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.

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.

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

> Level 1 measurements are quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
>
> Level 2 measurements are inputs other than quoted prices included in Level 1 that are observable either directly or indirectly.
>
> Level 3 measurements are unobservable inputs.

Revenue Recognition, Trade Receivables and Deferred Revenue

The Company generates revenues from product sales and the licensing of the rights to market and commercialize its products.

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

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

The license agreements the Company enters into normally generate three separate components of revenue: 1) an initial payment due on signing or when certain specific conditions are met; 2) royalties that are earned on an ongoing basis as sales are made or a pre-agreed transfer price and 3) milestone payments that are earned when cumulative sales reach certain levels. Revenue from the initial payments or licensing fee is recognized when all required conditions are met. Royalties are recognized as earned based on the licensee's sales. Revenue from the milestone payments is recognized when the cumulative revenue levels are reached. ASC 605-28, Milestone Method, is not used by the

Company as these milestones are sales-based and similar to a royalty and the achievement of the sales levels is neither based, in whole or in part, on the vendor's performance nor is a research or development deliverable.

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Sales Allowances

The Company accrues for product returns, volume rebates and promotional discounts in the same period the related sale is recognized.

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

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

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

Research and Development Costs

Research and development ("R&D") costs, including research performed under contract by third parties, are expensed as incurred. Major components of R&D expenses consist of testing, post marketing clinical trials, material purchases and regulatory affairs.

Stock-based Compensation

The Company accounts for stock-based compensation in accordance with ASC 718, Stock Based Compensation, which requires the recognition of the fair value of stock-based compensation as an expense in the calculation of net income. ASC 718 requires that stock-based compensation expense be based on awards that are ultimately expected to vest. Stock-based compensation for the year ended December 31, 2015 and 2014 have been reduced for estimated forfeitures. When estimating forfeitures, voluntary termination behaviors, as well as trends of actual option forfeitures, are considered. To the extent actual forfeitures differ from the Company's current estimates, cumulative adjustments to stock-based compensation expense are recorded.

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

Beneficial Conversion Features and Debt Discounts

If a conversion feature of convertible debt is not accounted for separately as a derivative instrument and provides for a rate of conversion that is below market value, this feature is characterized as a Beneficial Conversion Feature ("BCF"). A BCF is recorded by the Company as a debt discount. The Company amortizes the discount to interest expense over the life of the debt using the effective interest rate method. The Company's February 2014 Convertible Debenture and September 2014 Convertible Debenture each contain a BCF.

Recent Accounting Pronouncements

See Note 1 to our consolidated financial statements for the years ended December 31, 2015 and 2014. The adoption of recently implemented accounting rules and policies did not have any impact on our financial position, results of operations or cash flows for the years presented.

Off-Balance Sheet Arrangements

As of December 31, 2015, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K.

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Contractual Obligations

We have a three year operating lease for our corporate office facility located in San Diego, California, which requires the following payments:

	Total	2016	2017	2018	Thereafter
Operating Lease	$ 283,834	88,087	91,849	95,880	8,018

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

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

Item 8. Financial Statements and Supplementary Data.

See the consolidated financial statements commencing at page F-1 of this report.

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

The Board of Directors (the “Board”) of the Company approved the appointment of Hartley Moore Accountancy Corporation (“HMCPA") as the Company’s independent registered public accounting firm for the fiscal year ended December 31, 2015, effective January 6, 2016. In connection with the reorganization of HMCPA, its audit partners joined Hall and Company, Inc. (“Hall”) in February, 2016. HMCPA resigned as the independent auditor of the Company, effective February 15, 2016. HMCPA had been the Company’s auditor since January 6, 2016.

As a result of the above, the Board of Directors of the Company, on February 18, 2016, approved the resignation of HMCPA, effective on February 18, 2016, and the engagement of Hall as the Company’s independent registered public accounting firm for the fiscal year ended December 31, 2015, effective February 18, 2016.

The change in accountants did not result from any dissatisfaction with the quality of professional services rendered by HMCPA. The Company had not consulted with Hall for the fiscal year ended December 31, 2015 and the interim period ended February 18, 2016 regarding the application of accounting principles to any contemplated or completed transactions nor the type of audit opinion that might be rendered on the Company’s consolidated financial statements, and neither written or oral advice was provided that would be an important factor considered by the Company in reaching a decision as to accounting, auditing or financial reporting issues. There were no matters that were either the subject of a disagreement (as defined in paragraph 304(a)(1)(iv) of Regulation S-K) or a reportable event (as described in paragraph 304(a)(1)(v) of Regulation S-K).

In connection with the audit of the fiscal year ended December 31, 2015 and through February 15, 2016, there were no disagreements with HMCPA on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreements if not resolved to their satisfaction would have caused them to make reference in connection with their opinion to the subject matter of the disagreement. HMCPA have not issued any reports on the Company’s consolidated financial statements. During the Company's two most recent completed fiscal years and interim period through February 15, 2016, there were no "reportable events" as such term is described in Item 304(a)(1)(iv) of Regulation S-K with HMCPA.

EisnerAmper LLP (“Eisner”) was the Company’s independent registered public accounting firm for the fiscal years ended December 31, 2014 and 2013. During the two years ended December 31, 2014, and 2013 and through the date of their dismissal, there were (i) no disagreements (as described in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) between the Company and Eisner on any matter of accounting principles or practices, financial

statement disclosure or auditing scope or procedure which, if not resolved to Eisner's satisfaction, would have caused Eisner to make reference thereto in their reports on the consolidated financial statements for such years, and (ii) no "reportable events" within the meaning of Item 304(a)(1)(v) of Regulation S-K.

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During the year ended December 31, 2015 and the subsequent interim period through January 6, 2016, neither the Company nor anyone acting on its behalf has consulted with HMCPA regarding (i) the application of accounting principles to a specific transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's consolidated financial statements or the effectiveness of internal control over financial reporting, and neither a written report or oral advice was provided to the Company that HMCPA concluded was an important factor considered by the Company in reaching a decision as to any accounting, auditing, or financial reporting issue, (ii) any matter that was the subject of a disagreement within the meaning of Item 304(a)(1)(iv) of Regulation S-K, or (iii) any reportable event within the meaning of Item 304(a)(1)(v) of Regulation S-K.

Item 9A. Controls and Procedures.

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined under Exchange Act Rule 13a-15(e)) as of December 31, 2015. Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of December 31, 2015, these disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

Evaluation of disclosure controls and procedures.

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the Exchange Act. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Based on management's evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's report on internal control over financial reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f). Management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2015.

This annual report does not include an attestation report by our independent registered public accounting firm regarding internal control over financial reporting. As a smaller reporting company, our management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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Item 9B. Other Information.

None.

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PART III

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

The names of our executive officers and directors and their age, title, and biography as of March 30, 2016 are set forth below:

Name	Age	Title
Bassam Damaj, Ph.D.	48	President, Chief Executive Officer and Principal Financial Officer
Henry Esber, Ph.D.	77	Chairman of the Board of Directors
Vivian Liu	54	Director
Ziad Mirza, M.D.	54	Director

Directors are elected annually and hold office until the next annual meeting of the stockholders of the Company and until their successors are elected. Officers are elected annually and serve at the discretion of the Board of Directors.

Bassam Damaj, Ph.D., has served on our Board of Directors and as our President and Chief Executive Officer, since January 22, 2013. Before joining Innovus Pharma, Dr. Damaj served as President and Chief Executive Officer of Apricus Biosciences, Inc. (NASDAQ: APRI) (“Apricus Bio”) from December 2009 until November 2012. Before joining Apricus Bio, Dr. Damaj was a co-founder of Bio-Quant, Inc. and served as the Chief Executive Officer and Chief Scientific Officer and as a member of Bio-Quant’s board of directors from its inception in June 2000 until its acquisition by Apricus Bio in June 2011. In addition, Dr. Damaj was the founder, Chairman, President and Chief Executive Officer of R&D Healthcare, and the co-founder of Celltek Biotechnologies. He also served as a member of the Board of Directors of CreAgri, Inc. and was Member of the Scientific Advisory Board of MicroIslet, Inc. He is the author of the Immunological Reagents and Solutions reference book, the inventor of many patents and the author of numerous peer reviewed scientific publications. Dr. Damaj won a U.S. Congressional award for the Anthrax Multiplex Diagnostic Test in 2003. Dr. Damaj holds a Ph.D. degree in Immunology/Microbiology from Laval University and completed a postdoctoral fellowship in molecular oncology at McGill University. Dr. Damaj’s significant experience with our business and his significant executive leadership experience, including his experience leading several pharmaceutical companies, were instrumental in his selection as a member of the board of directors.

Henry Esber, Ph.D. has served as a member of our Board of Directors since January 2011 and has served as Chairman of the Board since January 18, 2013. In 2000, Dr. Esber co-founded Bio-Quant, Inc., a pre-clinical discovery contract research organization in San Diego, California. From 2000 to 2010, he served as its Senior Vice President and Chief Business Development Officer. Dr. Esber has more than 30 years of experience in the pharmaceutical service industry. Dr. Esber served on the Board of Directors of Apricus Bio from December 2009 to January 2013, and currently serves on the Board of Directors of several private pharmaceutical companies. Dr. Esber’s significant scientific background and experience was instrumental in his selection as a member of the board of directors.

Vivian Liu, has served as a member of our Board of Directors since December 2011 and served as our President, Chief Executive Officer and Chief Financial Officer from December 2011 to January 22, 2013. Prior to that, she served as the President and Chief Executive Officer of FasTrack Pharma from January 2011 to December 2011. In 1995, Ms. Liu co-founded NexMed, Inc., which in 2010 was renamed to Apricus BioSciences, Inc. (NASDAQ: APRI). Ms. Liu was NexMed’s President and Chief Executive Officer from 2007 to 2009. Prior to her appointment as President, Ms. Liu served in several executive capacities, including Executive Vice President, Chief Operating Officer, Chief Financial Officer, and Vice President of Corporate Affairs. She was appointed as a director of NexMed in 2007 and served as Chairman of its Board of Directors from 2009 to 2010. Ms. Liu has an M.P.A. from the University of Southern California and has a B.A. from the University of California, Berkeley. Ms. 'Liu’s significant

executive leadership experience, including her experience leading several pharmaceutical companies, as well as her membership on public company boards was instrumental in her selection as a member of the board of directors.

Ziad Mirza, M.D., has served as a member of our Board of Directors since December 2011, and served as Chairman of our Board of Directors from December 2011 to January 2013. He also served as FasTrack's Acting Chief Executive Officer from March 2010 to December 2010. He is the President and co-founder of Baltimore Medical and Surgical Associates. He is a Certified Medical Director of long term care through the American Medical Directors Association. He is also a Certified Physician Executive from the American College of Physician Executives. He consults for pharmaceutical companies on clinical trial design. He has a medical degree from the American University of Beirut and completed his residency at Good Samaritan Hospital in Baltimore. He received an M.B.A. from the University of Massachusetts. Dr. Mirza's significant medical and scientific background was instrumental in his selection as a member of the board of directors.

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Family Relationships

Dr. Mirza and Dr. Damaj are cousins. Otherwise, there are no family relationships among any of the members of our board of directors or our executive officers.

Board Independence

We are not a listed issuer, and therefore, under Item 407 of Regulation S-K, for purpose of determining whether our directors are independent, we are to use a definition of independence of a national securities exchange or of an inter-dealer quotation system which has requirements that a majority of the board of directors be independent, and state which definition is used. Whatever such definition we choose, we must use the same definition with respect to all directors. Our board of directors has determined that all of our current directors are independent as defined by the Nasdaq Marketplace Rules.

We are not required to have any independent members of the Board of Directors.

Meetings and Committees of the Board of Directors

During the fiscal year ended December 31, 2015, our board of directors held four meetings and approved certain actions by unanimous written consent. We expect our directors to attend all board and committee meetings and to spend the time needed and meet as frequently as necessary to properly discharge their responsibilities. Due to the limited size of our board of directors, we currently do not use board committees. As a result, the board as a whole carries out the functions of audit, nominating and compensation committees.

Involvement in Certain Legal Proceedings

Our Directors and Executive Officers have not been involved in any of the following events during the past ten years:

1. any bankruptcy petition filed by or against such person or any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;

2. any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);

3. being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining him from or otherwise limiting his involvement in any type of business, securities or banking activities or to be associated with any person practicing in banking or securities activities;

4. being found by a court of competent jurisdiction in a civil action, the Securities and Exchange Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;

5. being subject of, or a party to, any federal or state judicial or administrative order, judgment decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

6.

being subject of or party to any sanction or order, not subsequently reversed, suspended, or vacated, of any self-regulatory organization, any registered entity or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

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Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our officers and directors, and persons who own more than 10% of our common stock, to file reports of securities ownership and changes in such ownership with the SEC. Our officers and directors and persons who own more than 10% of our common stock also are required by rules promulgated by the SEC to furnish us with copies of all Section 16(a) reports they file. Based solely upon a review of the copies of such forms furnished to us and written representations from our directors and executive officers, we believe that all Section 16(a) filing requirements were timely met during the fiscal year ended December 31, 2015.

Code of Ethics

We have adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or persons performing similar functions, as well as all of our other officers, directors and employees. This code of ethics is a part of our code of business conduct and ethics, and is available on our corporate website at www.innovuspharma.com. In addition, a copy of the Code of Ethics is incorporated by reference as an exhibit.

Item 11. Executive Compensation.

The following table sets forth information concerning compensation earned for services rendered to us during the years ended December 31, 2015 and December 31, 2014 by (i) all individuals serving as our principal executive officer or acting in a similar capacity during the last completed fiscal year ("PEO"), regardless of compensation level; (ii) our two most highly compensated executive officers other than the PEO who were serving as executive officers at the end of each of the last two completed fiscal years and (iii) up to two additional individuals for whom disclosure would have been provided pursuant to clause (ii) but for the fact that the individual was not serving as an executive officer at the end of each of the last two completed fiscal years.

2014 and 2015 Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus	Stock Awards	Stock Unit Awards	All Other Compen-sation	Total
Bassam Damaj President and Chief Executive and Financial	2014	$ -(1)	$ 281,250 (2)	$ -	$ -	$ -	$ 281,250
Officer	2015	$ 106,993(1)	$ -	$ -	$ 646,500 (3)	$ -	$ 753,493
Lynnette Dillen Executive Vice President and Chief Financial	2014	$ 136,658	$ -	$ -	$ 198,000 (3)	$ -	$ 334,658
Officer (4)	2015	$ 182,560	$ -	$ -	$ 207,864 (3)	$ -	$ 390,424

(1) Pursuant to the LOC Convertible Debenture, Dr. Damaj has agreed not to draw a salary pursuant to his employment agreement for so long as payment of such salary would jeopardize the Company's ability to continue

as a going concern and not to draw any salary accrued through December 31, 2014.

(2) Restricted Stock Units issued in lieu of cash bonus.

(3) Represents the total grant date fair value, as determined under FASB ASC Topic 718, Stock Compensation, of restricted stock awards granted during the respective fiscal year.

(4) Ms. Dillen resigned as our chief financial officer and executive vice president in July, 2015

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Outstanding Equity Awards at Fiscal Year-End 2015

The following table sets forth information regarding outstanding equity awards held by our named executive officers at the end of fiscal 2015:

Name	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#)	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested ($)
Bassam Damaj	1,875,000	$ 131,250

Employment Agreements

Dr. Bassam Damaj

On January 22, 2013, the Company entered into an employment agreement (the "Employment Agreement") with Dr. Bassam Damaj ("Damaj") to serve as its President and Chief Executive Officer, which was amended on January 21, 2015.

The Employment Agreement has an initial term of five years, which term will be extended by an additional year on the fourth and each subsequent anniversary. Dr. Damaj earned a base salary of $375,000 for the first year, $440,000 in the second year and increasing a minimum of 10% per year thereafter. Dr. Damaj's salary will be accrued and not paid for so long as payment of such salary would jeopardize the Company's ability to continue as a going concern, in Dr. Damaj's sole determination. Damaj will have annual cash bonus targets equal to 75% and 30%, respectively, of base salary, based on performance objectives established by the board of directors, with the board of directors determining the amount of the annual bonus.

Damaj received a restricted stock unit grant of 6,000,000 shares of common stock on January 22, 2013, of which 2,000,000 shares vested immediately, and the remaining 4,000,000 shares vested in eight equal quarterly installments beginning on April 1, 2013.

Upon termination of the Employment Agreement for any reason, Damaj will receive (i) a pro-rata bonus during that fiscal year based on the number of days employed during that fiscal year and (ii) Company group medical, dental and vision insurance coverage for such Executive and their dependents for 12 months paid by the Company.

Pursuant to the Employment Agreement, if Damaj's employment is terminated as a result of death, disability or without Cause (as defined in the Employment Agreement) or Executive resigns for Good Reason (as defined in the Employment Agreement), Executive or their estate, as applicable, is entitled to the following payments and benefits, provided that a mutual release of claims is executed: (1) a cash payment in an amount equal to 1.5 times his then base salary and annual target bonus amount, or two times his then base salary and annual target bonus amount if such termination occurs within 24 months of a change of control; (2) Company group medical, dental and vision insurance coverage for Executive and his dependents for 24 months paid by the Company and (3) the automatic acceleration of the vesting and exercisability of outstanding unvested stock awards.

Director Compensation

The following table sets forth summary information concerning the total compensation paid to our non-employee directors in 2015 for services to our company.

Name	Fees Earned or Paid in Cash	Stock Awards	Stock Unit Awards	Total
Henry Esber	$-	$-	$64,833	$64,833
Vivian Liu	-	-	52,833	52,833
Ziad Mirza	-	-	52,833	52,833
Total:	$-	$-	$170,499	$170,499

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

The following table sets forth certain information regarding beneficial ownership of our common stock as of March 30, 2016 (the "Evaluation Date") by (a) each person known to us to beneficially own more than 5% of the outstanding shares of our common stock, (b) each director, (c) each of the named executive officers listed in the compensation tables included in this and (d) all of our current directors and executive officers as a group. Percent of beneficial ownership is based on 67,553,291 shares of our common stock outstanding as of the Evaluation Date.

NAME OF OWNER (1)	SHARES BENEFICIALLY OWNED (2)		PERCENTAGE OF COMMON STOCK (3)	
5% Stockholders				
Novalere Holdings LLC 199 Wells Ave, Suite 208 Newton, MA 02459	12,808,796		19.0	%
Directors and Named Executive Officers:				
Bassam Damaj	19,828,347		29.4	%
Lynnette Dillen – Former CFO	1,600,000		2.4	%
Henry Esber	3,677,097	(4)	5.5	%
Vivian Liu	889,683		1.3	%
Ziad Mirza	417,947		0.6	%
Officers and Directors as a Group (5 persons)	26,413,074		39.2	%

(1) Unless otherwise indicated in the footnotes to the following table, each person named in the table has sole voting and investment power and that person's address is c/o Innovus Pharmaceuticals, Inc., 9171 Towne Centre Drive, Suite 440, San Diego, California 92122.

(2) Beneficial Ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock subject to options or warrants currently exercisable or convertible, or exercisable or convertible within 60 days of March 30, 2016 are deemed outstanding for computing the percentage of the person holding such option or warrant but are not deemed outstanding for computing the percentage of any other person.

(3) Percentage based upon 67,553,291 shares of common stock issued and outstanding as of March 30, 2016.

(4) Includes 384,108 shares held by his spouse.

Equity Compensation Plan Information

The following table provides information as of December 31, 2015 regarding our equity compensation plans. We do not have any equity compensation plans that have been approved by our stockholders.

Plan Category	Number of Securities to be Issued Upon	Weighted-Average Exercise Price of Outstanding Options,	Number of Securities Remaining Available for

	exercise of Outstanding Options, Warrants and Rights	Warrants and Rights of	Future Issuance Under Equity Compensation Plans (excluding securities reflected in column(a))
	(a)	(b)	(c)
Equity Compensation Plans Not Approved by Security Holders:			
2013 Equity Incentive Plan	8,704,736	-	995,264
2014 Equity Incentive Plan	8,850,000	-	10,950,000
Total	17,554,736	-	11,945,264

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

Other than the following transactions and the transactions described under "Item 11. Executive Compensation" above, since January 1, 2014, there has not been, nor currently are there proposed, any transactions or series of similar transactions in which we were or are to be a participant and the amount involved exceeds or will exceed the lesser of $120,000 or 1% of the average of our total assets as of December 31, 2015 and 2014, and in which any of our directors, executive officers, holders of more than 5% of our common stock or any member of the immediate family of any of the foregoing persons, had or will have a direct or indirect material interest.

Related Party Financings

We have raised capital in various financing transactions in which related parties have been involved, and we have issued our securities to those related parties. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operation—Business Combinations and Recent Financings—Recent Financings," above.

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The table below sets forth the principal amount of the related party debt we issued in January 2012 to related parties and the number of shares of our common stock we issued to such related parties upon conversion of such debentures in February 2014, or indebtedness that remains outstanding at December 31, 2015.

	Outstanding Principal and Interest at date of conversion or repayment	Common Stock Issued on date of conversion	Original Principal Amount (in U.S. dollars)
Related Party Debt amount Converted during 2014:			
Line of Credit			
Bassam Damaj, President and Chief Executive and Principal Financial Officer	$ 476,165	1,190,411	$ 452,728
January 2012 Debentures:			
Vivian Liu, Board Member	$ 58,405	146,014	$ 50,000
Ziad Mirza, Board Member	$ 5,841	14,601	$ 5,000
Henry Esber, PhD., Chairman of the Board	$ 15,185	31,964	$ 13,000
January 2013 Debenture:			
Henry Esber, PhD., Chairman of the Board	$ 76,122	190,304	70,000
Related Party Debt Converted or Repaid during 2015:			
Line of Credit			
Bassam Damaj, President and Chief Executive and Principal Financial Officer - Repaid	$ 15,000	N/A	$ N/A
Notes Payable:			
Lynnette Dillen, former Executive Vice President and Chief Financial Officer - Repaid	$ 50,000	-	$ 50,000
Henry Esber, PhD., Chairman of the Board - Converted	$ 75,000	468,750	$ 75,000
Related Party Debt Received and Repaid during 2015:			
Notes Payable:			
Lynnette Dillen, former Executive Vice President and Chief Financial Officer - Repaid	$ 50,000	-	$ 50,000
Outstanding at December 31, 2015			
Line of credit:			

Bassam Damaj, President and Chief Executive and Principal Financial Officer	$ -	$ -	$ 409,192
Notes Payable:			
Bassam Damaj, President and Chief Executive Officer	$ -	$ -	$ 25,000

Dr. Damaj, our President, Chief Executive and Principle Financial Officer, is the holder of the LOC Convertible Debenture.

During 2015 and 2014, the Company borrowed approximately $50,000 and $574,000, respectively, from related parties. The Company recognized total interest expense on related party financings, including amortization of the discount, of $69,634 and $203,400 for the years ended December 31, 2015 and 2014, respectively. At December 31, 2014, there was an aggregate of $574,078 in related party financings, classified as long-term liabilities since such parties have agreed not to require repayment prior to April 2016.

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Item 14. Principal Accounting Fees and Services.

On January 6, 2016, the Company dismissed EisnerAmper LLP as our independent registered public accounting firm and appointed Hartley Moore Accountancy Corporation as our independent registered public accounting firm for the year ended December 31, 2015. Effective February 16, 2016, the audit partners at Hartley Moore Accountancy Corporation joined Hall & Company, Inc. and Hartley Moore Accountancy Corporation resigned as the independent auditor of the Company, effective February 15, 2016. The Company appointed Hall & Company, Inc. as our independent registered public accounting firm for the year ended December 31, 2015 and Hall & Company, Inc. has audited our consolidated financial statements for the year ended December 31, 2015.

The following table presents the aggregate fees for the periods presented for professional services rendered to us by Hall & Company, Inc, Hartley Moore Accountancy Corporation, and EisnerAmper LLP:

	Hall & Company 2015	Hartley Moore 2015	EisnerAmper 2015	EisnerAmper 2014
Audit Fees (1)	$ 11,200	$ 5,000	$ 95,470	$ 89,700

(1) "Audit Fees" represent fees for professional services provided in connection with the audit of our annual financial statements, review of financial statements included in our quarterly reports and related services normally provided in connection with statutory and regulatory filings and engagements by EisnerAmper LLP, Hartley Moore Accountancy Corporation and Hall & Company, Inc.

The Board of Directors has considered whether the provision of non-audit services is compatible with maintaining the principal accountant's independence.

Item 15. Exhibits, Financial Statement Schedules.

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

(1) Financial Statements:

Report of Hall and Company, Independent Registered Public Accounting Firm

Report of EisnerAmper, LLP, Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2015 and 2014

Consolidated Statements of Operations for the Years Ended December 31, 2015 and 2014

Consolidated Statements of Stockholders' Deficit for the Years Ended December 31, 2015 and 2014

Consolidated Statements of Cash Flows for the Years Ended December 31, 2015 and 2014

Notes to Consolidated Financial Statements

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

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

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

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

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Signatures

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

Date: March 30, 2016	Innovus Pharmaceuticals, Inc.	
	By:	/s/ Bassam Damaj Bassam Damaj President and Chief Executive Officer (principal executive officer)

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

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

Signature	Title	Date
/s/ Henry Esber Henry Esber, Ph.D.	Chairman of the Board	March 30, 2016
/s/ Bassam Damaj Bassam Damaj, Ph.D.	Director, President, Chief Executive Officer (principal executive officer) and Principal Financial and Accounting Officer	March 30, 2016
/s/ Ziad Mirza Ziad Mirza, M.D.	Director	March 30, 2016
/s/ Vivian Liu Vivian Liu	Director	March 30, 2016

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INDEX TO EXHIBITS

Exhibit No.	Description
2.1	Merger Agreement and Plan of Merger, dated as of July 13, 2011, by and among FasTrack, Inc., a Delaware corporation, North Horizon, Inc., a Nevada corporation and North First General, Inc., a Utah corporation, a wholly-owned subsidiary of North Horizon, Inc. filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on July 20, 2011 and incorporated herein by reference.
2.2	Asset Purchase Agreement dated April 19, 2013, between Innovus Pharmaceuticals, Inc. and Centric Research Institute, Inc. filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on April 24, 2013 and incorporated herein by reference.
2.3	Agreement and Plan of Merger, made as of December 24, 2013, by and among Innovus Pharmaceuticals, Inc., Innovus Acquisition Corporation, Semprae Laboratories, Inc., the major stockholders of Semprae Laboratories, Inc. party thereto and Quaker Bioventures II, L.P., as principal stockholder of Semprae Laboratories, Inc., filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on December 30, 2013 and incorporated herein by reference.
2.4	Agreement and Plan of Merger, dated February 4, 2015, by and among Innovus Pharmaceuticals, Inc., Innovus Pharma Acquisition Corporation, Innovus Pharma Acquisition Corporation II, Novalere FP, Inc. and Novalere Holdings, LLC, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on February 5, 2015 and incorporated herein by reference.
3.1	Articles of Incorporation of the Registrant as filed with the Office of the Secretary of State of the State of Nevada on July 23, 2007, filed as an exhibit to the Registrant's amended registration statement on Form 10-SB12G/A, filed with the SEC on December 28, 2007 and incorporated herein by reference.
3.2	Bylaws of the Registrant, filed as an exhibit to the Registrant's amended registration statement on Form 10-SB12G/A, filed with the SEC on December 28, 2007 and incorporated herein by reference.
3.3	Certificate of Amendment to Articles of Incorporation of the Registrant as filed with the Office of the Secretary of State of the State of Nevada on October 13, 2011 changing the Registrant's name from North Horizon, Inc., a Nevada corporation to Innovus Pharmaceuticals, Inc., a Nevada corporation, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on December 12, 2011 and incorporated herein by reference.
3.4	Certificate of Correction to the Company's Articles of Incorporation, dated July 30, 2013, filed with the Secretary of State for the State of Nevada, filed as an exhibit to the Registrant's annual report on Form 10-K, filed with the SEC on March 28, 2014 and incorporated herein by reference.
10.1	Form of Equity Unit Agreement dated May 15, 2013, between Innovus Pharmaceuticals, Inc. and an individual accredited investor, filed as an exhibit to the Registrant's quarterly report on Form 10-Q, filed with the SEC on August 13, 2013 and incorporated herein by reference.
10.2	Form of Amendment to 8% Convertible Debenture, dated May 4, 2013, filed as an exhibit to the Registrant's quarterly report on Form 10-Q, filed with the SEC on August 13, 2013 and incorporated herein by reference
10.3	Form of Amended and Restated 8% Convertible Debenture, dated November 11, 2013, between Innovus Pharmaceuticals, Inc. and debenture holders, filed as an exhibit to the Registrant's quarterly report on Form 10-Q, filed with the SEC on November 14, 2013 and incorporated herein by reference.
10.4	Form of Amended and Restated 8% Convertible Debenture Conversion Letter Agreement, dated February 19, 2014, filed as an exhibit to the Registrant's annual report on Form 10-K, filed with the SEC on March 28, 2014 and incorporated herein by reference.
10.5	Employment Agreement, dated January 22, 2013, between Innovus Pharmaceuticals, Inc. and Bassam Damaj, Ph.D., filed as an exhibit to the Registrant's annual report on Form 10-K, filed with the SEC on

March 19, 2013 and incorporated herein by reference.

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10.6	2013 Equity Incentive Plan of the Registrant, effective February 15, 2013, filed as an exhibit to the Registrant's registration statement on Form S-8, filed with the SEC on February 15, 2013 and incorporated herein by reference.
10.7	Form of Restricted Stock Agreement under the Registrant's 2013 Equity Incentive Plan, effective February 15, 2013, filed as an exhibit to the Registrant's registration statement on Form S-8, filed with the SEC on February 15, 2013 and incorporated herein by reference.
10.8	Form of Stock Unit Agreement under the Registrant's 2013 Equity Incentive Plan, effective February 15, 2013, filed as an exhibit to the Registrant's registration statement on Form S-8, filed with the SEC on February 15, 2013 and incorporated herein by reference.
10.9	Form of Nonstatutory Stock Option Agreement under the Registrant's 2013 Equity Incentive Plan, effective February 15, 2013, filed as an exhibit to the Registrant's registration statement on Form S-8, filed with the SEC on February 15, 2013 and incorporated herein by reference.
10.10	Form of Incentive Stock Option Agreement under the Registrant's 2013 Equity Incentive Plan, effective February 15, 2013, filed as an exhibit to the Registrant's registration statement on Form S-8, filed with the SEC on February 15, 2013 and incorporated herein by reference.
10.11	8% Convertible Debenture, dated January 22, 2013 between Innovus Pharmaceuticals, Inc. and Bassam Damaj, Ph.D., filed as an exhibit to the Registrant's annual report on Form 10-K, filed with the SEC on March 19, 2013 and incorporated herein by reference.
10.12	Amended and Restated 8% Convertible Debenture, dated March 18, 2013 between Innovus Pharmaceuticals, Inc. and Bassam Damaj, Ph.D., filed as an exhibit to the Registrant's annual report on Form 10-K, filed with the SEC on March 19, 2013 and incorporated herein by reference.
10.13	Amendment to Amended and Restated 8% Convertible Debenture, dated May 6, 2013 between Innovus Pharmaceuticals, Inc. and Bassam Damaj, Ph.D., filed as an exhibit to the Registrant's quarterly report on Form 10-Q, filed with the SEC on August 13, 2013 and incorporated herein by reference.
10.14	Amended and Restated 8% Convertible Debenture, dated November 11, 2013, between Innovus Pharmaceuticals, Inc. and Bassam Damaj, Ph.D., filed as an exhibit to the Registrant's quarterly report on Form 10-Q, filed with the SEC on November 14, 2013 and incorporated herein by reference.
10.15	Amendment to Second Amended and Restated 8% Convertible Debenture by and between the Company and Dr. Bassam Damaj, dated February 19, 2014, filed as an exhibit to the Registrant's annual report on Form 10-K, filed with the SEC on March 28, 2014 and incorporated herein by reference.
10.16	Offer Letter, dated May 24, 2013, between Innovus Pharmaceuticals, Inc. and Morgan Brown, filed as an exhibit to the Registrant's quarterly report on Form 10-Q, filed with the SEC on August 13, 2013 and incorporated herein by reference.
10.17	Change in Control and Severance Agreement, dated August 9, 2013 between Innovus Pharmaceuticals, Inc. and Morgan Brown, filed as an exhibit to the Registrant's quarterly report on Form 10-Q, filed with the SEC on August 13, 2013 and incorporated herein by reference.
10.18	Form of Officer and Director Indemnification Agreement, dated June 2013, filed as an exhibit to the Registrant's quarterly report on Form 10-Q, filed with

	the SEC on August 13, 2013 and incorporated herein by reference.
10.19	Subscription Agreement, dated June 12, 2013 between Innovus Pharmaceuticals, Inc. and the investor parties thereto, filed as an exhibit to the Registrant's quarterly report on Form 10-Q, filed with the SEC on August 13, 2013 and incorporated herein by reference.
10.20#	Amended and Restated Innovus Pharmaceuticals, Inc. Non-Employee Director Compensation Plan, dated October 1, 2013, filed as an exhibit to the Registrant's quarterly report on Form 10-Q, filed with the SEC on November 14, 2013 and incorporated herein by reference.

10.21	Amended and Restated 8% Convertible Debenture, dated November 11, 2013, between Innovus Pharmaceuticals, Inc. and Henry Esber, Ph.D., filed as an exhibit to the Registrant's quarterly report on Form 10-Q, filed with the SEC on November 14, 2013 and incorporated herein by reference.
10.22	Amended and Restated 8% Convertible Debenture Conversion Letter Agreement with Dr. Henry Esber, Ph.D., dated February 19, 2014, filed as an exhibit to the Registrant's annual report on Form 10-K, filed with the SEC on March 28, 2014 and incorporated herein by reference.
10.23	8% Debenture issued by Innovus Pharmaceuticals, Inc. on December 23, 2013, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on December 30, 2013 and incorporated herein by reference.
10.24#	Offer Letter, dated February 6, 2014, between Innovus Pharmaceuticals, Inc. and Lynnette Dillen, filed as an exhibit to the Registrant's annual report on Form 10-K, filed with the SEC on March 28, 2014 and incorporated here by references.
10.25	Securities Purchase Agreement, dated February 13, 2014 between Innovus Pharmaceuticals, Inc. and the investor party thereto, filed as an exhibit to the Registrant's annual report on Form 10-K, filed with the SEC on March 28, 2014 and incorporated herein by reference.
10.26	Original Issue Discount 10.0% Convertible Debenture issued on February 13, 2014, filed as an exhibit to the Registrant's annual report on Form 10-K, filed with the SEC on March 28, 2014 and incorporated herein by reference.
10.27	Common Stock Purchase Warrant, dated February 13, 2014, filed as an exhibit to the Registrant's annual report on Form 10-K, filed with the SEC on March 28, 2014 and incorporated herein by reference.
10.28	Third Amended and Restated 8% Convertible Debenture, by and between the Company and Dr. Bassam Damaj, dated July 22, 2014, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on July 23, 2014 and incorporated herein by reference.
10.29	8% Debenture between the Company and Dr. Henry Esber, Ph.D., dated May 30, 2014, filed as an exhibit to the Registrant's quarterly report on Form 10-Q, filed with the SEC on August 14, 2014 and incorporated herein by reference.
10.30	8% Debenture between the Company and Lynnette Dillen, dated June 17, 2014, filed as an exhibit to the Registrant's quarterly report on Form 10-Q, filed with the SEC on August 14, 2014 and incorporated herein by reference.
10.31	Debt Exchange Agreement, between Innovus Pharmaceuticals, Inc. and Blackbridge Capital, LLC, dated September 15, 2014, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on September 18, 2014 and incorporated herein by reference.
10.32	Innovus Pharmaceuticals, Inc. 2014 Equity Incentive Plan, filed as an exhibit to the registration statement on Form S-8, filed with the SEC on January 2, 2015 and incorporated herein by reference.
10.33	Form of Securities Purchase Agreement between the Company and Vista Capital Investments, LLC, dated January 21, 2015, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on January 23, 2015 and incorporated herein by reference.
10.34	Form of Securities Purchase Agreement between the Company and Lynnette Dillen, dated January 21, 2015, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on January 23, 2015 and incorporated

herein by reference.

10.35	Form of Promissory Note between the Company and Vista Capital Investments, LLC, dated January 21, 2015, filed as an exhibit to the Registrant’s current report on Form 8-K, filed with the SEC on January 23, 2015 and incorporated herein by reference.
10.36	Form of Promissory Note between the Company and Lynnette Dillen, dated January 21, 2015, filed as an exhibit to the Registrant’s current report on Form 8-K, filed with the SEC on January 23, 2015 and incorporated herein by reference.
10.37	Form of Warrant between the Company and Vista Capital Investments, LLC, dated January 21, 2015, filed as an exhibit to the Registrant’s current report on Form 8-K, filed with the SEC on January 23, 2015 and incorporated herein by reference.
10.38	Form of Warrant between the Company and Lynnette Dillen, dated January 21, 2015, filed as an exhibit to the Registrant’s current report on Form 8-K, filed with the SEC on January 23, 2015 and incorporated herein by reference.
10.39	Form of Warrant Amendment between the Company and Vista Capital Investments, LLC, dated January 21, 2015, filed as an exhibit to the Registrant’s current report on Form 8-K, filed with the SEC on January 23, 2015 and incorporated herein by reference.
10.40	Form of Warrant Amendment between the Company and Lynnette Dillen, dated January 21, 2015, filed as an exhibit to the Registrant’s current report on Form 8-K, filed with the SEC on January 23, 2015 and incorporated herein by reference.
10.41#	Employment Agreement, between Innovus Pharmaceuticals, Inc. and Lynnette Dillen, dated January 21, 2015, filed as an exhibit to the Registrant’s current report on Form 8-K, filed with the SEC on January 23, 2015 and incorporated herein by reference.
10.42#	Employment Agreement Amendment, between Innovus Pharmaceuticals, Inc. and Bassam Damaj, dated January 21, 2015, filed as an exhibit to the Registrant’s current report on Form 8-K, filed with the SEC on January 23, 2015 and incorporated herein by reference.
10.43	Registration Rights and Stock Restriction Agreement, dated February 4, 2015, by and between Innovus Pharmaceuticals, Inc., and Novalere Holdings, LLC, filed as an exhibit to the Registrant’s current report on Form 8-K, filed with the SEC on February 5, 2015 and incorporated herein by reference.
10.44	Voting Agreement, dated February 4, 2015, by and between Innovus Pharmaceuticals, Inc., and Novalere Holdings, LLC, filed as an exhibit to the Registrant’s current report on Form 8-K, filed with the SEC on February 5, 2015 and incorporated herein by reference.
10.45	Agreement, dated March 12, 2015, by and between Innovus Pharmaceuticals, Inc. and Gemini Master Fund, Ltd., filed as an exhibit to the Registrant’s current report on Form 8-K, filed with the SEC on March 16, 2015 and incorporated herein by reference.
10.46	Form of Amended and Restated Warrant, issued March 12, 2015 to Gemini Master Fund, Ltd., filed as an exhibit to the Registrant’s current report on Form 8-K, filed with the SEC on March 16, 2015 and incorporated herein by reference.
10.47	Blackbridge Convertible Promissory Note, dated September 29, 2014, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on October 3, 2014 and incorporated herein by reference.
10.48	Vista Note Amendment, dated July 30, 2015, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on August 3, 2015 and incorporated herein by reference.
10.49	Form of Securities Purchase Agreement, dated July 15, 2015, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on August 3, 2015 and incorporated herein by reference.
10.50	Form of Convertible Promissory Note, dated July 15, 2015, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on August 3, 2015 and incorporated herein by reference.
10.51	

	Form of Common Stock Purchase Warrant Agreement, dated July 15, 2015, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on August 3, 2015 and incorporated herein by reference.
10.52	Form of Registration Rights Agreement, dated July 15, 2015, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on August 3, 2015 and incorporated herein by reference.
10.53	Share Issuance Agreement, dated July 27, 2015, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on August 3, 2015 and incorporated herein by reference.
10.54	Form of Securities Purchase Agreement, dated August 25, 2015, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on September 2, 2015 and incorporated herein by reference.

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10.55	Form of Convertible Promissory Note, dated August 25, 2015, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on September 2, 2015 and incorporated herein by reference.
10.56	Form of Common Stock Purchase Warrant Agreement, dated August 25, 2015, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on September 2, 2015 and incorporated herein by reference.
10.57	Form of Registration Rights Agreement, dated August 25, 2015, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on September 2, 2015 and incorporated herein by reference.
10.58	Form of Share Issuance Agreement, dated August 27, 2015, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on September 2, 2015 and incorporated herein by reference.
10.59	Form of Purchase Agreement, dated February 19, 2016, by and among the Company and SBI Investments, LLC 2014-1, filed as an exhibit to the Registrant’s report on Form 8-K with the SEC on March 1, 2016 and incorporated herein by reference.
10.60	20% Secured Promissory Note, dated February 19, 2016 by and among the Company ad SGI Investments, LLC 2014-1, filed as an exhibit to the Registrant’s report of Form 8-K with the SEC on March 1, 2016 and incorporated herein by reference.
10.61	Security Agreement, dated February 19, 2016 by and among the Company and SGU Investments, LLC 2014-1, filed as an exhibit to the Registrant’s report of Form 8-K with the SEC on March 1, 2016 and incorporated herein by reference.
14.1*	Code of Ethics.
21.1*	List of Subsidiaries
23.1*	Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm.
23.2*	Consent of Hall and Company, Independent Registered Public Accounting Firm.
24.1	Power of Attorney, included as part of signature page to this report.
31.1*	Certification of the Registrant’s Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of the Registrant’s Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of the Registrant’s Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. SS. 1350, as adopted pursuant to Section. 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
*	Filed herewith
#	Management contract or compensatory plan

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Innovus Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of Innovus Pharmaceuticals, Inc. (the “Company”) as of December 31, 2014, and the related consolidated statements of operations, changes in stockholders’ equity (deficit) and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2014, and the consolidated results of its operations and its cash flows for the year ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1 to the consolidated financial statements, the Company’s President and Chief Executive Officer, who is also a major shareholder, has deferred the payment of his salary and provided a line of credit to the Company. The Company's liquidity and financing plans are also described in Note 1.

/s/ EisnerAmper LLP
March 31, 2015
Iselin, New Jersey

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Innovus Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of Innovus Pharmaceuticals, Inc. (the “Company”) as of December 31, 2015, and the related statements of operations, stockholders’ deficit, and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2015, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ HALL & COMPANY Certified Public Accountants & Consultants, Inc.

Irvine, CA
March 30, 2016

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INNOVUS PHARMACEUTICALS, INC.
Consolidated Balance Sheets

	As of December 31, 2015	2014
ASSETS		
CURRENT ASSETS		
Cash	$ 55,901	$ 7,479
Accounts receivable, net	83,097	191,601
Prepaid expenses	53,278	55,024
Deferred financing costs, net	97,577	-
Inventories	254,443	265,959
Total Current Assets	544,296	520,063
PROPERTY AND EQUIPMENT, NET	35,101	54,511
OTHER ASSETS		
Security deposits	14,958	21,919
Goodwill	549,368	429,225
Intangible assets, net	5,300,859	1,055,372
TOTAL ASSETS	$ 6,444,582	$ 2,081,090
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 691,365	$ 362,160
Deferred revenue and customer deposits	24,079	25,224
Accrued interest payable	79,113	52,568
Short-term loans payable	230,351	-
Derivative liabilities – embedded conversion feature	301,779	-
Derivative liabilities – warrants	432,793	-
Current portion of notes payable and convertible debentures, net of debt discount of $55,982 in 2014	73,200	314,018
Line of credit convertible debenture and non-convertible debenture – related parties, net of debt discount of $17,720 in 2015	391,472	-
Convertible debentures, net of debt discount of $952,464 in 2015	505,036	-
Total Current Liabilities	2,729,188	753,970
NON-CURRENT LIABILITIES		
Accrued compensation – less current portion	906,928	906,928
Notes payable and convertible debentures, net of current portion and debt discount of $67,726 in 2014	-	24,274
Line of credit convertible debenture and non-convertible debentures – related parties, net of current portion and debt discount of $0 in 2015 and $76,492 in 2014	25,000	497,586
Contingent consideration	3,229,804	324,379
Total Non-Current Liabilities	4,161,732	1,753,167

TOTAL LIABILITIES	6,890,920	2,507,137
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' DEFICIT		
Common stock: 150,000,000 shares authorized, at $0.001 par value, 47,141,230 and 27,112,263 shares issued and outstanding, respectively	47,141	27,113
Additional paid-in capital	14,941,116	10,778,807
Accumulated deficit	(15,434,595)	(11,231,967)
Total Stockholders' Deficit	(446,338)	(426,047)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 6,444,582	$ 2,081,090

See accompanying notes to these consolidated financial statements.

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INNOVUS PHARMACEUTICALS, INC.
Consolidated Statements of Operations

	For the Year Ended December 31,	
	2015	2014
NET REVENUES:		
License revenues	$ 5,000	$ 375,000
Product sales, net	730,717	655,113
Net Revenues	735,717	1,030,113
OPERATING EXPENSES:		
Cost of product sales	340,713	292,080
Research and development	-	143,914
General and administrative	3,910,192	4,378,749
Impairment of Goodwill	759,428	-
Total Operating Expenses	5,010,333	4,814,743
LOSS FROM OPERATIONS	(4,274,616)	(3,784,630)
OTHER INCOME AND (EXPENSES)		
Interest expense	(1,153,376)	(532,230)
Change in fair value of derivative liabilities	393,509	-
Other expense, net	(8,495)	-
Fair value adjustment for contingent consideration	115,822	(103,274)
Loss on extinguishment of debt	(32,500)	(406,833)
Total Other Expense, Net	(685,040)	(1,042,337)
LOSS BEFORE BENEFIT FROM INCOME TAXES	(4,959,656)	(4,826,967)
Benefit from income taxes	(757,028)	-
NET LOSS	$ (4,202,628)	$ (4,826,967)
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ (0.08)	$ (0.20)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK OUTSTANDING – BASIC AND DILUTED	52,517,530	24,384,037

See accompanying notes to these consolidated financial statements.

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INNOVUS PHARMACEUTICALS, INC.
Consolidated Statements of Cash Flows

	For the Year Ended December 31,	
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES		
NET LOSS	$ (4,202,628)	$ (4,826,967)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	28,950	63,450
Allowance for doubtful accounts	5,892	-
Common stock, restricted stock units and stock options issued for services and board compensation	1,508,769	2,258,068
Gain of purchase price adjustment to goodwill	(759,428)	
Impairment of goodwill	759,428	
Loss on extinguishment of debt	32,500	406,833
Change in fair value of contingent consideration	(115,822)	103,274
Change in fair value of derivative liabilities	(393,509)	-
Amortization of deferred financing costs	53,342	-
Shares of common stock issued for debt amendment	15,500	-
Fair value of embedded conversion feature in convertible debentures in excess of allocated proceeds	71,224	-
Amortization of debt discount	906,719	443,867
Amortization of intangible assets	550,789	114,006
Changes in operating assets and liabilities, net of acquisition amounts		
Accounts receivable	102,612	25,040
Prepaid expenses	27,653	(20,752)
Security deposits	6,961	22,200
Inventories	11,516	(88,108)
Accounts payable and accrued expenses	329,205	721,811
Accrued interest payable	29,745	86,353
Deferred revenue and customer deposits	(1,145)	(150,345)
Net Cash Used In Operating Activities	(1,031,727)	(841,270)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property & equipment	(9,540)	(38,989)
Purchase of intangible assets	(3,276)	(22,545)
Net Cash Used In Investing Activities	(12,816)	(61,534)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net proceeds from (repayments of) line of credit convertible debenture – related party	(14,886)	424,078
Proceeds from convertible debentures	1,325,000	50,000
Fees paid in connection with issuance of convertible debentures	(82,500)	-
Proceeds from short-term loans payable	258,278	-
Payments on short-term loans payable	(27,927)	-
Proceeds from notes payable and convertible debentures	130,000	340,000
Payments on notes payable and convertible debentures	(440,000)	-

Payment made on contingent consideration	-	(87,168)
Proceeds from non-convertible debentures - related party	50,000	150,000
Payments on non-convertible debentures - related party	(105,000)	-
Net Cash Provided By Financing Activities	1,092,965	876,910
NET CHANGE IN CASH	48,422	(25,894)
CASH AT BEGINNING OF YEAR	7,479	33,373
CASH AT END OF YEAR	$ 55,901	$ 7,479

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SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION :				
Cash paid for income taxes	$	2,400	$	-
Cash paid for interest	$	107,764	$	33,363

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION :				
Common stock issued for conversion of notes payable	$	92,000	$	110,581
Common stock issued for conversion of debentures – related party	$	75,000	$	643,226
Common stock issued for extinguishment of debt	$	-	$	779,000
Common stock issued for the purchase of Vesele	$	-	$	40,000
Common stock issued for acquisition	$	2,071,625	$	-
Fair value of the contingent consideration for acquisition	$	2,905,425	$	-
Return of shares of common stock related to license agreement	$	38,000	$	-
Fair value of warrants issued as deferred financing costs	$	68,419	$	-
Fair value of embedded conversion feature derivative liabilities recorded as debt discount	$	830,560	$	-
Relative fair value of common stock issued in connection with convertible debentures	$	374,474	$	-
Relative fair value of warrants issued in connection with convertible debentures	$	89,551	$	-
Fair value of warrant derivative liabilities recorded as debt discount	$	226,297	$	-
Fair value of beneficial conversion feature on line of credit convertible debenture – related party	$	8,321	$	-
Accrued interest added to principal in connection with amendment of notes payable	$	3,200	$	-
Exchange of restricted stock units for shares of common stock	$	500	$	-

See accompanying notes to these consolidated financial statements.

INNOVUS PHARMACEUTICALS, INC.
Consolidated Statements of Stockholders' Deficit
For the Years Ended December 31, 2015 and 2014

	Common Stock		Additional Paid-in	Accumulated	Stockholders'
	Shares	Amount	Capital	Deficit	Deficit
Balance at January 1, 2014	21,548,456	$ 21,549	$ 6,531,110	$ (6,405,000)	$ 147,659
Common stock and options issued for services	1,665,203	1,665	747,398	-	749,063
Common stock issued for product acquisition	142,857	143	39,857	-	40,000
Stock compensation expense	-	-	1,509,005	-	1,509,005
Common stock issued upon conversion of debt, of which 1,579,297 shares were issued to related parties	3,755,747	3,756	1,529,050	-	1,532,806
Convertible debt discount - beneficial conversion feature	-	-	325,855	-	325,855
Convertible debt discount - warrants	-	-	96,532	-	96,532
Net loss for year ended December 31, 2014	-	-	-	(4,826,967)	(4,826,967)
Balances at December 31, 2014	27,112,263	27,113	10,778,807	(11,231,967)	(426,047)
Common stock issued for services	1,780,625	1,780	208,749	-	210,529
Stock-based compensation	-	-	1,298,240	-	1,298,240
Common stock issued for product acquisition	12,947,657	12,948	2,058,677	-	2,071,625
Common stock issued upon conversion of convertible debentures, note payable and debentures – related party	699,260	699	166,301	-	167,000

Common stock issued for exchange of restricted stock units	500,000	500	(500)	-	-
Return of shares of common stock from CRI license transaction	(200,000)	(200)	(37,800)	-	(38,000)
Return of shares of common stock from Semprae merger transaction	(386,075)	(386)	(115,436)	-	(115,822)
Fair value of beneficial conversion on line of credit convertible debenture – related party	-	-	8,321	-	8,321
Shares of common stock issued for extension of February 2014 convertible debentures	250,000	250	32,250	-	32,500
Shares of common stock issued for amendment of January 2015 convertible debentures	100,000	100	15,400	-	15,500
Relative fair value of shares of common stock issued in connection with convertible debentures	4,337,500	4,337	370,137	-	374,474
Relative fair value of warrants issued in connection with convertible debentures	-	-	89,551	-	89,551
Fair value of warrants issued to placement agents in connection with convertible debentures	-	-	68,419	-	68,419
Net loss for year ended December 31, 2015	-	-	-	(4,202,628)	(4,202,628)
Balances at December 31, 2015	47,141,230	$ 47,141	$ 14,941,116	$ (15,434,595)	$ (446,338)

See accompanying notes to these consolidated financial statements.

INNOVUS PHARMACEUTICALS, INC.
Notes to the Consolidated Financial Statements
December 31, 2015 and 2014

NOTE 1 – ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Innovus Pharmaceuticals, Inc., together with its subsidiaries (collectively referred to as “Innovus”, “we”, “our” or the “Company”) is a San Diego, California-based pharmaceutical company that delivers safe and effective non-prescription medicine and consumer care products to improve men’s and women’s health and vitality and respiratory diseases.

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 +®.

Pipeline Products

Fluticare™ (Fluticasone propionate nasal spray). Innovus acquired the worldwide rights to market and sell the Fluticare™ brand (Fluticasone propionate nasal spray) and the related manufacturing agreement from Novalere FP in February 2015, the Over The Counter (OTC) Abbreviated New Drug Application (“ANDA”) filed at the end of 2014 by the manufacturer with the U.S. Food and Drug Administration (“FDA”) which, subject to FDA approval, 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.

Urocis® XR. On October 27, 2015, the Company entered into an exclusive distribution agreement with Laboratorios Q Pharma (Spain) to distribute and commercialize Urocis® XR in the US and Canada. Urocis® XR is 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.

AndroVit®. On October 27, 2015, the Company entered into an exclusive distribution agreement with Laboratorios Q Pharma (Spain) to distribute and commercialize AndroVit® in the US and Canada. AndroVit® is a proprietary supplement to support overall prostate and male sexual health currently marketed in Europe. AndroVit® was specifically formulated with ingredients known to support the normal prostate health and vitality and male sexual health.

Basis of Presentation and Principles of Consolidation

These consolidated financial statements have been prepared by management in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and include all assets, liabilities, revenues and expenses of the Company and its wholly-owned subsidiaries: FasTrack Pharmaceuticals, Inc. and Semprae Laboratories, Inc. (“Semprae”). Additionally, the revenues and expenses of Novalere, Inc. (“Novalere”) were included

from February 5, 2015 (date of acquisition) to December 31, 2015. All material intercompany transactions and balances have been eliminated. Certain items have been reclassified to conform to the current year presentation.

Use of Estimates

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

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Liquidity

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 domestically 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 deficit 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 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 note payable 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 materials and packaging and for operations.

As of December 31, 2015, we had $55,901 in cash and cash equivalents, approximately $1.6 million in cash available for use under the line of credit convertible debenture with our Chief Executive Officer ('CEO") 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 line of credit convertible debenture with our CEO 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. In addition, the Company's President and Chief Executive Officer, who is also a major shareholder, has deferred the payment of his salary earned thru December 31, 2014 and plans to continue to do so for 2016, if needed. He is also able to extend the maturity date of the line of credit, if needed.

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 convertible debentures is automatically converted to common stock at 60% of the volume weighted average price ("VWAP") during the ten consecutive trading day period preceding the later of the event of default or applicable cure period.

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 the Company 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 the Company 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. 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.
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.

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Fair Value Measurement

The Company's financial instruments are cash, accounts receivable, accounts payable, accrued liabilities, derivative liabilities and debt. The recorded values of cash, accounts receivable, accounts payable and accrued liabilities approximate their fair values based on their short-term nature. The recorded fair value of the convertible debentures, net of debt discount, is based upon the relative fair value calculation of the common stock and warrants issued in connection with the convertible debentures and the fair value of the embedded conversion feature. The fair values of the warrant derivative liabilities and embedded conversion feature derivative liabilities are based upon the Black Scholes Option Pricing Model ("Black-Scholes") and the Path-Dependent Monte Carlo simulation model calculations and are a level 3 measurement (see Note 9). The fair value of the contingent acquisition consideration is based upon the present value of expected future payments under the terms of the agreements and is a level 3 measurement (see Note 3). Based on borrowing rates currently available to the Company, the carrying values of the notes payable and convertible debentures approximate their respective fair values. The difference between the fair value and recorded values of the related-party notes payable and convertible debentures is not significant.

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

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

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

Level 3 measurements are unobservable inputs.

Cash and Cash Equivalents

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

Concentration of Credit Risk and Major Customers

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and accounts receivable. Cash held with financial institutions may exceed the amount of insurance provided by the Federal Deposit Insurance Corporation on such deposits. Accounts receivable consist primarily of amounts receivable from Sothema Laboratories under the Company's licensing agreements and from sales of Zestra®. The Company also requires a percentage of payment in advance for product orders with its larger partners. The Company performs ongoing credit evaluations of its customers and generally does not require collateral.

Revenues consist primarily of product sales and licensing rights to market and commercialize our products. The following table identifies customers with revenues that individually exceed 10% of the Company's net revenues for the years ended December 31, 2015 and 2014:

	2015		2014	
Retailer 1	$131,900	18 %	$171,600	16 %

Partner 1	$102,300	14	%	$-	-	%
Partner 2	$84,500	11	%	$-	-	%
Partner 3	$-	-	%	$175,000	17	%
Partner 4	$50,000	<10	%	$245,380	23	%

The first three customers listed accounted for 19%, 54% (payment received in January 2016) and 0%, respectively, of gross accounts receivable as of December 31, 2015. The first, fourth and fifth customers listed accounted for 11%, 44% and 27%, respectively, of accounts receivable as of December 31, 2014.

Over 90% of our sales are currently within the United States and Canada. The balance of the sales are to various other countries, none of which is 10 percent or greater.

Concentration of Suppliers

The Company has manufacturing relationships with a number of vendors or manufacturers for its products including: Sensum+®, EjectDelay®, Vesele®, Androferti® and the Zestra® line of products. Pursuant to these relationships, the Company purchases products through purchase orders with its manufacturers.

Inventories

Inventory is valued at the lower of cost or market using the first-in, first-out method. Inventory is shown net of obsolescence, determined based on shelf life or potential product replacement.

Property and Equipment

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

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Intangible Assets

Intangible assets with finite lives are amortized on a straight-line basis over their estimated useful lives, which range from 7 to 15 years. The useful life of the intangible asset is evaluated each reporting period to determine whether events and circumstances warrant a revision to the remaining useful life.

Business Combinations

We account for business combinations by recognizing the assets acquired, liabilities assumed, contractual contingencies, and contingent consideration at their fair values on the acquisition date. The final purchase price may be adjusted up to one year from the date of the acquisition. Identifying the fair value of the tangible and intangible assets and liabilities acquired requires the use of estimates by management and was based upon currently available data.

The Company allocated the excess of purchase price over the identifiable intangible and net tangible assets to goodwill. Such goodwill is not deductible for tax purposes and represents the value placed on entering new markets and expanding market share (see Note 3).

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

Goodwill

The Company tests its goodwill for impairment annually, or whenever events or changes in circumstances indicates an impairment may have occurred, by comparing its reporting unit's carrying value to its implied fair value. Impairment may result from, among other things, deterioration in the performance of the acquired business, adverse market conditions, adverse changes in applicable laws or regulations and a variety of other circumstances. If the Company determines that an impairment has occurred, it is required to record a write-down of the carrying value and charge the impairment as an operating expense in the period the determination is made. In evaluating the recoverability of the carrying value of goodwill, the Company must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the acquired assets. Changes in strategy or market conditions could significantly impact those judgments in the future and require an adjustment to the recorded balances. The goodwill was recorded as part of the acquisition of Semprae that occurred on December 24, 2013, and the acquisition of Novalere that occurred on February 5, 2015. The Company recorded $759,428 of goodwill related to the acquisition of Novalere as an income tax benefit and also recorded an impairment of $759,428 against this benefit. There was no impairment of goodwill for the year ended December 31, 2014.

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.

Deferred Financing Costs

Deferred financing costs represent costs incurred in connection with the issuance of the convertible debentures during the third quarter of the year ended December 31, 2015. Deferred financing costs related to the issuance of the convertible debentures are being amortized over the term of the financing instrument using the effective interest method and are recorded in interest expense in the accompanying consolidated statements of operations.

Beneficial Conversion Feature

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

Derivative Liabilities

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

Debt Extinguishment

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

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Income Taxes

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

The Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting this standard, the amount recognized in the financial statements is the largest benefit that has a greater than fifty percent (50%) likelihood of being realized upon ultimate settlement with the relevant tax authority. There were no uncertain tax positions at December 31, 2015 and 2014.

Revenue Recognition and Deferred Revenue

The Company generates revenues from product sales and the licensing of the rights to market and commercialize its products.

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

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

License Revenues: The license agreements the Company enters into normally generate three separate components of revenue: 1) an initial payment due on signing or when certain specific conditions are met; 2) royalties that are earned on an ongoing basis as sales are made or a pre-agreed transfer price and 3) milestone payments that are earned when cumulative sales reach certain levels. Revenue from the initial payments or licensing fee is recognized when all required conditions are met. Royalties are recognized as earned based on the licensee’s sales. Revenue from the milestone payments is recognized when the cumulative revenue levels are reached. FASB ASC 605-28, Milestone Method, is not used by the Company as these milestones are sales-based and similar to a royalty and the achievement of the sales levels is neither based, in whole or in part, on the vendor’s performance nor is a research or development deliverable.

Sales Allowances

The Company accrues for product returns, volume rebates and promotional discounts in the same period the related sale is recognized.

The Company’s product returns accrual is primarily based on estimates of future product returns over the period customers have a right of return, which is in turn based in part on estimates of the remaining shelf-life of products

when sold to customers. Future product returns are estimated primarily based on historical sales and return rates. The Company estimates its volume rebates and promotional discounts accrual based on its estimates of the level of inventory of its products in the distribution channel that remain subject to these discounts. The estimate of the level of products in the distribution channel is based primarily on data provided by the Company's customers.

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

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

The estimated reserve for sales returns and allowances, which is included in accounts receivable, was approximately $5,000 and $24,000 at December 31, 2015 and 2014, respectively.

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Cost of Product Sales

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

Research and Development Costs

Research and development ("R&D") costs, including research performed under contract by third parties, are expensed as incurred. Major components of R&D expenses consist of testing, post marketing clinical trials, material purchases and regulatory affairs.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with FASB ASC 718, Stock Based Compensation, which requires the recognition of the fair value of stock-based compensation as an expense in the calculation of net income. FASB ASC 718 requires that stock-based compensation expense be based on awards that are ultimately expected to vest. Stock-based compensation for the year ended December 31, 2015 and 2014 have been reduced for estimated forfeitures. When estimating forfeitures, voluntary termination behaviors, as well as trends of actual option forfeitures, are considered. To the extent actual forfeitures differ from the Company's current estimates, cumulative adjustments to stock-based compensation expense are recorded.

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

Equity Instruments Issued to Non-Employees for Services

Issuances of the Company's equity for services are measured at the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. The measurement date for the fair value of the equity instruments issued to consultants is determined at the earlier of (a) the date at which a commitment for performance to earn the equity instruments is reached (a "performance commitment" which would include a penalty considered to be of a magnitude that is a sufficiently large disincentive for nonperformance) or (b) the date at which performance is complete, and is based upon the quoted market price of the common stock at the date of issuance (See Note 8).

Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period presented. Diluted net loss per share is computed using the weighted average number of common shares outstanding during the periods plus the effect of dilutive securities outstanding during the periods. For the years ended December 31, 2015 and 2014, basic net loss per share are the same as diluted net loss per share as a result of the Company's common stock equivalents being anti-dilutive. See Note 8 for more details.

Recent Accounting Pronouncements

In February 2016, the FASB issued its new lease accounting guidance in Accounting Standards Update ("ASU") No. 2016-02, Leases (Topic 842). Under the new guidance, lessees will be required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: A lease liability, which is a lessee's

obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. Under the new guidance, lessor accounting is largely unchanged. Certain targeted improvements were made to align, where necessary, lessor accounting with the lessee accounting model and ASC 606, Revenue from Contracts with Customers. The new lease guidance simplified the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities. Lessees will no longer be provided with a source of off-balance sheet financing. Public business entities should apply the amendments in ASU 2016-02 for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. Lessees (for capital and operating leases) must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the consolidated financial statements. The modified retrospective approach would not require any transition accounting for leases that expired before the earliest comparative period presented. Lessees may not apply a full retrospective transition approach. Management is currently assessing the impact the adoption of ASU 2016-02 will have on our consolidated financial statements.

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

In September 2015, the FASB issued ASU 2015-16, Simplifying the Accounting for Measurement-Period Adjustments, which eliminates the requirement to retrospectively adjust the consolidated financial statements for measurement-period adjustments that occur in periods after a business combination is consummated. Measurement period adjustments are calculated as if they were known at the acquisition date, but are recognized in the reporting period in which they are determined. Additional disclosures are required about the impact on current-period income statement line items of adjustments that would have been recognized in prior periods if prior-period information had been revised. The guidance is effective for annual periods beginning after December 15, 2015 and is to be applied prospectively to adjustments of provisional amounts that occur after the effective date. Early application is permitted. The Company is evaluating the impact of adoption of this guidance on its consolidated financial position and results of operations.

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

In April 2015, the FASB has issued ASU No. 2015-03, Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. The amendments in this ASU 2015-03 require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this ASU 2015-03. For public business entities, the amendments are effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption of the amendments is permitted for financial statements that have not been previously issued. The amendments should be applied on a retrospective basis, wherein the balance sheet of each individual period presented should be adjusted to reflect the period-specific effects of applying the new guidance. Upon transition, an entity is required to comply with the applicable disclosures for a change in an accounting principle. These disclosures include the nature of and reason for the change in accounting principle, the transition method, a description of the prior-period information that has been retrospectively adjusted, and the effect of the change on the financial statement line items (i.e., debt issuance cost asset and the debt liability). The Company is

currently presenting $97,577 of deferred financing costs as a current asset and this will show up as a reduction of current liabilities when this new pronouncement is adopted next year.

In August 2014, the FASB issued ASU 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. This ASU 2014-15 describes how an entity should assess its ability to meet obligations and sets rules for how this information should be disclosed in the consolidated financial statements. The standard provides accounting guidance that will be used along with existing auditing standards. The ASU 2014-15 is effective for interim and annual periods beginning after December 15, 2016. Early application is permitted. The Company is in the process of evaluating the impact of this standard but does not expect this standard to have a material impact on the Company's consolidated financial position or results of operation.

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In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers. This updated guidance supersedes the current revenue recognition guidance, including industry-specific guidance. The updated guidance introduces a five-step model to achieve its core principal of the entity recognizing revenue to depict the transfer of goods or services to customers at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The updated guidance is effective for interim and annual periods beginning after December 15, 2016, and early adoption is not permitted. In August 2015, the FASB issued ASU No. 2015-14 which deferred the effective date by one year for public entities and others. The amendments in this ASU are effective for interim and annual periods beginning after December 15, 2017 for public business entities, certain not-for-profit entities, and certain employee benefit plans. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. Management has not selected a transition method and is currently assessing the impact the adoption of ASU 2014-09 will have on our consolidated financial statements.

NOTE 2 – LICENSE AGREEMENTS

CRI In-License Agreement

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

- all of CRI’s rights in past, present and future Sensum+® product formulations and presentations, and
- an exclusive, perpetual license to commercialize Sensum+® products in all territories except for the United States.

CRI has retained commercialization rights for Sensum+® in the United States.

In consideration for such assets and license, the Company issued 631,313 shares to CRI IN 2013. The Company will be required to issue to CRI shares of the Company’s common stock valued at an aggregate of $200,000 for milestones relating to additional clinical data received, which milestone has not yet been met. The number of shares to be issued was or will be determined based on the average of the closing price for the 10 trading days immediately preceding the issue date. CRI will have certain “piggyback” registration rights with respect to the shares described above, which rights provide that, if the Company registers shares of its common stock under the Securities Act in connection with a public offering, CRI will have the right to include such shares in that registration, subject to certain exceptions. The Company recorded an asset totaling $250,000 related to the CRI Asset Purchase Agreement and will amortize this amount over its estimated useful life of 10 years. The accumulated amortization at December 31, 2014 was $58,300.

The CRI Asset Purchase Agreement also requires the Company to pay to CRI up to $7 million in cash milestone payments based on first achievement of annual net sales targets plus a royalty based on annual net sales. The obligation for these payments expires on April 19, 2023 or the expiration of the last of CRI’s patent claims covering the product or its use outside the United States, whichever is sooner. No sales milestones have been met under this agreement in 2015 or 2014, and royalties owed to CRI were immaterial and included in net revenues.

Sothema Laboratories Agreement

On September 23, 2014, the Company entered into an exclusive license agreement with Sothema Laboratories, SARL, a Moroccan publicly traded company (“Sothema”), under which Innovus granted to Sothema an exclusive license to market and sell Innovus’ topical treatment for Female Sexual Interest/Arousal Disorder (“FSI/AD”) (based on the latest

Canadian approval of the indication), Zestra® and its high viscosity low osmolality water-based lubricant Zestra Glide® in the North African countries of Egypt, Morocco, Algeria, Tunisia and Libya, the Middle Eastern countries of Iraq, Jordan, Saudi Arabia and the United Arab Emirates and the West African countries of Benin, Burkina Faso, Cape Verde, Gambia, Ghana, Guinea, Guinea-Bissau, Ivory Coast, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone and Togo (collectively the "Territory").

Under the agreement, Innovus received an upfront payment and is eligible to receive up to approximately $171 million dollars upon and subject to the achievement of sales milestones based on cumulative supplied units of the licensed products in the Territory, plus a pre-negotiated transfer price per unit.

Pursuant to the guidance in ASC 605-28, Milestone Method, the milestones are considered substantive. The milestones enhance the value of the products and are the result of the Company's past efforts. The milestones are reasonable relative to all of the deliverables. The Company will recognize the revenue from the milestone payments when the cumulative supplied units volume is met. During the years ended December 31, 2015 and 2014, the Company recognized $0 and $200,000, respectively, in license fees related to this agreement, and no revenue was recognized for the sales milestones of the agreement. We believe the amount of the upfront payment received is reasonable compared to the amounts to be received upon obtainment of future milestones.

Orimed Pharma Agreement

On September 18, 2014, the Company entered into an exclusive license agreement with Orimed Pharma ("Orimed"), an affiliate of JAMP Pharma, under which Innovus granted to Orimed an exclusive license to market and sell in Canada, Innovus' (a) topical treatment for FSI/AD, Zestra®, (b) topical treatment for premature ejaculation, EjectDelay®, (c) product Sensum+™ to increase penile sensitivity and (d) high viscosity low osmolality water-based lubricant, Zestra Glide®.

Under the agreement, Innovus received an upfront payment and is eligible to receive up to approximately CN $94.5 million ($68.2 million USD based on December 31, 2015 exchange rate) upon and subject to the achievement of sales milestones based on cumulative gross sales in Canada by Orimed plus certain double-digit tiered royalties based on Orimed's cumulative net sales in Canada.

Pursuant to the guidance in ASC 605-28, Milestone Method, the milestones and quarterly royalty payments are considered substantive. The milestones enhance the value of the products and are the result of the Company's past efforts. The milestones are reasonable relative to all of the deliverables. The Company will recognize the revenue from the milestone payments when the cumulative gross sales volume is met. The Company will recognize the revenue from the royalty payments on a quarterly basis when the cumulative net sales have been met. During the years ended December 31, 2015 and 2014, the Company recognized $0 and $100,000, respectively in license fees related to this agreement and $2,000 and $0 in royalty payments, respectively, and no revenue was recognized for the sales milestones of the agreement. We believe the amount of the upfront payment received is reasonable compared to the amounts to be received upon obtainment of future milestones.

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Tramorgan Agreement

On September 18, 2014, the Company entered into an exclusive license and distribution agreement with Tramorgan Limited (“Tramorgan”), pursuant to which Tramorgan will market the Company’s topical consumer care product to increase penile sensitivity, Sensum+® in the United Kingdom (“UK”).

The agreement has an initial term through December 31, 2016 and can be extended thereafter for a twenty-four month period if Tramorgan has reached certain aggregate sales milestones. Pursuant to the agreement, Innovus is eligible to receive (a) up to $44 million dollars in sales milestone payments based on Tramorgan’s attainment of certain levels of cumulative gross sales amounts plus (b) fifty percent (50%) royalties based on Tramorgan’s net sales after applicable distribution costs in the UK. During the years ended December 31, 2015 and 2014, no revenue was recognized for the sales milestones and royalty payments of the agreement.

Ovation Pharma Agreements

On September 9, 2013, the Company entered into a license and distribution agreement with Ovation Pharma SARL (“Ovation”) under which it granted to Ovation an exclusive license to market and sell the Company’s topical treatment for reduced penile sensitivity, Sensum+®, in Morocco. Ovation may pay the Company up to approximately $11.25 million upon achievement of commercial milestones. In addition, Ovation has agreed to certain upfront minimum purchases of Sensum+™ based upon an agreed upon transfer price and yearly minimum purchases. During the years ended December 31, 2015 and 2014, the Company recognized $0 and $100,000, respectively, in revenue related to product sales from Ovation.

On September 9, 2013 the Company entered into a second license and distribution agreement with Ovation under which it granted to Ovation an exclusive license to market and sell the Company’s topical premature ejaculation treatment, EjectDelay®, in Morocco. Ovation may pay the Company up to approximately $18.6 million allocated among a fixed upfront license fee and the achievement of regulatory and commercial milestones. In addition, Ovation has agreed to certain upfront minimum purchases of EjectDelay ®based upon an agreed upon transfer price and minimum yearly purchases.

The Company determined that the fixed upfront license fee payment was a separate deliverable under the EjectDelay® license and distribution agreement and therefore recorded a receivable on its balance sheet. There were no additional obligations or deliverables associated with the license. During the years ended December 31, 2015 and 2014, the Company recognized $0 and $75,000, respectively, in revenue related to the upfront license fee from Ovation.

Elis Pharmaceuticals Agreement

On July 4, 2015, the Company announced that it had entered into an exclusive license agreement with Elis Pharmaceuticals, an emirates company (“Elis”), under which Innovus Pharma granted to Elis an exclusive license to market and sell to market and sell Innovus Pharma’s topical product Zestra® EjectDelay®, Sensum+® and Zestra Glide® in Turkey and select African and gulf countries. Under the agreement, Innovus Pharma is eligible to receive up to $35.5 million in sales milestone payments plus an agreed-upon transfer price upon sale of products. The Company had preliminary listed Syria, Yemen and Somalia as countries in the definition of licensed territories, but these countries were removed by the agreement of both parties from the agreement effective the date of signing of the agreement. The Company did not recognize any revenues from this agreement during the year ended December 31, 2015.

Khandelwal Laboratories Agreement

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

Bio Task Agreement

On December 3, 2015, the Company entered into an exclusive license and distribution agreement with Bio Task based in Malaysia ("Bio Task") under which the Company has granted to Bio Task an exclusive ten-year distribution right to market and sell in Malaysia the Company's products including Zestra ® increase Female Sexual Arousal and Desire and Satisfaction, EjectDelay ® for treating premature ejaculation, Sensum + ® to increase penile sensitivity, Vesele ® for sexual functions and cognitive responses and Zestra Glide ® the high viscosity water based lubricant. Under the agreement, the Company will receive an upfront payment and is eligible to receive up to $34 million in sales milestone payments plus an agreed-upon transfer price. The Company did not recognize any revenues from this agreement during the year ended December 31, 2015.

NOTE 3 – BUSINESS ACQUISITIONS

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, the Company acquired the worldwide rights to market and sell the Fluticare™ brand (Fluticasone propionate nasal spray) and the related manufacturing agreement from Novalere FP. The Company currently anticipates that the Abbreviated New Drug Application ("ANDA") filed in November 2014 by the manufacturer with the U.S. Food and Drug Administration ("FDA") may be approved in 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.

Under the terms of the Merger Agreement, at the Closing Date, the Novalere Stockholders received 50% of the Consideration Shares (the "Closing Consideration Shares") and the remaining 50% of the Consideration Shares (the "ANDA Consideration Shares") will be delivered only if an ANDA of Fluticasone Propionate Nasal Spray of Novalere Manufacturing Partners (the "Target Product") is approved by the Food and Drug Administration (the "ANDA Approval"). A portion of the Closing Consideration Shares and, if ANDA Approval is obtained prior to the 18 month anniversary of the Closing Date, a portion of the ANDA Consideration Shares, will be held in escrow for a period of 18 months from the Closing Date to be applied towards any indemnification claims by the Company pursuant to the Merger Agreement.

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

The closing price of the Company's common stock on the Closing Date was $0.20 per share. The Company issued 12,947,657 Closing Consideration Shares of its common stock at the Closing Date, the Fair Market Value, ('FMV") of the Closing Consideration Shares was $2,071,625 as of the Closing Date. 12,280,796 shares were placed in escrow to

cover any potential claims that the Company might have with respect to disclosures made by Novalere.

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

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

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

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

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

The total purchase price is summarized as follows:

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

The fair values of acquired assets and liabilities are based on preliminary cash flow projections and other assumptions. The preliminary fair values of acquired intangible assets were determined using several significant unobservable inputs for projected cash flows and a discount rate. These inputs are considered Level 3 inputs under the fair value measurements and disclosure guidance. The transaction has been accounted for as a business combination under the acquisition method of accounting. Accordingly, the tangible assets and identifiable intangible assets acquired and liabilities assumed have been recorded at fair value, with the remaining purchase price recorded as goodwill.

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

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

Acquired assets net of assumed liabilities	$ 4,977,049

The Company recorded $759,428 of goodwill related to the acquisition of Novalere as an income tax benefit and also recorded an impairment of $759,428 against this benefit.

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

The establishment of the fair value of the consideration for a Merger, and the allocation to identifiable tangible and intangible assets and liabilities, requires the extensive use of accounting estimates and management judgment. The fair values assigned to the assets acquired and liabilities assumed were based on estimates and assumptions. There has been no change to the estimated fair value of the contingent consideration of $2,905,425 through December 31, 2015.

Supplemental Pro Forma Information for Acquisition of Novalere (unaudited)

The following unaudited supplemental pro forma information for the years ended December 31 2015 and 2014, assumes the acquisition of Novalere had occurred as of January 1, 2015 and 2014, giving effect to purchase accounting adjustments such as amortization of intangible assets. The pro forma data is for informational purposes only and may not necessarily reflect the actual results of operations had Novalere been operated as part of the Company since January 1, 2015 and 2014.

	Year Ended December 31, 2015		Year Ended December 31, 2014	
	As Reported	Pro Forma (unaudited)	As Reported	Pro Forma (unaudited)
Net revenues	$735,717	$735,717	$1,030,113	$1,030,113
Net loss	$(4,202,628)	$(4,578,521)	$(4,826,967)	$(8,350,196)
Net loss per share of common stock – basic and diluted	$(0.08)	$(0.09)	$(0.20)	$(0.22)
Weighted average number of shares outstanding – basic and diluted	52,517,530	53,794,559	24,384,037	37,331,694

Purchase of Semprae Laboratories, Inc. in 2013

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

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

The agreement to pay the annual Royalty resulted in the recognition of a contingent consideration, which is recognized at the inception of the transaction, and subsequent changes to estimate of the amounts of contingent consideration to be paid will be recognized as charges or credits in the consolidated statement of operations. The fair value of the contingent consideration is based on preliminary cash flow projections, growth in expected product sales and other assumptions. Based on the assumptions, the fair value of the Royalty was determined to be $308,273 at the date of acquisition. The fair value of the Royalty was determined by applying the income approach, using several significant unobservable inputs for projected cash flows and a discount rate of 40% commensurate with the Company’s cost of capital and expectation of the revenue growth for products at their life cycle stage. These inputs are considered

Level 3 inputs under the fair value measurements and disclosure guidance. During 2015 and 2014, approximately $0 and $87,000, respectively, was paid under this arrangement. The fair value of the expected royalties to be paid was increased by $0 and $103,274 during the years ended December 31, 2015 and 2014, respectively, which resulted in a loss on change in fair value of contingent consideration and is included in other income and expense in the accompanying consolidated statements of operations. The fair value of contingent consideration was $324,379 at December 31, 2015 and 2014, based on the new estimated fair value of the consideration, net of the amounts to be returned to the Company as discussed above.

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NOTE 4 – ASSETS

Inventories

Inventories consist of the following:

	December 31, 2015	December 31, 2014
Raw materials and supplies	$77,649	$191,186
Work in process	90,540	-
Finished goods	86,254	74,773
Total	$254,443	$265,959

Property and Equipment

Property and equipment consists of the following:

	December 31, 2015	December 31, 2014
Computer equipment	$5,254	$5,254
Office furniture and fixtures	33,376	33,376
Production equipment	276,479	266,939
Software	338,976	338,976
Total cost	654,085	644,545
Less accumulated depreciation	618,984	590,034
Property and equipment, net	$35,101	$54,511

Depreciation expense for the years ended December 31, 2015 and 2014 was $28,950 and $63,450, respectively.

Intangible Assets

Amortizable intangible assets consist of the following:

December 31, 2015

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

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December 31, 2014

	Amount	Accumulated Amortization	Net Amount	Useful Lives (years)
Patent & Trademarks	$264,321	$ (23,671)	$240,650	7 - 14
Customer Contracts	611,119	(62,262)	548,857	10
Sensum+® license (from CRI)	272,545	(31,250)	241,295	10
Vesele® trademark	25,287	(717)	24,570	8
Total	$1,173,272	$ (117,900)	$1,055,372	

Amortization expense for the years ended December 31, 2015 and 2014 was $550,789 and $114,006, respectively. Expected future amortization expense at December 31 2015 is approximately $589,400 for each of the next five years and $2,354,000 thereafter.

Goodwill

The changes in the carrying value of the Company's goodwill for the years ended December 31, 2015 and 2014 is as follows:

	December 31, 2015
Beginning balance December 31, 2013	$ 421,372
Purchase price adjustment for acquisition of Semprae Laboratories, Inc. in 2013	7,853
Ending Balance December 31, 2014	429,225
Acquisition of Novalere (see Note 3)	120,143
Release of valuation allowance in connection with acquisition of Novalere (see Note 10)	759,428
Impairment of valuation allowance in connection with acquisition of Novalere (see Note 10)	(759,428)
Ending Balance December 31, 2015	$ 549,368

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

Short-Term Loans Payable

Included in this amount is $218,218 of short-term non-convertible financings and $12,133 to finance our business insurance premiums. The short-term non-convertible financings are from three funding sources and all balances are guaranteed by the Company's CEO.

Notes Payable and Convertible Debentures

The following table summarizes the outstanding unsecured notes payable and convertible debentures, excluding the third quarter 2015 convertible debentures financing, at December 31:

	2015	2014
Current notes payable and convertible debentures:		
February 2014 Convertible Debenture	$-	$330,000
July 2015 Debenture (Amended August 2014 Debenture)	73,200	40,000
Total current notes payable and convertible debentures	73,200	370,000

Less: Debt discount	-	(55,982)
	$73,200	$314,018
Long-term notes-payable and convertible debentures		
September 2014 Convertible Debenture	$-	$92,000
Less: Debt discount	-	(67,726)
	$-	$24,274

December 2013 Debenture

On December 23, 2013, the Company issued an 8% debenture to an unrelated third party accredited investor in the principal amount of $350,000 (the "December 2013 Debenture"). The December 2013 Debenture bore interest at the rate of 8% per annum. The principal amount and interest was payable on August 31, 2014. On August 31, 2014, the maturity date of the December 2013 Debenture was extended to September 15, 2014.

On September 15, 2014, a third party investor ("Investor") purchased the December 2013 Debenture and subsequently on September 15, 2014 the Company entered into a debt exchange agreement with the Investor, pursuant to which the Company issued 1,900,000 shares of the Company's common stock with a fair value of $779,000 based upon the quoted market price at issuance, in exchange for the retirement of the December 2013 Debenture. During the year ended December 31, 2014 the Company recorded a $406,833 loss on the extinguishment of debt.

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July 2015 Debenture (Amended August 2014 Debenture)

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

September 2014 Convertible Debenture

On September 29, 2014, the Company issued a convertible promissory note (the “Note”) to an unrelated third party accredited investor for $50,000. The Note had a principal face amount of $92,000, did not accrue interest and was due on March 28, 2016 (the “Maturity Date”). The Note bore the right to convert any part of the principal amount under the Note into shares of the Company’s common stock at a conversion price of $0.40 per share (the “Conversion Price”). On the Maturity Date, any outstanding principal due under the Note would have been automatically converted into shares of common stock at the Conversion Price. The Note prohibited the holder from converting the Note to the extent that, as a result of such conversion, the holder would have beneficially own more than 9.99%, in the aggregate, of the issued and outstanding shares of common stock calculated immediately after giving effect to the issuance of shares of common stock upon the conversion of the Note. The Note contains a BCF. The intrinsic value of the BCF at the date of issuance was determined by measuring the difference between the accounting conversion price and the intrinsic value of the stock at the commitment date. The Company recorded a debt discount for the intrinsic value of the BCF, which was limited to the proceeds with an offsetting increase to additional paid-in-capital. The BCF of $37,400 along with the OID of $42,000 had been included in the consolidated balance sheet at December 31, 2014 as a discount to the related debt security, and was being accreted as non-cash interest expense over the expected term of the Note using the effective interest method. The Note was converted into 230,000 shares common stock according to the terms of the note, by the investor on March 30, 2015. As such, the Company recorded the conversion of the note and the remaining debt discount was charged to interest expense during the year ended December 31, 2015.

January 2015 Non-Convertible Debenture

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

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

The Vista Warrants are measured at fair value and classified as a liability because these warrants contain anti-dilution protection and therefore cannot be considered indexed to the Company’s own stock which is a requirement for the scope exception as outlined under FASB ASC 815. The estimated fair value of the Vista Warrants was determined using the Probability Weighted Black-Scholes Option-Pricing Model, resulting in a fair value of $99,999 on the date they were issued. The allocation of the proceeds of the debt was initially recorded using the residual method, at $1, net of a debt discount of $109,999 for the fair value of the Vista Warrants and the OID. The discount was being accreted

as non-cash interest expense over the expected term of the January 2015 Non-Convertible Debenture using the effective interest method. During the year ended December 31, 2015, the full amount of debt discount has been accreted to interest expense. The fair value of the Vista Warrants will be affected by changes in inputs to that model including our stock price, expected stock price volatility, the contractual term and the risk-free interest rate. The Company will continue to classify the fair value of the Vista Warrants as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability, whichever comes first. The anti-dilution protection for the Vista Warrants survives for the life of the warrants which ends in January 2020 and has been classified as a liability (see Note 9).

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February 2014 Convertible Debenture

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

The February 2014 Convertible Debenture bore interest at the rate of 10% per annum and the principal amount and interest were payable on March 13, 2015. The effective interest rate was calculated considering the OID, the BCF and the Warrant Agreement. The February 2014 Convertible Debenture could have been converted in whole or in part at any time prior to the maturity date by the holder at a conversion price of $0.40 per share, subject to adjustment. The Company had the option to redeem the February 2014 Convertible Debenture before its maturity by payment in cash of 125% of the then outstanding principal amount plus accrued interest and other amounts due.

The February 2014 Convertible Debenture was issued with an OID of $30,000. The OID was included in the consolidated balance sheet as a debt discount to the related debt security and was being accreted as non-cash interest expense over the expected term of the debt.

The Warrant Agreement provides the holder with the right to acquire up to 250,000 shares of common stock at an exercise price of $0.50 per share, subject to standard certain adjustments as described in the Warrant Agreement, at any time through the fifth anniversary of its issuance date. The allocated relative fair value of the Warrant Agreement of $96,533 had been included in the consolidated balance sheet as a debt discount to the related debt security and was being accreted as non-cash interest expense over the expected term of the debt.

The February 2014 Convertible Debenture contains a BCF. The intrinsic value of the BCF at the date of issuance was determined by measuring the difference between the accounting conversion price and the intrinsic value of the stock at the commitment date. The Company recorded a debt discount for the intrinsic value of the BCF, which was limited to the proceeds with an offsetting increase to additional paid-in-capital. The BCF of $179,032 along with the original issue discount of $30,000 had been included in the consolidated balance sheet at December 31, 2014 as a debt discount to the related debt security and was being accreted as non-cash interest expense over the expected term of the February 2014 Convertible Debenture using the effective interest method.

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

September 2015. The anti-dilution protection for the warrants survives for the life of the warrants which ends in March 2020 (see Note 9).

Interest Expense

The Company recognized interest expense on the short-term loans payable and unsecured (non-related party) notes payable and convertible debentures of $102,105 and $33,452 for the years ended December 31, 2015 and 2014, respectively. Amortization of the debt discount to interest expense during the years ended December 31, 2015 and 2014 totaled $310,006 and $283,348 respectively.

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Convertible Debentures - Third Quarter 2015 Financing

The following table summarizes the outstanding Third Quarter 2015 Convertible Debentures at December 31, 2015 and 2014:

	2015	2014
Investor 1 - July 27, 2015	$500,000	$-
Investor 1 - September 30, 2015	100,000	-
Investor 2 - August 25, 2015	500,000	-
Investor 2 - September 21, 2015	100,000	-
Investor 3 – August 27, 2015	125,000	-
Sub-total of gross proceeds received	1,325,000	-
Plus: Original issue discount (10%)	132,500	-
Face amount	1,457,500	-
Less: Debt discount	(952,464	-
Carrying value	505,036	-
Less: Current portion	(505,036	-
Convertible debentures – long-term	$-	$-

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 (net of OID) 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, with certain adjustment provisions 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 1,325,000 shares of common stock and the placement agent to purchase 483,333 shares of common stock (aggregating 1,808,333 shares of the Company's common stock) at an exercise price of $0.30 per share (See Note 8); and
2. 4,337,500 restricted shares of common stock to the Buyers.

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

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

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

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

Interest Expense

The Company recognized interest expense on the Q3 2015 Notes of $26,754 for the year ended December 31, 2015. The debt discount recorded for the Q3 2015 Notes totaling $1,427,085 is being amortized as interest expense over the term of the Q3 2015 using the effective interest method. Total amortization of the debt discount on the Q3 2015 Notes to interest expense for the year ended December 31, 2015 was $474,621.

The Company incurred debt issuance costs of $82,500 and the fair value of the warrants issued to the placement agent totaled $68,419. Such costs are amortized to interest expense over the term of the Q3 2015 Notes and the Company amortized $53,342 to interest expense during the year ended December 31, 2015.

NOTE 6 – DEBENTURES – RELATED PARTIES

The following table summarizes the long-term outstanding debentures to related parties at December 31, 2015 and 2014.

	2015	2014
Line of credit convertible debenture – related party	$409,192	$424,078
2014 non-convertible debentures - related parties	25,000	150,000
Total	434,192	574,078

Less : Debt discount	(17,720)	(76,492)
Carrying value	416,472	497,586
Less: Current portion	(391,472)	-
Total long-term debentures – related parties	$25,000	$497,586

January 2012 Convertible Debentures

In January 2012, the Company issued 8% convertible debentures in the aggregate principal amount of $174,668 (the "January 2012 Debentures") to six individuals. Under their original terms, the January 2012 Debentures were payable in cash at the earlier of January 13, 2013 or when the Company completes a financing with minimum gross proceeds of $4 million (the "Financing"), and the holders had the right to convert outstanding principal and interest accrued into the Company's securities that were issued to the investors in the Financing.

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The January 2012 Debentures contained a BCF of $40,889, which had been included in the balance sheet as a discount to the related debt security, and was being accreted as non-cash interest expense over the expected term of the debt using the effective interest method.

During 2013, four of the five holders of the outstanding January 2012 Debentures agreed to amend and restate the debentures to provide for automatic conversion into securities of the Company upon the earlier of either (a) the closing of the Financing and (b) July 1, 2016. The fifth holder of the January 2012 Debentures in the amount of $20,000 did not amend the debenture.

On February 19, 2014, the Company agreed with all five holders of the January 2012 Debentures, to convert such debentures into shares of the Company's common stock at a conversion price of $0.40 per share, and to terminate the January 2012 Debentures upon conversion. Immediately prior to conversion, the January 2012 Debentures had an aggregate principal and interest amount of $190,013, which was converted into 475,032 shares of the Company's common stock and terminated. The remaining discount of $37,195 related to the BCF was recorded as interest expense in 2014.

January 2013 Convertible Debenture

In January 2013, the Company issued a convertible debenture in the principal amount of $70,000 to a director of the Company (the "January 2013 Debenture") with terms identical to those of the January 2012 Debentures. In 2013, the terms were amended to provide for automatic conversion into securities of the Company upon the earlier of either (a) the closing of the Financing and (b) July 1, 2016.

The January 2013 Debenture contained a BCF of $18,651, which was included in the balance sheet as a discount to the related debt security, and was accreted as non-cash interest expense over the expected term of the loan using the effective interest method.

On February 19, 2014, the Company agreed with the holder of the January 2013 Debenture to convert such debenture on the same terms described above for the January 2012 Debentures. The principal and interest amount owed under the January 2013 Debenture immediately prior to conversion was $76,122, which was converted into 190,304 shares of the Company's common stock and terminated. The remaining discount of $16,965 related to the BCF was recorded as interest expense in 2014.

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, as defined, and (4) the holder had sole discretion to determine whether or not to make an advance upon the Company's request.

During 2013, the LOC Convertible Debenture was further amended to: (1) increase the maximum principal amount available for borrowing to $1 million plus any amounts of salary or related payments paid to Dr. Damaj prior to the termination of the funding commitment; and (2) change the holder's funding commitment to automatically terminate on the earlier of either (a) when the Company completes a financing with minimum net proceeds of at least $4 million, or (b) July 1, 2016. The securities to be issued upon automatic conversion will be either the Company's securities that are issued to the investors in a Qualified Financing or, if the financing does not occur by July 1, 2016, shares of the Company's common stock based on a conversion price of $0.312 per share, 80% times the quoted market price of the

Company's common stock on the date of the amendment. The LOC Convertible Debenture continues to bear interest at a rate of 8% per annum. The other material terms of the LOC Convertible Debenture were not changed. The Company recorded a debt discount for the intrinsic value of the BCF with an offsetting increase to additional paid-in-capital. The BCF is being accreted as non-cash interest expense over the expected term of the LOC debenture to its stated maturity date using the effective interest rate method.

On February 19, 2014, the Company agreed with its CEO 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.

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

On August 12, 2015, the principal amount that may be borrowed was increased to $2,000,000 and the automatic termination date described above was extended to October 1, 2016. The conversion price is $.16 per share, 80% times the quoted market price of the Company's common stock on the date of the amendment.

During the year ended December 31, 2015 and 2014, the Company borrowed $114 and $424,078, respectively, under the LOC Convertible Debenture and it repaid $15,000 during 2015. The Company recorded a BCF of $8,321 for the year ended December 31, 2015 and, as of December 31, 2015, the Company owed $409,192 in principal amount under the LOC Convertible Debenture and there was approximately $1.6 million remaining on the line of credit and available to use.

January 2015 Non-Convertible Debenture - Former CFO

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

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

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

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

2014 Non-Convertible Notes – Related Parties

On January 29, 2014, the Company issued an 8% note, in the amount of $25,000, to the Company's President and CEO. The principal amount and interest were payable on January 22, 2015. This note was amended to extend the maturity date until January 22, 2017. This note is still outstanding at December 31 2015.

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

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

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

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Interest Expense

The Company recognized interest expense on the outstanding debentures to related parties totaling $69,634 and $42,881 during the years ended December 31, 2015 and 2014, respectively. Amortization of the debt discount to interest expense during the years ended December 31, 2015 and 2014 totaled $122,092 and $160,519, respectively.

NOTE 7 – RELATED PARTY TRANSACTIONS

Related Party Borrowings

There were several related party borrowings which are described in more detail in Note 6.

Accrued Compensation – Related Party

Accrued compensation includes accruals for employee wages and vacation pay. The components of accrued compensation as of December 31, 2015 and 2014 are as follows:

	2015	2014
Wages	$ 1,178,909	$ 791,987
Vacation	170,371	114,941
Payroll taxes on the above	93,510	-
Total	1,442,790	906,928
Classified as long-term	(906,928)	(906,928)
Accrued compensation	$ 535,862	$ -

Accrued employee wages at December 31 2015 are entirely, and at December 31, 2014 relate primarily, to wages owed to the Company's CEO and President. Under the terms of his employment agreement, wages are to be accrued but no payment made for so long as payment of such salary would jeopardize the Company's ability to continue as a going concern. The CEO started to receive salary in the third quarter of 2015. Under the third quarter 2015 financing agreement, salaries prior to January 1, 2015 cannot be repaid until the debentures are repaid in full or otherwise extinguished by conversion or other means and, accordingly, the accrued compensation is shown as a long-term liability. The remaining accrued compensation of $535,862 is included in accounts payable and accrued expenses in the accompanying consolidated balance sheet at December 31, 2015.

NOTE 8 – STOCKHOLDERS' EQUITY

Capital Stock

The Company is authorized to issue 150,000,000 shares, all of which are common stock with a par value of $0.001 per share.

Issuances of Common Stock

On January 17, 2013, the Company entered into a service agreement with a third party pursuant to which the Company agreed to issue over the term of the agreement 250,000 shares of Company common stock in exchange for services to be rendered. On September 18, 2013, the Company extended the term of the agreement and agreed to issue an additional aggregate of 300,000 shares of common stock in exchange for services to be rendered. The term was further extended in April 2014 and the Company agreed to issue an additional 300,000 shares of common stock in exchange for services to be rendered over the term of the agreement. During the years ended December 31, 2015 and

2014, the Company issued 140,000 and 300,000 shares of common stock, respectively, and recognized $20,650 and $82,500 of services expense, respectively, under this agreement. This agreement was terminated in June 2015.

On June 28, 2013, the Company entered into an agreement with a consultant to provide drug development pre-clinical consulting services for Sensum+™ and EjectDelay®. In consideration of such services, the Company issued 126,296 shares in 2014 to the consultant, which were valued at the closing price of the Company's common stock on the date of issuance. The aggregate value of the shares issued was $55,521 in 2014, which corresponds to the service period of the consultant's services. As of December 31, 2014, the studies have completed and the consulting services have terminated.

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On February 19, 2014, the Company agreed with the holders of the January 2012 Debentures, January 2013 Debenture, and the LOC Convertible Debenture to convert such debentures into shares of the Company's common stock at a conversion price of $0.40 per share. The conversion terminated the January 2012 Debentures and the January 2013 Debenture. The conversion of the LOC Convertible Debenture, would convert the then outstanding principal and interest owed as of such date. The Company issued a total of 1,855,747 shares of the Company's common stock that had a value prior to the conversion of $742,299 in 2014.

On September 15, 2014, the Company entered into a debt exchange agreement with the investor, pursuant to which the Company agreed to issue 1,900,000 shares of the Company's common stock of $790,507 based on the value at issuance, in exchange for the retirement of the December 2013 Debenture. The holder of the December 2013 Debenture sold it to the investor prior to the debt exchange agreement.

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

On August 27, 2014, the Company agreed to issue 200,000 shares of Company common stock pursuant to a consulting contract with a third party for services. The Company issued 100,000 shares of stock pursuant to this agreement on September 2, 2014. The remaining 100,000 shares were issued on November 4, 2014. The Company extended the consulting contract in January 2015 and agreed to issue an additional 200,000 shares. The issued shares have been valued at the closing price of the Company's common stock on the date of issuance and are expensed over the period that the services are rendered. The Company recognized expense of $38,000 and $37,500 during the years ended December 31, 2015 and 2014, respectively, related to services provided in general and administrative expense in the accompanying consolidated statement of operations.

On January 23, 2015, the Company entered into a settlement agreement with CRI whereby CRI returned 200,000 shares of common stock initially issued for a product license acquired. The share return was in consideration for the Company completing certain product development and regulatory efforts relating to the sale of the product in foreign territories and reduced the intangible asset value by the fair value of such shares totaling $38,000.

On September 17, 2015 a consultant terminated his arrangement with the Company and exchanged 500,000 of his restricted stock units for 500,000 shares of common stock. The Company had previously recognized stock-based compensation expense of $110,621 (cumulative to date of termination), which was greater than the fair value of the stock issued to him. Accordingly, no additional compensation expense was recognized.

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

The Company issued an additional 1,037,500 and 343,907 shares of common stock and expensed $124,691 and $101,300, during the years ended December 31, 2015 and 2014 respectively, to other consultants for various services, which is included in general and administrative expense in the accompanying consolidated statement of operations. The shares were issued under the Company's 2013 Equity Incentive Plan (the "Incentive Plan") or under the corresponding Plans, as filed with the Securities Exchange Commission. All issued shares have been valued at the closing price of the Company's common stock on the date of issuance.

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

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2013 Equity Plan

The Company has issued common stock, restricted stock units and stock option awards to employees, non-executive directors and outside consultants under the 2013 Incentive Plan, which was approved by the Company's Board of Directors in February of 2013. The 2013 Incentive Plan allows for the issuance of up to 10,000,000 shares of the Company's common stock to be issued in the form of stock options, stock awards, stock unit awards, stock appreciation rights, performance shares and other share-based awards. The exercise price for all equity awards issued under the 2013 Incentive Plan is based on the fair market value of the common stock. Currently, because the Company's common stock is quoted on the OTCQB, the fair market value of the common stock is equal to the last-sale price reported by the OTCQB as of the date of determination, or if there were no sales on such date, on the last date preceding such date on which a sale was reported. Generally, each vested stock unit entitles the recipient to receive one share of Company common stock which is eligible for settlement at the earliest of their termination, a change in control of the Company or a specified date. Restricted stock units can vest according to a schedule or immediately upon award. Stock options generally vest over a three-year period, first year cliff vesting with quarterly vesting thereafter on the three-year awards, and have a ten-year life. Stock options outstanding are subject to time-based vesting as described above and thus are not performance-based. As of December 31, 2015, 995,264 shares were available under this plan.

2014 Equity Plan

The Company has issued common stock, restricted stock units and stock option awards to employees, non-executive directors and outside consultants under the 2014 Incentive Plan, which was approved by the Company's Board of Directors in November 2014. The 2014 Incentive Plan allows for the issuance of up to 20,000,000 shares of the Company's common stock to be issued in the form of stock options, stock awards, stock unit awards, stock appreciation rights, performance shares and other share-based awards. The exercise price for all equity awards issued under the 2014 Incentive Plan is based on the fair market value of the common stock. Currently, because the Company's common stock is quoted on the OTCQB, the fair market value of the common stock is equal to the last-sale price reported by the OTCQB as of the date of determination, or if there were no sales on such date, on the last date preceding such date on which a sale was reported. Generally, each vested stock unit entitles the recipient to receive one share of Company common stock which is eligible for settlement at the earliest of their termination, a change in control of the Company or a specified date. Restricted stock units can vest according to a schedule or immediately upon award. Stock options generally vest over a three-year period, first year cliff vesting with quarterly vesting thereafter on the three-year awards and have a ten-year life. Stock options outstanding are subject to time-based vesting as described above and thus are not performance-based. As of December 31, 2015 10,950,000 shares were available under this plan.

Stock-Based Compensation

The stock-based compensation expense for the years ended December 31, 2015 and 2014 was $1,298,240 and $1,509,005, respectively, for the issuance of restricted stock units and stock options to management, directors and consultants. The Company calculates the fair value of the restricted stock units based upon the quoted market value of the common stock at the date of grant. The Company calculates the fair value of each stock option award on the date of grant using Black-Scholes.

Stock Options

For the years ended December 31, 2015 and 2014, the following weighted average assumptions were utilized for the stock options granted during the period:

	2015	2014
Expected life (in years)	6.0	6.0
Expected volatility	228.78%	224.42% - 236.78%
Average risk free interest rate	2.16%	1.69% - 2.02%
Dividend yield	0%	0%
Grant date fair value	$ 0.10	$ 0.31

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

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

	Options	Weighted average exercise price	Weighted remaining contractual life (years)	Aggregate intrinsic value
Outstanding at December 31, 2013	21,000	$0.64	9.9	-
Granted	92,000	$0.31	9.6	-
Exercised	-	-	-	-
Cancelled	-	-	-	-
Forfeited	-	-	-	-
Outstanding at December 31, 2014	113,000	$0.37	9.5	-
Granted	83,000	$0.10	9.7	-
Exercised	-	-	-	-
Cancelled	-	-	-	-
Forfeited	-	-	-	-
Outstanding at December 31, 2015	196,000	$0.31	9.0	$-
Vested at December 31, 2014	113,000	$0.37	9.5	$-
Vested at December 31, 2015	196,000	$0.31	9.0	$-

The aggregate intrinsic value is calculated as the difference between the exercise price of all outstanding stock options and the quoted price of the Company's common stock at December 31, 2015. At December 31, 2015 and 2014, the aggregate intrinsic value of all outstanding stock options was $0. During the years ended December 31, 2015 and 2014, the Company recognized stock-based compensation from stock options of $8,564 and $28,615, respectively.

Restricted Stock Units

The following table summarizes the number of restricted stock units activity for the years ended December 31, 2015 and 2014 under both plans:

	Restricted Stock Units
Outstanding at December 31, 2013	6,311,250
Granted	1,958,989
Expired	-
Cancelled	-
Forfeited	-
Outstanding at December 31, 2014	8,270,239
Granted	10,354,497
Exchanged	(500,000
Cancelled	(570,000
Outstanding at December 31, 2015	17,554,736
Vested at December 31, 2014	7,228,565
Vested at December 31, 2015	14,398,487

The vested restricted stock units at December 31, 2015 and 2014 have not settled and are not showing as issued and outstanding shares of the Company. Settlement of these vested restricted stock units will occur on the earliest of (i) the

date of termination of service of the employee or consultant, (ii) change of control of the Company, or (iii) 10 years from date of issuance. Settlement of vested restricted stock units may be made in the form of (i) cash, (ii) shares, or (iii) any combination of both, as determined by the board of directors and is subject to certain criteria having been fulfilled by the recipient.

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Significant grants of stock units as of December 31, 2015 are as follows:

On February 15, 2013, the Company entered into a stock unit agreement with its President and Chief Executive Officer pursuant to his employment agreement. Under the terms of the agreement, the Company issued 6,000,000 stock units, 2,000,000 of the units vested immediately, while the remaining 4,000,000 vest in eight equal quarterly installments until January 1, 2015, subject to his continued service to the Company as of the vesting date. As of December 31, 2015, all of the stock units have vested under this agreement and there were 500,000 stock units which vested during the year ended December 31, 2015.

In connection with the appointment of our former Executive Vice President and Chief Financial Officer, the Company entered into an employment letter with her on February 6, 2014. Under the terms of the employment letter, Ms. Dillen received 600,000 restricted stock units. 200,000 of the units vested after six months of employment, while the remaining 400,000 vest in eight equal quarterly installments until August 6, 2016, subject to her continued service to the Company as of the vesting date. In July 2015, Ms. Dillen terminated employment with the Company. As of December 31, 2015, 350,000 restricted stock units have vested under this agreement and the remaining 250,000 units have been forfeited. The restricted stock units were exchanged for shares of common stock in March 2016.

On February 6, 2014, the Company issued 852,273 stock units to the President and CEO in lieu of cash for the annual bonus and recognized and expensed equal to the fair value of such shares in 2014.

During the years ended December 31, 2015 and 2014, the Company issued 10,354,497 and 1,959,489 restricted stock units to employees, board members and consultants. In 2015, 9,370,000 were from the 2014 Plan and vest one-third on the issuance date and then monthly for the next 2 years. The balances were from the 2014 plan and vested immediately. The grant date fair value of restricted stock units issued in 2015 and 2014 was $1,363,413 and $493,906, respectively. During the year ended December 31, 2015, 500,000 units were exercised and 320,000 units were forfeited. For the year ended December 31, 2015 and 2014, the Company recognized $1,289,676 and $1,496,146 of stock-based compensation expense for the vested units. As of December 31, 2015, compensation expense related to unvested shares not yet recognized in the consolidated statement of operations was $441,876 and will be recognized over 1.25 years.

Warrants

During the year ended December 31, 2014, the Company issued 380,973 warrants in connection with the 2011 Dawson James notes (which were repaid in 2013). The warrants have an exercise price of $0.10 and expire December 6, 2018.

In February, 2014, the Company issued 250,000 warrants in connection with the February 2014 Convertible Debentures. The warrants had an exercise price of $0.50 per share and expire February 13, 2019. On March 6, 2015 the Company entered into an agreement with the note holder to extend the February 2014 Convertible Debentures for six months. As consideration for the extension, the Company issued the note holder an additional 250,000 warrants, reduced the exercise price of the warrants from $0.50 to $0.30 per share and extended the expiration date to March 12, 2020. The warrants were also amended to include certain anti-dilution protection, including protection upon dilutive issuances. In connection with the third quarter 2015 convertible debenture financing, the exercise price of these warrants was reduced to $0.0896 per share and an additional 1,173,410 warrants were issued per the anti-dilution protection afforded in the warrant agreement during the year ended December 31, 2015. The increase in the fair value of the warrants from the additional warrants issued is included in the change in fair value of derivative liabilities in the consolidated statement of operations (Note 9).

In January, 2015, the Company issued 500,000 warrants in connection with the January 2015 Non-Convertible Debentures. The warrants are exercisable for five years from the closing date at an exercise price of $0.30 per share of common stock or January 21, 2020. The warrants contain anti-dilution protection, including protection upon dilutive issuances. In connection with the third quarter 2015 convertible debenture financing, the exercise price of these warrants was reduced to $0.0896 per share and an additional 1,173,410 warrants were issued per the anti-dilution protection afforded in the warrant agreement during the year ended December 31, 2015. The increase in the fair value of the warrants from the additional warrants issued is included in the change in fair value of derivative liabilities in the consolidated statement of operations (Note 9).

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

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In connection with the Third Quarter 2015 Financing the Company issued 1,808,333 warrants with an exercise price of $0.30 per share (see Note 5).

At December 31, 2015, there are 6,372,831 fully vested warrants outstanding.

Net Loss per Share

Commencing in the period ended September 30, 2015 we determined that restricted stock units that are vested but the issuance and delivery of the shares are deferred until the employee or director resigns should be included in the basic and diluted net loss per share calculations.

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

The weighted average restricted stock units vested but deferred until the employee or director resigns outstanding used in the basic and diluted net loss per share calculation for the year ended December 31, 2015 was 11,157,751.

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

The weighted average restricted stock units vested but deferred until the employee or director resigns outstanding during the year ended December 31, 2014 was 5,465,864. The total weighted average shares outstanding during the year ended December 31, 2014 would have been 29,849,900. The impact on the previously reported basic and diluted net loss per share would have been a decrease in the basic and diluted net loss per share of $0.04 to a net loss per share of $0.16 for the year ended December 31, 2014.

The following table shows the anti-dilutive shares excluded from the calculation of basic and diluted net loss per common share as of December 31, 2015 and 2014:

	As of December 31,	
	2015	2014
Gross number of shares excluded:		
Restricted stock units - unvested	3,156,249	1,041,674
Stock options	196,000	113,000
Convertible debentures	12,751,512	2,115,195
Warrants	6,372,831	630,973
Total	22,476,592	3,900,842

The above table does not include the ANDA Consideration Shares related to the Novalere acquisition, as they are considered contingently issuable (see Note 3).

NOTE 9 – DERIVATIVE LIABILITIES

The warrants issued in connection with the January 2015 Non-Convertible Debenture, January 2015 Non-Convertible Debenture to the former CFO and the February 2014 Convertible Debenture are measured at fair value and classified as a liability because these warrants contain anti-dilution protection and therefore, cannot be considered indexed to the Company's own stock which is a requirement for the scope exception as outlined under FASB ASC 815. The estimated fair value of the warrants was determined using the Probability Weighted Black-Scholes Option-Pricing Model, resulting in a value of $226,297 at the date of issuance. The fair value will be affected by changes in inputs to that

model including our stock price, expected stock price volatility, the contractual term and the risk-free interest rate. The Company will continue to classify the fair value of the warrants as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability, whichever comes first. The anti-dilution protection for the warrants survives for the life of the warrants which ends in January 2020 and March 2020.

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The assumptions for the Probability Weighted Black-Scholes Option-Pricing Model for the year ended December 31, 2015 are represented in the table below for the warrants issued with the January 2015 Non-Convertible Debenture, January 2015 Non-Convertible Debenture to the former CFO and the February 2014 Convertible Debenture, reflected on a per share common stock equivalent basis.

	December 31, 2015	
Expected life (in years)	4.06 – 5.00	
Expected volatility	226	%
Average risk free interest rate	1.15% - 1.54	%
Dividend yield	0	%

The Company has determined the embedded conversion features of the Q3 2015 Notes to be derivative liabilities because the terms of the embedded conversion features contain anti-dilution protection and therefore, cannot be considered indexed to the Company's own stock which is a requirement for the scope exception as outlined under FASB ASC 815. The embedded conversion features are to be measured at fair value and classified as a liability with subsequent changes in fair value recorded in earnings at the end of each reporting period. The Company has determined the fair value of the derivative liabilities using a Path-Dependent Monte Carlo Simulation. The fair value of the derivative liabilities using such option pricing model will be affected by changes in inputs to that model and is based on the individual characteristics of the embedded conversion features on the valuation date as well as assumptions for volatility, remaining expected life, risk-free interest rate, credit spread, and probability of default by the Company and acquisition of the Company. The Company will continue to classify the fair value of the embedded conversion features as a liability until the conversion features are exercised, expire or are amended in a way that would no longer require these embedded conversion features to be classified as a liability, whichever comes first. The anti-dilution protection for the embedded conversion features survive the life of the Q3 2015 which mature at various dates in August 2016 through October 2016.

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

		December 31, 2015	
Stock price	$	0.07 – $0.16	
Strike price	$	0.15	
Expected life (in years)		0.74 – 1.08	
Expected volatility		101% – 119	%
Average risk free interest rate		0.28% – 0.60	%

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

	Fair value	Level 1	Level 2	Level 3	Total
	$301,779	$-	$-	$301,779	$301,779

Embedded conversion feature derivative liabilities					
Warrant derivative liabilities	432,793	-	-	432,793	432,793
Total	$734,572	$-	$-	$734,572	$734,572

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

Fair Value Measurements Using Level 3 Inputs

Warrant derivative liabilities		December 31, 2015	
Beginning balance December 31, 2014	$	-	
Initial fair value of warrant derivative liability with January 2015 Non-Convertible Debenture		99,999	
Initial fair value of warrant derivative liability with January 2015 Non-Convertible Debenture to Former CFO		49,999	
Initial fair value of warrant derivative liability with the February 2014 Convertible Debentures		76,299	
Change in Fair Value		206,496	
Ending Balance December 31, 2015	$	432,793	
Embedded conversion feature derivative liabilities			
Beginning Balance December 31, 2014	$	-	
Initial fair value of embedded conversion feature derivative liabilities with the Q3 2015 Notes		901,784	
Change in Fair Value		(600,005	)
Ending Balance December 31, 2015	$	301,779	

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NOTE 10 – INCOME TAXES

The Company is subject to taxation in the United States and California. The benefit from income taxes for the years ended December 31, 2015 and 2014 are summarized below:

	2015	2014
Current:		
Federal	$ (759,428)	$ -
State	2,400	-
Total current	(757,028)	-
Deferred:		
Federal	(67,000)	1,680,000
State	34,000	300,000
Change in valuation allowance	33,000	(1,980,000)
Total deferred	-	-
Income tax provision (benefit)	$ (757,028)	$ -

As a result of the Novalere acquisition and the intangible assets acquired (see Note 3), the Company released $759,428 of its deferred tax valuation allowance during the year ended December 31, 2015 which is recorded as an increase in goodwill (see Note 4) and benefit from income taxes in the accompanying consolidated statement of operations. The Company also recorded an impairment against this goodwill of $759,428. At December 31, 2015, the Company had federal net operating loss carry forwards of approximately $8,901,000 which may be offset against future taxable income through 2035, and a California net operating loss carryforward of approximately $8,471,000. No net deferred tax assets are recorded at December 31, 2015 or 2014, as all deferred tax assets and liabilities have been fully offset by a valuation allowance due to the uncertainty of future utilization.

At December 31, 2015 and 2014, deferred tax assets (liabilities) consist of the following:

	2015	2014
Net operating loss carry-forwards	$ 3,521,000	$ 2,218,000
State taxes	1,000	-
Equity based instruments	2,181,000	1,515,000
Deferred compensation	575,000	361,000
Intangibles	158,000	173,000
Derivative liabilities	331,000	-
Warrants	-	759,000
Other	106,000	46,000
Total deferred tax assets	6,873,000	5,072,000
Intangibles	(1,687,000)	-
Debt discount	(142,000)	-
Other	(5,000)	-
Total deferred tax liabilities	(1,834,000)	-
Less: valuation allowance	(5,039,000)	(5,072,000)
Net deferred tax assets	-	-

At December 31, 2015 and 2014, the Company has recorded a full valuation allowance against its net deferred tax assets of approximately $5,039,000 and $5,072,000 respectively. The change in the valuation allowance during the year ended December 31, 2015 was a decrease of approximately $33,000 and a full valuation allowance has been recorded since, in the judgement of management, these net deferred tax assets are not more likely than not to be realized. The ultimate realization of deferred tax assets and liabilities is dependent upon the generation of future taxable income during periods in which those temporary differences and carryforwards become deductible or are utilized.

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

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

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

A reconciliation of the statutory federal income tax rate for the year ended December 31, 2015 and 2014 to the effective tax rate is as follows:

	2015	2014
Expected federal tax	34.00 %	34.00 %
State tax (net of federal benefit)	(0.04)%	6.13 %
Release of valuation allowance	18.10%	-%
Other	(0.01)%	0.89%
Valuation allowance	(33.97)%	(41.02)%
Total	18.08%	-%

The Company follows FASB ASC 740-10, Uncertainty in Income Taxes. The Company recognizes interest and penalties associated with uncertain tax positions as a component of income tax expense. The Company does not have any unrecognized tax benefits or a liability for uncertain tax positions at December 31, 2015 and 2014. The Company does not expect to have any unrecognized tax benefits within the next twelve months. The Company recognizes accrued interest and penalties associated with uncertain tax positions, if any, as part of income tax expense. There were no tax related interest and penalties recorded for 2015 and 2014. Since the Company incurred net operating losses in every tax year since inception, all of its income tax returns are subject to examination and adjustments by the IRS for at least three years following the year in which the tax attributes are utilized.

NOTE 11 – COMMITMENTS AND CONTINGENCIES

As described more fully in Note 2, the Company has several licensing agreements which could result in substantial payments upon the obtainment of contractual milestones.

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

The Company has annual royalty payments in connection with the Semprae acquisition discussed in Note 3.

The Company leases its facility under a non-cancelable operating lease arrangement which commenced on December 10, 2013 and currently ends on January 31, 2019. Future minimum lease payments under this lease are as follows:

Year Ended December 31, 2016	$88,087
Year Ended December 31, 2017	91,849
Year Ended December 31, 2018	95,880
Year Ended December 31, 2019	8,018
Total minimum lease payments	$283,834

The base rent expense for the years ended December 31, 2015 and 2014 was $86,931 and $73,092, respectively. The total rent, which included utilities, parking and other payments, was $97,480 and $92,297, respectively.

The Company does not currently utilize any off-balance-sheet financing.

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Litigation

The Company is party to certain legal actions arising out of the normal course of its business. In our opinion, none of these actions will have a material effect on the Company's operations, financial condition, or liquidity.

NOTE 12 – SUBSEQUENT EVENTS

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 the Company 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 the Company 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. 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.

Stock Issuances

From January 1, 2016 through March 30, 2016 the Company issued a total of 17,297,061 shares of its common stock from the exercise of RSUs by its CEO, former CFO and a consultant. The Company also issued 2,900,000 shares to consultants and 215,000 shares related to the Semprae acquisition.