold at a 10% OID and we received an aggregate total of \$1,242,500 in funds thereunder after debt issuance costs of \$82,500). The principal amount due under the Q3 2015 Notes was \$1,457,500. The Q3 2015 Notes and accrued interest were convertible into shares of our common stock (the “Common Stock”) beginning six months from the date of execution, at a conversion price of \$0.15 per share, with certain adjustment provisions noted below. The maturity date of the first and second Q3 2015 Note was August 26, 2016. The third Q3 2015 Note had a maturity date of September 24, 2016, the fourth had a maturity date of September 26, 2016, the fifth was October 20, 2016 and the sixth was October 29, 2016. The Q3 2015 Notes bore interest on the unpaid principal amount at the rate of 5% per annum from the date of issuance until the same became due and payable, whether at maturity or upon acceleration or by prepayment or otherwise.

Notwithstanding the foregoing, upon the occurrence of an Event of Default, as defined in such Q3 2015 Note, a Default Amount was equal to the sum of (i) the principal amount, together with accrued interest due thereon through the date of payment payable at the holder’s option in cash or common stock and (ii) an additional amount equal to the principal amount payable at our option in cash or common stock. For purposes of payments in common stock, the following conversion formula applied: the conversion price shall be the lower of: (i) the fixed conversion price (\$0.15) or (ii) 60% multiplied by the volume weighted average price of our common stock during the ten consecutive trading days immediately prior to the later of the Event of Default or the end of the applicable cure period. Certain other conversion rates applied in the event of the sale or merger of us, default and other defined events. The embedded

conversion feature of these notes contained anti-dilution protection, therefore, were treated as derivative instruments (see Note 9).

We could have prepaid the Q3 2015 Notes at any time on the terms set forth in the Q3 2015 Notes at the rate of 115% of the then outstanding balance of the Q3 2015 Notes. Under the terms of the Q3 2015 Notes, we could not effect certain corporate and business actions during the term of the Q3 2015 Notes, although some could have been done with proper notice. Pursuant to the Purchase Agreement, with certain exceptions, the Q3 2015 Note holder had a right of participation during the term of the Q3 2015 Notes; additionally, we granted the Q3 2015 Note holder registration rights for the shares of common stock underlying the Q3 2015 Notes pursuant to Registration Rights Agreements.

F-26

Table of Contents

In addition, bundled with the convertible debt, we sold:

1. A common stock purchase warrant to each Buyer, which allows the Buyers to purchase an aggregate of 1,325,000 shares of common stock and the placement agent to purchase 483,333 shares of common stock (aggregating 1,808,333 shares of our common stock) at an exercise price of \$0.30 per share (see Note 8); and
2. 4,337,500 restricted shares of common stock to the Buyers.

A Registration Rights Agreement was signed and, as a result, we filed a Registration Statement on September 11, 2015 and filed an Amended Form S-1 on October 26, 2015, November 12, 2015 and December 10, 2015 and the Amended Form S-1 became effective December 18, 2015.

We allocated the proceeds from the Q3 2015 Notes to the convertible debt, warrants and restricted shares of common stock issued based on their relative fair values. We determined the fair value of the warrants using Black-Scholes with the following range of assumptions:

	December 31, 2015
Expected terms (in years)	5.00
Expected volatility	101% – 119%
Risk-free interest rate	1.37% – 1.58%
Dividend yield	-

The fair value of the restricted shares of common stock issued was based on the market price of our common stock on the date of issuance of the Q3 2015 Notes. The allocation of the proceeds to the warrants and restricted shares of common stock based on their relative fair values resulted in us recording a debt discount of \$89,551 and \$374,474, respectively. The remaining proceeds of \$860,975 were initially allocated to the debt. We determined that the embedded conversion features in the Q3 2015 Notes were a derivative instrument which was required to be bifurcated from the debt host contracts and recorded at fair value as a derivative liability. The fair value of the embedded conversion features at issuance was determined using a Path-Dependent Monte Carlo Simulation (see Note 9 for assumptions used to calculate fair value). The initial fair value of the embedded conversion features were \$901,784, of which, \$830,560 is recorded as a debt discount. The initial fair value of the embedded conversion feature derivative liabilities in excess of the proceeds allocated to the debt was \$71,224, and was immediately expensed and recorded as interest expense during the year ended December 31, 2015 in the accompanying consolidated statement of operations. The Q3 2015 Notes were also issued at an OID of 10% and the OID of \$132,500 was recorded as an addition to the principal amount of the Q3 2015 Notes and a debt discount in the accompanying consolidated balance sheet.

Total debt issuance costs incurred in connection with the Q3 2015 Notes was \$150,919, of which, \$68,419 is the fair value of the warrants to purchase 483,333 shares of common stock issued to the placement agents. The debt issuance costs were recorded as a debt discount and were being amortized to interest expense using the effective interest method over the term of the Q3 2015 Notes.

During the year ended December 31, 2016, the Q3 2015 Notes holders elected to convert all principal and interest outstanding of \$1,515,635 into 10,104,228 shares of common stock at a conversion price of \$0.15 per share (see Note 8). As a result of the conversion of the outstanding principal and interest balance into shares of common stock, the

fair value of the embedded conversion feature derivative liabilities of \$2,018,565 on the date of conversion was reclassified to additional paid-in capital (see Note 9) and the remaining unamortized debt discount was amortized to interest expense during the year ended December 31, 2016.

2016 Financing

The following table summarizes the outstanding 2016 Convertible Debentures at December 31, 2016:

2016

Convertible debentures	\$1,559,922
Less: Debt discount	(845,730)
Carrying value	714,192
Less: Current portion	(714,192)
Convertible debentures – long-term	\$-

Table of Contents

In the second and third quarter of 2016, we entered into Securities Purchase Agreements with eight accredited investors (the “Investors”), pursuant to which we received aggregate gross proceeds of \$3,000,000 (net of OID) pursuant to which we sold:

Nine convertible promissory notes of the Company totaling \$3,303,889 (each a “2016 Note” and collectively the “2016 Notes”) (the 2016 Notes were sold at a 10% OID and we received an aggregate total of \$2,657,500 in funds thereunder after debt issuance costs of \$342,500). The 2016 Notes and accrued interest are convertible into shares of our common stock at a conversion price of \$0.25 per share, with certain adjustment provisions noted below. The maturity date of the 2016 Notes issued on June 30, 2016 and July 15, 2016 is July 30, 2017 and the maturity date of the 2016 Notes issued on July 25, 2016 is August 25, 2017. The 2016 Notes bear interest on the unpaid principal amount at the rate of 5% per annum from the date of issuance until the same becomes due and payable, whether at maturity or upon acceleration or by prepayment or otherwise.

Notwithstanding the foregoing, upon the occurrence of an Event of Default, as defined in such 2016 Notes, a Default Amount is equal to the sum of (i) the principal amount, together with accrued interest due thereon through the date of payment payable at the holder’s option in cash or common stock and (ii) an additional amount equal to the principal amount payable at our option in cash or common stock. For purposes of payments in common stock, the following conversion formula shall apply: the conversion price shall be the lower of: (i) the fixed conversion price (\$0.25) or (ii) 75% multiplied by the volume weighted average price of our common stock during the ten consecutive trading days immediately prior to the later of the Event of Default or the end of the applicable cure period. For purposes of the Investors request of repayment in cash but we are unable to do so, the following conversion formula shall apply: the conversion price shall be the lower of: (i) the fixed conversion price (\$0.25) or (ii) 60% multiplied by the lowest daily volume weighted average price of our common stock during the ten consecutive trading days immediately prior to the conversion. Certain other conversion rates apply in the event of the sale or merger of us, default and other defined events.

We may prepay the 2016 Notes at any time on the terms set forth in the 2016 Notes at the rate of 110% of the then outstanding balance of the 2016 Notes. Pursuant to the Securities Purchase Agreements, with certain exceptions, the Investors have a right of participation during the term of the 2016 Notes; additionally, we granted the 2016 Note holders registration rights for the shares of common stock underlying the 2016 Notes up to \$1,000,000 pursuant to Registration Rights Agreements. We filed a Form S-1 Registration Statement on August 9, 2016, filed an Amended Form S-1 on August 23, 2016 and August 24, 2016 and the Amended Form S-1 became effective August 25, 2016.

In addition, bundled with the convertible debt, we sold:

1.
A common stock purchase warrant to each Investor, which allows the Investors to purchase an aggregate of 3,000,000 shares of common stock and the placement agent to purchase 1,220,000 shares of common stock (aggregating 4,220,000 shares of our common stock) at an exercise price of \$0.40 per share (see Note 8); and
2.
7,500,000 restricted shares of common stock to the Investors.

We allocated the proceeds from the 2016 Notes to the convertible debenture, warrants and restricted shares of common stock issued based on their relative fair values. We determined the fair value of the warrants using Black-Scholes with the following range of assumptions:

December 31,

	2016
Expected terms (in years)	5.00
Expected volatility	229%
Risk-free interest rate	1.01% – 1.15%
Dividend yield	-

The fair value of the restricted shares of common stock issued to Investors was based on the market price of our common stock on the date of issuance of the 2016 Notes. The allocation of the proceeds to the warrants and restricted shares of common stock based on their relative fair values resulted in us recording a debt discount of \$445,603 and \$1,127,225, respectively. The remaining proceeds of \$1,427,172 were initially allocated to the debt. We determined that the embedded conversion features in the 2016 Notes were a derivative instrument which was required to be bifurcated from the debt host contract and recorded at fair value as a derivative liability. The fair value of the embedded conversion features at issuance was determined using a Path-Dependent Monte Carlo Simulation Model (see Note 9 for assumptions used to calculate fair value). The initial fair value of the embedded conversion features were \$3,444,284, of which, \$687,385 is recorded as a debt discount. The initial fair value of the embedded conversion feature derivative liabilities in excess of the proceeds allocated to the debt, after the allocation of debt proceeds to the debt issuance costs, was \$2,756,899, and was immediately expensed and recorded as interest expense during the year ended December 31, 2016 in the accompanying condensed consolidated statement of operations. The 2016 Notes were also issued at an OID of 10% and the OID of \$303,889 was recorded as an addition to the principal amount of the 2016 Notes and a debt discount in the accompanying consolidated balance sheet.

Table of Contents

Total debt issuance costs incurred in connection with the 2016 Notes was \$739,787, of which, \$357,286 is the fair value of the warrants to purchase 1,220,000 shares of common stock issued to the placement agents. The debt issuance costs have been recorded as a debt discount and are being amortized to interest expense using the effective interest method over the term of the 2016 Notes.

During the year ended December 31, 2016, certain of the 2016 Notes holders elected to convert principal and interest outstanding of \$1,749,070 into 6,996,280 shares of common stock at a conversion price of \$0.25 per share (see Note 8). As a result of the conversion of the principal and interest balance into shares of common stock, the fair value of the embedded conversion feature derivative liabilities of \$1,093,263 on the date of conversion was reclassified to additional paid-in capital (see Note 9) and the amortization of the debt discount was accelerated for the amount converted and recorded to interest expense during the year ended December 31, 2016.

Interest Expense

We recognized interest expense on the Q3 2015 Notes and 2016 Notes for the year ended December 31, 2016 and 2015 of \$80,095 and \$26,754, respectively. The debt discount recorded for the 2016 Notes are being amortized as interest expense over the term of the 2016 Notes using the effective interest method. Total amortization of the debt discount on the Q3 2015 Notes and 2016 Notes to interest expense for the years ended December 31, 2016 and 2015 was \$3,508,199 and \$527,964, respectively.

NOTE 6 – DEBENTURES – RELATED PARTIES

The following table summarizes the outstanding debentures to a related party at December 31, 2016 and 2015:

	2016	2015
Line of credit convertible debenture – related party	\$-	\$409,192
2014 non-convertible debenture – related party	-	25,000
Total	-	434,192
Less : Debt discount	-	(17,720)
Carrying value	-	416,472
Less: Current portion	-	(391,472)
Total long-term debentures – related party	\$-	\$25,000

Line of Credit Convertible Debenture

In January 2013, we entered into a line of credit convertible debenture with our President and Chief Executive Officer (the “LOC Convertible Debenture”). Under the terms of its original issuance: (1) we could request to borrow up to a maximum principal amount of \$250,000 from time to time; (2) amounts borrowed bore an annual interest rate of 8%; (3) the amounts borrowed plus accrued interest were payable in cash at the earlier of January 14, 2014 or when we complete a Financing, as defined, and (4) the holder had sole discretion to determine whether or not to make an advance upon our request.

During 2013, the LOC Convertible Debenture was further amended to: (1) increase the maximum principal amount available for borrowing to \$1 million plus any amounts of salary or related payments paid to Dr. Damaj prior to the termination of the funding commitment; and (2) change the holder’s funding commitment to automatically terminate on the earlier of either (a) when we complete a financing with minimum net proceeds of at least \$4 million, or (b) July

1, 2016. The securities to be issued upon automatic conversion would have been either our securities that were issued to the investors in a Qualified Financing or, if the financing did not occur by July 1, 2016, shares of the our common stock based on a conversion price of \$0.312 per share, 80% times the quoted market price of our common stock on the date of the amendment. The LOC Convertible Debenture bore interest at a rate of 8% per annum. The other material terms of the LOC Convertible Debenture were not changed. We recorded a debt discount for the intrinsic value of the BCF with an offsetting increase to additional paid-in-capital. The BCF was being accreted as non-cash interest expense over the expected term of the LOC debenture to its stated maturity date using the effective interest rate method.

On July 22, 2014, we agreed with our CEO to increase the principal amount that may be borrowed from \$1,000,000 to \$1,500,000. All other terms of the LOC Convertible Debenture remained the same.

On August 12, 2015, the principal amount that may be borrowed was increased to \$2,000,000 and the automatic termination date described above was extended to October 1, 2016. The LOC Convertible Debenture was not renewed upon expiration. The conversion price was \$0.16 per share, 80% times the quoted market price of our common stock on the date of the amendment.

During the years ended December 31, 2016 and 2015, we borrowed \$0 and \$114, respectively, under the LOC Convertible Debenture and recorded a beneficial conversion feature of \$3,444 and \$8,321, respectively, for the amounts borrowed and accrued interest. We repaid the LOC Convertible Debenture balance and accrued interest in full during the year ended December 31, 2016.

Table of Contents

January 2015 Non-Convertible Debenture - Former CFO

On January 21, 2015, we entered into a securities purchase agreement with our former Chief Financial Officer whereby we issued and sold a promissory note in the principal face amount of \$55,000 and warrants to purchase up to 250,000 shares of our common stock for gross proceeds of \$50,000. We recorded an OID of \$5,000 upon issuance.

The note was due on July 31, 2015 and accrued a one-time interest charge of 8% on the closing date. The warrants are exercisable for five years from the closing date at an exercise price of \$0.30 per share of common stock. The warrants contain anti-dilution protection, including protection upon dilutive issuances. The principal and interest balance of \$59,400 was repaid on July 31, 2015.

The warrants issued in connection with the note, are measured at fair value and classified as a liability because these warrants contain anti-dilution protection and therefore, cannot be considered indexed to our own stock which is a requirement for the scope exception as outlined under FASB ASC 815. The estimated fair value of the warrants was determined using the Probability Weighted Black-Scholes Model, resulting in a fair value of \$49,999 on the date they were issued.

The allocation of the proceeds of the debt was initially recorded using the residual method, at \$1, net of a debt discount of \$54,999 for the fair value of the warrants and the OID. The discount was accreted as non-cash interest expense over the expected term of the note using the effective interest method and the unamortized balance was expensed upon repayment. The fair value of the warrants will be affected by changes in inputs to that model including our stock price, expected stock price volatility, the contractual term and the risk-free interest rate. We will continue to classify the fair value of the warrants as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability, whichever comes first. The anti-dilution protection for the warrants survives for the life of the warrants which ends in January 2020 (see Note 9).

2014 Non-Convertible Notes – Related Parties

On January 29, 2014, we issued an 8% note, in the amount of \$25,000, to our President and Chief Executive Officer. The principal amount and interest were payable on January 22, 2015. This note was amended to extend the maturity date until January 22, 2017. We repaid the principal note balance and accrued interest in full in August 2016.

On May 30, 2014, we issued an 8% debenture, in the amount of \$50,000, to a member of our Board of Directors. The principal amount and interest were payable on May 30, 2015 and the repayment date had been extended to May 30, 2016. On August 5, 2015 the debenture was converted into 313,177 shares of common stock.

On June 17, 2014, we issued an 8% debenture, in the amount of \$50,000, to our former Chief Financial Officer. The principal and interest were payable on June 16, 2015 and were repaid in July 2015.

On August 25, 2014, we issued an 8% debenture, in the amount of \$25,000, to a member of our Board of Directors. The principal amount and interest were payable on August 25, 2015. In July 2015, the repayment date was extended to May 30, 2016. On August 5, 2015 the debenture was converted into 156,083 shares of common stock.

Interest Expense

We recognized interest expense on the outstanding debentures to related parties totaling \$17,430 and \$69,634 during the years ended December 31, 2016 and 2015, respectively. Amortization of the debt discount to interest expense during the years ended December 31, 2016 and 2015 totaled \$21,164 and \$122,092, respectively.

NOTE 7 – RELATED PARTY TRANSACTIONS

Related Party Borrowings

There were certain related party borrowings that were repaid in full or converted into shares of common stock during the years ended December 31, 2016 and 2015 which are described in more detail in Note 6.

Accrued Compensation – Related Party

Accrued compensation includes accruals for employee wages, vacation pay and target-based bonuses. The components of accrued compensation as of December 31, 2016 and 2015 are as follows:

	2016	2015
Wages	\$1,455,886	\$1,178,909
Vacation	261,325	170,371
Bonuses	449,038	-
Payroll taxes on the above	133,344	93,510
Total	2,299,593	1,442,790
Classified as long-term	(1,531,904)	(906,928)
Accrued compensation	\$767,689	\$535,862

F-30

Table of Contents

Accrued employee wages at December 31 2016 and 2015 are entirely related to wages owed to our President and Chief Executive Officer. Under the terms of his employment agreement, wages are to be accrued but no payment made for so long as payment of such salary would jeopardize our ability to continue as a going concern. The CEO started to receive payment of salary in July 2016. Under the third quarter 2015 financing agreement, salaries prior to January 1, 2015 totaling \$906,928 could not be repaid until the debentures were repaid in full or otherwise extinguished by conversion or other means and, accordingly, the accrued compensation was shown as a long-term liability. During the year ended December 31, 2016, the Q3 2015 Notes were fully converted into shares of common stock. We do not expect to pay the accrued wages and related payroll tax amounts within the next 12 months and thus is classified as a long-term liability.

NOTE 8 – STOCKHOLDERS’ EQUITY (DEFICIT)

Capital Stock

We have 292,500,000 authorized shares of common stock with a par value of \$0.001 per share which were increased in November 2016 upon approval from our stockholders from 150,000,000 authorized shares. In November 2016, our stockholders approved the Amended and Restated Articles of Incorporation to authorize a class of undesignated or "blank check" preferred stock, consisting of 7,500,000 shares at \$0.001 par value per share. Shares of preferred stock may be issued in one or more series, with such rights, preferences, privileges and restrictions to be fixed by the Board of Directors.

Issuances of Common Stock

2016 Issuances

On January 6, 2016 and April 5, 2016, we entered into a consulting agreement with a third party pursuant to which we agreed to issue, over the term of the agreements, an aggregate of 1,560,000 shares of common stock in exchange for services to be rendered. During the year ended December 31, 2016, we issued 1,560,000 shares under the agreement related to services provided and recognized the fair value of the shares issued of \$184,958 in general and administrative expense in the accompanying consolidated statement of operations. The 1,560,000 shares of common stock vested on the date of issuance and the fair value of the shares of common stock was based on the market price of our common stock on the date of vesting.

In January 2016, we issued 300,000 shares of common stock for services and recorded an expense of \$17,000, which is included in general and administrative expense in the accompanying consolidated statement of operations. The 300,000 shares of common stock vested on the date of issuance and the fair value of the shares of common stock was based on the market price of our common stock on the date of vesting.

On February 10, 2016, we entered into a service agreement with a third party pursuant to which we agreed to issue, over the term of the agreement, 3,000,000 shares of common stock in exchange for services to be rendered. During the year ended December 31, 2016, we issued 3,000,000 shares under the agreement related to services provided and recognized the fair value of the shares issued of \$352,500 in general and administrative expense in the accompanying consolidated statement of operations. The 3,000,000 shares of common stock vested on the date of issuance and the fair value of the shares of common stock was based on the market price of our common stock on the date of vesting.

On February 19, 2016, we entered into a consulting agreement with a third party, pursuant to which we agreed to issue, over the term of the agreement, 1,750,000 shares of common stock in exchange for services to be rendered. During the year ended December 31, 2016, we issued 1,750,000 shares under the agreement related to

services provided in connection with the acquisition of Beyond Human® (see Note 3) and recognized the fair value of the shares issued of \$181,013 in general and administrative expense in the accompanying consolidated statement of operations. The 1,750,000 shares of common stock vested on the date of issuance and the fair value of the shares of common stock was based on the market price of our common stock on the date of vesting.

In April and August 2016, we issued an aggregate of 3,385,354 shares of common stock upon the cashless exercise of warrants to purchase 5,042,881 shares of common stock. Upon exercise of certain warrants in April 2016, the fair value of the warrant derivative liability on the date of exercise was reclassified to additional paid-in capital (see Note 9).

F-31

Table of Contents

In April, May, August and October 2016, we issued an aggregate of 1,012,500 shares of common stock for services and recorded an expense of \$192,043, which is included in general and administrative expense in the accompanying consolidated statement of operations. The 1,012,500 shares of common stock vested on the date of issuance and the fair value of the shares of common stock was based on the market price of our common stock on the date of vesting.

On April 27, 2016, we entered into a service agreement with a third party pursuant to which we agreed to issue 300,000 shares of common stock in exchange for services to be rendered over the 3 month term of the agreement. The shares of common stock issued were non-forfeitable and the fair value of \$28,500 was based on the market price of our common stock on the date of vesting. During the year ended December 31, 2016, we recognized \$28,500 in general and administrative expense in the accompanying consolidated statement of operations.

In May and December 2016, we issued an aggregate of 2,361,111 shares of restricted common stock to certain note holders in connection with their notes payable. The relative fair value of the shares of restricted common stock issued was determined to be \$276,167 and was recorded as a debt discount (see Note 5).

In May and June 2016, the Buyers of the Q3 2015 Notes elected to convert \$1,515,635 in principal and interest into 10,104,228 shares of common stock (see Note 5). Upon conversion, the fair value of the embedded conversion feature derivative liability on the date of conversion was reclassified to additional paid-in capital (see Note 9).

On June 16, 2016, we entered into a consulting agreement with a third party pursuant to which we agreed to issue 250,000 restricted shares of common stock in exchange for services to be rendered. In July 2016, we issued 250,000 fully-vested shares under the agreement related to services to be provided over the term of the agreement which ended on December 16, 2016. The fair value of the shares issued of \$47,500 was based on the market price of our common stock on the date of vesting. On December 16, 2016, we amended the consulting agreement to extend the term to June 16, 2017 and in connection with the amendment issued 80,000 fully-vested shares for services to be provided over the remaining term of the amended agreement. The fair value of the shares issued of \$14,640 was based on the market price of our common stock on the date of vesting. During the year ended December 31, 2016, we recognized \$48,720 in general and administrative expense in the accompanying consolidated statement of operations and the remaining unamortized expense of \$13,420 is included in prepaid expense and other current assets in the accompanying consolidated balance sheet at December 31, 2016.

In July 2016, we issued 100,000 shares of common stock to CRI pursuant to the Amended CRI Asset Purchase Agreement (see Note 2). The fair value of the restricted shares of common stock of \$23,000 was based on the market price of our common stock on the date of issuance and is included in research and development expense in the accompanying consolidated statement of operations.

On August 3, 2016, we entered into a service agreement with a third party pursuant to which we issued 75,000 fully-vested restricted shares of common stock in exchange for services to be rendered over the term of the agreement which ended on November 10, 2016. The fair value of the shares issued of \$32,250 was based on the market price of our common stock on the date of vesting. On November 17, 2016, we entered into a new service agreement with the same third party and in connection with the new agreement issued 275,000 fully-vested shares for services to be provided over the term of the new service agreement through May 17, 2017. The fair value of the shares issued of \$69,575 was based on the market price of our common stock on the date of vesting. During the year ended December 31, 2016, we recognized \$49,644 in general and administrative expense in the accompanying consolidated statement of operations and the remaining unamortized expense of \$52,181 is included in prepaid expense and other current assets in the accompanying consolidated balance sheet at December 31, 2016.

On August 23, 2016, we entered into a consulting agreement with a third party pursuant to which we agreed to issue 1,600,000 restricted shares of common stock, payable in four equal installments, in exchange for services to be rendered over the agreement which ends on August 23, 2017. The shares were considered fully-vested and non-refundable at the execution of the agreement. In September and December 2016, we issued a total of 800,000 shares of common stock under the agreement. The fair value of the shares issued of \$360,000 was based on the market price of our common stock on the date of agreement. As a result of the shares being fully-vested at the execution of the agreement but payable in equal installments, we recorded a liability for the fair value of the remaining 800,000 shares of common stock to be issued of \$360,000 which is included in accounts payable and accrued expense in the accompanying consolidated balance sheet at December 31, 2016. Upon issuance of the remaining shares, we will reclassify the liability to common stock and additional paid-in-capital. During the year ended December 31, 2016, we recognized \$255,000 in general and administrative expense in the accompanying consolidated statement of operations and the remaining unamortized expense of \$465,000 is included in prepaid expense and other current assets in the accompanying consolidated balance sheet at December 31, 2016.

On September 1, 2016, we entered into a service agreement with a third party pursuant to which we agreed to issue, over the term of the agreement, 2,000,000 shares of common stock in exchange for services to be rendered. During the year ended December 31, 2016, we issued 1,330,000 shares under the agreement related to services provided and recognized the fair value of the shares issued of \$332,970 in general and administrative expense in the accompanying consolidated statement of operations. The 1,330,000 shares of common stock vested on the date of issuance and the fair value of the shares of common stock was based on the market price of our common stock on the date of vesting.

Table of Contents

In November 2016, we issued 12,808,796 shares of common stock to Novalere Holdings in connection with the Amendment and Supplement to a Registration Rights and Stock Restriction Agreement and \$2,971,641 of the acquisition contingent consideration was reclassified from liabilities to equity (see Note 3).

During the year ended December 31, 2016, we issued 215,000 shares of common stock for legal fees in connection with the Semprae merger transaction and recognized the fair value of the shares issued of \$64,500 in general and administrative expense in the accompanying consolidated statement of operations.

During the year ended December 31, 2016, we issued 19,315,994 shares of common stock in exchange for vested restricted stock units.

In connection with the issuance of the 2016 Notes, we issued restricted shares of common stock totaling 7,500,000 to the Investors. The relative fair value of the restricted shares of common stock totaling \$1,127,225 was recorded as a debt discount (see Note 5).

In the third and fourth quarter of 2016, certain 2016 Notes holders elected to convert \$1,749,070 in principal and interest into 6,996,280 shares of common stock (see Note 5). Upon conversion, the fair value of the embedded conversion feature derivative liability on the date of conversion was reclassified to additional paid-in capital (see Note 9).

During the year ended December 31, 2016, five of our warrant holders exercised their warrants to purchase shares of common stock totaling 1,033,800 at an exercise price of \$0.30 per share. We received gross cash proceeds of \$310,140.

2015 Issuances

On January 17, 2013, we entered into a service agreement with a third party pursuant to which we agreed to issue over the term of the agreement 250,000 shares of our common stock in exchange for services to be rendered. On September 18, 2013, we extended the term of the agreement and agreed to issue an additional aggregate of 300,000 shares of common stock in exchange for services to be rendered. The term was further extended in April 2014 and we agreed to issue an additional 300,000 shares of common stock in exchange for services to be rendered over the term of the agreement. During the year ended December 31, 2015, we issued 140,000 and recognized \$20,650 of services expense under this agreement. This agreement was terminated in June 2015.

On March 17, 2015, we entered into a consulting agreement for services. In consideration of such services, we issued 28,125 shares of our common stock to the consultant on said date and valued them at \$3,938 based on the closing price of the stock on the date of issuance. The fair value of such shares was recognized in general and administrative expense in the accompanying consolidated statement of operations.

On August 27, 2014, we agreed to issue 200,000 shares of our common stock pursuant to a consulting contract with a third party for services. We extended the consulting contract in January 2015 and agreed to issue an additional 200,000 shares. The issued shares have been valued at the closing price of our common stock on the date of issuance and are expensed over the period that the services are rendered. We recognized expense of \$38,000 during the year ended December 31, 2015 related to services provided in general and administrative expense in the accompanying consolidated statement of operations.

On January 23, 2015, we entered into a settlement agreement with CRI whereby CRI returned 200,000 shares of common stock initially issued for a product license acquired. The share return was in consideration for us completing

certain product development and regulatory efforts relating to the sale of the product in foreign territories and reduced the intangible asset value by the fair value of such shares totaling \$38,000.

On September 17, 2015, we issued 500,000 shares of common stock in exchange for vested restricted stock units.

On September 29, 2015 we issued 375,000 shares of common stock for services and recorded an expense of \$23,250, which is included in general and administrative expense in the accompanying consolidated statement of operations.

We issued an additional 1,037,500 shares of common stock and expensed \$124,691 during the year ended December 31, 2015 to other consultants for various services, which is included in general and administrative expense in the accompanying consolidated statement of operations. All issued shares have been valued at the closing price of our common stock on the date of issuance.

See Note 5 for more details on the shares of common stock issued in connection with the Q3 2015 Notes, shares of common stock issued upon conversion of convertible debentures and note payable and shares of common stock issued in connection with the extension and amendment of certain convertible debentures during 2015. See Note 3 for more details on the shares of common stock issued in connection with the Novalere acquisition during 2015 and the return of shares of common stock during 2015 in connection with the Semptrae merger transaction.

Table of Contents

2013 Equity Incentive Plan

We have issued common stock, restricted stock units and stock option awards to employees, non-executive directors and outside consultants under the 2013 Equity Incentive Plan (“2013 Plan”), which was approved by our Board of Directors in February of 2013. The 2013 Plan allows for the issuance of up to 10,000,000 shares of our common stock to be issued in the form of stock options, stock awards, stock unit awards, stock appreciation rights, performance shares and other share-based awards. The exercise price for all equity awards issued under the 2013 Plan is based on the fair market value of the common stock. Currently, because our common stock is quoted on the OTCQB, the fair market value of the common stock is equal to the last-sale price reported by the OTCQB as of the date of determination, or if there were no sales on such date, on the last date preceding such date on which a sale was reported. Generally, each vested stock unit entitles the recipient to receive one share of our common stock which is eligible for settlement at the earliest of their termination, a change in control of us or a specified date. Restricted stock units can vest according to a schedule or immediately upon award. Stock options generally vest over a three-year period, first year cliff vesting with quarterly vesting thereafter on the three-year awards, and have a ten-year life. Stock options outstanding are subject to time-based vesting as described above and thus are not performance-based. As of December 31, 2016, no shares were available under the 2013 Plan.

2014 Equity Incentive Plan

We have issued common stock, restricted stock units and stock options to employees, non-executive directors and outside consultants under the 2014 Equity Incentive Plan (“2014 Plan”), which was approved by our Board of Directors in November 2014. The 2014 Plan allows for the issuance of up to 20,000,000 shares of our common stock to be issued in the form of stock options, stock awards, stock unit awards, stock appreciation rights, performance shares and other share-based awards. The exercise price for all equity awards issued under the 2014 Plan is based on the fair market value of the common stock. Generally, each vested stock unit entitles the recipient to receive one share of our common stock which is eligible for settlement at the earliest of their termination, a change in control of us or a specified date. Restricted stock units can vest according to a schedule or immediately upon award. Stock options generally vest over a three-year period, first year cliff vesting with quarterly vesting thereafter on the three-year awards and have a ten-year life. Stock options outstanding are subject to time-based vesting as described above and thus are not performance-based. As of December 31, 2016, 146,314 shares were available under the 2014 Plan.

2016 Equity Incentive Plan

On March 21, 2016, our Board of Directors approved the adoption of the 2016 Equity Incentive Plan and on October 20, 2016 adopted the Amended and Restated 2016 Equity Incentive Plan (“2016 Plan”). The 2016 Plan was then approved by our stockholders in November 2016. The 2016 Plan allows for the issuance of up to 20,000,000 shares of our common stock to be issued in the form of stock options, stock awards, stock unit awards, stock appreciation rights, performance shares and other share-based awards. The 2016 Plan includes an evergreen provision in which the number of shares of common stock authorized for issuance and available for future grants under the 2016 Plan will be increased each January 1 after the effective date of the 2016 Plan by a number of shares of common stock equal to the lesser of: (a) 4% of the number of shares of common stock issued and outstanding on a fully-diluted basis as of the close of business on the immediately preceding December 31, or (b) a number of shares of common stock set by our Board of Directors. The exercise price for all equity awards issued under the 2016 Plan is based on the fair market value of the common stock. Generally, each vested stock unit entitles the recipient to receive one share of our common stock which is eligible for settlement at the earliest of their termination, a change in control of the us or a specified date. Restricted stock units can vest according to a schedule or immediately upon award. Stock options generally vest over a three-year period, first year cliff vesting with quarterly vesting thereafter on the three-year awards and have a ten-year life. Stock options outstanding are subject to time-based vesting as described above and

thus are not performance-based. As of December 31, 2016, 15,837,500 shares were available under the 2016 Plan.

Stock-Based Compensation

The stock-based compensation expense for the years ended December 31, 2016 and 2015 was \$954,753 and \$1,298,240, respectively, for the issuance of restricted stock units and stock options to management, directors and consultants. We calculate the fair value of the restricted stock units based upon the quoted market value of the common stock at the date of grant. We calculate the fair value of each stock option award on the date of grant using Black-Scholes. As of December 31, 2016, the remaining unamortized stock-based compensation expense to be recognized in the consolidated statement of operations was approximately \$1.0 million and will be recognized over a remaining weighted-average term of 2.5 years.

Stock Options

For the years ended December 31, 2016 and 2015, the following weighted average assumptions were utilized for the stock options granted during the period:

	2016	2015
Expected life (in years)	10.0	6.0
Expected volatility	227.2%	228.8%
Average risk-free interest rate	1.76%	2.16%
Dividend yield	-	-
Grant date fair value	\$0.18	\$0.10

Table of Contents

The dividend yield of zero is based on the fact that we have never paid cash dividends and has no present intention to pay cash dividends. Expected volatility is based on the historical volatility of our common stock over the period commensurate with the expected life of the stock options. Expected life in years is based on the “simplified” method as permitted by ASC Topic 718. We believe that all stock options issued under its stock option plans meet the criteria of “plain vanilla” stock options. We use a term equal to the term of the stock options for all non-employee stock options. The risk-free interest rate is based on average rates for treasury notes as published by the Federal Reserve in which the term of the rates correspond to the expected term of the stock options.

The following table summarizes the number of stock options outstanding and the weighted average exercise price:

	Options	Weighted average exercise price	Weighted remaining contractual life (years)	Aggregate intrinsic value
Outstanding at December 31, 2014	113,000	\$0.37	9.5	-
Granted	83,000	\$0.10	10.0	-
Exercised	-	-	-	-
Cancelled	-	-	-	-
Forfeited	-	-	-	-
Outstanding at December 31, 2015	196,000	\$0.31	9.0	-
Granted	91,500	\$0.17	10.0	-
Exercised	-	-	-	-
Cancelled	(50,000)	\$0.31	-	-
Forfeited	-	-	-	-
Outstanding at December 31, 2016	237,500	\$0.22	8.6	\$14,293
Vested at December 31, 2015	196,000	\$0.31	9.0	\$-
Vested at December 31, 2016	237,500	\$0.22	8.6	\$14,293

The aggregate intrinsic value is calculated as the difference between the exercise price of all outstanding stock options and the quoted price of our common stock at December 31, 2016. During the years ended December 31, 2016 and 2015, we recognized stock-based compensation from stock options of \$20,390 and \$8,564, respectively.

Restricted Stock Units

The following table summarizes the restricted stock unit activity for the years ended December 31, 2016 and 2015:

	Restricted Stock Units
Outstanding at December 31, 2014	8,270,239
Granted	10,354,497
Exchanged	(500,000)
Cancelled	(570,000)
Outstanding at December 31, 2015	17,554,736
Granted	14,636,106
Exchanged	(19,315,994)
Cancelled	-

Outstanding at December 31, 2016 12,874,848

Vested at December 31, 2015 14,398,487

Vested at December 31, 2016 8,493,600

The vested restricted stock units at December 31, 2016 and 2015 have not settled and are not showing as issued and outstanding shares of ours but are considered outstanding for earnings per share calculations. Settlement of these vested restricted stock units will occur on the earliest of (i) the date of termination of service of the employee or consultant, (ii) change of control of us, or (iii) 10 years from date of issuance. Settlement of vested restricted stock units may be made in the form of (i) cash, (ii) shares, or (iii) any combination of both, as determined by the board of directors and is subject to certain criteria having been fulfilled by the recipient.

F-35

Table of Contents

During the years ended December 31, 2016 and 2015, we issued 14,636,106 and 10,354,497 restricted stock units to employees, board members and consultants. In 2016, 886,107 were from the 2013 Plan and vested immediately, 9,999,999 were from the 2014 Plan and 3,750,000 were from the 2016 Plan. A total of 6,000,001 of 9,999,999 restricted stock units issued under the 2014 Plan vested immediately and the remaining 3,999,998 vested upon the closing of the Beyond Human® asset acquisition. The restricted stock units issued under the 2016 Plan vest as to 25% on the one year anniversary from the date of grant and then in equal quarterly installments for the next two years. In 2015, 9,370,000 were from the 2014 Plan and vest one-third on the issuance date and then monthly for the next two years. The remaining restricted stock units in 2015 were from the 2014 Plan and vested immediately. The grant date fair value of restricted stock units issued during the years ended December 31, 2016 and 2015 was \$1,499,268 and \$1,363,413, respectively. For the years ended December 31, 2016 and 2015, we recognized \$934,363 and \$1,289,676, respectively, of stock-based compensation expense for the vested units. As of December 31, 2016, compensation expense related to unvested shares not yet recognized in the consolidated statement of operations was approximately \$1.0 million and will be recognized over a remaining weighted-average term of 2.5 years.

Warrants

During the year ended December 31, 2014, we issued 380,973 warrants in connection with notes payable (which were repaid in 2013). The warrants have an exercise price of \$0.10 and expire December 6, 2018. Warrants to purchase 245,157 shares of common stock were exercised under the cashless exercise provisions of the warrant agreement in July 2016, which resulted in the issuance of 191,908 shares of common stock. The intrinsic value of the warrants on the date of exercise was \$86,359.

In February, 2014, we issued 250,000 warrants in connection with the February 2014 Convertible Debentures. The warrants had an exercise price of \$0.50 per share and expire February 13, 2019. On March 6, 2015 we entered into an agreement with the note holder to extend the February 2014 Convertible Debentures for six months. As consideration for the extension, we issued the note holder an additional 250,000 warrants, reduced the exercise price of the warrants from \$0.50 to \$0.30 per share and extended the expiration date to March 12, 2020. The warrants were also amended to include certain anti-dilution protection, including protection upon dilutive issuances. In connection with the Q3 2015 Notes, the exercise price of these warrants was reduced to \$0.0896 per share and an additional 1,173,410 warrants were issued per the anti-dilution protection afforded in the warrant agreement during the year ended December 31, 2015. These warrants were exercised under the cashless exercise provisions of the warrant agreement in April 2016. In connection with the exercise of the warrants, we agreed to reduce the exercise price of these warrants to \$0.07 per share which resulted in an additional 469,447 warrants being issued in April 2016 prior to exercise. The warrants exercised were classified as derivative liabilities and, upon exercise, the fair value of the warrant derivative liability was reclassified to additional paid-in capital (see Note 9). The intrinsic value of the warrants on the date of exercise was \$53,629.

In January, 2015, we issued 500,000 warrants in connection with the January 2015 Non-Convertible Debentures. The warrants were exercisable for five years from the closing date at an exercise price of \$0.30 per share of common stock or January 21, 2020. The warrants contained anti-dilution protection, including protection upon dilutive issuances. In connection with the Q3 2015 Notes, the exercise price of these warrants was reduced to \$0.0896 per share and an additional 1,173,410 warrants were issued per the anti-dilution protection afforded in the warrant agreement during the year ended December 31, 2015. These warrants were exercised under the cashless exercise provisions of the warrant agreement in April 2016. In connection with the exercise of the warrants, we agreed to reduce the exercise price of these warrants to \$0.0565 per share which resulted in an additional 981,457 warrants being issued in April 2016 prior to exercise. The warrants exercised were classified as derivative liabilities and, upon exercise, the fair value of the warrant derivative liability was reclassified to additional paid-in capital (see Note 9). The intrinsic value of the warrants on the date of exercise was \$99,121.

In January 2015, we issued 250,000 warrants with an exercise price of \$0.30 per share to our former Chief Financial Officer in connection with the January 2015 debenture. The warrants expire on January 21, 2020. The warrants contain anti-dilution protection, including protection upon dilutive issuances. In connection with the Q3 2015 Notes, the exercise price of these warrants was reduced to \$0.0896 per share and an additional 586,705 warrants were issued per the anti-dilution protection afforded in the warrant agreement during the year ended December 31, 2015. The increase in the fair value of the warrants from the additional warrants issued is included in the change in fair value of derivative liabilities in the consolidated statement of operations during the year ended December 31, 2015 (see Note 9).

In connection with the Q3 2015 Notes, we issued 1,808,333 warrants with an exercise price of \$0.30 per share and expire in 2020 (see Note 5). Warrants to purchase 1,033,800 shares of common stock were exercised during the year ended December 31, 2016. The intrinsic value of the warrants on the dates of exercise was \$150,200.

In connection with the 2016 Notes, we issued 4,220,000 warrants to the Investors and placement agents with an exercise price of \$0.40 per share and expire in 2021 (see Note 5).

Table of Contents

At December 31, 2016 and 2015, there are 5,967,054 and 6,372,831 fully vested warrants outstanding, respectively. The weighted average exercise price of outstanding warrants at December 31, 2016 is \$0.34 per share, the weighted average remaining contractual term is 4.2 years and the aggregate intrinsic value of the outstanding warrants is \$104,160.

Net Loss per Share

Restricted stock units that are vested but the issuance and delivery of the shares are deferred until the employee or director resigns are included in the basic and diluted net loss per share calculations.

The weighted average shares of common stock outstanding used in the basic and diluted net loss per share calculation for the years ended December 31, 2016 and 2015 was 85,436,145 and 41,359,779, respectively.

The weighted average restricted stock units vested but issuance of the common stock is deferred until there is a change in control, a specified date in the agreement or the employee or director resigns used in the basic and diluted net loss per share calculation for the years ended December 31, 2016 and 2015 was 8,670,237 and 11,157,751, respectively.

The total weighted average shares outstanding used in the basic and diluted net loss per share calculation for the years ended December 31, 2016 and 2015 was 94,106,382 and 52,517,530, respectively.

The following table shows the anti-dilutive shares excluded from the calculation of basic and diluted net loss per common share as of December 31, 2016 and 2015:

As of December 31,

	2016	2015
--	------	------

Gross number of shares excluded:

Restricted stock units - unvested	4,381,248	3,156,249
Stock options	237,500	196,000
Convertible debentures and accrued interest	6,414,132	12,751,512
Warrants	5,967,054	6,372,831
Total	16,999,934	22,476,592

The above table does not include the ANDA Consideration Shares related to the Novalere acquisition totaling 138,859 and 12,947,655 at December 31, 2016 and 2015, respectively, as they are considered contingently issuable (see Note 3).

NOTE 9 – DERIVATIVE LIABILITIES

The warrants issued in connection with the January 2015 Non-Convertible Debenture, January 2015 Non-Convertible Debenture to the former Chief Financial Officer and the February 2014 Convertible Debenture are measured at fair value and classified as a liability because these warrants contain anti-dilution protection and therefore, cannot be considered indexed to our own stock which is a requirement for the scope exception as outlined under FASB ASC

815. The estimated fair value of the warrants was determined using the Probability Weighted Black-Scholes Model, resulting in a value of \$226,297 at the date of issuance. The fair value will be affected by changes in inputs to that model including our stock price, expected stock price volatility, the contractual term and the risk-free interest rate. We will continue to classify the fair value of the warrants as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability, whichever comes first. The anti-dilution protection for the warrants survives for the life of the warrants which ends in January 2020. Certain of these warrants were exercised under the cashless exercise provisions of the warrant agreement in April 2016 and, as a result, the fair value of the warrant derivative liability on the date of exercise totaling \$518,224 was reclassified to additional paid-in capital (see Note 8).

The derivative liabilities are a Level 3 fair value measure in the fair value hierarchy and the assumptions for the Probability Weighted Black-Scholes Option-Pricing Model for the years ended December 31, 2016 and 2015 are represented in the table below:

	2016	2015
Expected life (in years)	3.1 – 4.0	4.1 – 5.0
Expected volatility	188% – 230%	226%
Average risk-free interest rate	0.86% – 1.47%	1.15% – 1.54%
Dividend yield	-	-

We have determined the embedded conversion features of the Q3 2015 Notes and 2016 Notes (see Note 5) to be derivative liabilities because the terms of the embedded conversion features contain anti-dilution protection and therefore, cannot be considered indexed to our own stock which is a requirement for the scope exception as outlined under FASB ASC 815. The embedded conversion features are to be measured at fair value and classified as a liability with subsequent changes in fair value recorded in earnings at the end of each reporting period. We have determined the fair value of the derivative liabilities using a Path-Dependent Monte Carlo Simulation Model. The fair value of the derivative liabilities using such model will be affected by changes in inputs to that model and is based on the individual characteristics of the embedded conversion features on the valuation date as well as assumptions for volatility, remaining expected life, risk-free interest rate, credit spread, probability of default by us and acquisition of us. We will continue to classify the fair value of the embedded conversion features as a liability until the conversion features are exercised, expire or are amended in a way that would no longer require these embedded conversion features to be classified as a liability, whichever comes first. During the year ended December 31, 2016, the Q3 2015 Notes were fully converted and certain 2016 Notes were converted into shares of common stock which resulted in the fair value of the embedded conversion feature derivative liability on the dates of conversion of \$3,111,828 to be reclassified to additional paid-in capital (see Note 8). The anti-dilution protection for the embedded conversion features survive the life of the 2016 Notes which mature at July 30, 2017 and August 25, 2017.

Table of Contents

The derivative liabilities are a Level 3 fair value measure in the fair value hierarchy and a summary of quantitative information with respect to valuation methodology and significant unobservable inputs used for our embedded conversion feature derivative liabilities that are categorized within Level 3 of the fair value hierarchy during the years ended December 31, 2016 and 2015 are as follows:

	2016	2015
Stock price	\$0.05 – 0.50	\$0.07 – 0.16
Strike price	\$0.15 – 0.25	\$0.15
Expected life (in years)	0.3 – 1.1	0.7 – 1.1
Expected volatility	121% – 274%	101% – 119%
Average risk-free interest rate	0.28% – 0.69%	0.28% – 0.60%

At December 31, 2016 and 2015, the estimated Level 3 fair values of the embedded conversion feature and warrant derivative liabilities measured on a recurring basis are as follows:

At December 31, 2016

	Fair value	Level 1	Level 2	Level 3	Total
Embedded conversion feature derivative liabilities	\$319,674	\$-	\$-	\$319,674	\$319,674
Warrant derivative liabilities	164,070	-	-	164,070	164,070
Total	\$483,744	\$-	\$-	\$483,744	\$483,744

At December 31, 2015

	Fair value	Level 1	Level 2	Level 3	Total
Embedded conversion feature derivative liabilities	\$301,779	\$-	\$-	\$301,779	\$301,779
Warrant derivative liabilities	432,793	-	-	432,793	432,793
Total	\$734,572	\$-	\$-	\$734,572	\$734,572

The following table presents the activity for the Level 3 embedded conversion feature and warrant derivative liabilities measured at fair value on a recurring basis for the years ended December 31, 2016 and 2015:

Warrant derivative liabilities:

Beginning balance December 31, 2014	\$-
Initial fair value of warrant derivative liability with January 2015 Non-Convertible Debenture	99,999
Initial fair value of warrant derivative liability with January 2015 Non-Convertible Debenture to Former Chief Financial Officer	49,999
Initial fair value of warrant derivative liability with the February 2014 Convertible Debentures	76,299
Change in fair value	206,496
Ending balance December 31, 2015	432,793
Reclassification of fair value of warrant derivative liability to additional paid-in capital upon cashless exercise of warrants	(518,224)

Change in fair value	249,501
Ending balance December 31, 2016	\$164,070
Embedded conversion feature derivative liabilities:	
Beginning balance December 31, 2014	\$-
Initial fair value of embedded conversion feature derivative liabilities with the Q3 2015 Notes	901,784
Change in fair Value	(600,005)
Ending balance December 31, 2015	301,779
Initial fair value of embedded conversion feature derivative liabilities with the 2016 Notes	3,444,284
Reclassification of fair value of embedded conversion feature derivative liability to additional paid-in capital upon conversions of Q3 2015 Notes	(2,018,565)
Reclassification of fair value of embedded conversion feature derivative liability to additional paid-in capital upon conversions of 2016 Notes	(1,093,263)
Change in fair value	(314,561)
Ending balance December 31, 2016	\$319,674

Table of Contents

NOTE 10 – INCOME TAXES

We are subject to taxation in the United States and California. The provision for (benefit from) income taxes for the years ended December 31, 2016 and 2015 are summarized below:

	2016	2015
Current:		
Federal	\$(800)	\$(759,428)
State	3,200	2,400
Total current	2,400	(757,028)
Deferred:		
Federal	2,552,758	(525,815)
State	650,597	(96,157)
Change in valuation allowance	(3,203,355)	621,972
Total deferred	-	-
Income tax provision (benefit)	\$2,400	\$(757,028)

As a result of the Novalere acquisition and the intangible assets acquired (see Note 3), we released \$759,428 of its deferred tax valuation allowance during the year ended December 31, 2015 which is recorded as an increase in goodwill (see Note 4) and benefit from income taxes in the accompanying consolidated statement of operations. We also recorded an impairment against this goodwill of \$759,428. At December 31, 2016, we had federal net operating loss carry forwards of approximately \$20,890,000 which may be offset against future taxable income through 2036, and a California net operating loss carryforward of approximately \$19,736,000. No net deferred tax assets are recorded at December 31, 2016 and 2015, as all deferred tax assets and liabilities have been fully offset by a valuation allowance due to the uncertainty of future utilization.

At December 31, 2016 and 2015, the approximate deferred tax assets (liabilities) consist of the following:

	2016	2015
Net operating loss carry-forwards	\$8,108,000	\$3,792,000
State taxes	1,000	1,000
Equity based instruments	374,000	1,585,000
Deferred compensation	916,000	575,000
Intangibles	-	158,000
Derivative liabilities	127,000	120,000
Other	125,000	106,000
Total deferred tax assets	9,651,000	6,337,000

Edgar Filing: INNOVUS PHARMACEUTICALS, INC. - Form 10-K

Intangibles	(1,572,000)	(1,687,000)
Warrants	(170,000)	(23,000)
Debt discount	(252,000)	(172,000)
Other	(4,000)	(5,000)
Total deferred tax liabilities	(1,998,000)	(1,887,000)
Less: valuation allowance	(7,653,000)	(4,450,000)
Net deferred tax assets	\$-	\$-

F-39

Table of Contents

At December 31, 2016 and 2015, we have recorded a full valuation allowance against its net deferred tax assets of approximately \$7,653,000 and \$4,450,000 respectively. The change in the valuation allowance during the years ended December 31, 2016 and 2015 was an increase of approximately \$3,203,000 and a decrease of approximately \$622,000, respectively, and a full valuation allowance has been recorded since, in the judgement of management, these net deferred tax assets are not more likely than not to be realized. The ultimate realization of deferred tax assets and liabilities is dependent upon the generation of future taxable income during periods in which those temporary differences and carryforwards become deductible or are utilized.

Pursuant to Section 382 of the Internal Revenue Code of 1986, the annual utilization of a company's net operating loss carryforwards could be limited if we experience a change in ownership of more than 50 percentage points within a three-year period. An ownership change occurs with respect to a corporation if it is a loss corporation on a testing date and, immediately after the close of the testing date, the percentage of stock of the corporation owned by one or more five-percent shareholders has increased by more than 50 percentage points over the lowest percentage of stock of such corporation owned by such shareholders at any time during the testing period. We do not believe such an ownership change occurred subsequent to the reverse merger transaction.

We have experienced an ownership change with regard to Semprae operating losses. Out of approximately \$19,482,000 of Federal and California NOLs as of December 24, 2013, only approximately \$44,000 per year can be used going forward for a total of approximately \$844,000 each.

We have experienced an ownership change with regard to Novalere operating losses. A study has not been completed to evaluate the impact on the utilization of those losses.

A reconciliation of the statutory federal income tax rate for the years ended December 31, 2016 and 2015 to the effective tax rate is as follows:

	2016	2015
Expected federal tax	34.00%	34.00%
State tax (net of federal benefit)	(0.02)%	(0.04)%
Contingent consideration	(3.15)%	0.94%
Fair value of embedded conversion feature in excess of allocated debt proceeds	(5.01)%	-%
Restricted stock	(7.34)%	-%
Release of valuation allowance	-%	18.10%
Other	0.86%	0.57%
Valuation allowance	(19.36)%	(35.49)%
Total	(0.02)%	18.08%

We follow FASB ASC 740-10, Uncertainty in Income Taxes. We recognize interest and penalties associated with uncertain tax positions as a component of income tax expense. We do not have any unrecognized tax benefits or a liability for uncertain tax positions at December 31, 2016 and 2015. We do not expect to have any unrecognized tax benefits within the next twelve months. We recognize accrued interest and penalties associated with uncertain tax positions, if any, as part of income tax expense. There were no tax related interest and penalties recorded for 2016 and 2015. Since we incurred net operating losses in every tax year since inception, all of its income tax returns are subject to examination and adjustments by the IRS for at least three years following the year in which the tax attributes are utilized.

NOTE 11 – COMMITMENTS AND CONTINGENCIES

Royalties and Other Obligations

As described more fully in Note 2, we have several licensing agreements which could result in substantial payments for royalties and upon the obtainment of contractual milestones, as well as, certain minimum purchase order requirements.

As described more fully in Note 3, the Novalere Stockholders are entitled to receive earn-out payments.

We have annual royalty payments in connection with the Semprae acquisition discussed in Note 3.

F-40

Table of Contents

Operating Lease

In December 2013, we entered into a lease agreement for 2,578 square feet of office space that commenced on December 10, 2013 and continues until January 31, 2019. Monthly rent at December 31, 2016 is in the amount of \$7,347, with an approximate 4% increase in the base rent amount on an annual basis.

Rent expense for the years ended December 31, 2016 and 2015 was \$88,513 and \$86,931, respectively. The following represents future annual minimum lease payments as of December 31, 2016:

2017	\$91,849
2018	95,880
2019	8,018
Total	\$195,747

Employment Agreements

We have entered into employment agreements with certain of our officers and employees which payment and benefits would become payable in the event of termination by us for any reason other than cause, or upon change in control of our Company, or by the employee for good reason.

Litigation

In the ordinary course of business, we may face various claims brought by third parties and we may, from time to time, make claims or take legal actions to assert our rights, including intellectual property disputes, contractual disputes and other commercial disputes. Any of these claims could subject us to litigation. Management believes the outcomes of currently pending claims are not likely to have a material effect on our consolidated financial position and results of operations.

Indemnities

In addition to the indemnification provisions contained in our directors and officers. These agreements require us, among other things, to indemnify the director or officer against specified expenses and liabilities, such as attorneys' fees, judgments, fines and settlements, paid by the individual in connection with any action, suit or proceeding arising out of the individual's status or service as our director or officer, other than liabilities arising from willful misconduct or conduct that is knowingly fraudulent or deliberately dishonest, and to advance expenses incurred by the individual in connection with any proceeding against the individual with respect to which the individual may be entitled to indemnification by us. We also indemnify our lessor in connection with our facility lease for certain claims arising from the use of the facilities. These indemnities do not provide for any limitation of the maximum potential future payments we could be obligated to make. Historically, we have not incurred any payments for these obligations and, therefore, no liabilities have been recorded for these indemnities in the accompanying consolidated balance sheets.

NOTE 12 – SUBSEQUENT EVENTS

We have evaluated subsequent events through the filing date of this Form 10-K and determined that no subsequent events have occurred that would require recognition in the consolidated financial statements or disclosures in the notes thereto other than as disclosed below.

In January and February 2017, we issued 1,159,023 shares of common stock to various consultants for services rendered. The fair value of the common stock issued was approximately \$321,000.

In March 2017, certain 2016 Notes holders elected to convert principal and interest of \$350,610 into 1,402,440 shares of common stock.

On January 1, 2017, the Company and CRI agreed to extend the term of the Amended CRI Asset Purchase Agreement to December 31, 2017 (see Note 2). In connection with the extension, we issued restricted shares of common stock totaling 225,000 to CRI as a prepayment of royalties due on net profit of Sensum+® in the U.S. in 2017. The royalty prepayment amount is \$45,000 as the number of shares of common stock issued was based on the closing price of our common stock on December 30, 2016. If CRI does not earn royalties larger than the prepaid amount of \$45,000 in 2017, the term of the Amended CRI Asset Purchase Agreement is automatically extended one additional year to December 31, 2018.

On January 4, 2017, we signed an employment agreement with Randy Berholtz, MBA, JD to become the Executive Vice President, Corporate Development and General Counsel of the Company. He will also become the Secretary of the Company. Mr. Berholtz began his position on January 9, 2017. Mr. Berholtz had previously been a part-time consultant for us from July 2013 to mid-May 2016. The Company and Mr. Berholtz entered into an employment agreement, effective, January 9, 2017 wherein Mr. Berholtz received RSUs covering 2,000,000 shares of our common stock; 666,666 of which will vest after one year of employment. The remaining RSU's will vest in eight equal quarterly installments over two years of continued service.

Table of Contents

On January 19, 2017, we entered into a securities purchase agreement with an unrelated third party investor in which the investor loaned us gross proceeds of \$150,000 pursuant to a 5% promissory note (“Q1 2017 Note Payable”). The note has an OID of \$15,000 and requires payment of \$165,000 in principal upon maturity. The Q1 2017 Note Payable bears interest at the rate of 5% per annum and the principal amount and interest are payable at maturity on November 18, 2017. In connection with the Q1 2017 Note Payable, we issued the investor 330,000 restricted shares of common stock.

F-42