INNOVUS PHARMACEUTICALS, INC.
Form 10-K
March 30, 2016

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, 2015

Commission file number: 000-52991

INNOVUS PHARMACEUTICALS, INC.
(Name of registrant as specified in its charter)

Nevada	90-0814124
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
9171 Towne Centre Drive, Suite 440, San Diego, CA	92122
(Address of principal executive offices)	(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 o No x

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 o No x

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 x No o

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

x No o

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. o

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

Large accelerated filer	o	Accelerated filed	¨
Non-accelerated filer	o	Smaller reporting company	x

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

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The aggregate market value of the voting common equity held by non-affiliates as of June 30, 2015, based on the closing sales price of the common stock as quoted on the OTCQB Market was $1,781,990. For purposes of this computation, all officers, directors, and 5 percent beneficial owners of the registrant are deemed to be affiliates. Such determination should not be deemed an admission that such directors, officers, or 5 percent beneficial owners are, in fact, affiliates of the registrant.

Outstanding Shares

As of March 30, 2016, the registrant had 67,553,291 shares of common stock outstanding.

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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 "we", "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®" and other trademarks and intellectual property of ours appearing 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 "may," "should," "could," "would," "expects," "plans," "bel "anticipates," "intends," "estimates," "approximates," "predicts," or "projects," or the negative or other variation of such w 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, 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 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 market directly or through commercial partners to primary care physicians, urologists, gynecologists and therapists, and directly to consumers through on-line channels, retailers and wholesalers. Our business model leverages our ability to acquire and in-license commercial products that are supported by scientific, and or clinical evidence, place them through our existing supply chain, retail and on-line channels to tap new markets and drive demand for such products and to establish physician relationships. We currently market five products in the United States and six in multiple countries around the world through our commercial partners: (1) Zestra®, a non-medicated, patented consumer care product that has been clinically proven to increase desire, arousal and satisfaction in women; (2) EjectDelay®, an over-the-counter monograph-compliant benzocaine-based topical gel for treating premature ejaculation; (3) Sensum+®, a non-medicated consumer care cream that increases penile sensitivity (ex-US); (4) Zestra Glide®, a clinically-tested, high viscosity and low osmolality water-based lubricant, (5) Vesele®, a proprietary and novel oral dietary supplement to maximize nitric oxide beneficial effects on sexual functions and brain health. Vesele® contains a patented formulation of L-Arginine and L-Citrulline in combination with the natural absorption enhancer Bioperine® and (6) Androferti® (in the US and Canada) to support overall male reproductive health and sperm quality. In addition the Company has a pipeline of three additional products including FlutiCare™ OTC for Allergic Rhinitis, if its ANDA is approved by the U.S. FDA, Urocis® XR, a proprietary extended release of Vaccinium Marcocarpon (cranberry) shown to provide 24 hour coverage in the body to increase compliance of the use of the product to get full benefit, and AndroVit®, 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.

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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, which had two commercial products in the U.S. and Canada and it became our wholly-owned subsidiary.

In February 2015, we entered into a merger agreement, whereby we acquired Novalere and its worldwide rights to the Fluticare™ brand (Fluticasone propionate nasal spray) and the related manufacturing agreement from Novalere FP. Innovus currently anticipates that the ANDA filed in November 2014 by the manufacturer with the U.S. Food and Drug Administration ("FDA") may be approved in the first half of 2016, which, when and if approved, may allow the Company to market and sell Fluticare™ over the counter. An ANDA is an application for a U.S. generic drug approval for an existing licensed medication or approved drug.

Our Strategy

Our corporate strategy focuses on two primary objectives:

1. Developing a diversified product portfolio of exclusive, unique and patented non-prescription pharmaceutical and consumer health products through: (a) the acquisition of products or obtaining exclusive rights to market such products and (b) the introduction of line extensions and reformulations of currently marketed products and

2. Building an innovative, global sales and marketing model through commercial partnerships with established complimentary partners that: (a) generates revenue and (b) requires a lower cost structure compared to traditional pharmaceutical companies.

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 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 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 of (1) Ex-U.S. rights to Sensum+® from Centric Research Institute, or CRI, (2) Zestra® and Zestra® Glide from Semprae, (3) Vesele® from Trōphikōs, (4) US and Canada rights to Androferti® from Laboratorios Q Pharma (Spain) and (5) FlutiCare® from Novalere;

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, 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. Second, we are working to expand our online presence through relationships with well-known online sellers that we believe have sufficient customers to warrant our relationship with them. 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;

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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 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 6 commercial partnerships covering our products in 28 countries outside the U.S.;

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 utilizing our integrated distribution channels, thus receiving multiple product economies of scale from our distribution partners.

Our Products

Marketed Products

We currently market five products in the United States and six in multiple countries around the world through our commercial partners: (1) Zestra®, a non-medicated, patented consumer care product that has been clinically proven to increase desire, arousal and satisfaction in women; (2) EjectDelay®, an over-the-counter monograph-compliant benzocaine-based topical gel for treating premature ejaculation; (3) Sensum+®, a non-medicated consumer care cream that increases penile sensitivity (ex-US); (4) Zestra Glide®, a clinically-tested, high viscosity and low osmolality water-based lubricant, (5) Vesele®, a proprietary and novel oral dietary supplement to maximize nitric oxide beneficial effects on sexual functions and brain health. Vesele® contains a patented formulation of L-Arginine and L-Citrulline in combination with the natural absorption enhancer Bioperine® and (6) Androferti® (in the US and Canada) to support overall male reproductive health and sperm quality. While we generate revenue from the sale of our six products, most revenue is currently generated by Zestra®, Zestra® Glide, EjectDelay® and Sensum +®.

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 retailers such as Walmart, 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. Forty-three percent (43%) of women age 18-59 experience some sort of sexual difficulties with no approved prescription products. The arousal liquid market is estimated to be around $500 million on a worldwide basis. Zestra® achieved 0.5% of the US and Canada market share in 2013.

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EjectDelay®

EjectDelay® is our proprietary, clinical proven OTC 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 billion with a 10.3% annual growth rate. (The Journal of Sexual Medicine in 2007 Sex Med 2007) Topical anesthetics make up 14% of the total PE market.

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. Users reported a ~50% increase in penile sensitivity with the use of Sensum+®.

Zestra Glide®

Zestra Glide® is a clinically-tested water-based longer lasting lubricant. We acquired Zestra Glide in our acquisition of Semprae 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 million in the U.S.

Vesele®

Vesele® is a proprietary oral supplement of Arginine with high absorption backed with strong 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. Positive effects on brain health were translated by an increase in recall of words and names.

Androferti®

Androferti® (in the US and Canada) is a proprietary supplement that supports overall male reproductive health and sperm quality and has been shown in multiple 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.

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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 OTC Abbreviated New Drug Application ("ANDA") filed at the end of 2014 by the manufacturer with the U.S. Food and Drug Administration ("FDA") which, subject to FDA approval, may allow the Company to market and sell Fluticare™ over-the-counter following an approval of the Fluticare™ brand name which requires up to six month review.. An ANDA is an application for a U.S. generic drug approval for an existing licensed medication or approved drug. 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 billion annually in the U.S.

Urocis® XR

Urocis® XR, a proprietary 24 hours extended release of Vaccinium Marcocarpon for urinary tract infection shown to provide 24 hour coverage in the body to increase compliance of the use of the product to get full benefit. The product is a high seller for Q Pharma in Europe due to its efficacy. 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% in the 7 million people in the US. Urinary tract infections typically affect post-pubescent females and the elderly.

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.

Sales and Marketing Strategy

Our sales and marketing strategy is based on (a) 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 (b) working with exclusive commercial partners outside of the U.S. that would be responsible for sales and marketing in those territories. We market and distribute our products in the U.S. through retailers, wholesalers and online channels. The Company promotes its products directly to physicians, urologists, gynecologists and therapists and to other healthcare providers through a co-promotion partnership with Consortia Health. 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 the incremental spending impact on the Company.

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 on 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. and we are looking to establish contract manufacturing for certain of our products in Europe and the Middle Eastern and Northern Africa

region 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 the Company’s products in the U.S.

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US 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 US 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 United States 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.

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.

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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 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;

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.

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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 profits, 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.

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.

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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, 2015 and 2014, we incurred research and development costs totaling $0 and $143,914, respectively.

Employees

We currently have one full-time employee, 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.

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 Related to our Business

We will need additional funding or we will be forced to curtail or cease operations. Our current cash, plus the amount available to us under the funding commitment from our President and Chief Executive Officer and from our product sales and license revenue, is anticipated to sustain operations through at least the next 12 months.

As of December 31, 2015, we had total cash of approximately $56,000, approximately $1.6 million in cash available for use under the LOC Convertible Debenture with a related party (See Note 6 to consolidated financial statements) and $83,097 in net accounts receivable. The Company expects that its existing capital resources, revenues from sales of its products and upcoming sales milestone payments from the commercial partners signed for its products, along with the funds currently available for use under the LOC Convertible Debenture and equity instruments available to pay certain vendors and consultants will be sufficient to allow the Company to continue its operations, commence the product development process and launch selected products through at least the next 12 months.

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 employees will continue to agree to this arrangement.

We currently have no other funding commitments. If Dr. Damaj were not to perform on his funding commitment, we may not have the financial resources available to pursue remedies against him and, if we do pursue remedies against him, such actions could significantly impair our relationship with Dr. Damaj, potentially leading to the loss of his services.

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We therefore will need additional funding, either through Dr. Damaj's commitment, or other sources of equity or debt financings or partnering arrangements. To the extent we raise additional capital through the sale of equity securities, the issuance of those securities could result in dilution to our shareholders. In addition, if we obtain 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.

There is no assurance that we will be successful in raising the additional funds needed to fund our business plan. If we are not able to raise sufficient capital in the near future, our continued operations will be in jeopardy and we may be forced to cease operations and sell or otherwise transfer all or substantially all of our remaining assets.

We have never been profitable and have incurred an accumulated deficit of approximately $15,434,595 as of December 31, 2015. Our ability to generate further revenue and become profitable will depend, among other things, on (1) growing the current sales of our products including Zestra®, Zestra Glide®, EjectDelay® Sensum+®, Vesele®, Fluticare™, and Androferti® (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. If we are unable to accomplish these objectives, we may be unable to generate substantial revenue or achieve profitability.

We have a short operating history and have not produced significant revenues 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 OTC healthcare products. While we have been in existence for years, we only began our current business model in 2013 and have only generated approximately $0.74 million and $1.0 million in revenue in 2015 and 2014, respectively, 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 revenues over a period of time, and may not produce significant revenues 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.

We have a history of losses which may continue and which may negatively impact our ability to achieve our business objectives.

We incurred net losses of $4.2 million and $4.8 million for the years ended December 31, 2015 and 2014, respectively. At December 31, 2015, we had an accumulated deficit of $15.4 million. We cannot assure you that we can achieve or sustain profitability on a quarterly or annual basis in the future. Our operations are subject to the risks and competition inherent in the establishment of a business enterprise. There can be no assurance that future operations will be profitable. Revenues and profits, 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.

The success of our business currently depends on the successful continuous commercialization of our five 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.

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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 or 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 $2 million in sales of our products to date. 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.

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 revenues 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.

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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.

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

Although our operations are based in the United States, we conduct business outside the United States 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 United States 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;

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. However, we may not be able to identify suitable acquisition opportunities. We may pay for acquisitions with our common stock or with convertible securities, which may dilute your investment in our common stock, or we may decide to pursue acquisitions that investors may not agree with. In connection with our latest acquisition, we have also agreed to substantial earn-out arrangements. To the extent we defer the payment of the purchase price for any acquisition through a cash earn-out arrangement, it will reduce our cash flows in subsequent periods. In addition, acquisitions 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.

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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 the size of our Company, 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, 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

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, revenues, 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.

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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.

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 United States. 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.

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 United States or in international markets; countries other than the United States may have less restrictive patent laws than those upheld by United States 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 United States 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.

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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.

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 or not merited, 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 U.S. Patent and Trademark Office 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.

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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 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 revenues from the sale of this drug and our revenues will not grow as quickly as we anticipate.

Risks Related to Owning our Common Stock

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

As detailed elsewhere in this annual report, since June 2015 we have issued approximately 26, 707,746 shares, or 39.5% of our shares outstanding as of March 30, 2016, of which approximately 13 million were issued in conjunction with our acquisition of Novalere. While substantially all of those shares were restricted securities, such shares may be sold under Rule 144 of the Securities Act of 1933, subject to any applicable holding period. As such, sales of 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 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.

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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 revenues, 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;

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 or not meritorious, 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.

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In addition, Chapter 78 of the Nevada Revised Statutes 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 the ability of our Company 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 our Company 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.

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.

Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

As of March 30, 2016, our directors, executive officers and principal stockholders (those beneficially owning in excess of 5%), and their respective affiliates, beneficially own approximately 36% of our outstanding shares of common stock. As a result, these stockholders, acting together, would have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, would have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

delaying, deferring or preventing a change in corporate control;

impeding a merger, consolidation, takeover or other business combination involving us or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

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

The SEC has adopted Rule 15g-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 receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased

In order to approve 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.

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, 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, 2015.

Item 2. Properties.

We maintain our principal office at 9171 Towne Centre Drive, Suite 440, San Diego, California 92122. Our telephone number at that office is (858) 964-5123. Our lease agreement was entered into on January 15, 2014 and extended on November 2, 2015 to expire on January 31, 2019. Our current monthly rental rate under the agreement is $7,347.

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. We maintain a website at www.innovuspharma.com and the information contained on that website is not deemed to be a part of this annual report.

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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.

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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 under the trading symbol "INNV." 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. 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.

	2015		2014	
	High	Low	High	Low
First Quarter	$ .28	$ .13	$ 0.93	$ 0.26
Second Quarter	$ .19	$ .11	$ 0.50	$ 0.24
Third Quarter	$ .16	$ .05	$ 0.50	$ 0.11
Fourth Quarter	$ .12	$ .05	$ 0.42	$ 0.15

As of March 30, 2016, we had 545 record holders of our common stock. The number of record holders does not include holders who hold their stock in "street 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

During the fiscal year ended December 31, 2015, we did not sell any unregistered securities that have not been previously reported as sales of unregistered securities 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.

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

The following information should be read in conjunction with the consolidated financial statements and notes thereto appearing elsewhere in this report.

Overview

We are an emerging 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 provide innovative and uniquely presented and packaged health solutions through our over-the-counter, ("OTC") medicines and consumer and health products, which we market directly or through commercial partners to primary care physicians, urologists, gynecologists and therapists and directly to consumers through on-line channels, retailers and wholesalers. Our business model leverages our ability to acquire and in-license commercial products that are supported by scientific and or clinical evidence, place them through our existing supply chain, retail and on-line channels to tap new markets and drive demand for such products and to establish physician relationships. We currently market five products in the United States and signed commercial agreements in 60 countries around the world through our commercial partners.

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The Company has five products in the United States and six in multiple countries around the world through our commercial partners: (1) Zestra®, a non-medicated, patented consumer care product that has been clinically proven to increase desire, arousal and satisfaction in women; (2) EjectDelay®, an over-the-counter monograph-compliant benzocaine-based topical gel for treating premature ejaculation; (3) Sensum+®, a non-medicated consumer care cream that increases penile sensitivity (ex-US); (4) Zestra Glide®, a clinically-tested, high viscosity and low osmolality water-based lubricant, (5) Vesele®, a proprietary and novel oral dietary supplement to maximize nitric oxide beneficial effects on sexual functions and brain health. Vesele® contains a patented formulation of L-Arginine and L-Citrulline in combination with the natural absorption enhancer Bioperine® and (6) Androferti® (in the US and Canada) to support overall male reproductive health and sperm quality. In addition the Company has a pipeline of three additional products including FlutiCare™ OTC for Allergic Rhinitis, if its ANDA is approved by the U.S. FDA, Urocis® XR, a proprietary extended release of Vaccinium Marcocarpon (cranberry) shown to provide 24 hour coverage in the body to increase compliance of the use of the product to get full benefit, and AndroVit®, 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.

Our Strategy

Our corporate strategy focuses on two primary objectives:

1. Developing a diversified product portfolio of exclusive, unique and patented non-prescription pharmaceutical and consumer health products through: (a) the acquisition of products or obtaining exclusive rights to market such products and (b) the introduction of line extensions and reformulations of currently marketed products and

2. Building an innovative, global sales and marketing model through commercial partnerships with established complimentary partners that: (a) generates revenue and (b) requires a lower cost structure compared to traditional pharmaceutical companies.

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.

Business Combinations

The following transactions are critical to understanding our business and financial statements.

Acquisition of Novalere

On February 5, 2015 (the "Closing Date”), the Company, 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 the Company (“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 the Company. Pursuant to the articles of merger effectuating the Merger, Merger Subsidiary II changed its name to Novalere, Inc.

With the Merger, Innovus acquired the worldwide rights to market and sell the Fluticare™ brand (Fluticasone propionate nasal spray) and the related manufacturing agreement from Novalere FP. Innovus currently anticipates that the ANDA filed in November 2014 by the manufacturer with the U.S. Food and Drug Administration ("FDA") may be approved in the first half of 2016, which, when and if approved, may allow the Company to market and sell Fluticare™ over the counter. An ANDA is an application for a U.S. generic drug approval for an existing licensed medication or approved drug.

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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.

Signing of Secured Loan Agreements and Closing of Financing

On February 24, 2016, the Company and SBI Investments, LLC, 2014-1 ("SBI") entered into a Closing Statement in which SBI loaned Innovus gross proceeds of $550,000 pursuant to a Purchase Agreement, 20% Secured Promissory Note and Security Agreement ("Note"), all dated February 19, 2016 (collectively, the "Finance Agreements"), to purchase substantially all of the assets of Beyond Human, LLC, a Texas limited liability company ("Beyond Human"). Of the $550,000 gross proceeds, $300,000 was paid into an escrow account held by a third party bank to be released to Beyond Human upon closing of the transaction, $242,500 was provided directly to Innovus for use in building the Beyond Human business and $7,500 was provided for attorneys' fees.

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

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

Results of Operations

Fiscal year Ended December 31, 2015 Compared to Fiscal year Ended December 31, 2014

Revenues

We recognized net revenues of $735,717 for the year ended December 31, 2015, compared to $1,030,113 for the year ended December 31, 2014. Revenue was generated from the acquisition of and subsequent launch of our commercial products in the U.S., as well as the launch of our products with four of our international commercial partners. The 2014 revenues included $375,000 in upfront fees related to the licensing agreements with Ovation Pharma, Orimed Pharma, and Sothema.

Cost of Product Sales

We recorded cost of product sales of $340,713 for the year ended December 31, 2015, compared to $292,080 for the year ended December 31, 2014. The cost of product sales includes the cost of inventory, shipping and royalties.

Research and Development

Research and development expenses decreased to $0 for the year ended December 31, 2015 from $143,914 for the year ended December 31, 2014. The decrease of research and development in 2015 is due to the fact that our products are commercial and on the market and do not require any further research and development.

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General and Administrative

General and administrative expenses increased by $290,871 to $4,274,616 for the year ended December 31, 2015, from $4,378,749 for the year ended December 31, 2014. There was an increase of approximately $759,000 due to an impairment of goodwill in 2015. Otherwise, general and administrative expenses decreased by 468,557 primarily due to a decrease in stock-based compensation and professional fees, offset by an increase in amortization expense associated with intangible assets. Additionally, our general and administrative expenses include professional fees, investor relations, insurance premiums, public reporting costs and general corporate expenses. We expect our general and administrative expenses to increase most notably in the area of compensation as we build our business and increase our sales and commercialization efforts of our products.

Other Income and Expense

We recognized interest expense of $1,153,376 and $532,230 for the years ended December 31, 2015 and 2014, respectively, which includes non-cash interest expense of $1,046,785 related to the amortization of the debt discounts, deferred financing fees, debt extensions and conversions in 2015 and $443,867 in 2014. This increase was primarily due to the amortization of the debt discount and deferred financing fees related to the third quarter 2015 convertible debt financing. In 2015, certain warrants and the embedded conversion feature in the convertible debentures issued in the third quarter of 2015 were classified as derivative liabilities which were required to be recorded at fair value. In connection with the change in the fair value of the derivative liabilities during 2015, we recorded a gain of $393,509. We recognized a loss from extinguishment of debt of $406,833 in 2014 related to the re-purchase and subsequent cancellation of the Lourmarin note. Also included in other expenses in 2014 is a fair value adjustment of $103,274 for the Contingent Consideration related to the re-measurement of the royalty due to the former shareholders from the Semprae acquisition and income from the same item of $115,822 in 2015.

Income Taxes

We recognized a benefit from income taxes of $757,028 during the year ended December 31, 2015 compared to $0 for the year ended December 31, 2014. 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

We recognized net losses of $4,202,628 and $4,826,967 for the years ended December 31, 2015 and 2014, respectively.

Liquidity and Capital Resources

Historically, we have funded losses from operations through the sale of equity and issuance of debt instruments, primarily to related parties including directors and officers. Combined with minimal 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 and negative cash flows from operations each year since our inception. Through December 31, 2015, we had an accumulated deficit of $15,434,595.

As of December 31, 2015, we had approximately $56,000 in cash and cash equivalents, $1.6 million in cash available for use under the LOC Convertible Debenture and $83,097 in net accounts receivable. We have raised funds through the issuance of convertible debentures and sale of common stock. We have also utilized equity instruments where possible to pay for services from vendors and consultants. Furthermore, we have an arrangement with our Chief

Executive Officer which provides for a line of credit to us and permits the deferral of salary payments as described below. Based upon these factors and arrangements we believe our cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months. We expect that our short-term operating expenses will be substantial as we continue to sell and support our products and attract and retain key personnel.

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.

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

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

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Significant borrowings include the following:

Line of Credit Convertible Debenture

In January 2013, the Company entered into a line of credit convertible debenture with its President and Chief Executive Officer (the "LOC Convertible Debenture"). Under the terms of its original issuance: (1) the Company 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 the Company completes a Financing and (4) the holder had sole discretion to determine whether or not to make an advance upon the Company's request.
On February 19, 2014, the Company agreed with the holder of the LOC Convertible Debenture to convert the then outstanding principal and interest owed as of such date into shares of the Company's common stock at a conversion price of $0.40 per share. The principal and interest amount owed under the LOC Convertible Debenture immediately prior to conversion was $476,165, which was converted into 1,190,411 shares of the Company's common stock. The debt discount of $89,452 related to the BCF for the converted portion was recorded as interest expense.

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.

During the year ended December 31, 2015, the Company borrowed $114 under the LOC Convertible Debenture and we repaid $15,000. The Company recorded a BCF of $8,3214 for the year ended December 31, 2015 and, as of December 31, 2015, the Company owed $409,192 in principal amount under this Debenture and there was approximately $1.6 million remaining on the line of credit and available to use.

Third Quarter 2015 Convertible Debentures

In the third quarter of 2015, the Company entered into Securities Purchase Agreements with three (3) accredited investors (the "Buyers"), pursuant to which the Company received aggregate gross proceeds of $1,325,000 pursuant to which it sold:

Six (6) Convertible Promissory Notes of the Company. Two in the principal amount of $275,000, one for $550,000, one for $137,500, and two for $110,000 (each a "Q3 2015 Note" and collectively the "Q3 2015 Notes") (the Q3 2015 Notes were sold at a 10% OID and the Company 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 is $1,457,500. The Q3 2015 Notes and accrued interest are convertible into shares of common stock of the Company (the "Common Stock") beginning six (6) months from the date of execution, at a conversion price of $0.15 per share, which can be adjusted as noted below. The maturity date of the first and second Q3 2015 Note is August 26, 2016. The third Q3 2015 Note has a maturity date of September 24, 2016 the fourth has a maturity date of September 26, 2016, the fifth is October 20, 2016 and the sixth is October 29, 2016. The Q3 2015 Notes bear interest on the unpaid principal amount at the rate of five percent (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 Q3 2015 Note, a "Default Amount" 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 the Company's 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 ($0.15) or (ii) 60% multiplied by the volume weighted average price of the Company's 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 apply in the event of the sale or merger of the Company, default and other defined events.

The Company may prepay 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, the Company shall not effect certain corporate and business actions during the term of the Q3 2015 Notes, although some may be done with proper notice. Pursuant to the Purchase Agreement, with certain exceptions, the Note holder has a right of participation during the term of the Q3 2015 Notes; additionally, the Company granted the Q3 2015 Note holder registration rights for the shares of common stock underlying the Q3 2015 Notes pursuant to Registration Rights Agreements.

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

1. A Common Stock Purchase Warrant to each Buyer, which allows the Buyers to purchase an aggregate of 1,320,000 shares of common stock and the placement agent to purchase 483,333 shares of common stock (aggregating 1,808,333 shares of the Company at a variable exercise price of $0.30, subject to down-round protection in case of default, and

2. 4,337,500 restricted shares of Common Stock to the Buyers.

In addition, a Registration Rights Agreement was signed and, as a result, the Company filed a Registration Statement on September 11, 2015 and filed Amended Forms S–1 on October 26, 2015, November 12, 2015 and December 10, 2015

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Sources and Uses of Cash

The Company's operations have been financed primarily through advances from officers, directors and related parties, outside capital, revenues generated from the launch of its products and commercial partnerships signed for the sale and distribution of its products domestic and internationally. These funds have provided the Company with the resources to operate its business, sell and support its products, attract and retain key personnel and add new products to its portfolio. The Company has experienced net losses and negative cash flows from operations each year since its inception. As of December 31, 2015, the Company had an accumulated deficit of $15,434,595 and a working capital deficiency of $2,184,892.

The Company has raised funds through the issuance of debt and the sale of common stock. The Company has also issued equity instruments in certain circumstances to pay for services from vendors and consultants. For the year ended December 31, 2015, the Company raised $1,505,000 in funds, which included $1,325,000 from the issuance of convertible debentures (with warrants and common stock) to three unrelated parties, $130,000 from the issuance of notes payable to two unrelated third parties and $50,000 in proceeds from the issuance of a non-convertible debt instrument to a related party. 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 buy raw material and packaging and for operations.

In the event the Company does not pay the convertible debentures upon their maturity, or after the remedy period, the principal amount and accrued interest on the note is automatically converted to common stock at a 40% discount to the market value of common stock.

The Company's actual needs will depend on numerous factors, including timing of introducing its products to the marketplace, its ability to attract additional ex-US distributors for its products and its ability to in-license in non-partnered territories and/or develop new product candidates. The Company may also seek to raise capital, debt or equity from outside sources to pay for further expansion and development of its business and to meet current obligations. Such capital may not be available to the Company when it needs it on terms acceptable to the Company, if at all.

In addition, the Company continues to seek new licensing agreements from third-party vendors to commercialize its products in territories outside the U.S., which could result in upfront, milestone, royalty and/or other payments. The Company may also seek to raise capital, debt or equity, from outside sources to pay for further expansion and development of its business and to meet current obligations. Such capital may not be available to the Company when it needs it on terms acceptable to the Company, if at all. However, the Company's actual needs will depend on numerous factors, including timing of introducing its products to the marketplace, its ability to attract additional ex-US distributors for its products and its ability to in-license in non-partnered territories and/or develop new product candidates. The Company may also seek to raise capital, debt or equity, from outside sources to pay for further expansion and development of its business and to meet current obligations. Such capital may not be available to the Company when it needs it on terms acceptable to the Company, if at all.

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 US generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses 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 the following accounting policies are critical in the preparation of our financial statements:

Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. The Company evaluates 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.

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Fair Value Measurement

The Company's financial instruments are cash, accounts receivable, accounts payable, accrued liabilities and debt. The recorded values of cash, trade accounts receivable, accounts payable and accrued liabilities approximate their fair values based on their short-term nature. The Company recorded values of convertible debentures and convertible debt, net of the discount, is based upon relative fair value calculations and the conversion feature value. The fair value of the warrant and derivative liabilities are based upon Black Scholes and Monte Carlo simulation model calculations and are a level 3 measurement. The fair value of contingent consideration is based upon the present value of expected future payments under the terms of the agreements and is a level 3 measurement.