INNOVUS PHARMACEUTICALS, INC.
Form 10-K
April 02, 2018

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, 2017

Commission file number: 000-52991

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

Nevada (State or other jurisdiction of incorporation or organization)	90-0814124 (IRS Employer Identification No.)
8845 Rehco Road, San Diego, CA (Address of principal executive offices)	92121 (Zip code)

Registrant's telephone number: 858-964-5123

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

Securities registered under Section 12 (g) of the Act:
Common Stock $0.001 par value

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files) Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a nonaccelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
Emerging growth company	

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

As of June 30, 2017, the last business day of the registrant’s most recently completed second fiscal quarter, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately $11.7 million, based on the closing price of $0.1126 for the registrant’s common stock as quoted on the OTCQB Market on that date. For purposes of this calculation, it has been assumed that shares of common stock held by each director, each officer and each person who owns 10% or more of the outstanding common stock of the registrant are held by affiliates of the registrant. The treatment of these persons as affiliates for purposes of this calculation is not conclusive as to whether such persons are, affiliates of the registrant for any other purpose.

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:

As of March 29, 2018, the registrant had 192,555,147 shares of common stock outstanding.

Portions of the registrant’s definitive proxy statement for its 2018 Annual Meeting of Stockholders (Proxy Statement) are incorporated by reference in Part III of this annual report on Form 10-K (Annual Report), to the extent stated herein.

TABLE OF CONTENTS

		Page
PART I		1
FORWARD LOOKING STATEMENTS		1
Item 1.	Business.	2
Item 1A.	Risk Factors.	12
Item 1B.	Unresolved Staff Comments.	22
Item 2.	Properties.	22
Item 3.	Legal Proceedings.	23
Item 4.	Mine Safety Disclosures.	23
PART II		24
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchase of Equity Securities.	24
Item 6.	Selected Financial Data.	26
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations.	27
Item 7A.	Quantitative and Qualitative Disclosures about Market Risk.	39
Item 8.	Financial Statements and Supplementary Data.	39
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.	39
Item 9A.	Controls and Procedures.	39
Item 9B.	Other Information.	40
PART III		41
Item 10.	Directors, Executive Officers and Corporate Governance.	41
Item 11.	Executive Compensation.	41
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.	41
Item 13.	Certain Relationships and Related Transactions, and Director Independence.	41

Item 14. Principal Accountant Fees and Services. 41

PART IV 42

Item 15. Exhibits and Financial Statement Schedules. 42

Table of Contents

PART I

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

"Zestra®", "Zestra Glide®", "EjectDelay®", "Sensum+®", "Vesele®", "Beyond Human®", "Androferti®", "RecalMax™", "
"FlutiCare®", "Xyralid®", "AllerVarx®", "Apeaz®", "ArthriVarx®", "Diabasens™", "Musclin™", and "Regenerum™" and
trademarks and intellectual property of ours appearing in this report are our property, unless indicated otherwise.
Can-C® is a registered trademark of International AntiAging Systems that is licensed to the Company. Amazon® is a registered trademark owned by Amazon Technologies, Inc., eBay® is a registered trademark owned by eBay, Inc., Wish.com is owned by Wish, Inc., Sears.com is owned by Sears Brands, LLC, Walmart.com® is a registered trademark owned by Wal-Mart Stores, Inc., and Walgreens.com is owned by Walgreen Co. This report contains additional trade names and trademarks of other companies. We do not intend our use or display of other companies' trade names or trademarks to imply an endorsement or sponsorship of us by such companies, or any relationship with any of these companies.

FORWARD LOOKING STATEMENTS

Certain statements in this report, including information incorporated by reference, are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements reflect current views about future events and financial performance based on certain assumptions. They include opinions, forecasts, intentions, plans, goals, projections, guidance, expectations, beliefs or other statements that are not statements of historical fact. Words such as "will," "may," "should," "could," "would," "expects," "plans," "believe
"anticipates," "intends," "estimates," "approximates," "predicts," "forecasts," "potential," "continue," or "projects," or the nega
other variation of such words, and similar expressions may identify a statement as a forward-looking statement. Any statements that refer to projections of our future financial performance, our anticipated growth and trends in our business, our goals, strategies, focus and plans, and other characterizations of future events or circumstances, including statements expressing general optimism about future operating results and the development of our products, are forward-looking statements.

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

We undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this Annual Report on Form 10-K. Readers are urged to carefully review

and consider the various disclosures made throughout the entirety of this Annual Report on Form 10-K, which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

Table of Contents

Item 1.
Business

Overview

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

Our business model leverages our ability to (a) develop and build our current pipeline of proprietary products, and (b) to also acquire outright or in-license commercial products that are supported by scientific and/or clinical evidence, place them through our existing supply chain, retail and on-line (including our Amazon®, eBay®, Wish.com, Sears.com, Walmart.com®, and Walgreens.com on-line stores and other e-commerce business platforms) channels to tap new markets and drive demand for such products and to establish physician relationships. We currently have 28 products marketed in the United States with 12 of those being marketed and sold in multiple countries around the world through some of our 18 international commercial partners. We currently expect to launch an additional seven to ten products in the U.S. in 2018 and we currently have approvals to launch certain of our already marketed products in at least six additional countries.

Corporate Structure

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

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

In February 2015, we entered into a merger agreement, whereby we acquired Novalere, Inc. and its worldwide rights to the FlutiCare® brand (fluticasone propionate nasal spray).

Our Strategy

Our corporate strategy focuses on two primary objectives:

1. Developing a diversified product portfolio of exclusive, unique and patented non-prescription OTC and branded ANDA drugs, devices, consumer health products, and clinical supplements through: (a) the introduction of line extensions and reformulations of either our or third-party currently marketed products; (b) the development of new proprietary OTC products, supplements and devices and (c) the acquisition of products or obtaining exclusive

licensing rights to market such products; and

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

Table of Contents

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

Focusing on acquisition and licensing of commercial, non-prescription pharmaceutical and consumer health products, supplements and certain related devices that are well aligned with current therapeutic areas of male and female sexual health, urology, pain, vitality and respiratory diseases. In general, we seek non-prescription pharmaceutical (OTC monograph, Rx to OTC ANDA switched drugs) and consumer health products, supplements and certain related devices that are already marketed with scientific and/or clinical data and evidence that are aligned with our therapeutic areas, which we then can grow through promotion to physicians and expanding sales through our existing retail and online channels and commercial partners on a worldwide basis. We have done this through our acquisitions and licensing of (1) Sensum+® from Centric Research Institute or CRI, (2) Zestra® and Zestra Glide® from Semprae, (3) Vesele® from Trōphikōs, LLC, (4) U.S. and Canada rights to Androferti® from Laboratorios Q Pharma (Spain), (5) FlutiCare® from Novalere, (6) UriVarx® from Seipel Group, (7) Can-C® eye drops and supplement from International AntiAging Systems, (8) our 9 Beyond Human® supplements from Beyond Human, LLC, (9) MZS™, melatonin from International AntiAging Systems and (10) Musclin™ from the University of Iowa;

Increasing the number of U.S. non-exclusive distribution channel partners for print media, direct mailing 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 four-pronged approach. First, we are seeking to increase our print media and direct to consumer mailings for our products. Second, we are seeking to expand the number of OTC direct selling partners, such as the larger in-store retail and wholesale distributors for selected products, and to expand sales to the more regional, statewide and local distributors, such as regional pharmacy chains, large grocery stores and supplement and health stores for selected products. Third, we are working to expand our online presence through relationships with well-known online sellers and the building of our own platforms such as established Amazon®, eBay®, Wish.com, Sears.com, Walmart.com® and Walgreens.com among other stores. Fourth, we are seeking to expand sales of our OTC products directly through sampling programs and detailing to physicians, urologists, gynecologists, therapists and to other healthcare providers who generally are used to recommending to their patients products that are supported by strong scientific and/or clinical data and evidence;

Seeking commercial partnerships outside the U.S. and developing consistent international commercial and distribution systems . We seek to develop a strong network of international distribution partners outside of the U.S. To do so, we are relying in part on past relationships that Dr. Bassam Damaj, our President and Chief Executive Officer, has had with certain commercial partners globally. In addition, we believe we have the ability to develop new relationships with commercial distributors who can demonstrate they have leading positions in their regions and can provide us with effective marketing and sales efforts and teams to detail our products to physicians and therapists. Our commercial partners outside the U.S. are responsible for storing, distributing and promoting our products to physicians, urologists, gynecologists, therapists and to other healthcare providers. We have already entered into 18 commercial partnerships covering our products in 110 countries outside the U.S.;

Developing our own proprietary products and a proprietary patent and trademark portfolio to protect the therapeutic products and categories we desire to enter. We have developed certain of our products ourselves, such as Apeaz® for

pain, Xyralid® for hemorrhoids and Diabasens™ a diabetic foot cream. 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. To date, we have four issued U.S. patents, seven U.S. patent applications, ten foreign patents, and four foreign patent applications. We also currently have 23 U.S. trademark registrations, 29 U.S. trademark applications, 25 foreign trademark registrations and 25 foreign trademark applications; and

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

Table of Contents

Our Products

Marketed Products

We currently market and sell 28 products in the U.S. and 12 in multiple countries around the world through our 18 international commercial partners:

1.
Vesele® for promoting sexual health (U.S. and U.K.);
2.
Zestra® for female arousal (U.S., U.K., Denmark, Belgium, France, Malaysia, India, Monaco, Canada, Morocco, the UAE, Hong Kong, South Africa and South Korea);
3.
Zestra Glide® (U.S, Canada and the MENA countries);
4.
EjectDelay® indicated for the treatment of premature ejaculation (U.S. and Canada);
5.
Sensum+® to alleviate reduced penile sensitivity (U.S., U.K. and Morocco);
6.
Beyond Human® Testosterone Booster;
7.
Beyond Human® Ketones;
8.
Beyond Human® Krill Oil;
9.
Beyond Human® Omega 3 Fish Oil;
10.
Beyond Human® Eagle Vision Formula;
11.
Beyond Human® Blood Sugar;
12.
Beyond Human® Colon Cleanse;
13.
Beyond Human® Green Coffee Extract;
14.
Beyond Human® Growth Agent;
15.
RecalMax™ for brain health;
16.
Androferti® (U.S. and Canada) supports overall male reproductive health and sperm quality;
17.
UriVarx® for overactive bladder and urinary incontinence;
18.
PEVarx® to support peak sexual performance and stamina;
19.
ProstaGorx® for prostate support;
20.
FlutiCare® for allergy symptom relief;

21.
Apeaz® for pain relief;
22.
AllerVarx® for allergy relief;
23.
ArthriVarx® for joint pain;
24.
Xyralid® a hemorrhoid cream;
25.
Can-C® Eye Drops;
26.
Can-C® capsules, an eye care supplement;
27.
MZS™, a melatonin formula to stabilize circadian rhythms, improve hormonal cyclicity and boost immunity; and
28.
Diabasens™, a diabetic foot cream.

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

(1)
Vesele®

Vesele® is a proprietary oral supplement of Arginine with high absorption backed with clinical use data in men and women for sexual dysfunction. Vesele® contains a patented formulation of L-Arginine and L-Citrulline in combination with the natural absorption enhancer Bioperine®. The beneficial effects of Vesele® on sexual and cognitive functions were confirmed in a four month U.S. 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.

(2)
Zestra®

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

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

Table of Contents

(3)
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 $200.0 million in the U.S. (Symphony IRI Group Study, 2012).

(4)
EjectDelay®

EjectDelay® is our proprietary, clinical proven OTC FDA monograph compliant 7.5% benzocaine gel for premature ejaculation. Benzocaine acts to inhibit the voltage-dependent sodium channels on the nerve membrane, stopping the propagation of the action potential and resulting in temporary numbing of the application site. EjectDelay® is applied to the head of the penis ten minutes before intercourse. Premature Ejaculation, or PE, is the absence of voluntary control over ejaculation resulting in ejaculation either preceding vaginal entry or occurring immediately upon vaginal entry and is defined as an ejaculation latency time of less than one minute. It is estimated that over 30% of males suffer from PE with a market size of $1.0 billion with a 10.3% annual growth rate. Topical anesthetics make up 14% of the total PE market (The Journal of Sexual Medicine in 2007 Sex Med 2007).

(5)
Sensum+®

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

(6)
Beyond Human® Testosterone Booster (“BHT”)

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

(7)
Beyond Human® Ketones

Beyond Human® Ketones is a proprietary blend of compounds and antioxidants, including resveratrol, African Mango Seed Extract, Green Tea Extract, Cayenne, Acai Fruit, Grapefruit and Kelp. It is designed to provide customers with increased energy and a faster metabolism to burn fat.

(8)

Beyond Human® Krill Oil

Beyond Human® Krill Oil is a supplement that delivers Omega-3-6-9, an essential fatty acid that is not produced by your body. It has been shown to help with the prevention of heart disease, inflammation, and improves cardiovascular health.

(9)
Beyond Human® Omega 3 Fish Oil

Beyond Human® Omega 3 Fish Oil is a high quality formula with ingredients in a natural balance. Omega-3 is a great way to maintain a healthy immune system and improve brain function.

(10)
Beyond Human® Eagle Vision Formula

Beyond Human® Eagle Vision Formula utilizes antioxidant power to keep eyes safe from harmful free radicals.

(11)
Beyond Human® Blood Sugar

Beyond Human® Blood Sugar contains Biotin (B7) a chemical that acts similar to insulin in helping reduce blood sugar levels and risk of bacterial infections.

Table of Contents

(12)
Beyond Human® Colon Cleanse

Beyond Human® Colon Cleanse is a supplement designed to promote colon health.

(13)
Beyond Human® Green Coffee Extract

Beyond Human® Green Coffee Extract contains the pure extract of chlorogenic acid which is among the world's most popular weight loss supplements.

(14)
Beyond Human® Growth Agent

Beyond Human® Growth Agent contains hGH or Human Growth Hormone and is designed to increase muscle mass, and bolster endurance deeper among other effects.

(15)
RecalMax™

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

(16)
Androferti®

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

(17)
UriVarx®

UriVarx® is a proprietary supplement clinically proven in a published Phase 2 clinical trial to reduce urinary urgency, accidents and both day and night frequency in Overactive Bladder ("OAB") and Urinary Incontinence ("UI") patients. UriVarx® was tested in OAB and UI patients in a 152 double blind placebo patient study over a period of eight weeks yielding up to 60% in reduction of urinary urgency and nocturnia.

(18)
PEVarx®

PEVArx® is a proprietary supplement clinically proven to support peak sexual performance and stamina in a multi-center, non-interventional study in 665 men.

(19)
ProstaGorx®

ProstaGorx® is a clinical strength, multi-response prostate supplement, scientifically formulated to effectively maintain good prostate health and help in preventing prostate issues in the future.

(20)
FlutiCare® (Fluticasone propionate nasal spray)

FlutiCare® is a nasal spray in the form of fluticasone propionate that has been the most prescribed nasal spray to patients in the U.S. for more than five consecutive years. The nasal steroid market is over $1.0 billion annually in the U.S. (Reed, Lee and McCrory, “The Economic Burden of Allergic Rhinitis”, Pharmacoecomics 2004, 22 (6) 345-361).

(21)
Apeaz®

We developed our proprietary product Apeaz®, which is an OTC FDA monograph compliant drug containing the active drug ingredient methyl salicylate and indicated for the minor aches and pains of muscles and joints associated with simple backaches, arthritis, strains, bruises and sprains.

(22)
AllerVarx®

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

Table of Contents

(23)
ArthriVarx®

This nutritional supplement is designed to relieve the pain associated with arthritis.

(24)
Xyralid®

Xyralid® is a lidocaine based OTC FDA monograph compliant cream for the relief of pain and symptoms caused by hemorrhoids.

(25)
Can-C® Eye Drops

Can-C® is an eye drops lubricant containing the antioxidant N-Acetylcarnosine molecule which we have licensed the rights to sell on a worldwide basis from a third party.

(26)
Can-C® Supplement

Can-C® Supplement is used with Can-C® Eye Drops and is thought to help to enhance free radical protection and reduce the oxidative environment inside the eye. We have licensed the rights to sell the Can-C® Supplement form a third party.

(27)
MZS™ Sleep Aid

MZS™ Sleep Aid is a supplement containing melatonin, zinc and selenium to help in improving sleep patterns in people.

(28)
Diabasens™

Diabasens™ is a proprietary cream designed to increase blood flow in the diabetic foot.

Pipeline Products

In addition, we currently expect to launch in the U.S. the following products in 2018 subject to the applicable regulatory approvals if required:

(1)
UriVarx™ UTI Urine Strips

UriVarx™ UTI Urine Strips are FDA cleared diagnostic strips for home use that a man or woman can use to determine if they have a urinary tract infection. They will be sold with our UriVarx® supplement product described above as well as on their own as replacement strips. The UriVarx™ UTI Urine Strips are manufactured by our partner, ACON Laboratories, Inc. We currently expect to launch the UriVarx™ UTI Urine Strips in the second quarter of 2018.

(2)
Xyralid® Suppositories

Xyralid® Suppositories are OTC FDA monograph suppositories indicated for the relief of both internal and external hemorrhoidal symptoms. The drug works by constricting or shrinking swollen hemorrhoidal tissues and gives prompt soothing relief from painful burning, itching and discomfort. We currently expect to launch this product in the second quarter of 2018.

(3)
GlucoGorx™ Supplement, Glucometer, Lancing Device and GlucoGorx™ Strips

GlucoGorx™ is a supplement made of a combination of herbs and nutrients designed to balance and maintain healthy blood sugar levels. The Glucometer, Lancing Device and GlucoGorx™ Strips are part of an expected FDA cleared kit that we will bundle with GlucoGorx™ to provide customers with the ability to utilize the supplement's benefits and to test their blood sugar levels in their own homes in a quick and efficient manner. The Glucometer, Lancing Device and GlucoGorx™ Strips are manufactured by our partner ACON Laboratories, Inc. We currently expect to launch this product and the kit in the second half of 2018.

(4)
Vesele™ Nitric Oxide Strips

We have developed the Vesele™ Nitric Oxide Strips to be used with our supplement product Vesele® to measure saliva levels of nitric oxide and help consumers monitor the effect of Vesele® real time on their blood flow increase. We currently expect to launch this product in the second quarter of 2018.

(5)
RecalMax™ Nitric Oxide Strips

We have developed the RecalMax™ Nitric Oxide Strips to be used with our product RecalMax™ to measure saliva levels of nitric oxide and help consumers monitor the effect of RecalMax™ real time on their blood flow increase. We currently expect to launch this product in the second quarter of 2018.

Table of Contents

(6)
Musclin™

Musclin™ is a proprietary supplement made of two FDA Generally Recognized As Safe (GRAS) approved ingredients designed to increase muscle mass, endurance and activity. The main ingredient in Musclin™ is a natural activator of the transient receptor potential cation channel, subfamily V, member 3 (TRPV3) channels on muscle fibers responsible to increase fibers width resulting in larger muscles. We currently expect to launch this product in the second half of 2018.

(7)
Regenerum™

Regenerum™ is a proprietary product containing two natural molecules; one is an activator of the TRPV3 channels resulting in the increase of muscle fiber width, and the second targets a different unknown receptor to build the muscle's capacity for energy production and increases physical endurance, allowing longer and more intense exercise. Regenerum™ is being developed for patients suffering from muscle wasting. We currently expect to launch this product in 2019 pending successful clinical trials in patients with muscle wasting or cachexia.

In addition to the above product pipeline, the Company currently intends to license and acquire other products that it may launch in 2018.

Sales and Marketing Strategy U.S. and Internationally

Our sales and marketing strategy is based on (a) the use of direct to consumer advertisements in print and online media through our proprietary Beyond Human™ sales and marketing platform acquired in March 2016, which in addition to the print includes extensive on-line media channels through our Amazon®, eBay®, Wish.com, Sears.com, Walgreens.com and Walmart.com® sites, over 170 websites and over 2.5 million subscribers, (b) working with direct retail and wholesale commercial channel partners in the U.S. and also directly marketing the products ourselves to physicians, urologists, gynecologists and therapists and to other healthcare providers, and (c) working with exclusive commercial partners outside of the U.S. that would be responsible for sales and marketing in those territories. We have now fully integrated most of our existing line of products such as Vesele®, Sensum+®, UriVarx®, Zestra®, RecalMax™, Xyralid®, FlutiCare®, Apeaz® and other products into the Beyond Human™ sales and marketing platform. We plan to integrate other products upon their commercial launches in 2018. We also market and distribute our products in the U.S. through retailers, wholesalers and other online channels. Our strategy outside the U.S. is to partner with companies who can effectively market and sell our products in their countries through their direct marketing and sales teams. The strategy of using our partners to commercialize our products is designed to limit our expenses and fix our cost structure, enabling us to increase our reach while minimizing our incremental spending.

Our current OTC, Rx-to-OTC ANDA switch drugs and consumer care products marketing strategy is to focus on four main U.S. markets, all of which we believe to be each in excess of $1.0 billion: (1) Sexual health (female and male sexual dysfunction and health); (2) Urology (bladder and prostate health); (3) Respiratory disease;(4) Brain health; and (5) Pain. We will focus our current efforts on these four markets and will seek to develop, acquire or license products that we can sell through our sales channels in these fields.

Manufacturers and Single Source Suppliers

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

Government Regulation

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

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

Table of Contents

U.S. Food and Drug Administration

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

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

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

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

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

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

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

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

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

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

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.

Table of Contents

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

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

BioEquivalency Studies

Studies to measure bioavailability and/or establish bioequivalence of a product are important elements in support of investigational new drug applications, or INDs, new drug applications, or NDAs, ANDAs and their supplements. As part of INDs and NDAs for orally administered drug products, bioavailability studies focus on determining the process by which a drug is released from the oral dosage form and moves to the site of action. Bioavailability data provide an estimate of the fraction of the drug absorbed, as well as its subsequent distribution and elimination. Bioavailability can be generally documented by a systemic exposure profile obtained by measuring drug and/or metabolite concentration in the systemic circulation over time. The systemic exposure profile determined during clinical trials in the IND period can serve as a benchmark for subsequent bioequivalence studies. Studies to establish bioequivalence between two products are important for certain changes before approval for a pioneer product in NDA and ANDA submissions and in the presence of certain post-approval changes in NDAs and ANDAs. In bioequivalence studies, an applicant compares the systemic exposure profile of a test drug product to that of a reference drug product. For two orally or intra-nasally administered drug products to be bioequivalent, the active drug ingredient or active moiety in the test product must exhibit the same rate.

OTC Monograph Process

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

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

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

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

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

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

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

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

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

Table of Contents

Other Regulatory Requirements

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

Meeting record-keeping requirements;

Reporting of adverse experiences with the drug;

Providing the FDA with updated safety and efficacy information;

Reporting on advertisements and promotional labeling;

Drug sampling and distribution requirements; and

Complying with electronic record and signature requirements.

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

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

Competition

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

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

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

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

Table of Contents

Research and Development

We have used outside contract research organizations to carry out our research and development activities. During the years ended December 31, 2017 and 2016, we incurred research and development costs totaling $38,811, and $77,804, respectively. This decrease was a result of the cost of salary and the related health benefits for an employee in 2016 compared to 2017 and the conclusion of testing, non-human primate safety studies and clinical studies for our products Zestra®, Zestra Glide®, EjectDelay® and Sensum+® completed in 2016 compared to 2017. In addition, in 2016, we issued shares of common stock to CRI with a fair value of $23,000 for certain clinical and regulatory milestone payments due under the in-license agreement for Sensum+®.

Employees

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

Intellectual Property Protection

Our ability to protect our intellectual property, including our technology, will be an important factor in the success and continued growth of our business. We protect our intellectual property through trade secrets law, patents, copyrights, trademarks and contracts. Some of our technology relies upon third-party licensed intellectual property.

We currently hold four patents in the U.S. and ten patents registered outside the U.S. We currently have seven patent applications pending in the U.S. and four patent applications pending in countries other than the U.S. We also have exclusive U.S. rights to multiple patents in the U.S. and Europe licensed under the product license agreements we have with NTC Pharma and Q Pharma.
We own 23 trademark registrations in the U.S. and have 29 trademark applications pending in the U.S. We also own 25 trademarks registered outside of the U.S., with 25 applications currently pending.

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

Company Information

Our executive offices are located at 8845 Rehco Road, San Diego, California 92121 and our telephone number at such office is (858) 964-5123. Our website address is innovuspharma.com. Information contained on our website is not deemed part of this Annual Report.

Item 1A.
Risk Factors.

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

Risks Associated with Our Financial Condition

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

As of December 31, 2017, we had an accumulated deficit of approximately $35.6 million. In addition, we incurred net losses of approximately $6.5 million and $13.7 million for the years ended December 31, 2017 and 2016, respectively. These losses may continue in the future. We expect to continue to incur significant sales and marketing, research and development, and general and administrative expense. As a result, we will need to generate significant revenue to achieve profitability, and we may never achieve profitability. Revenue and profit, if any, will depend upon various factors, including (1) growing the current sales of our products, (2) the successful acquisition of additional commercial products, (3) raising capital to implement our growth strategy, (4) obtaining any applicable regulatory approvals of our proposed product candidates, (5) the successful licensing and commercialization of our proposed product candidates, and (6) growth and development of our operations. We may not achieve our business objectives and the failure to achieve such goals would have an adverse impact on us.

Table of Contents

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

We have not been profitable since inception. As of December 31, 2017, we had approximately $1.6 million in cash. We had a net loss of approximately $6.5 million and $13.7 million for the years ended December 31, 2017 and 2016, respectively. Additionally, sales of our existing products are significantly below the levels necessary to achieve positive cash flow. Although we expect that our existing capital resources and revenue from sales of our products will be sufficient to allow us to continue our operations, commence the product development process and launch selected products through at least April 1, 2019, no assurances can be given that we will not need to raise additional capital to fund our business plan. If we are not able to raise sufficient capital, our continued operations may be in jeopardy and we may be forced to cease operations and sell or otherwise transfer all or substantially all of our remaining assets.

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

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

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

We have historically funded our operations partly through the issuance of debt securities. If we obtain additional debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting funds available for our business activities. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or curtail our operations. In addition, we may be required to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to technologies or products that we would otherwise seek to develop or commercialize ourselves or license rights to technologies or products on terms that are less favorable to us than might otherwise be available.

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

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

U.S. federal income tax reform could adversely affect us.

On December 22, 2017, President Trump signed into law the "Tax Cuts and Jobs Act" (TCJA) that significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. We do not expect tax reform to have a material impact to our projection of minimal cash taxes or to our net operating losses. Our net deferred tax assets and liabilities will be revalued at the newly enacted U.S. corporate rate, and the impact will be recognized in our tax expense in the year of enactment. We continue to examine the impact this tax reform legislation may have on our business. The impact of this tax reform on holders of our common stock is uncertain and could be adverse. This Annual Report does not discuss any such tax legislation or the manner in which it might affect purchasers of our common stock. We urge our stockholders, including purchasers of common stock in this offering, to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

Risks Associated with Our Business Model

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

We have a short operating history with our current business model, which involves the commercialization, licensing and development of over-the-counter healthcare products. While we have been in existence for years, we only began our current business model in 2013 and only generated approximately $1.0 million in net revenue in 2014, approximately $736,000 in 2015 and approximately $8.8 million and $4.8 million in net revenue for the years ended December 31, 2017 and 2016, 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 revenue over a period of time, and may not produce significant revenue in the near term, which may harm our ability to obtain additional financing and may require us to reduce or discontinue our operations. You must consider our business and prospects in light of the risks and difficulties we will encounter as an early-stage company. We may not be able to successfully address these risks and difficulties, which could significantly harm our business, operating results and financial condition.

Table of Contents

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

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

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

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

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

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

Our sales and marketing function is currently very limited and we currently rely on direct to consumer advertisements and third parties to help us promote our products to physicians in the U.S., as well as, 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 $4.8 million in net revenue in 2016, and approximately $8.8 million during the year ended December 31, 2017. 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 revenue would decrease and we would incur net losses as a result of sales of the product, if any sales could be made.

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

Table of Contents

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

Our U.S. business could be adversely affected by changes as a result of the current U.S. presidential administration.

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

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

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

Potentially reduced protection for intellectual property rights;

Unexpected changes in tariffs, trade barriers and regulatory requirements;

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

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

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

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.

Table of Contents

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

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

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

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

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

The availability of funding sufficient to meet increased capital needs;

Diversion of management's attention; and

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

Completing acquisitions may require significant management time and financial resources. In addition, acquired companies may have liabilities that we failed, or were unable, to discover in the course of performing due diligence investigations. We cannot assure you that the indemnification granted to us by sellers of acquired companies will be sufficient in amount, scope or duration to fully offset the possible liabilities associated with businesses or properties we assume upon consummation of an acquisition. We may learn additional information about our acquired businesses that materially adversely affect us, such as unknown or contingent liabilities and liabilities related to compliance with applicable laws. Any such liabilities, individually or in the aggregate, could have a material adverse effect on our business.

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

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

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

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

Successfully grow our marketing, distribution and sales infrastructure; and

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.

Table of Contents

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

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

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

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

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

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

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

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

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

Risks Relating to Intellectual Property

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

We may face additional litigation owing to the nature and sales channels of our products.

Since we currently have 28 products on the market in the U.S. and have growing revenue, from time to time, we may face product liability litigation and/or other litigation owing to the manner that we market and sell certain of our products such as through nationwide newspaper advertisements, direct mailing or other direct to consumer campaigns. If we are unsuccessful in defending claims brought against us, such as those brought in the case described in Item 3 of this Annual Report on Form 10-K, the result could have a material impact on the profit and losses of the Company.

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

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

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

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

The third-party manufacturer from the Novalere acquisition may never receive ANDA approval to manufacture FlutiCare®, which we are relying upon to generate future revenue outside the U.S. and as a second source of supply within the U.S.

Because of the unpredictability of the FDA review process for generic drugs, the ANDA filed by the third-party manufacturer to enable it to manufacture our product FlutiCare® may never be approved by the FDA for a variety of reasons. If such ANDA is not approved, we will not be able to realize revenue from the sale of this drug outside of the U.S. unless we secure another manufacturing source and we will not have a second source of supply for the manufacturing of FlutiCare® in the U.S.

Table of Contents

Risks Related to Ownership of our Common Stock

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

As of December 31, 2017, we had 167,420,605 shares of common stock outstanding. A substantial number of those shares are restricted securities and such shares may be sold under Rule 144 of the Securities Act of 1933, as amended ("Securities Act"), subject to any applicable holding period. As such, sales of the above shares or other substantial amounts of our common stock in the public or private markets, or the availability of such shares for sale by us, including the issuance of common stock upon conversion and/or exercise of outstanding convertible securities, warrants and options, could adversely affect the price of our common stock. We may sell additional shares or securities convertible into shares of common stock, which could adversely affect the market price of shares of our common stock. In addition, the sale of a substantial number of shares of our common stock, or anticipation of such sales, could make it more difficult for us to obtain future financing. To the extent the trading price of our common stock at the time of exercise of any of our outstanding options or warrants exceeds their exercise price, such exercise will have a dilutive effect on our stockholders.

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

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

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

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

Developments involving our discovery efforts and clinical trials;

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

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.

Table of Contents

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

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

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

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

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

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

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

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

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.

Table of Contents

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

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

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

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

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

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

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

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

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

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

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

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

Item 1B.
Unresolved Staff Comments.

There are no unresolved staff comments at December 31, 2017.

Item 2.
Properties.

In October 2017, we entered into a commercial lease agreement for 16,705 square feet of office and warehouse space in San Diego, CA that commenced on December 1, 2017 and continues until April 30, 2023. The initial monthly base rent is $20,881 with an approximate 3% increase in the base rent amount on an annual basis, as well as, rent abatement for rent due from January 2018 through May 2018. We hold an option to extend the lease an additional 5 years at the end of the initial term. Under the terms of the lease we are also entitled to a tenant improvement allowance of $100,000 in which completion of the tenant improvements and receipt of the allowance was in 2018.

We believe that our existing facilities are suitable and adequate to meet our current business requirements, but we may 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.

Table of Contents

Item 3.
Legal Proceedings.

James L. Yeager, Ph.D., and Midwest Research Laboratories, LLC v. Innovus Pharmaceuticals, Inc. On January 18, 2018, Dr. Yeager and Midwest Research Laboratories (the "Plaintiffs") filed a complaint in the Illinois Northern District Court in Chicago, Illinois, which Plaintiffs amended on February 26, 2018 ("Amended Complaint"). The Amended Complaint alleges that the Company violated Dr. Yeager's right of publicity and made unauthorized use of his name, likeness and identity in advertising materials for its product Sensum+®. Plaintiffs seek actual and punitive damages, costs and attorney's fees, an injunction and corrective advertising. We intend to file a response to the Amended Complaint by May 21, 2018. We believe that the Plaintiffs' allegations and claims are wholly without merit, and we intend to defend the case vigorously and assert counterclaims against the Plaintiffs. More specifically, we believe that we secured and paid for all of the rights claimed by Dr. Yeager from his company Centric Research Institute ("CRI") pursuant to agreements with CRI (the "CRI Agreements") and that CRI has indemnification obligations under the CRI Agreements for all expenses and losses associated with the claims made by the Plaintiffs.

From time to time, in addition to the matter identified above, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in the matter identified above or other matters may harm our business.

Item 4.
Mine Safety Disclosures.

Not applicable.

Table of Contents

PART II

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

Market Information

Our common stock is available for quotation on the OTCQB Marketplace under the trading symbol "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 Marketplace. The quotes represent inter-dealer prices, without adjustment for retail mark-up, markdown or commission and may not represent actual transactions. The trading volume of our securities fluctuates and may be limited during certain periods. As a result of these volume fluctuations, the liquidity of an investment in our securities may be adversely affected.

	2017		2016	
	High	Low	High	Low
First Quarter	$0.390	$0.100	$0.100	$0.028
Second Quarter	$0.150	$0.082	$0.369	$0.049
Third Quarter	$0.139	$0.087	$0.663	$0.205
Fourth Quarter	$0.117	$0.078	$0.330	$0.161

As of March 29, 2018, we had 564 record holders of our common stock. The number of record holders does not include holders who hold their stock in "street name" or "nominee name" inside bank or brokerage accounts.

Dividend Policy

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

Table of Contents

Equity Compensation Plan Information

The following table provides information as of December 31, 2017 regarding our equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column(a))
	(a)	(b)	(c)
Equity Compensation Plans Approved by Security Holders:			
Amended and Restated 2016 Equity Incentive Plan	4,168,987	$0.305	(1) 21,008,882
Equity Compensation Plans Not Approved by Security Holders:			
2013 Equity Incentive Plan	1,036,849	$0.157	(1) 89,516
2014 Equity Incentive Plan	8,073,999	$0.145	(1) 49,367
Total	13,279,835	$0.153	(1) 21,147,765

(1) Excludes outstanding RSUs, which have no associated exercise price.

Table of Contents

Recent Sales of Unregistered Securities

For the fourth quarter of 2017, we issued 669,328 restricted shares of our common stock valued at $57,688 in exchange for services under existing consulting and service agreements with third parties.

For the fourth quarter of 2017, certain 2016 and 2017 Notes Payable holders elected to exchange $515,546 in principal and interest into 8,592,431 shares of common stock.

We entered into a private financing for $850,000 on December 4, 2017 and December 13, 2017 with three institutional investors. We issued 1,600,000 restricted shares of common stock to the investors in connection with the notes payable. In connection with this financing, we issued 1,119,851 restricted shares of common stock to a third-party consultant valued at $98,761.

Each of the securities were offered and sold in transactions exempt from registration under the Securities Act, in reliance on Section 4(a)(2) thereof and Rule 506 of Regulation D thereunder and/or Section 3(a)(9) of the Securities Act. Each of the investors represented that it was an "accredited investor" as defined in Regulation D under the Securities Act.

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

Use of Proceeds from the Sale of Registered Securities

On March 15, 2017, our registration statement on Form S-1 (File No. 333-215851) was declared effective by the SEC for our public offering pursuant to which we sold an aggregate of 25,666,669 shares of our common stock at an offering price of $0.15 per share. There has been no material change in our use of proceeds from our public offering as described in our final prospectus filed with the SEC on March 17, 2017 pursuant to Rule 424(b).

Item 6.
Selected Financial Data.

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

Table of Contents

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

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

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

Overview

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

Our business model leverages our ability to (a) develop and build our current pipeline of proprietary products, and (b) to also acquire outright or in-license commercial products that are supported by scientific and/or clinical evidence, place them through our existing supply chain, retail and on-line (including our Amazon®, eBay®, Wish.com, Sears.com, Walmart.com®, and Walgreens.com on-line stores and other e-commerce business platforms) channels to tap new markets and drive demand for such products and to establish physician relationships. We currently have 28 products marketed in the United States with 12 of those being marketed and sold in multiple countries around the world through some of our 18 international commercial partners. We currently expect to launch an additional seven to ten products in the U.S. in 2018 and we currently have approvals to launch certain of our already marketed products in at least six additional countries.

Our Strategy

Our corporate strategy focuses on two primary objectives:

1.

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

2.
Building an innovative, U.S. and global sales and marketing model through direct to consumer approaches such as our proprietary Beyond Human™ sales and marketing platform, the addition of new online platforms such as Amazon®, eBay®, Wish.com, Sears.com, Walmart.com® and Walgreens.com and commercial partnerships with established international complimentary partners that: (a) generates revenue, and (b) requires a lower cost structure compared to traditional pharmaceutical companies, thereby increasing our gross margins.

Table of Contents

Our Products

We currently market and sell 28 products in the U.S. and 12 in multiple countries around the world through our 18 international commercial partners:

1.
Vesele® for promoting sexual health (U.S. and U.K.);
2.
Zestra® for female arousal (U.S., U.K., Denmark, Belgium, France, Malaysia, India, Monaco, Canada, Morocco, the UAE, Hong Kong, South Africa and South Korea);
3.
Zestra Glide® (U.S., Canada and the MENA countries);
4.
EjectDelay® indicated for the treatment of premature ejaculation (U.S. and Canada);
5.
Sensum+® to alleviate reduced penile sensitivity (U.S., U.K. and Morocco);
6.
Beyond Human® Testosterone Booster;
7.
Beyond Human® Ketones;
8.
Beyond Human® Krill Oil;
9.
Beyond Human® Omega 3 Fish Oil;
10.
Beyond Human® Eagle Vision Formula;
11.
Beyond Human® Blood Sugar;
12.
Beyond Human® Colon Cleanse;
13.
Beyond Human® Green Coffee Extract;
14.
Beyond Human® Growth Agent;
15.
RecalMax™ for brain health;
16.
Androferti® (U.S. and Canada) supports overall male reproductive health and sperm quality;
17.
UriVarx® for overactive bladder and urinary incontinence;
18.
PEVarx® to support peak sexual performance and stamina;
19.
ProstaGorx® for prostate support;
20.
FlutiCare® for allergy symptom relief;
21.

Apeaz® for pain relief;
22.
AllerVarx® for allergy relief;
23.
ArthriVarx® for joint pain;
24.
Xyralid® a hemorrhoid cream;
25.
Can-C® Eye Drops;
26.
Can-C® Supplement, an eye care anti-oxidant supplement;
27.
MZS™ Sleep Aid, a sleep aid supplement; and
28.
Diabasens™, a cream to increase blood flow in the diabetic foot.

In addition, we currently expect to launch in the U.S. the following products in 2018, subject to the applicable regulatory approvals, if required:

1.
UriVarx™ UTI Urine Strips are FDA approved diagnostic strips that a man or woman can use to determine if they have a urinary tract infection (second quarter of 2018);
2.
Xyralid® Suppositories are designed to be rectal suppositories for the relief of hemorrhoids (second quarter of 2018);
3.
Vesele™ Nitric Oxide Strips for measurement of nitric oxide levels (second quarter of 2018);
4.
RecalMax™ Nitric Oxide Strips for measurement of nitric oxide levels (second quarter of 2018);
5.
GlucoGorx™ Supplement, Glucometer, Lancing Device and GlucoGorx™ Strips. GlucoGorx™ is a supplement designed to help diabetics and others control their levels of blood sugar. The Glucometer, Lancing Device and GlucoGorx™ Strips are part of an FDA approved kit that we will bundle with GlucoGorx™ (second half of 2018);
6.
Musclin™ for muscle growth (second half of 2018);and
7.
Regenerum™ for muscle wasting (2019).

Table of Contents

Sales and Marketing Strategy U.S. and Internationally

Our sales and marketing strategy is based on (a) the use of direct to consumer advertisements in print and online media through our proprietary Beyond Human™ sales and marketing platform acquired in March 2016, which in addition to the print includes extensive on-line media channels through our Amazon®, eBay®, Wish.com, Sears.com, Walgreens.com and Walmart.com® sites, over 170 websites and over 2.5 million subscribers, (b) working with direct retail and wholesale commercial channel partners in the U.S. and also directly marketing the products ourselves to physicians, urologists, gynecologists and therapists and to other healthcare providers, and (c) working with exclusive commercial partners outside of the U.S. that would be responsible for sales and marketing in those territories. We have now fully integrated most of our existing line of products such as Vesele®, Sensum+®, UriVarx®, Zestra®, RecalMax™, Xyralid®, FlutiCare®, Apeaz® and other products into the Beyond Human™ sales and marketing platform. We plan to integrate other products upon their commercial launches in 2018. We also market and distribute our products in the U.S. through retailers, wholesalers and other online channels. Our strategy outside the U.S. is to partner with companies who can effectively market and sell our products in their countries through their direct marketing and sales teams. The strategy of using our partners to commercialize our products is designed to limit our expenses and fix our cost structure, enabling us to increase our reach while minimizing our incremental spending.

Our current OTC, Rx-to-OTC ANDA switch drugs and consumer care products marketing strategy is to focus on four main U.S. markets all of which we believe to be each in excess of $1.0 billion: (1) Sexual health (female and male sexual dysfunction and health); (2) Urology (bladder and prostate health); (3) Respiratory disease; (4) Brain health; and (5) Pain. We will focus our current efforts on these four markets and will seek to develop, acquire or license products that we can sell through our sales channels in these fields.

Recent Developments

West-Ward Pharmaceuticals Commercial Agreement

In May 2017, we entered into a commercial agreement with West-Ward Pharmaceuticals International Limited (“WWPIL”), a wholly-owned subsidiary of Hikma Pharmaceuticals PLC (“Hikma”) (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY). Pursuant to the commercial agreement, WWPIL provided us with the rights to launch our branded, fluticasone propionate nasal spray USP, 50 mcg per spray (FlutiCare®), under WWPIL’s FDA approved ANDA No. 207957 in the U.S. in mid-November 2017. The initial term of the commercial agreement is for two years, and upon expiration of the initial term, the agreement will automatically renew for subsequent one-year terms unless either party notifies the other party in writing of its desire not to renew at least 90 days prior to the end of the then current term. The agreement requires us to meet certain minimum product batch purchase requirements in order for the agreement to continue to be in effect.

Ex-U.S. Product License Agreements

On January 18, 2018, we entered into an exclusive ten-year license agreement with Lavasta Pharma FZ-LLC, a Dubai company (“Lavasta”), under which we granted to Lavasta an exclusive license to market and sell ProstaGorx® in the Kingdom of Saudi Arabia, Algeria, Egypt, the United Arab Emirates, Lebanon, Jordan, Kuwait, Morocco, Tunisia, Bahrain, Oman, Qatar, and Turkey, among other countries. If any country in the territory under this agreement is ever listed on the U.S. Department of Treasury’s restricted OFAC List or other list of countries that a U.S. OTC pharma company cannot do business with, then such country shall be removed from the list of countries included in the territory in this agreement for such applicable restricted period. Under the agreement, we received a non-refundable upfront payment and we will sell products to Lavasta at an agreed-upon transfer price. Lavasta also has minimum

annual purchase requirements for the products during the term of the agreement.

On January 5, 2018, we entered into an exclusive ten-year license agreement with Acerus Pharmaceuticals Corporation, a Canadian company ("Acerus"), under which we granted to Acerus an exclusive license to market and sell UriVarx® in Canada. Under the agreement, we received a non-refundable upfront payment, we will be eligible to receive up to CAD$1.65 million (USD$1.31 million at December 31, 2017) in milestone payments based on Acerus achieving certain sales targets and we will sell UriVarx® to Acerus at an agreed-upon transfer price. Acerus also has minimum annual purchase requirements for UriVarx® during the term of the agreement.

On April 24, 2017, we entered into an exclusive ten-year license agreement with Densmore Pharmaceutical International, a Monaco company ("Densmore"), under which we granted to Densmore an exclusive license to market and sell our topical treatment for Female Sexual Interest/Arousal Disorder ("FSI/AD") Zestra® in France and Belgium. Under the agreement, we received a non-refundable upfront payment and Densmore is obligated to order certain minimum annual quantities of Zestra® at a pre-negotiated transfer price per unit during the term of the agreement. In July 2017, we entered into an amendment to the agreement with Densmore to expand the product territory to Singapore and Vietnam.

Table of Contents

2018 Warrant Exercises

In the first quarter of 2018, eleven of our warrant holders exercised their Series B Warrants to purchase shares of common stock totaling 18,925,002 at an exercise price of $0.15 per share. We received net cash proceeds of approximately $2.7 million. The remaining Series B Warrants totaling 6,741,667 expired on March 21, 2018.

2018 and 2017 Notes Payable Financing

In the first quarter of 2018, we entered into a securities purchase agreement with three unrelated third-party investors in which the investors loaned us gross proceeds of $1,227,500. The promissory notes have an OID of $269,375 and bear interest at the rate of 0% per annum. The principal amount of $1,496,875 is to be repaid in twelve equal monthly installments. Monthly installments of $68,490 began in February 2018 and are due through January 2019, and monthly installments of $56,250 begin in April 2018 and are due through March 2019. In connection with the promissory notes, we issued 1,282,000 restricted shares of common stock to the investors. In connection with this financing in the first quarter of 2018, we issued 936,054 restricted shares of common stock to a third-party consultant.

In February and March 2018, we entered into securities purchase agreements with two unrelated third-party investors in which the investors loaned us gross proceeds of $650,000 pursuant to 5% promissory notes. The notes have an OID of $70,000 and requires payment of $720,000 in principal. The notes bear interest at the rate of 5% per annum and the principal amount and interest are payable at maturity on October 28, 2018 for the note issued in February and in three installments on October 1, 2018, January 1, 2019 and April 1, 2019 for the note issued in March. In connection with the notes, we issued the investors restricted shares of common stock totaling 1,485,000.

In the fourth quarter of 2017, we entered into a securities purchase agreement with two unrelated third-party investors in which the investors loaned us gross proceeds of $1,000,000 pursuant to a 0% promissory note. The notes have an OID of $200,000 and require nine payments of $66,667 in principal per month through July 2018 and twelve payments of $50,000 in principal per month through December 2018. The notes bear no interest per annum. In connection with the notes, we issued the investors restricted shares of common stock totaling 600,000. In connection with the financing, we issued 1,119,851 restricted shares of common stock to a third-party consultant.

In December 2017, we entered into a securities purchase agreement with an unrelated third-party investor in which the investor loaned us gross proceeds of $350,000 pursuant to a 5% promissory note. The note has an OID of $40,000, bears interest at 5% per annum and requires principal and interest payments of $139,750, $133,250 and $131,625 on June 15, 2018, September 15, 2018 and December 15, 2018, respectively. In connection with the note, we issued the investor restricted shares of common stock totaling 1,000,000.

Table of Contents

Results of Operations

Year Ended December 31, 2017 Compared to Year Ended December 31, 2016

	Year Ended December 31, 2017	Year Ended December 31, 2016	$ Increase (Decrease)	% Increase (Decrease)
NET REVENUE:				
Product sales, net	$8,806,300	$4,817,603	$3,988,697	82.8%
License revenue	10,000	1,000	9,000	900.0%
Net revenue	8,816,300	4,818,603	3,997,697	83.0%
OPERATING EXPENSE:				
Cost of product sales	1,848,325	1,083,094	765,231	70.7%
Research and development	38,811	77,804	(38,993)	(50.1)%
Sales and marketing	6,853,559	3,621,045	3,232,514	89.3%
General and administrative	5,174,827	5,870,572	(695,745)	(11.9)%
Total operating expense	13,915,522	10,652,515	3,263,007	30.6%
LOSS FROM OPERATIONS	(5,099,222)	(5,833,912)	(734,690)	(12.6)%
OTHER INCOME (EXPENSE):				
Interest expense	(872,166)	(6,661,694)	(5,789,528)	(86.9)%
Loss on extinguishment of debt	(700,060)	-	700,060	100.0%
Other income (expense), net	(6,878)	1,649	(8,527)	(517.1)%
Fair value adjustment for contingent consideration	194,034	(1,269,857)	(1,463,891)	(115.3)%
Change in fair value of derivative liabilities	(16,596)	65,060	(81,656)	(125.5)%
Total other expense, net	(1,401,666)	(7,864,842)	(6,463,176)	(82.2)%
LOSS BEFORE PROVISION FOR INCOME TAXES	(6,500,888)	(13,698,754)	(7,197,866)	(52.5)%
Provision for income taxes	3,200	2,400	800	33.6%
NET LOSS	$(6,504,088)	$(13,701,154)	$(7,197,066)	(52.5)%

Table of Contents

Net Revenue

We recognized net revenue of approximately $8.8 million and $4.8 million for the years ended December 31, 2017 and 2016, respectively. The increase in net revenue in 2017 was primarily the result of the product sales generated through the sales and marketing platform acquired in the Beyond Human® asset acquisition in March 2016. The increase was also due to the launch of UriVarx® at the end of the fourth quarter 2016 and the launch of ProstaGorx® and Apeaz® with ArthriVarx® in 2017. These new product launches generated net revenue of approximately $4.3 million during the year ended December 31, 2017. The increase was also attributed to sales of Vesele® and Sensum+®, which generated net revenue of approximately $2.5 million for Vesele®, and $0.9 million for Sensum+® during the year ended December 31, 2017 compared to approximately $2.9 million for Vesele® and $0.6 million for Sensum+® during the year ended December 31, 2016. The decrease of approximately $0.4 million in Vesele® net revenue for the year ended December 31, 2017 compared to 2016 is primarily due to the sales of Vesele® being negatively impacted in the third quarter of 2017 by the natural disasters in Florida and Texas as these two states have some of the largest populations of our target demographic for Vesele® in the U.S. Further contributing to the overall increase in net revenue was an increase in international product sales as we signed an exclusive license and distribution agreement in April 2017 for the sale of Zestra® in France and Belgium and, in August 2017, we shipped the initial order under such agreement resulting in net revenue of approximately $0.1 million during the year ended December 31, 2017. In March 2017, we also shipped the initial order under our South Korea license and distribution agreement resulting in net revenue of $60,000 during the year ended December 31, 2017. Due to the recent license and distribution agreements entered into in 2017 and 2018, we expect this will lead to an increase in product sales of UriVarx®, ProstaGorx®, Zestra® and Zestra Glide® through our Ex-U.S. sales channel in 2018. The increase in net revenue from the sale of products through the Beyond Human™ sales and marketing platform was offset by decreases in our other existing product sales channels to major retailers and wholesalers as we concentrated our sales efforts and resources on the continued integration of our existing products into the Beyond Human™ sales and marketing platform. The decreases in existing product sales channels resulted in net revenue from the Zestra® products decreasing approximately $0.1 million during the year ended December 31, 2017 when compared to the same period in 2016.

Cost of Product Sales

We recognized cost of product sales of approximately $1.8 million and $1.1 million for the years ended December 31, 2017 and 2016, respectively. The cost of product sales includes the cost of inventory, shipping and royalties. The increase in cost of product sales is a result of higher shipping costs due to an increase in the number of units shipped. The increase in the gross margin to 79.0% in 2017 compared to 77.5% in 2016 is due to the higher margins earned on the increased volume of our product sales through the Beyond Human™ sales and marketing platform. The increased margin in 2017 is also due to fewer sales when compared to 2016 through our retail and wholesale sales channels, which have lower margins.

Research and Development

We recognized research and development expense of approximately $39,000 and $78,000 for the years ended December 31, 2017 and 2016, respectively. The research and development expense includes salary and the related health benefits for an employee who was terminated in January 2017, as well as costs for stability testing and other development related costs for our products. The decrease in 2017 is also attributed to the fair value of the shares of common stock issued to CRI totaling $23,000 for certain clinical and regulatory milestone payments due under the in-license agreement for Sensum+®, as well as clinical costs incurred related to post marketing studies for Vesele® and Beyond Human® Testosterone Booster in 2016 that did not occur in 2017.

Sales and Marketing

We recognized sales and marketing expense of approximately $6.9 million and $3.6 million for the years ended December 31, 2017 and 2016, respectively. Sales and marketing expense consists primarily of print advertisements and sales and marketing support. The increase in sales and marketing expense during the year ended December 31, 2017 when compared to the same period in 2016 is due to the increase in the number of products integrated into the Beyond Human™ sales and marketing platform, as well as the costs of our third-party customer service call center due to the higher volume of sales orders received as a result of the Beyond Human® asset acquisition. Also, initial product launches require larger advertising spends in an effort to increase brand awareness. Total direct advertising costs for the year ended December 31, 2017 was $5.4 million compared to $2.7 million in 2016.

General and Administrative

We recognized general and administrative expense of approximately $5.2 million and $5.9 million for the years ended December 31, 2017 and 2016, respectively. General and administrative expense consists primarily of investor relation expense, legal, accounting, public reporting costs and other infrastructure expense related to the launch of our products. Additionally, our general and administrative expense includes professional fees, insurance premiums and general corporate expense. The decrease is primarily due to the decrease in stock-based compensation to employees, directors and consultants of approximately $1.5 million during the year ended December 31, 2017 compared to 2016. The decrease was offset by increases in merchant processing fees due to increased credit card sales volume and increased payroll and related costs due to the increase in headcount when compared to 2016.

Table of Contents

Other Income and Expense

We recognized interest expense of approximately $0.9 million and $6.7 million for the years ended December 31, 2017 and 2016, respectively. Interest expense primarily includes interest related to our debt, amortization of debt discounts and the fair value of the embedded conversion feature derivative liability in excess of the proceeds allocated to the debt (see Notes 5, 6 and 9 to the accompanying consolidated financial statements included elsewhere in this Annual Report). Due to the shares, warrants and cash discounts provided to our lenders, the effective interest rate is significantly higher than the coupon rate. The decrease in interest expense during the year ended December 31, 2017 is due to the larger amount of debt discount amortization in 2016 compared to 2017 as a result of the convertible debt and note payable financings completed in 2016 and 2015, as well as, the fair value in excess of the allocated proceeds of the embedded conversion feature in the convertible debt financings completed in June and July 2016.

We recognized a loss on extinguishment of debt of approximately $0.7 million during the year ended December 31, 2017. The loss on debt extinguishment was the result of the securities exchange agreement entered into with a certain 2016 and 2017 Notes Payable holder, as well as, the required prepayment of the 2016 Notes from the cash proceeds received through the public equity offering in March 2017. In exchange for the settlement of approximately $0.7 million in principal and interest, we issued 11,432,747 shares of common stock with a fair value of $1.1 million. As a result, the remaining unamortized debt discount of approximately $17,000 and the fair value of the common stock issued in excess of the debt settled of approximately $0.4 million were recorded as a loss on debt extinguishment during the year ended December 31, 2017. Under the terms of the 2016 Notes, we were required to prepay the outstanding principal and interest of the convertible debentures with the cash proceeds received from an equity offering with an offering price less than the current conversion price of the debentures of $0.25 per share, as well as incur a 10% prepayment penalty. As a result of the prepayment, the remaining unamortized debt discount of approximately $0.4 million, the prepayment penalty of $0.1 million and the extinguishment of the embedded conversion feature derivative liability of $0.2 million were recorded as a loss on debt extinguishment during the year ended December 31, 2017.

We recognized a gain from the fair value adjustment for contingent consideration of approximately $0.2 million for the year ended December 31, 2017 compared to a loss of $1.3 million for the year ended December 31, 2016. Fair value adjustment for contingent consideration consists primarily of the change in the fair value of the contingent ANDA shares of common stock issuable to individual members of Novalere Holdings, LLC in connection with our acquisition in 2015 and the royalty contingent consideration to Semprae (see Note 3 to the accompanying consolidated financial statements included elsewhere in this Annual Report).

We recognized a gain (loss) from the change in fair value of derivative liabilities of approximately $(17,000) and $65,000 for the years ended December 31, 2017 and 2016, respectively. Change in fair value of derivative liabilities primarily includes the change in the fair value of the warrants and embedded conversion features classified as derivative liabilities. The loss on change in fair value of derivative liabilities during the year ended December 31, 2017 is primarily due to the increase in our stock price from December 31, 2016 through the date of conversion of certain of the convertible debentures in 2017, which resulted in the fair value of the embedded conversion features at the conversion date to be higher than the fair value at December 31, 2016.

Income Taxes

We recognized a provision for income taxes of $3,200 for the year ended December 31, 2017 compared to $2,400 for the year ended December 31, 2016. The change is due to the use of a tax refund of $800 in 2016.

Net Loss

Net loss for the year ended December 31, 2017 was approximately $(6.5 million), or $(0.04) basic and diluted net loss per share, compared to a net loss for the same period in 2016 of $(13.7 million), or $(0.15) basic and diluted net loss per share.

Liquidity and Capital Resources

Historically, we have funded losses from operations through the sale of equity and issuance of debt instruments. Combined with revenue, these funds have provided us with the capital to operate our business, to sell and support our products, attract and retain key personnel, and add new products to our portfolio. To date, we have experienced net losses each year since our inception. As of December 31, 2017, we had an accumulated deficit of $35.6 million and a working capital deficit of $1.4 million.

As of March 29, 2018, we had approximately $4.6 million in cash. Although no assurances can be given, we currently plan to raise additional capital through the sale of equity or debt securities. We expect, however, that our existing capital resources, the proceeds received from the exercise of warrants and issuance of notes payable in the first quarter of 2018 totaling $4.5 million (see Note 12 in the accompanying consolidated financial statements included elsewhere in this Annual Report), revenue from sales of our products and upcoming new product launches and sales milestone payments from the commercial partners signed for our products, and equity instruments available to pay certain vendors and consultants, will be sufficient to allow us to continue our operations, commence the product development process and launch selected products through at least the next 12 months. In addition, our CEO, who is also a significant shareholder, has deferred the remaining payment of his salary earned through June 30, 2016 totaling $1.5 million for at least the next 12 months.

Table of Contents

Our principle debt instruments include the following:

September, October and December 2017 Notes Payable

On September 20, 2017, we entered into a securities purchase agreement with an unrelated third-party investor in which the investor loaned us gross proceeds of $150,000 pursuant to a 5% promissory note. The note has an OID of $15,000 and requires payment of $165,000 in principal upon maturity. The note bears interest at the rate of 5% per annum and the principal amount and interest are payable at maturity on May 20, 2018. In connection with the note, we issued the investor restricted shares of common stock totaling 895,000. The remaining principal balance under this note is $165,000 at December 31, 2017.

On October 17, 2017, October 20, 2017 and December 4, 2017, we entered into a securities purchase agreement with two unrelated third-party investors in which the investors loaned us gross proceeds of $500,000 in October 2017 and $500,000 in December 2017 pursuant to 0% promissory notes. The notes have an OID of $200,000 and require nine payments of $66,667 in principal per month through July 2018 and twelve payments of $50,000 in principal per month through December 2018. The notes bear no interest per annum. In connection with the notes, we issued the investors restricted shares of common stock totaling 600,000 in December 2017. In March 2018, we entered into a securities exchange agreement with one of the note holders. In connection with the securities exchange agreement, we issued a total of 2,250,000 shares of common stock in exchange for the settlement of principal due under the note payable totaling $166,667. The remaining principal balance under these notes as of December 31, 2017, inclusive of the March 2018 securities exchange agreement, is $833,333.

On December 13, 2017, we entered into a securities purchase agreement with an unrelated third-party investor in which the investor loaned us gross proceeds of $350,000 pursuant to a 5% promissory note. The note has an OID of $40,000, bears interest at 5% per annum and requires principal and interest payments of $139,750, $133,250 and $131,625 on June 15, 2018, September 15, 2018 and December 15, 2018, respectively. In connection with the note, we issued the investor restricted shares of common stock totaling 1,000,000 in December 2017. The remaining principal balance under this note is $390,000 at December 31, 2017.

2018 Notes Payable

In the first quarter of 2018, we entered into a securities purchase agreement with three unrelated third-party investors in which the investors loaned us gross proceeds of $1,227,500. The promissory notes have an OID of $269,375 and bear interest at the rate of 0% per annum. The principal amount of $1,496,875 is to be repaid in twelve equal monthly installments. Monthly installments of $68,490 began in February 2018 and are due through January 2019 and monthly installments of $56,250 begin in April 2018 and are due through March 2019. In connection with the promissory notes, we issued 1,282,000 restricted shares of common stock to the investors.

In February and March 2018, we entered into securities purchase agreements with two unrelated third-party investors in which the investors loaned us gross proceeds of $650,000 pursuant to 5% promissory notes. The notes have an OID of $70,000 and requires payment of $720,000 in principal. The notes bear interest at the rate of 5% per annum and the principal amount and interest are payable at maturity on October 28, 2018 for the note issued in February and in three installments on October 1, 2018, January 1, 2019 and April 1, 2019 for the note issued in March. In connection with the notes, we issued the investors restricted shares of common stock totaling 1,485,000.

February 2016 Note Payable

On February 24, 2016, the Company and SBI Investments, LLC, 2014-1 ("SBI") entered into an agreement in which SBI loaned us gross proceeds of $550,000 pursuant to a purchase agreement, 20% secured promissory note and security agreement ("February 2016 Note Payable"), all dated February 19, 2016 (collectively, the "Finance Agreements"). Pursuant to the Finance Agreements, the principal amount of the February 2016 Note Payable was $550,000 and the interest rate thereon is 20% per annum. We began to pay principal and interest on the February 2016 Note Payable on a monthly basis beginning on March 19, 2016 for a period of 24 months and the monthly mandatory principal and interest payment amount thereunder is $28,209. The monthly amount shall be paid by us through a deposit account control agreement with a third-party bank in which SBI shall be permitted to take the monthly mandatory payment amount from all revenue received by us from the Beyond Human® assets in the transaction. The maturity date for the February 2016 Note Payable was February 19, 2018. The February 2016 Note Payable was secured by SBI through a first priority secured interest in all of the Beyond Human® assets acquired by us in the transaction including all revenue received by us from these assets. The principal balance of the February 2016 Note Payable as of December 31, 2017 was $54,985 and was repaid in full in February 2018.

Net Cash Flows

	For the Year Ended December 31, 2017	For the Year Ended December 31, 2016
Net cash used in operating activities	$(2,361,723)	$(1,784,258)
Net cash used in investing activities	(57,516)	(172,103)
Net cash provided by financing activities	3,154,165	2,730,393
Net change in cash	734,926	774,032
Cash at beginning of the year	829,933	55,901
Cash at the end of the year	$1,564,859	$829,933

Table of Contents

Operating Activities

For the year ended December 31, 2017, cash used in operating activities was approximately $2.4 million, consisting primarily of the net loss for the period of approximately $6.5 million, which was primarily offset by non-cash common stock, restricted stock units and stock options issued for services and compensation of approximately $1.1 million, amortization of debt discount of $0.8 million, loss on debt extinguishment of $0.7 million, change in fair value of derivative liabilities of $17,000, and amortization of intangible assets of $0.6 million. The non-cash expense was offset with the gain on change in fair value of contingent consideration of approximately $0.2 million. Additionally, working capital changes consisted of cash increases of approximately $1.1 million related to a decrease in prepaid expense and other current assets of approximately $0.1 million, $0.4 million related to an increase in accrued compensation, $14,000 related to increase in deferred revenue and customer deposits, and $1.8 million related to an increase in accounts payable and accrued expense, partially offset by a cash decrease related to accrued interest of $3,000, increase in accounts receivable of $42,000, and increase in inventories of $1.1 million. The increase in net cash used in operating activities from 2016 was mainly due to expanding our operations, including hiring additional personnel, commercialization and marketing activities related to our newly launched products in 2017 and those acquired in 2016, as well as, purchasing more finished goods inventory to fulfill the forecasted increase in net revenue in 2018.

Investing Activities

For the year ended December 31, 2017, cash used in investing activities was approximately $58,000, which consisted of the purchase of property and equipment for our new corporate office location in December 2017, as well as a contingent royalty payment to Semprae for Zestra® product sales in 2016. Cash used in investing activities in 2016 consisted of the contingent consideration payment of approximately $0.2 million made to the seller of the Beyond Human® assets, as well as a contingent royalty payment to Semprae for Zestra® product sales in 2015.

Financing Activities

For the year ended December 31, 2017, cash provided by financing activities was approximately $3.2 million, consisting primarily of the net proceeds from the public equity offering of $3.3 million and notes payable of $1.7 million, offset by the repayment of convertible debentures of approximately $1.2 million, notes payable and short-term loans payable of $0.5 million, and the prepayment penalty on the repayment of the convertible debentures of $0.1 million. Cash provided by financing activities in 2016 was primarily related to net proceeds from notes payable and convertible debentures of approximately $3.6 million, proceeds from warrant exercises of $0.3 million, and proceeds from short-term loans payable of $22,000, offset by the repayment of notes payable and short-term loans payable of $0.7 million, payment of financing costs in connection with convertible debentures of $40,000, and the repayment of the related-party line of credit convertible debenture of $0.4 million.

Sources of Capital

Our operations have been financed primarily through the sale of equity and issuance of debt instruments and revenues generated from the launch of our products and commercial partnerships signed for the sale and distribution of our products domestic and internationally. These funds have provided us with the resources to operate our business, sell and support our products, attract and retain key personnel and add new products to our portfolio. We have experienced net losses and negative cash flows from operations each year since our inception. As of December 31, 2017, we had an accumulated deficit of approximately $35.6 million and a working capital deficit of $1.4 million.

We have raised funds through the issuance of debt and the sale of common stock. We have also issued equity instruments in certain circumstances to pay for services from vendors and consultants. For the year ended December 31, 2017, we raised approximately $5.0 million in funds, which included net proceeds of $3.3 million from the public equity offering in March 2017 and $1.7 million from the issuance of notes payable. The funds raised through the public equity offering and issuance of the notes payable were primarily used to pay off accounts payable, to increase inventory and for the expanded operations in 2017. The proceeds from the public equity offering were also required to be used to pay off the remaining 2016 convertible debentures in March 2017. The outstanding notes payable principal and interest balance at December 31, 2017 was approximately $1.6 million.

Table of Contents

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

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

Critical Accounting Policies and Management Estimates

The SEC defines critical accounting policies as those that are, in management’s view, important to the portrayal of our financial condition and results of operations and demanding of management’s judgment. Our discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, 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 that the accounting policies described below are critical to understanding our business, results of operations and financial condition because they involve the use of more significant judgments and estimates in the preparation of our consolidated financial statements. An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and any changes in the assumptions used in making the accounting estimates that are reasonably likely to

occur could materially impact our consolidated financial statements.

Revenue Recognition and Deferred Revenue

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

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

Table of Contents

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

Sales Allowances

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

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

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

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

Stock-Based Compensation

We account for stock-based compensation in accordance with FASB ASC 718, Stock Based Compensation. All stock-based payments to employees and directors, including grants of stock options, warrants, restricted stock units ("RSUs") and restricted stock, are recognized in the consolidated financial statements based upon their estimated fair values. We use Black-Scholes to estimate the fair value of stock-based awards. The estimated fair value is determined at the date of grant. FASB ASC 718 requires that stock-based compensation expense be based on awards that are ultimately expected to vest. Prior to the adoption of ASU No. 2016-09, Improvements to Employee Share-Based Payment Accounting, on January 1, 2017, stock-based compensation had been reduced for estimated forfeitures. When estimating forfeitures, voluntary termination behaviors, as well as trends of actual option forfeitures, were considered. To the extent actual forfeitures differed from then current estimates, cumulative adjustments to stock-based compensation expense were recorded. As a result of the adoption of ASU No. 2016-09 as of January 1, 2017, we have made an entity-wide accounting policy election to account for forfeitures when they occur. There is no cumulative-effect adjustment as a result of the adoption of this ASU as our estimated forfeiture rate prior to adoption of this ASU was 0%.

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

Equity Instruments Issued to Non-Employees for Services

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

Table of Contents

Business Combinations

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

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

Goodwill and Intangible Assets

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

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

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

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

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

Long-Lived Assets

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

Table of Contents

Derivative Liabilities

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

Recent Accounting Pronouncements

On January 1, 2017, the Company adopted FASB ASU No. 2016-15, Statement of Cash Flows (Topic 230) – Classification of Certain Cash Receipts and Cash Payments. We elected to early adopt ASU 2016-15 and, as a result, the prepayment penalty of $127,247 in connection with the extinguishment of the 2016 Notes (see Note 5 in the accompanying consolidated financial statements included elsewhere in this Annual Report) in March 2017 is classified as a financing cash outflow in the accompanying consolidated statement of cash flows for the year ended December 31, 2017. The adoption of this ASU did not have a material impact on our consolidated financial position, results of operations and related disclosures and had no other impact to the accompanying consolidated statement of cash flows for the years ended December 31, 2017 and 2016.

See Note 1 to our consolidated financial statements for the years ended December 31, 2017 and 2016 included elsewhere in this Annual Report for additional recent accounting pronouncements.

Off-Balance Sheet Arrangements

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

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

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

Item 8.
Financial Statements and Supplementary Data.

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

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

None.

Item 9A.
Controls and Procedures.

Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer ("CEO"), our principal executive officer, and our Vice President, Finance ("VP of Finance"), our principal financial and accounting officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2017, the end of the period covered by this Annual Report, pursuant to Rules 13a-15(b) and 15d-15(b) under the Securities Exchange Act of 1934, as amended ("Exchange Act").

In connection with that evaluation, our CEO and VP of Finance concluded that, as of December 31, 2017, our disclosure controls and procedures were effective. For the purpose of this review, disclosure controls and procedures means controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. These disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal accounting and financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Table of Contents

Management’s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, our CEO and VP of Finance and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with accepted accounting principles generally accepted in the United States of America. Our management, under the supervision and with the participation of our CEO and VP of Finance, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations (“COSO”). Based on such evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2017.

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the year ended December 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

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

Item 9B.
Other Information.

None.

Table of Contents

PART III

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

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

Item 11.
Executive Compensation.

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

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

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

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

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

Item 14.
Principal Accountant Fees and Services.

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

Table of Contents

PART IV

Item 15.
Exhibits and Financial Statement Schedules.

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

(1) Consolidated Financial Statements:

Report of Hall and Company, Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2017 and 2016

Consolidated Statements of Operations for the Years Ended December 31, 2017 and 2016

Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2017 and 2016

Consolidated Statements of Cash Flows for the Years Ended December 31, 2017 and 2016

Notes to Consolidated Financial Statements

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

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

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

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

Table of Contents

Signatures

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

Date: April 2, 2018 Innovus Pharmaceuticals, Inc.

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

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

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

Signature	Title	Date
/s/ Bassam Damaj Bassam Damaj, Ph.D.	Director, President and Chief Executive Officer (Principal Executive Officer)	April 2, 2018
/s/ Rauly Gutierrez Rauly Gutierrez, CPA	Vice President, Finance (Principal Accounting and Financial Officer)	April 2, 2018
/s/ Henry Esber Henry Esber, Ph.D.	Chairman of the Board of Directors	April 2, 2018
/s/ Ziad Mirza Ziad Mirza, M.D.	Director	April 2, 2018
/s/ Vivian Liu Vivian Liu	Director	April 2, 2018

Table of Contents

INDEX TO EXHIBITS

Exhibit No.	Description
2.1	Merger Agreement and Plan of Merger, dated as of July 13, 2011, by and among FasTrack, Inc., a Delaware corporation, North Horizon, Inc., a Nevada corporation and North First General, Inc., a Utah corporation, a wholly-owned subsidiary of North Horizon, Inc. filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on July 20, 2011 and incorporated herein by reference.
2.2	Asset Purchase Agreement dated April 19, 2013, between Innovus Pharmaceuticals, Inc. and Centric Research Institute, Inc. filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on April 24, 2013 and incorporated herein by reference.
2.3	Agreement and Plan of Merger, made as of December 24, 2013, by and among Innovus Pharmaceuticals, Inc., Innovus Acquisition Corporation, Semprae Laboratories, Inc., the major stockholders of Semprae Laboratories, Inc. party thereto and Quaker Bioventures II, L.P., as principal stockholder of Semprae Laboratories, Inc., filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on December 30, 2013 and incorporated herein by reference.
2.4	Agreement and Plan of Merger, dated February 4, 2015, by and among Innovus Pharmaceuticals, Inc., Innovus Pharma Acquisition Corporation, Innovus Pharma Acquisition Corporation II, Novalere FP, Inc. and Novalere Holdings, LLC, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on February 5, 2015 and incorporated herein by reference.
2.5	Asset Purchase Agreement, dated February 8, 2016, by and between Innvous Pharmaceuticals, Inc. and Beyond Human LLC, filed as an exhibit to the Registrant's current report on Form 8-k, filed with the SEC on February 11, 2016, and incorporated herein by reference.
3.1	Amended and Restated Articles of Incorporation of the Registrant as filed with the Office of the Secretary of State of the State of Nevada on October 10, 2016, filed as an exhibit to the Registrant's registration statement on Form S-8, filed with the SEC on November 28, 2016, and incorporated herein by reference.
3.2	Amended and Restated Bylaws of the Registrant, filed as an exhibit to the Registrant's registration statement on Form S-8, filed with the SEC on November 28, 2016, and incorporated herein by reference.
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.
4.1	Form of Securities Purchase Agreement filed as Exhibit 4.1 to the Registrant's report on Amendment No. 1 to Form S-1 filed with the SEC on March 13, 2017 and incorporated herein by reference.
4.2	Form of Series A and Series B Warrant filed as Exhibit 4.2 to the Registrant's report on Amendment No. 1 to Form S-1 filed with the SEC on March 13, 2017 and incorporated herein by reference.
4.3	Form of Placement Agent Warrant filed as Exhibit 4.3 to the Registrant's report on Amendment No. 1 to Form S-1 filed with the SEC on March 13, 2017 and incorporated herein by reference.
10.1#	Employment Agreement, dated January 22, 2013, between Innovus Pharmaceuticals, Inc. and Bassam Damaj, Ph.D., filed as an exhibit to the Registrant's annual report on Form 10-K, filed with the SEC on March 19, 2013, and incorporated herein by reference.
10.2#	

	2013 Equity Incentive Plan of the Registrant, effective February 15, 2013, filed as an exhibit to the Registrant's registration statement on Form S-8, filed with the SEC on February 15, 2013, and incorporated herein by reference.
10.3#	Form of Restricted Stock Agreement under the Registrant's 2013 Equity Incentive Plan, effective February 15, 2013, filed as an exhibit to the Registrant's registration statement on Form S-8, filed with the SEC on February 15, 2013, and incorporated herein by reference.
10.4#	Form of Stock Unit Agreement under the Registrant's 2013 Equity Incentive Plan, effective February 15, 2013, filed as an exhibit to the Registrant's registration statement on Form S-8, filed with the SEC on February 15, 2013, and incorporated herein by reference.
10.5#	Form of Nonstatutory Stock Option Agreement under the Registrant's 2013 Equity Incentive Plan, effective February 15, 2013, filed as an exhibit to the Registrant's registration statement on Form S-8, filed with the SEC on February 15, 2013, and incorporated herein by reference.
10.6#	Form of Incentive Stock Option Agreement under the Registrant's 2013 Equity Incentive Plan, effective February 15, 2013, filed as an exhibit to the Registrant's registration statement on Form S-8, filed with the SEC on February 15, 2013, and incorporated herein by reference.
10.7#	Form of Officer and Director Indemnification Agreement, dated June 2013, filed as an exhibit to the Registrant's quarterly report on Form 10-Q, filed with the SEC on August 13, 2013, and incorporated herein by reference.
10.8#	Amended and Restated Innovus Pharmaceuticals, Inc. Non-Employee Director Compensation Plan, dated October 1, 2013, filed as an exhibit to the Registrant's quarterly report on Form 10-Q, filed with the SEC on November 14, 2013, and incorporated herein by reference.
10.9#	Innovus Pharmaceuticals, Inc. 2014 Equity Incentive Plan, filed as an exhibit to the registration statement on Form S-8, filed with the SEC on January 2, 2015, and incorporated herein by reference.

Table of Contents

10.10	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.
10.11	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.
10.12#	Employment Agreement Amendment, between Innovus Pharmaceuticals, Inc. and Bassam Damaj, dated January 21, 2015, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on January 23, 2015, and incorporated herein by reference.
10.13	Registration Rights and Stock Restriction Agreement, dated February 4, 2015, by and between Innovus Pharmaceuticals, Inc., and Novalere Holdings, LLC, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on February 5, 2015, and incorporated herein by reference.
10.14	Voting Agreement, dated February 4, 2015, by and between Innovus Pharmaceuticals, Inc., and Novalere Holdings, LLC, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on February 5, 2015, and incorporated herein by reference.
10.15	Form of Securities Purchase Agreement, dated July 15, 2015, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on August 3, 2015, and incorporated herein by reference.
10.16	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.
10.17	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.
10.18	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.
10.19	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.
10.20	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.
10.21	20% Secured Promissory Note, dated February 19, 2016 by and among the Company ad 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.
10.22	Security 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.
10.23	Form of Securities Purchase Agreement, dated June 30, 2016, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on July 6, 2016, and incorporated herein by reference.
10.24	Form of Convertible Promissory Note, dated June 30, 2016, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on July 6, 2016, and incorporated herein by reference.
10.25	Form of Common Stock Purchase Warrant Agreement, dated June 30, 2016, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on July 6, 2016, and incorporated herein by reference.
10.26	Form of Registration Rights Agreement, filed as an exhibit to the Registrant's current report on Form 8-K, filed with the SEC on July 6, 2016, and incorporated herein by reference.
10.27	Garden State Securities Engagement Agreement, filed as an exhibit to the Registrant's Registration Statement on Form S-1, filed with the SEC on August 9, 2016, and incorporated herein by reference.
10.28	

	H.C. Wainwright and Co., LLC Engagement Agreement filed as an exhibit to the Registrant's Registration Statement on Form S-1, filed with the SEC on August 9, 2016, and incorporated herein by reference.
10.29	First Amendment to the Securities Purchase Agreement filed as an exhibit to the Registrant's Registration Statement on Form S-1, filed with the SEC on August 9, 2016, and incorporated herein by reference.
10.30	10% Debenture, filed as an exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on August 15, 2016, and incorporated herein by reference.
10.31	Securities Purchase Agreement, filed as an exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on August 15, 2016, and incorporated herein by reference.
10.32	Promissory Note, filed as an exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on August 15, 2016, and incorporated herein by reference.
10.33#	Employment Agreement, between Innovus Pharmaceuticals, Inc. and Robert Hoffman, dated September 6, 2016, filed as an exhibit to the Registrant’s current report on Form 8-K, filed with the SEC on August 29, 2016 and incorporated herein by reference.
10.34#	Employment Agreement, between Innovus Pharmaceuticals, Inc. and Randy Berholtz, dated January 9, 2017, filed as an exhibit to the Registrant’s current report on Form 8-K, filed with the SEC on January 6, 2017, and incorporated herein by reference.
10.35#	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.
10.36#	Amended and Restated 2016 Equity Incentive Plan of the Registrant, filed as an exhibit to the Registrant’s registration statement on Form S-8, filed with the SEC on November 28, 2016, and incorporated herein by reference.

Table of Contents

10.37	H.C. Wainwright and Co., LLC Engagement Agreement, dated January 17, 2017, filed as an exhibit to the Registrant's registration statement on Form S-1, filed with the SEC on February 1, 2017, and incorporated herein by reference.
10.38#	Employment Agreement, dated as of September 23, 2016 by and between Innovus Pharmaceuticals, Inc. and Rauly Gutierrez (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 14, 2017)
14.1*	Code of Ethics
21.1*	List of Subsidiaries
23.1*	Consent of Hall and Company, Independent Registered Public Accounting Firm
24.1*	Power of Attorney, included as part of signature page to this Annual Report.
31.1*	Certification of the Registrant's

31.2*	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.
32.1**	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.
32.2**	Certification of the Registrant's Principal Executive Officer pursuant to 18 U.S.C. SS. 1350, as adopted pursuant to Section. 906 of the Sarbanes-Oxley Act of 2002.
	Certification of the Registrant's Principal Financial Officer pursuant to 18 U.S.C. SS. 1350, as adopted pursuant to Section. 906 of the Sarbanes-Oxley

	Act of 2002.
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
**	Furnished herewith
#	Management contract or compensatory plan or arrangement

Table of Contents

Report of Independent Registered Public Accounting Firm

To the shareholders and the board of directors of Innovus Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Innovus Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2017 and 2016, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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 opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Hall & Company
We have served as the Company's auditor since 2016
Irvine, CA
April 2, 2018

Table of Contents

INNOVUS PHARMACEUTICALS, INC.
Consolidated Balance Sheets

	December 31, 2017	December 31, 2016
ASSETS		
Assets:		
Cash	$1,564,859	$829,933
Accounts receivable, net	68,259	33,575
Prepaid expense and other current assets	363,080	863,664
Inventories	1,725,698	599,856
Total current assets	3,721,896	2,327,028
Property and equipment, net	62,454	29,569
Deposits	20,881	14,958
Goodwill	952,576	952,576
Intangible assets, net	4,273,099	4,903,247
Total assets	$9,030,906	$8,227,378
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities:		
Accounts payable and accrued expense	$2,607,121	$1,210,050
Accrued compensation	1,118,293	767,689
Deferred revenue and customer deposits	24,690	11,000
Accrued interest payable	3,648	47,782
Derivative liabilities – embedded conversion features	-	319,674
Derivative liabilities – warrants	58,609	164,070
Contingent consideration	28,573	170,015

Short-term loans payable	65,399	-
Current portion of notes payable, net of debt discount of $437,355 and $216,403, respectively	1,239,296	626,610
Convertible debentures, net of debt discount of $0 and $845,730, respectively	-	714,192
Total current liabilities	5,145,629	4,031,082
Accrued compensation – less current portion	1,531,904	1,531,904
Notes payable, net of current portion and debt discount of $0 and $468, respectively	-	54,517
Contingent consideration – less current portion	1,450,430	1,515,902
Total non-current liabilities	2,982,334	3,102,323
Total liabilities	8,127,963	7,133,405
Commitments and contingencies		
Stockholders’ equity:		
Preferred stock: 7,500,000 shares authorized, at $0.001 par value, no shares issued and outstanding at December 31, 2017 and 2016, respectively	-	-
Common stock: 292,500,000 shares authorized, at $0.001 par value, 167,420,605 and 121,694,293 shares issued and outstanding at December 31, 2017 and 2016, respectively	167,421	121,694
Additional paid-in capital	36,375,359	30,108,028
Accumulated deficit	(35,639,837)	(29,135,749)
Total stockholders' equity	902,943	1,093,973
Total liabilities and stockholders’ equity	$9,030,906	$8,227,378

See accompanying notes to these consolidated financial statements.

Table of Contents

INNOVUS PHARMACEUTICALS, INC.
Consolidated Statements of Operations

	For the Year Ended December 31,	
	2017	2016
Net revenue:		
Product sales, net	$8,806,300	$4,817,603
License revenue	10,000	1,000
Net revenue	8,816,300	4,818,603
Operating expense:		
Cost of product sales	1,848,325	1,083,094
Research and development	38,811	77,804
Sales and marketing	6,853,559	3,621,045
General and administrative	5,174,827	5,870,572
Total operating expense	13,915,522	10,652,515
Loss from operations	(5,099,222)	(5,833,912)
Other income (expense):		
Interest expense	(872,166)	(6,661,694)
Loss on extinguishment of debt	(700,060)	-
Other income (expense), net	(6,878)	1,649
Fair value adjustment for contingent consideration	194,034	(1,269,857)
Change in fair value of derivative liabilities	(16,596)	65,060
Total other expense, net	(1,401,666)	(7,864,842)
Loss before provision for income taxes	(6,500,888)	(13,698,754)
Provision for income taxes	3,200	2,400
Net loss	$(6,504,088)	$(13,701,154)
Net loss per share of common stock – basic and diluted	$(0.04)	$(0.15)
Weighted average number of shares of common stock outstanding – basic and diluted	157,933,458	94,106,382

See accompanying notes to these consolidated financial statements.

F-2

Table of Contents

INNOVUS PHARMACEUTICALS, INC.
Consolidated Statements of Stockholders' Equity
For the Years Ended December 31, 2017 and 2016

	Common Stock		Additional Paid-in	Accumulated	Stockholders' Equity
	Shares	Amount	Capital	Deficit	(Deficit)
Balance at January 1, 2016	47,141,230	$47,141	$14,941,116	$(15,434,595)	$(446,338)
Common stock issued for services	10,732,500	10,733	1,802,216	-	1,812,949
Stock-based compensation	-	-	954,753	-	954,753
Common stock issued to Novalere Holdings, LLC for payment of contingent consideration	12,808,796	12,809	2,958,832	-	2,971,641
Common stock issued upon conversion of convertible debentures and accrued interest	17,100,508	17,100	3,247,605	-	3,264,705
Common stock issued for vested restricted stock units	19,315,994	19,316	(19,316)	-	-
Fair value of beneficial conversion feature on line of credit convertible debenture – related party	-	-	3,444	-	3,444
Relative fair value of shares of common stock issued in connection with notes payable and convertible debentures	9,861,111	9,861	1,393,531	-	1,403,392
Relative fair value of warrants issued in connection with convertible debentures	-	-	445,603	-	445,603
Fair value of warrants issued to placement agents in connection with convertible debentures	-	-	357,286	-	357,286
Common stock issued for legal costs from Semprae merger transaction	215,000	215	64,285	-	64,500
Common stock issued in connection with license agreement	100,000	100	22,900	-	23,000
Common stock issued upon cashless exercise of warrants	3,385,354	3,385	(3,385)	-	-
Common stock issued upon exercise of warrants	1,033,800	1,034	309,106	-	310,140
Reclassification of embedded conversion feature derivative liability upon conversion of convertible debentures	-	-	3,111,828	-	3,111,828
	-	-	518,224	-	518,224

Reclassification of warrant derivative liability upon cashless exercise of warrants					
Net loss for year ended December 31, 2016	-	-	-	(13,701,154)	(13,701,154)
Balances at December 31, 2016	121,694,293	121,694	30,108,028	(29,135,749)	1,093,973
Common stock issued for services	2,891,105	2,891	626,112	-	629,003
Stock-based compensation	-	-	336,007	-	336,007
Common stock issued upon conversion of convertible debentures, notes payable and accrued interest	12,835,187	12,835	1,458,603	-	1,471,438
Common stock issued for vested restricted stock units	92,000	92	(92)	-	-
Relative fair value of shares of common stock issued in connection with notes payable	2,825,000	2,825	214,080	-	216,905
Fair value of shares of common stock issued as financing fees in connection with notes payable	1,119,851	1,120	97,641	-	98,761
Common stock issued upon exercise of stock options	71,500	72	4,807	-	4,879
Sale of common stock and warrants, net of offering costs	25,666,669	25,667	3,282,106	-	3,307,773
Reclassification of embedded conversion feature derivative liability upon conversion of convertible debentures	-	-	203,630	-	203,630
Common stock issued for the prepayment of royalties due under CRI License Agreement	225,000	225	44,437	-	44,662
Net loss for year ended December 31, 2017	-	-	-	(6,504,088)	(6,504,088)
Balances at December 31, 2017	167,420,605	$167,421	$36,375,359	$(35,639,837)	$902,943

See accompanying notes to these consolidated financial statements.

Table of Contents

INNOVUS PHARMACEUTICALS, INC.
Consolidated Statements of Cash Flows

	For the Year Ended December 31	
	2017	2016
Cash flows from operating activities:		
Net loss	$(6,504,088)	$(13,701,154)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	11,751	5,532
Allowance for doubtful accounts	7,067	2,066
Common stock, restricted stock units and stock options issued to employees, board of directors and consultants for compensation and services	1,135,611	2,684,602
Loss on extinguishment of debt	700,060	-
Fair value of embedded conversion feature in convertible debentures in excess of allocated proceeds	-	2,756,899
Change in fair value of contingent consideration	(194,034)	1,269,857
Change in fair value of derivative liabilities	16,596	(65,060)
Amortization of debt discount	778,054	3,646,161
Amortization of intangible assets	630,148	624,404
Changes in operating assets and liabilities, net of acquisition amounts		
Accounts receivable	(41,751)	47,456
Prepaid expense and other current assets	112,516	(279,786)
Inventories	(1,125,842)	(345,413)
Deposits	(5,923)	-
Accounts payable and accrued expense	1,757,071	694,547
Accrued compensation	350,604	856,803
Accrued interest payable	(3,253)	31,907
Deferred revenue and customer deposits	13,690	(13,079)
Net cash used in operating activities	(2,361,723)	(1,784,258)
Cash flows from investing activities:		
Purchase of property and equipment	(44,636)	-
Payment on contingent consideration	(12,880)	(172,103)
Net cash used in investing activities	(57,516)	(172,103)
Cash flows from financing activities:		

Repayments of line of credit convertible debenture – related party	-	(409,192)
Proceeds from short-term loans payable	-	21,800
Payments on short-term loans payable	(32,471)	(252,151)
Proceeds from notes payable and convertible debentures	1,650,000	3,574,000
Payments on notes payable	(426,347)	(449,204)
Proceeds from stock option and warrant exercises	4,879	310,140
Financing costs in connection with convertible debentures	-	(40,000)
Proceeds from sale of common stock and warrants, net of offering costs	3,307,773	-
Payments on convertible debentures	(1,222,422)	(25,000)
Prepayment penalty on extinguishment of convertible debentures	(127,247)	-
Net cash provided by financing activities	3,124,165	2,730,393
Net change in cash	734,926	774,032
Cash at beginning of year	829,933	55,901
Cash at end of year	$1,564,859	$829,933

Table of Contents

Supplemental disclosures of cash flow information:		
Cash paid for income taxes	$5,600	$-
Cash paid for interest	$89,931	$229,046
Supplemental disclosures of non-cash investing and financing activities:		
Common stock issued for conversion of convertible debentures, notes payable and accrued interest	$1,093,381	$3,264,705
Reclassification of the fair value of the embedded conversion features from derivative liability to additional paid-in capital upon conversion	$203,630	$3,111,828
Relative fair value of common stock issued in connection with notes payable recorded as debt discount	$216,905	$276,167
Fair value of common stock issued as financing fees in connection with notes payable recorded as debt discount	$98,761	$-
Proceeds from note payable paid to seller in connection with acquisition	$-	$300,000
Financing costs paid with proceeds from note payable	$-	$7,500
Cashless exercise of warrants	$-	$3,385
Fair value of the contingent consideration for acquisition	$-	$330,000
Reclassification of the fair value of the warrants from derivative liability to additional paid-in capital upon cashless exercise	$-	$518,224
Relative fair value of warrants issued in connection with convertible debentures recorded as debt discount	$-	$445,603
Relative fair value of common stock issued in connection with convertible debentures recorded as debt discount	$-	$1,127,225
Fair value of embedded conversion feature derivative liabilities recorded as debt discount	$-	$687,385
Fair value of warrants issued to placement agents in connection with convertible debentures recorded as debt discount	$-	$357,286
Fair value of unamortized non-forfeitable common stock issued to consultant included in prepaid expense and other current assets	$-	$170,600
Fair value of non-forfeitable common stock issued to consultant included in accounts payable and accrued expense	$360,000	$360,000
Issuance of shares of common stock for vested restricted stock units	$92	$19,316
Fair value of common stock issued for prepayment of future royalties due under the CRI License Agreement included in prepaid expense and other current assets	$44,662	$-
Proceeds from short-term loans payable for payment of business insurance premiums	$97,871	$-
Common stock issued to Novalere Holdings for payment of the acquisition contingent consideration as a result of an amendment and supplement to the registration rights and stock restriction agreement	$-	$2,971,641
Fair value of beneficial conversion feature on line of credit convertible debenture – related party	$-	$3,444

See accompanying notes to these consolidated financial statements.

Table of Contents

INNOVUS PHARMACEUTICALS, INC.
Notes to Consolidated Financial Statements
December 31, 2017 and 2016

NOTE 1 – ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

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

We generate revenue from 28 commercial products in the United States, including 12 of these commercial products in multiple countries around the world through our 18 international commercial partners. Our commercial product portfolio includes (a) Beyond Human® Testosterone Booster, (b) Beyond Human® Growth Agent, (c) Zestra® to increase female arousal and desire, (d) EjectDelay® for premature ejaculation, (e) Sensum+® for reduced penile sensitivity, (f) Zestra Glide®, (g) Vesele® for promoting sexual health, (h) Androferti® to support overall male reproductive health and sperm quality, (i) RecalMax™ for cognitive brain health, (j) Beyond Human® Green Coffee Extract, (k) Beyond Human® Eagle Vision Formula, (l) Beyond Human® Blood Sugar, (m) Beyond Human® Colon Cleanse, (n) Beyond Human® Ketones, (o) Beyond Human® Krill Oil, (p) Beyond Human® Omega 3 Fish Oil, (q) UriVarx® for bladder health, (r) ProstaGorx® for prostate health, (s) AllerVarx® for management of allergy symptoms, (t) Apeaz® indicated for arthritis pain relief, (u) ArthriVarx® for joint health, (v) PEVarx® for extension of sexual intercourse time, (w) FlutiCare® for allergy symptom relief, (x) Xyralid® for relief of pain and symptoms caused by hemorrhoids, (y) Can-C® eye drops and supplement for lubricating the eye and to enhance free radical protection and reduce the oxidative environment inside the eye, (z) MZS™ melatonin for improved sleeping, and (aa) Diabasens™ a cream designed to increase blood flow in the diabetic foot. While we generate revenue from the sale of our commercial products, most revenue is currently generated by Vesele®, Zestra®, Zestra® Glide, RecalMax™, Sensum+®, UriVarx®, ProstaGorx®, FlutiCare®, AllerVarx®, Apeaz®, ArthriVarx®, Xyralid®, PEVarx® and Beyond Human® Testosterone Booster.

Pipeline Products

UriVarx™ UTI Urine Strips. UriVarx™ UTI Urine Strips are FDA cleared diagnostic strips for home use that a man or woman can use to determine if they have a urinary tract infection. They will be sold with our UriVarx® supplement product as well as on their own as replacement strips. The UriVarx™ UTI Urine Strips are manufactured by our partner, ACON Laboratories, Inc. We currently expect to launch the UriVarx™ UTI Urine Strips in the second quarter of 2018.

Xyralid® Suppositories. Xyralid® Suppositories are OTC FDA monograph suppositories indicated for the relief of both internal & external hemorrhoidal symptoms. The drug works by constricting or shrinking swollen hemorrhoidal tissues and gives prompt soothing relief from painful burning, itching and discomfort. We currently expect to launch this product in the second quarter of 2018.

GlucoGorx™ Supplement, Glucometer, Lancing Device ad GlucoGorx™ Strips. GlucoGorx™ is a supplement made of a combination of herbs and nutrients designed to balance and maintain healthy blood sugar levels. The Glucometer, Lancing Device and GlucoGorx™ Strips are part of an expected FDA cleared kit that we will bundle with GlucoGorx™ to

provide customers with the ability to utilize the supplement's benefits and to test their blood sugar levels in their own homes in a quick and efficient manner. The Glucometer, Lancing Device and GlucoGorx™ Strips are manufactured by our partner ACON Laboratories, Inc. We currently expect to launch this product and the kit in the second half of 2018.

Vesele™ Nitric Oxide Strips. We have developed the Vesele™ Nitric Oxide Strips to be used with our supplement product Vesele® to measure saliva levels of nitric oxide and help consumers monitor the effect of Vesele® real time on their blood flow increase. We currently expect to launch this product in the second quarter of 2018.

RecalMax™ Nitric Oxide Strips. We have developed the RecalMax™ Nitric Oxide Strips to be used with our product RecalMax™ to measure saliva levels of nitric oxide and help consumers monitor the effect of RecalMax™ real time on their blood flow increase. We currently expect to launch this product in the second quarter of 2018.

Table of Contents

Musclin™. Musclin™ is a proprietary supplement made of two FDA Generally Recognized As Safe (GRAS) approved ingredients designed to increase muscle mass, endurance and activity. The main ingredient in Musclin™ is a natural activator of the transient receptor potential cation channel, subfamily V, member 3 (TRPV3) channels on muscle fibers responsible to increase fibers width resulting in larger muscles. We currently expect to launch this product in the second half of 2018.

Regenerum™. Regenerum™ is a proprietary product containing two natural molecules, one is an activator the TRPV3 channels resulting in the increase of muscle fiber width and the second targeting a different unknown receptor to build the muscle's capacity for energy production and increases physical endurance, allowing longer and more intense exercise. Regenerum™ is being developed for patients suffering from muscle wasting. We currently expect to launch this product in 2019 pending successful clinical trials in patients with muscle wasting or cachexia.

In addition to the above listed product pipeline, we are continuously looking to add additional drugs, supplements and medical devices to our pipeline.

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 (“U.S. GAAP”), and include all assets, liabilities, revenues and expenses of the Company and its wholly owned subsidiaries: FasTrack Pharmaceuticals, Inc., Semprae Laboratories, Inc. (“Semprae”) and Novalere, Inc. (“Novalere”). All material intercompany transactions and balances have been eliminated. Certain items have been reclassified to conform to the current year presentation.

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, sales returns and chargebacks, realizability of inventories, valuation of deferred tax assets, goodwill and intangible assets, valuation of contingent acquisition consideration, recoverability of long-lived assets and goodwill, fair value of derivative liabilities and the valuation of equity-based instruments and beneficial conversion features. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from these estimates under different assumptions or conditions.

Liquidity

Our operations have been financed primarily through proceeds from convertible debentures and notes payable, sales of our common stock and revenue generated from our products domestically and internationally by our partners. These funds have provided us with the resources to operate our business, sell and support our products, attract and retain key personnel and add new products to our portfolio. We have experienced net losses and negative cash flows from operations each year since our inception. As of December 31, 2017, we had an accumulated deficit of $35,639,837 and a working capital deficit of $1,423,733.

In March 2017, we raised net cash proceeds of $3,307,773 from the sale of common stock and warrants in a registered public offering (see Note 8) and in the first quarter of 2018, we received net cash proceeds of $2.7 million from the exercise of warrants (see Note 12). Additionally, during fiscal 2017 and the first quarter of 2018 we raised $1,650,000

and $1,877,500, respectively, in gross proceeds from the issuance of notes payable to six investors (see Notes 5 and 12). We have also issued equity instruments in certain circumstances to pay for services from vendors and consultants.

As of December 31, 2017, we had $1,564,859 in cash. During the year ended December 31, 2017, we had net cash used in operating activities of $2,361,723. We expect that our existing capital resources, the proceeds received from the exercise of warrants and issuance of notes payable in the first quarter of 2018 totaling $4.5 million (see Note 12), revenue from sales of our products and upcoming sales milestone payments from the commercial partners signed for our products will be sufficient to allow us to continue our operations, commence the product development process and launch selected products through at least the next 12 months. In addition, our CEO, who is also a significant shareholder, has deferred the remaining payment of his salary earned through June 30, 2016 totaling $1,531,904 for at least the next 12 months. Our actual needs will depend on numerous factors, including timing of introducing our products to the marketplace, our ability to attract additional international distributors for our products and our ability to in-license in non-partnered territories and/or develop new product candidates. Although no assurances can be given, we currently intend to raise additional capital through the sale of debt or equity securities to provide additional working capital, pay for further expansion and development of our business, and to meet current obligations. Such capital may not be available to us when we need it or on terms acceptable to us, if at all.

Table of Contents

Fair Value Measurement

Our financial instruments are cash, accounts receivable, accounts payable, accrued liabilities, derivative liabilities, contingent consideration and debt. The recorded values of cash, accounts receivable, accounts payable and accrued liabilities approximate their fair values based on their short-term nature. The fair values of the warrant derivative liabilities and embedded conversion feature derivative liabilities are based upon the Black Scholes Option Pricing Model ("Black-Scholes") and the Path-Dependent Monte Carlo Simulation Model calculations, respectively, and are a Level 3 measurement (see Note 9). The fair value of the contingent acquisition consideration is based upon the 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 us, the carrying values of the notes payable and short-term loans payable approximate their respective fair values.

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

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

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

Level 3 measurements are unobservable inputs.

Cash

Cash consists of cash held with financial institutions. Cash held with financial institutions may exceed the amount of insurance provided by the Federal Deposit Insurance Corporation on such deposits.

Concentration of Credit Risk, Major Customers and Segment Information

Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash and accounts receivable. Accounts receivable consist primarily of sales of Zestra® to U.S. based retailers and Ex-U.S. partners. We also require a percentage of payment in advance for product orders with our larger partners. We perform ongoing credit evaluations of our customers and generally do not require collateral.

Revenues consist primarily of product sales and licensing rights to market and commercialize our products. We have no customers that accounted for 10% or more of our total net revenue during the years ended December 31, 2017 and 2016. As of December 31, 2017 and 2016 four customers and three customers accounted for 72% and 62% of total net accounts receivable, respectively.

We categorize revenue by geographic area based on selling location. All operations are currently located in the U.S.; therefore, over 90% of our sales are currently within the U.S. The balance of the sales are to various other countries, none of which is 10% or greater.

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

Concentration of Suppliers

We have manufacturing relationships with a number of vendors or manufacturers for our various products. Pursuant to these relationships, we purchase products through purchase orders with our manufacturers.

Inventories

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

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

Table of Contents

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.

Business Combinations

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

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

Goodwill and Intangible Assets

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

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

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

Impairment may result from, among other things, deterioration in the performance of the acquired business, adverse market conditions, adverse changes in applicable laws or regulations and a variety of other circumstances. If we

determine that an impairment has occurred, it is required to record a write-down of the carrying value and charge the impairment as an operating expense in the period the determination is made. In evaluating the recoverability of the carrying value of goodwill, we must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the acquired assets. Changes in strategy or market conditions could significantly impact those judgments in the future and require an adjustment to the recorded balances.

The goodwill was recorded as part of the acquisition of Semprae that occurred on December 24, 2013, the acquisition of Novalere that occurred on February 5, 2015, and the asset acquisition of Beyond Human® that closed on March 1, 2016. There was no impairment of goodwill for the years ended December 31, 2017 and 2016.

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

Table of Contents

Long-Lived Assets

We review our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. We evaluate assets for potential impairment by comparing estimated future undiscounted net cash flows to the carrying amount of the assets. If the carrying amount of the assets exceeds the estimated future undiscounted cash flows, impairment is measured based on the difference between the carrying amount of the assets and fair value. Assets to be disposed of would be separately presented in the consolidated balance sheet and reported at the lower of the carrying amount or fair value less costs to sell and are no longer depreciated. The assets and liabilities of a disposal group classified as held-for-sale would be presented separately in the appropriate asset and liability sections of the consolidated balance sheet, if material. During the years ended December 31, 2017 and 2016, we did not recognize any impairment of our long-lived assets.

Debt Issuance Costs

Debt issuance costs represent costs incurred in connection with the notes payable and convertible debentures during the years ended December 31, 2017 and 2016. Debt issuance costs related to the issuance of the convertible debentures and notes payable are recorded as a reduction to the debt balances in the accompanying consolidated balance sheets. The debt issuance costs are being amortized to interest expense over the term of the financing instruments using the effective interest method (see Note 5).

Beneficial Conversion Feature

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

Derivative Liabilities

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

Debt Extinguishment

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

Income Taxes

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

We recognize the benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting this standard, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the relevant tax authority. There were no uncertain tax positions at December 31, 2017 and 2016 (see Note 10).

Table of Contents

Revenue Recognition and Deferred Revenue

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

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

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

Sales Allowances

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

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

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

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

The estimated reserve for sales returns and allowances, which is included in accounts payable and accrued expense in the accompanying consolidated balance sheets, was approximately $53,000 and $61,000 at December 31, 2017 and 2016, respectively.

Cost of Product Sales

Cost of product sales includes the cost of inventories, shipping costs, royalties and inventory reserves. We are required to make royalty payments based upon the net sales of three of our marketed products, Zestra®, Sensum+® and Vesele®. In October 2017, the royalty obligation for Vesele® ended (see Note 11).

Advertising Expense

Advertising costs, which primarily includes print and online media advertisements, are expensed as incurred and are included in sales and marketing expense in the accompanying consolidated statements of operations. Advertising costs were approximately $5,388,000 and $2,680,000 for the years ended December 31, 2017 and 2016, respectively.

Table of Contents

Research and Development Costs

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

Stock-Based Compensation

We account for stock-based compensation in accordance with FASB ASC 718, Stock Based Compensation. All stock-based payments to employees and directors, including grants of stock options, warrants, restricted stock units ("RSUs") and restricted stock, are recognized in the consolidated financial statements based upon their estimated fair values. We use Black-Scholes to estimate the fair value of stock-based awards. The estimated fair value is determined at the date of grant. FASB ASC 718 requires that stock-based compensation expense be based on awards that are ultimately expected to vest. Prior to the adoption of Accounting Standards Update ("ASU") ASU No. 2016-09, Improvements to Employee Share-Based Payment Accounting, on January 1, 2017, stock-based compensation had been reduced for estimated forfeitures. When estimating forfeitures, voluntary termination behaviors, as well as trends of actual option forfeitures, were considered. To the extent actual forfeitures differed from then current estimates, cumulative adjustments to stock-based compensation expense were recorded. As a result of the adoption of ASU No. 2016-09 as of January 1, 2017, we have made an entity-wide accounting policy election to account for forfeitures when they occur. There is no cumulative-effect adjustment as a result of the adoption of this ASU as our estimated forfeiture rate prior to adoption of this ASU was 0%.

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

Equity Instruments Issued to Non-Employees for Services

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

Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding and vested but deferred RSUs during the period presented. Diluted net loss per share is computed using the weighted average number of common shares outstanding and vested but deferred RSUs during the periods plus the effect of dilutive securities outstanding during the periods. For the years ended December 31, 2017 and 2016, basic

net loss per share is the same as diluted net loss per share as a result of our common stock equivalents being anti-dilutive. See Note 8 for more details.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers. This updated guidance supersedes the current revenue recognition guidance, including industry-specific guidance. The updated guidance introduces a five-step model to achieve its core principal of the entity recognizing revenue to depict the transfer of goods or services to customers at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In August 2015, the FASB issued ASU 2015-14 which deferred the effective date by one year for public entities and others. The amendments in this ASU are effective for interim and annual periods beginning after December 15, 2017 for public business entities, certain not-for-profit entities, and certain employee benefit plans. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. In March 2016, the FASB issued ASU 2016-08 which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU 2016-10 which clarifies the principle for determining whether a good or service is “separately identifiable” and, therefore, should be accounted for separately. In May 2016 the FASB issued ASU 2016-12 which clarifies the objective of the collectability criterion. A separate update issued in May 2016 clarifies the accounting for shipping and handling fees and costs as well as accounting for consideration given by a vendor to a customer. The guidance includes indicators to assist an entity in determining whether it controls a specified good or service before it is transferred to the customers.

Table of Contents

We adopted the standard on January 1, 2018. Upon adoption of this standard, we will use the modified retrospective approach. Under the modified approach, an entity recognizes “the cumulative effect of initially applying the ASU as an adjustment to the opening balance of retained earnings of the annual reporting period that includes the date of initial application” (revenue in periods presented in the consolidated financial statements before that date is reported under guidance in effect before the change). Using this approach, an entity applies the guidance in the ASU to existing contracts (those for which the entity has remaining performance obligations) as of, and new contracts after, the date of initial application. The ASU is not applied to contracts that were completed before the effective date (i.e., an entity has no remaining performance obligations to fulfill). Entities that elect the modified approach must disclose an explanation of the impact of adopting the ASU, including the consolidated financial statement line items and respective amounts directly affected by the standard’s application.

Our revenue is primarily generated from the sale of finished product to customers. Those sales predominantly contain a single delivery element and revenue is recognized at a single point in time when ownership, risks and rewards transfer. The timing of revenue recognition for these product sales are not materially impacted by the new standard. However, we utilized a comprehensive approach to assess the impact of the guidance on our current contract portfolio by reviewing our current accounting policies and practices to identify potential differences that resulted from applying the new requirements to our revenue contracts, including evaluation of performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price, allocating the transaction price to each separate performance obligation and accounting treatment of costs to obtain and fulfill contracts. We continue to make significant progress on the potential impact on our accounting policies and internal control processes including system readiness. In addition, we will update certain disclosures, as applicable, included in our filings pursuant to the Securities Exchange Act of 1934, as amended, to meet the requirements of the new guidance in 2018.

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features. The amendments in Part I of this ASU change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity’s own stock. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic earnings per share. For public business entities, the amendments are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted in any interim or annual period, with any adjustments reflected as of the beginning of the fiscal year of adoption. The amendments should be applied retrospectively to outstanding financial instruments with down round features by means of either a cumulative-effect adjustment to the consolidated statement of financial position as of the beginning of the first fiscal year and interim period of adoption or retrospectively to each prior reporting period presented in accordance with the guidance on accounting changes. We are currently in the process of evaluating the effect this standard will have on our derivative liabilities and the impact on our consolidated financial position and results of operation.

In January 2017, the FASB issued ASU 2017-04, Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. The update simplifies how an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit’s goodwill with the carrying amount. This update is effective for annual and

interim periods beginning after December 15, 2019, and interim periods within that reporting period. While we are still in the process of completing our analysis on the impact this guidance will have on the consolidated financial statements and related disclosures, we do not expect the impact to be material.

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

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230) – Classification of Certain Cash Receipts and Cash Payments. This ASU provides clarification regarding how certain cash receipts and cash payments are presented and classified in the statement of cash flows. This ASU addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. The issues addressed in this ASU that will affect us is classifying debt prepayments or debt extinguishment costs and contingent consideration payments made after a business combination. This update is effective for annual and interim periods beginning after December 15, 2017, and interim periods within that reporting period and is to be applied using a retrospective transition method to each period presented. Early adoption is permitted. We have elected to early adopt ASU 2016-15 as of January 1, 2017 and, as a result, the prepayment penalty of $127,247 in connection with the extinguishment of the 2016 Notes (see Note 5) in March 2017 is classified as a financing cash outflow in the accompanying consolidated statement of cash flows for the year ended December 31, 2017. The adoption of this ASU did not have a material impact on our consolidated financial position, results of operations and related disclosures and had no other impact to the accompanying consolidated statement of cash flows for the years ended December 31, 2017 and 2016.

Table of Contents

In March 2016, the FASB issued ASU No. 2016-09, Improvements to Employee Share-Based Payment Accounting, which amends ASC Topic 718, Compensation - Stock Compensation. The ASU involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, forfeitures, classification of awards as either equity or liabilities and classification on the statement of cash flows. Certain of these changes are required to be applied retrospectively, while other changes are required to be applied prospectively. ASU 2016-09 is effective for public business entities for annual reporting periods beginning after December 15, 2016, and interim periods within that reporting period. Early adoption will be permitted in any interim or annual period, with any adjustments reflected as of the beginning of the fiscal year of adoption. As a result of the adoption of this ASU as of January 1, 2017, we have made an entity-wide accounting policy election to account for forfeitures when they occur. There is no cumulative-effect adjustment as a result of the adoption of this ASU as our estimated forfeiture rate prior to adoption of this ASU was 0%. The adoption of this ASU did not have a material impact on our consolidated financial statements and related disclosures.

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

In November 2015, the FASB issued 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. The adoption of this ASU as of January 1, 2017 did not have a material impact on our consolidated financial statements and related disclosures.

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 ASU 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 adoption of this ASU as of January 1, 2017 did not have a material impact on our consolidated financial statements and related disclosures.

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 condensed consolidated financial statements. The standard provides accounting guidance that will be used along with existing auditing standards. The ASU 2014-15 is effective for the annual period ending after December 15, 2016. Early application is permitted. The adoption of this ASU as of January 1, 2017 did not have a material impact on our consolidated financial statements and related disclosures.

Table of Contents

NOTE 2 – LICENSE AGREEMENTS

In-License Agreements

NTC S.r.l. In-License Agreement

On December 15, 2016, the Company and NTC S.r.l ("NTC") entered into a license and distribution agreement ("NTC License Agreement") pursuant to which we acquired the rights to use, market and sell NTC's proprietary modified release bilayer tablet formerly known as LERTAL® for the management of allergic rhinitis in the U.S. and Canada. Such licensed product is sold by us under the name AllerVarx® in the U.S. and Canada. Under this agreement, we are obligated to pay a non-refundable upfront license fee of €15,000, or $15,684 USD, and cash payments of up to €120,000 ($143,743 USD based on December 31, 2017 exchange rate) upon the achievement of certain sales milestones. The non-refundable upfront license is included in sales and marketing expense in the accompanying consolidated statement of operations for the year ended December 31, 2016. No other amounts have been paid under this agreement.

Seipel Group Pty Ltd. In-License Agreement

On September 29, 2016, the Company and Seipel Group Pty Ltd. ("SG") entered into a license and purchase agreement ("SG License Purchase Agreement") pursuant to which we acquired the exclusive rights to use, market and sell SG's proprietary dietary supplement formula known as Urox® for bladder support in the U.S. and worldwide. Under this agreement, we have agreed to minimum purchase order requirements of 25,000 units per calendar quarter beginning 12 months after our initial order to retain our exclusivity (see Note 11) and paid a brokerage fee of $200,000 which is included in sales and marketing expense in the accompanying consolidated statement of operations for the year ended December 31, 2016. We have met the quarterly minimum purchase order requirements under this agreement as of December 31, 2017.

CRI In-License Agreement

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

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

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

On June 9, 2016, the Company and CRI amended the CRI Asset Purchase Agreement ("Amended CRI Asset Purchase Agreement") to provide us commercialization rights for Sensum+® in the U.S. through our Beyond Human™ sales and marketing platform through December 31, 2016. On January 1, 2017, the Company and CRI agreed to extend the term of the Amended CRI Asset Purchase Agreement to December 31, 2017. In connection with the extension, we issued restricted shares of common stock totaling 225,000 to CRI as a prepayment of royalties due on net profit of Sensum+® in the U.S. in 2017. The royalty prepayment amount is $44,662 as the number of shares of common stock issued was based on the closing price of our common stock on December 30, 2016. Since CRI did not earn royalties larger than the prepaid amount of $44,662 in 2017, the term of the Amended CRI Asset Purchase Agreement is automatically extended one additional year to December 31, 2018.

In consideration for the CRI Asset Purchase Agreement, we issued 631,313 shares of common stock to CRI in 2013. We recorded an asset totaling $250,000 related to the CRI Asset Purchase Agreement and are amortizing this amount over its estimated useful life of 10 years. Under the CRI Asset Purchase Agreement, we were required to issue to CRI shares of our common stock valued at an aggregate of $200,000 for milestones relating to additional clinical data to be received. As a result of the Amended CRI Asset Purchase Agreement, the Company and CRI agreed to settle the clinical milestone payments with a payment of 100,000 shares of restricted common stock. The fair value of the restricted shares of common stock of $23,000 was based on the market price of our common stock on the date of issuance and is included in research and development expense in the accompanying consolidated statement of operations for the year ended December 31, 2016.

The CRI Asset Purchase Agreement also requires us to pay to CRI up to $7.0 million in cash milestone payments based on first achievement of annual Ex-U.S. net sales targets plus a royalty based on annual Ex-U.S. net sales. The obligation for these payments expires on April 19, 2023 or the expiration of the last of CRI’s patent claims covering the product or its use outside the U.S., whichever is sooner. No sales milestone obligations have been met and no royalties are owed to CRI under this agreement during the years ended December 31, 2017 and 2016.

In consideration for the Amended CRI Asset Purchase Agreement, we are required to pay CRI a percentage of the monthly net profit, as defined in the agreement, from our sales of Sensum+® in the U.S. through our Beyond Human™ sales and marketing platform. During the years ended December 31, 2017 and 2016, no amounts have been earned by CRI under the Amended CRI Asset Purchase Agreement.

Table of Contents

Out-License Agreements

Densmore Pharmaceutical International Agreement

On April 24, 2017, we entered into an exclusive ten-year license agreement with Densmore Pharmaceutical International, a Monaco company ("Densmore"), under which we granted to Densmore an exclusive license to market and sell our topical treatment for Female Sexual Interest/Arousal Disorder ("FSI/AD") Zestra® in France and Belgium. Under the agreement, we received a non-refundable upfront payment of $7,500 which was recognized as revenue in the accompanying consolidated statement of operations for the year ended December 31, 2017. We believe the amount of the upfront payment received is reasonable compared to the amounts to be received upon obtainment of future minimum order quantities. Densmore is obligated to order certain minimum annual quantities of Zestra® at a pre-negotiated transfer price per unit during the term of the agreement. During the year ended December 31, 2017, we recognized revenue for the sale of products related to this agreement of $100,341.

In July 2017, we entered into an amendment to the agreement with Densmore to expand the product territory to Singapore and Vietnam.

Luminarie Pty Ltd. Agreement

On May 16, 2017, we entered into an exclusive ten-year license agreement with Luminarie Pty Ltd., a Australia company ("Luminarie"), under which we granted to Luminarie an exclusive license to market and sell our topical treatment for FSI/AD Zestra® and Zestra Glide® in Australia, New Zealand and the Philippines. Luminarie received approval for Zestra® as a Class I Medical Device in Australia in July 2017 and New Zealand in September 2017. Luminarie is obligated to order certain minimum annual quantities of Zestra® and Zestra Glide® at a pre-negotiated transfer price per unit during the term of the agreement. During the year ended December 31, 2017, we did not recognize any revenue for the sale of products related to this agreement.

LI USA Co. Agreement

On November 9, 2016, we entered into an exclusive ten-year license agreement with J&H Co. LTD, a South Korea company ("J&H"), under which we granted to J&H an exclusive license to market and sell our topical treatment for Female Sexual Interest/Arousal Disorder ("FSI/AD") Zestra® and Zestra Glide® in South Korea. Under the agreement, J&H is obligated to order minimum annual quantities of Zestra® and Zestra Glide® totaling $2.0 million at a pre-negotiated transfer price per unit through March 2018. The minimum annual order quantities by J&H are to be made over a 12-month period following the approval of the product by local authorities and beginning upon the completion of the first shipment of product. Our partner recently received the approval to import the product and placed its first order in March 2017. During the years ended December 31, 2017 and 2016, we recognized $60,000 and $0 in revenue for the sale of products related to this agreement.

On October 26, 2017, the exclusive license and distributor rights under this agreement were assigned to LI USA Co., a U.S. company ("LI USA"), from J&H and LI USA is now the distributor under this agreement. LI USA is controlled by the same original owners as J&H. All terms and conditions of the original agreement remain intact.

Sothema Laboratories Agreement

On September 23, 2014, we entered into an exclusive license agreement with Sothema Laboratories, SARL, a Moroccan publicly traded company ("Sothema"), under which we granted to Sothema an exclusive license to market

and sell Zestra® (based on the latest Canadian approval of the indication) and Zestra Glide® in several Middle Eastern and African countries (collectively the "Territory").

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

As the sales-based milestones do not meet the definition of a milestone under ASC 605-28, we will recognize the revenue from the milestone payments when the cumulative supplied units' volume is met. During the years ended December 31, 2017 and 2016, we recognized $0 and $16,056, respectively, in net revenue for the sales of products related to this agreement, and no revenue was recognized for the sales-based milestones of the agreement.

Orimed Pharma Agreement

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

Table of Contents

Under the agreement, we received an upfront payment of $100,000 and are eligible to receive additional consideration upon and subject to the achievement of sales milestones based on cumulative gross sales in Canada by Orimed plus double-digit tiered royalties based on Orimed's cumulative net sales in Canada. We believe the amount of the upfront payment received is reasonable compared to the amounts to be received upon obtainment of future sales-based milestones.

As the sales-based milestones do not meet the definition of a milestone under ASC 605-28, we will recognize the revenue from the milestone payments when the cumulative gross sales volume is met. We will recognize the revenue from the royalty payments on a quarterly basis when the cumulative net sales have been met. During the years ended December 31, 2017 and 2016, under this agreement we recognized $31,015 and $42,153, respectively, in net revenue for the sales of products and no revenue was recognized for the sales-based milestones. During the years ended December 31, 2017 and 2016, we recognized royalty payments of $4,112 and $1,252, respectively.

Khandelwal Laboratories Agreement

On September 9, 2015, we entered into an exclusive license and distribution agreement with Khandelwal Laboratories, an Indian company ("KLabs") under which we have granted to KLabs an exclusive ten-year distribution right to market and sell in the Indian Subcontinent, which is defined as India, Nepal, Bhutan, Bangladesh and Sri Lanka our products including Zestra®, EjectDelay®, Sensum+® and Zestra Glide®. If KLabs exceeds its minimum yearly orders, the agreement has two five-year term extensions. During the years ended December 31, 2017 and 2016, we recognized $5,371 and $0, respectively, in net revenue for the sales of products related to this agreement.

Elis Pharmaceuticals Agreements

On July 4, 2015, we announced that we had entered into an exclusive license and distribution agreement with Elis Pharmaceuticals, an emirates company ("Elis"), under which we granted to Elis an exclusive ten-year distribution right to market and sell Zestra® EjectDelay®, Sensum+® and Zestra Glide® in Turkey and select African and gulf countries. If Elis exceeds its minimum yearly orders, the agreement has a ten-year term extension. Under the agreement, we are eligible to receive certain sales milestone payments plus an agreed-upon transfer price upon sale of products. We had preliminary listed Syria, Yemen and Somalia as countries in the definition of licensed territories, but these countries were removed by the agreement of both parties from the agreement effective the date of signing of the agreement. As the sales-based milestones are not considered a milestone under ASC 605-28, we will recognize the revenue from the milestone payments when the cumulative gross sales volume is met. We did not recognize any revenue from this agreement during the years ended December 31, 2017 and 2016.

On October 31, 2016, we entered into another exclusive license and distribution agreement with Elis under which we granted to Elis an exclusive ten-year distribution right to market and sell Zestra® in Lebanon. Under the agreement, we are eligible to receive certain sales milestone payments plus an agreed-upon transfer price upon sale of products. As the sales-based milestones are not considered a milestone under ASC 605-28, we will recognize the revenue from the milestone payments when the cumulative gross sales volume is met. During the years ended December 31, 2017 and 2016, no revenue was recognized related to this agreement.

NOTE 3 – BUSINESS AND ASSET ACQUISITIONS

Acquisition of Assets of Beyond Human® in 2016

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

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

The total purchase price is summarized as follows:

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

Table of Contents

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

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

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

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

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

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

which is included in fair value adjustment for contingent consideration in the accompanying consolidated statement of operations for the year ended December 31, 2016.

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

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

	Year Ended December 31, 2016	
	As Reported	Pro Forma (unaudited)
Net revenues	$4,818,603	$4,868,241
Net loss	$(13,701,154)	$(13,700,702)
Net loss per share of common stock – basic and diluted	$(0.15)	$(0.15)
Weighted average number of shares outstanding – basic and diluted	94,106,382	94,106,382

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

Table of Contents

Acquisition of Novalere in 2015

On February 5, 2015 (the "Closing Date"), Innovus, Innovus Pharma Acquisition Corporation, a Delaware corporation and a wholly-owned subsidiary of Innovus ("Merger Subsidiary I"), Innovus Pharma Acquisition Corporation II, a Delaware corporation and a wholly-owned subsidiary of Innovus ("Merger Subsidiary II"), Novalere FP, Inc., a Delaware corporation ("Novalere FP") and Novalere Holdings, LLC, a Delaware limited liability company ("Novalere Holdings"), as representative of the shareholders of Novalere (the "Novalere Stockholders"), entered into an Agreement and Plan of Merger (the "Merger Agreement"), pursuant to which Merger Subsidiary I merged into Novalere and then Novalere merged with and into Merger Subsidiary II (the "Merger"), with Merger Subsidiary II surviving as a wholly-owned subsidiary of Innovus. Pursuant to the articles of merger effectuating the Merger, Merger Subsidiary II changed its name to Novalere, Inc.

With the Merger, we acquired the worldwide rights to market and sell the FlutiCare® brand (fluticasone propionate nasal spray) and the related third-party manufacturing agreement for the manufacturing of FlutiCare® ("Acquisition Manufacturer") from Novalere FP. The OTC Abbreviated New Drug Application ("ANDA") for fluticasone propionate nasal spray was filed at the end of 2014 by our third-party manufacturer and partner, who is currently selling the prescription version of the drug, with the FDA and the OTC ANDA is still subject to FDA approval. An ANDA is an application for a U.S. generic drug approval for an existing licensed medication or approved drug. A prescription ANDA ("RX ANDA") is for a generic version of a prescription pharmaceutical and an OTC ANDA is for a generic version of an OTC pharmaceutical.

Due to the delay in approval of the Acquisition Manufacturer's OTC ANDA by the FDA, in May 2017, we announced a commercial relationship with a different third-party manufacturer (West-Ward Pharmaceuticals International Limited or "WWPIL") who has an FDA approved OTC ANDA for fluticasone propionate nasal spray under which they have agreed to manufacture our FlutiCare® OTC product for sale in the U.S. (see Note 11). We currently still anticipate that the OTC ANDA filed in November 2014 by the Acquisition Manufacturer with the FDA may be approved in 2018. As we hold the worldwide rights to market and sell FlutiCare® under the manufacturing agreement with the Acquisition Manufacturer, we believe the agreement with the Acquisition Manufacturer will still provide us with the opportunity to market and sell FlutiCare® ex-U.S. and, if the OTC ANDA is approved by the FDA, a second source of supply within the U.S., if ever needed.

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

In addition, the Novalere Stockholders are entitled to receive, if and when earned, earn-out payments (the "Earn-Out Payments"). For every $5.0 million in Net Revenue (as defined in the Merger Agreement) realized from the sales of FlutiCare® through the manufacturing agreement with the Acquisition Manufacturer, 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 Novalere Stockholders are only entitled to the Earn-Out Payments from the Acquisition Manufacturer's OTC ANDA under review by the FDA and have no earn-out rights to the sales of FlutiCare® supplied by WWPIL under the commercial agreement entered into in May 2017.

On November 12, 2016, we entered into an Amendment and Supplement to a Registration Rights and Stock Restriction Agreement (the "Agreement") with Novalere Holdings pursuant to which we agreed to issue 12,808,796 shares of our common stock (the “Novalere Shares”) that were issuable pursuant to agreement upon the approval of the Acquisition Manufacturer’s OTC ANDA for fluticasone propionate nasal spray by the FDA. In connection with the issuance of the Novalere Shares, Novalere Holdings also agreed to certain restrictions, and to an extension in the date to register the Novalere Shares and all other shares of our common stock held by Novalere Holdings until the second quarter of 2017. In the event a registration statement to register the Novalere Shares was not filed by February 1, 2017, and did not become effective by May 15, 2017, we would have been required to issue additional shares of common stock as a penalty to Novalere Holdings equal to 10% of the total shares to be registered of 25,617,592. We filed a Registration Statement on Form S-1 on February 1, 2017 to register the 25,617,592 shares of common stock issued to Novalere Holdings and the Form S-1 was declared effective on March 15, 2017. As a result of the issuance of the Novalere Shares, the fair value of the Novalere Shares on the date of issuance of $2,971,641 was reclassified from liabilities to equity. During the year ended December 31, 2016, there was an increase in the estimated fair value of the Novalere Shares of $1,332,670 due to the amended agreement entered into with Novalere Holdings (see above) which is included in fair value adjustment for contingent consideration in the accompanying consolidated statement of operations. The remaining 138,859 ANDA consideration shares not issuable yet will be issued upon FDA approval of the ANDA filed by the Acquisition Manufacturer and the estimated fair value of such remaining shares of $9,275 and $32,215 is included in contingent consideration in the accompanying consolidated balance sheets at December 31, 2017 and 2016, respectively. During the years ended December 31, 2017 and 2016, there was an increase/(decrease) in the estimated fair value of the remaining 138,859 ANDA consideration shares totaling $(22,940) and $13,886, respectively, which is included in fair value adjustment for contingent consideration in the accompanying consolidated statements of operations.

Table of Contents

There was no change to the estimated fair value of the future earn-out payments of $1,248,126 during the years ended December 31, 2017 and 2016.

Purchase of Semprae Laboratories, Inc. in 2013

On December 24, 2013 (the "Semprae Closing Date"), we, through Merger Sub, obtained 100% of the outstanding shares of Semprae in exchange for the issuance of 3,201,776 shares of our common stock, which shares represented 15% of our total issued and outstanding shares as of the close of business on the Closing Date, whereupon Merger Sub was renamed Semprae Laboratories, Inc. We agreed to pay the former shareholders an annual royalty ("Royalty") equal to 5% of the net sales from Zestra® and Zestra Glide® and any second generation products derived primarily therefrom ("Target Products") up until the time that a generic version of such Target Product is introduced worldwide by a third party.

The 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. The fair value of the Royalty was determined by applying the income approach, using several significant unobservable inputs for projected cash flows and a discount rate of approximately 22% commensurate with our cost of capital and expectation of the revenue growth for products at their life cycle stage. These inputs are considered Level 3 inputs under the fair value measurements and disclosure guidance. During the years ended December 31, 2017 and 2016, $12,881 and $22,103 have been paid under this arrangement, respectively. The fair value of the expected royalties to be paid was increased/(decreased) by $(171,094) and $103,301 during the years ended December 31, 2017 and 2016, respectively, which is included in the fair value adjustment for contingent consideration in the accompanying consolidated statements of operations. The fair value of the contingent consideration was $221,602 and $405,577 at December 31, 2017 and December 31, 2016, respectively, based on the new estimated fair value of the consideration.

NOTE 4 – ASSETS AND LIABILITIES

Inventories

Inventories consist of the following:

	December 31,	
	2017	2016
Raw materials and supplies	$164,469	$85,816
Work in process	152,935	48,530
Finished goods	1,408,294	465,510
Total	$1,725,698	$599,856

Property and Equipment

Property and equipment consists of the following:

	December 31,	
	2017	2016
Computer equipment	$22,473	$5,254
Office furniture and fixtures	34,249	33,376
Leasehold improvements	24,658	-
Production equipment	278,365	276,479
Software	338,976	338,976
Total cost	698,721	654,085
Less accumulated depreciation	(636,267)	(624,516)
Property and equipment, net	$62,454	$29,569

Depreciation expense for the years ended December 31, 2017 and 2016 was $11,751 and $5,532, respectively.

Table of Contents

Intangible Assets

Amortizable intangible assets consist of the following:

	December 31, 2017			
	Amount	Accumulated Amortization	Net Amount	Useful Lives (years)
Patent & Trademarks	$417,597	$(124,809)	$292,788	7 – 15
Customer Contracts	611,119	(249,540)	361,579	10
Sensum+® License (from CRI)	234,545	(107,464)	127,081	10
Vesele® Trademark	25,287	(10,208)	15,079	8
Beyond Human® Website and Trade Name	222,062	(72,206)	149,856	5 – 10
Novalere Manufacturing Contract	4,681,000	(1,355,540)	3,325,460	10
Other Beyond Human® Intangible Assets	4,730	(3,474)	1,256	1 – 3
Total	$$6,196,340	$(1,923,241)	$4,273,099	

	December 31, 2016			
	Amount	Accumulated Amortization	Net Amount	Useful Lives (years)
Patent & Trademarks	$417,597	$(91,201)	$326,396	7 – 15
Customer Contracts	611,119	(188,428)	422,691	10
Sensum+® License (from CRI)	234,545	(84,009)	150,536	10
Vesele® Trademark	25,287	(7,047)	18,240	8
Beyond Human® Website and Trade Name	222,062	(32,821)	189,241	5 – 10
Novalere Manufacturing Contract	4,681,000	(887,440)	3,793,560	10
Other Beyond Human® Intangible Assets	4,730	(2,147)	2,583	1 – 3
Total	$6,196,340	$(1,293,093)	$4,903,247	

Amortization expense for the years ended December 31, 2017 and 2016 was $630,148 and $624,404, respectively. The following table summarizes the approximate expected future amortization expense as of December 31, 2017 for intangible assets:

2018	$630,000

2019	629,000
2020	629,000
2021	600,000
2022	592,000
Thereafter	1,193,000
	$4,273,000

Table of Contents

Prepaid Expense and Other Current Assets

Prepaid expense and other current assets consist of the following:

	December 31,	
	2017	2016
Prepaid insurance	$109,990	$69,976
Prepaid inventory	124,871	20,750
Merchant net settlement reserve receivable	-	221,243
Prepaid consulting and other expense	83,557	21,094
Prepaid CRI royalties (see Note 2)	44,662	-
Prepaid consulting and other service stock-based compensation expense (see Note 8)	-	530,601
Total	$363,080	$863,664

Goodwill

The change in the carrying value of our goodwill for the year ended December 31, 2016 is as follows:

Beginning balance December 31, 2015	$549,368
Asset acquisition of Beyond Human® (see Note 3)	403,208
Ending balance December 31, 2016	$952,576

There was no change in the carrying value of our goodwill during the year ended December 31, 2017.

Table of Contents

Accounts Payable and Accrued Expense

Accounts payable and accrued expense consist of the following:

	December 31,	
	2017	2016
Accounts payable	$2,305,884	$647,083
Accrued credit card balances	72,719	31,654
Accrued royalties	132,326	73,675
Sales returns and allowances	52,904	60,853
Accrual for stock to be issued to consultants (see Note 7)	-	360,000
Accrued other	43,288	36,785
Total	$2,607,121	$1,210,050

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

Short-Term Loan Payable

The short-term loan payable consists of the financing of our business insurance premiums with a third party totaling $97,871. Under the financing agreements we are required to make nine monthly installment payments of $11,155. The balance outstanding as of December 31, 2017 is $65,399.

Notes Payable

The following table summarizes the outstanding notes payable at December 31, 2017 and 2016:

	2017	2016
Notes payable:		
February 2016 Note Payable	$54,984	$347,998
December 2016 and September 2017 Notes Payable	165,000	550,000
October and December 2017 Notes Payable	1,066,667	-
December 2017 Note Payable	390,000	-
Total notes payable	1,676,651	897,998
Less: Debt discount	(437,355)	(216,871)
Carrying value	1,239,296	681,127
Less: Current portion	(1,239,296)	(626,610)
Notes payable, net of current portion	$-	$54,517

The following table summarizes the future minimum payments as of December 31, 2017 for the notes payable:

2018 $ 1,676,651

February 2016 Note Payable

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

We began to pay principal and interest on the February 2016 Note Payable on a monthly basis beginning on March 19, 2016 for a period of 24 months and the monthly mandatory principal and interest payment amount thereunder was $28,209. The monthly amount was to be paid by us through a deposit account control agreement with a third-party bank in which SBI was permitted to take the monthly mandatory payment amount from all revenue received by us from the Beyond Human® assets in the transaction. The February 2016 Note Payable was secured by SBI through a first priority secured interest in all of the Beyond Human® assets acquired by us in the transaction including all revenue received by us from these assets. The maturity date for the February 2016 Note Payable was February 19, 2018. In February 2018, the February 2016 Notes Payable was repaid in full.

Table of Contents

December 2016, January 2017 and September 2017 Notes Payable

On December 5, 2016, January 19, 2017 and September 20, 2017, we entered into a securities purchase agreement with three unrelated third-party investors in which the investors loaned us gross proceeds of $500,000 in December 2016, $150,000 in January 2017 and $150,000 in September 2017 pursuant to a 5% promissory note ("2016 and 2017 Notes Payable"). The notes have an Original Issue Discount ("OID") of $80,000 and require payment of $880,000 in principal upon maturity. The 2016 and 2017 Notes Payable bear interest at the rate of 5% per annum and the principal amount and interest are payable at maturity on October 4, 2017, November 18, 2017 and May 20, 2018 for those received in December 2016, January 2017 and September 2017, respectively.

In connection with the 2016 and 2017 Notes Payable, we issued the investors restricted shares of common stock totaling 1,111,111 in December 2016, 330,000 in January 2017 and 895,000 in September 2017. The fair value of the restricted shares of common stock issued was based on the market price of our common stock on the date of issuance of the 2016 and 2017 Notes Payable (see Note 8). The allocation of the proceeds received to the restricted shares of common stock based on their relative fair value and the OID resulted in us recording a debt discount of $232,203 in December 2016, $59,217 in January 2017 and $70,169 in September 2017. The discount is being amortized to interest expense using the effective interest method over the term of the 2016 and 2017 Notes Payable.

In August, September and October 2017, we entered into a securities exchange agreement with certain of the 2016 and 2017 Notes Payable holders. In connection with the securities exchange agreements, we issued a total of 11,432,747 shares of common stock in exchange for the settlement of principal and interest due under the 2016 and 2017 Notes Payable totaling $742,771. The fair value of the shares of common stock issued was based on the market price of our common stock on the date of the securities exchange agreements (see Note 8). Due to the settlement of the principal and interest balance of $742,771 into shares of common stock, the transaction was recorded as a debt extinguishment and the fair value of the shares of common stock issued in excess of the settled principal and interest balance totaling $378,057 and the remaining unamortized debt discount as of the date of settlement of $17,175 were recorded as a loss on debt extinguishment in the accompanying consolidated statement of operations for the year ended December 31, 2017.

The remaining principal balance of $165,000 under the 2016 and 2017 Notes Payable is due on May 20, 2018.

October and December 2017 Notes Payable

On October 17, 2017, October 20, 2017 and December 4, 2017, we entered into a securities purchase agreement with two unrelated third-party investors in which the investors loaned us gross proceeds of $500,000 in October 2017 and $500,000 in December 2017 pursuant to a 0% promissory note ("October and December 2017 Notes Payable"). The notes have an OID of $200,000 and require nine payments of $66,667 in principal per month through July 2018 and twelve payments of $50,000 in principal per month through December 2018. The October and December 2017 Notes Payable bear no interest per annum. The effective interest rate is 27% per annum for the notes issued in October and 20% per annum for the notes issued in December.

In connection with the October and December 2017 Notes Payable, we issued the investors restricted shares of common stock totaling 600,000 in December 2017. The fair value of the restricted shares of common stock issued was based on the market price of our common stock on the date of issuance of the October and December 2017 Notes Payable (see Note 8). The allocation of the proceeds received to the restricted shares of common stock based on their relative fair value and the OID resulted in us recording a debt discount of $100,000 in October 2017 and $149,712 in December 2017. In connection with the financing, we issued 576,373 restricted shares of common stock in October

2017 and 543,478 restricted shares of common stock in December 2017 to a third-party consultant. The fair value of the restricted shares of common stock issued of $48,761 in October 2017 and $50,000 in December 2017 were recorded as a debt discount to the carrying value of the notes payable. The discount is being amortized to interest expense using the effective interest method over the term of the October and December 2017 Notes Payable.

In March 2018, we entered into a securities exchange agreement with one of the October and December 2017 Notes Payable holders. In connection with the securities exchange agreement, we issued a total of 2,250,000 shares of common stock in exchange for the settlement of principal due under the note payable totaling $166,667 (see Note 12).

December 2017 Note Payable

On December 13, 2017, we entered into a securities purchase agreement with an unrelated third-party investor in which the investor loaned us gross proceeds of $350,000 pursuant to a 5% promissory note (“December 2017 Note Payable”). The note has an OID of $40,000, bears interest at 5% per annum and requires principal and interest payments of $139,750, $133,250 and $131,625 on June 15, 2018, September 15, 2018 and December 15, 2018, respectively.

Table of Contents

In connection with the December 2017 Note Payable, we issued the investor restricted shares of common stock totaling 1,000,000 in December 2017. The fair value of the restricted shares of common stock issued was based on the market price of our common stock on the date of issuance of the December 2017 Note Payable (see Note 8). The allocation of the proceeds received to the restricted shares of common stock based on their relative fair value and the OID resulted in us recording a debt discount of $107,807 in December 2017. The discount is being amortized to interest expense using the effective interest method over the term of the December 2017 Note Payable.

July 2015 Debenture (Amended August 2014 Debenture)

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

May 2016 Debenture

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

May 2016 Notes Payable

On May 6, 2016, we entered into a securities purchase agreement with an unrelated third party investor in which the investor loaned us gross proceeds of $50,000 pursuant to a 3% promissory note ("May 6, 2016 Note Payable"). The May 6, 2016 Note Payable bore interest at the rate of 3% per annum. The principal amount and interest were payable on November 6, 2016. The note was repaid in full in June 2016.

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

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

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

Interest Expense

We recognized interest expense on notes payable of $72,747 and $151,924 for the years ended December 31, 2017 and 2016, respectively. Amortization of the debt discount to interest expense during the years ended December, 2017 and 2016 totaled $348,006 and $116,798, respectively.

Convertible Debentures

2016 Financing

The following table summarizes the outstanding 2016 convertible debentures at December 31, 2017 and 2016:

	2017	2016
Convertible debentures	$-	$1,559,922
Less: Debt discount	-	(845,730)
Carrying value	-	714,192
Less: Current portion	-	(714,192)
Convertible debentures, net of current portion	$-	$-

Table of Contents

In the second and third quarter of 2016, we entered into Securities Purchase Agreements with eight accredited investors (the "Investors"), pursuant to which we received aggregate gross proceeds of $3.0 million (net of OID) pursuant to which we sold:

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

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

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

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

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

2.
7,500,000 restricted shares of common stock to the Investors.

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

	December 31, 2016
Expected terms (in years)	5.00
Expected volatility	229%
Risk-free interest rate	1.01% – 1.15%
Dividend yield	-

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

Table of Contents

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

During the years ended December 31, 2017 and 2016, certain of the 2016 Notes holders elected to convert principal and interest outstanding of $350,610 and $1,749,070 into 1,402,440 and 6,996,280 shares of common stock, respectively, at a conversion price of $0.25 per share (see Note 8). As a result of the conversion of the principal and interest balance into shares of common stock, the fair value of the embedded conversion feature derivative liabilities of $203,630 and $1,093,263 on the date of conversion was reclassified to additional paid-in capital (see Note 8) and the amortization of the debt discount was accelerated for the amount converted and recorded to interest expense during the years ended December 31, 2017 and 2016, respectively.

As a result of the completion of a public equity offering in March 2017 (see Note 8), we were required to prepay the outstanding principal and accrued interest balance of the 2016 Notes with the cash proceeds received from such offering. The outstanding principal and accrued interest balance of $1,272,469 was repaid in March 2017, as well as, a 10% prepayment penalty of $127,247. Due to the acceleration of repayment of the 2016 Notes as a result of the public equity offering, the transaction was recorded as a debt extinguishment and the 10% prepayment penalty of $127,247 and the remaining unamortized debt discount as of the date of repayment of $415,682 were recorded as a loss on debt extinguishment in the accompanying consolidated statement of operations for the year ended December 31, 2017. The repayment of the outstanding principal and accrued interest balance of the 2016 Notes resulted in the extinguishment of the embedded conversion feature derivative liability and thus the fair value as of the date of repayment of $238,101 was recorded as a reduction to the loss on debt extinguishment in the accompanying consolidated statement of operations for the year ended December 31, 2017.

2015 Financing

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

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

During the year ended December 31, 2016, the Q3 2015 Notes holders elected to convert all principal and interest outstanding of $1,515,635 into 10,104,228 shares of common stock at a conversion price of $0.15 per share (see Note 8). As a result of the conversion of the outstanding principal and interest balance into shares of common stock, the fair value of the embedded conversion feature derivative liabilities of $2,018,565 on the date of conversion was reclassified to additional paid-in capital (see Note 9) and the remaining unamortized debt discount was amortized to

interest expense during the year ended December 31, 2016.

Interest Expense

We recognized interest expense on the Q3 2015 Notes and 2016 Notes for the years ended December 31, 2017 and 2016 of $19,544 and $80,095, respectively. Total amortization of the debt discount on the Q3 2015 Notes and 2016 Notes to interest expense for the years ended December 31, 2017 and 2016 was $430,048 and $3,508,199, respectively.

NOTE 6 – DEBENTURES – RELATED PARTIES

Line of Credit Convertible Debenture

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

Table of Contents

During 2013, the LOC Convertible Debenture was further amended to: (1) increase the maximum principal amount available for borrowing to $1 million plus any amounts of salary or related payments paid to Dr. Damaj prior to the termination of the funding commitment; and (2) change the holder's funding commitment to automatically terminate on the earlier of either (a) when we complete a financing with minimum net proceeds of at least $4 million, or (b) July 1, 2016. The securities to be issued upon automatic conversion would have been either our securities that were issued to the investors in a Qualified Financing or, if the financing did not occur by July 1, 2016, shares of the our common stock based on a conversion price of $0.312 per share, 80% times the quoted market price of our common stock on the date of the amendment. The LOC Convertible Debenture bore interest at a rate of 8% per annum. The other material terms of the LOC Convertible Debenture were not changed. We recorded a debt discount for the intrinsic value of the BCF with an offsetting increase to additional paid-in-capital. The BCF was being accreted as non-cash interest expense over the expected term of the LOC debenture to its stated maturity date using the effective interest rate method.

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

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

During the year ended December 31, 2016 no amounts were borrowed under the LOC Convertible Debenture and we recorded a beneficial conversion feature of $3,444 for accrued interest. We repaid the LOC Convertible Debenture balance and accrued interest in full during the year ended December 31, 2016.

2014 Non-Convertible Notes – Related Parties

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

Interest Expense

We recognized interest expense on the outstanding debentures to related parties totaling $17,430 during the year ended December 31, 2016. Amortization of the debt discount to interest expense during the year ended December 31, 2016 totaled $21,164.

Table of Contents

NOTE 7 – RELATED PARTY TRANSACTIONS

Related Party Borrowings

There were certain related party borrowings that were repaid in full during the year ended December 31, 2016 which are described in more detail in Note 6.

Accrued Compensation – Related Party

Accrued compensation includes accruals for employee wages, vacation pay and target-based bonuses. The components of accrued compensation as of December 31, 2017 and 2016 are as follows:

	December 31,	
	2017	2016
Wages	$1,431,686	$1,455,886
Vacation	342,284	261,325
Bonus	742,481	449,038
Payroll taxes on the above	133,746	133,344
Total	2,650,197	2,299,593
Classified as long-term	(1,531,904)	(1,531,904)
Accrued compensation	$1,118,293	$767,689

Accrued employee wages at December 31, 2017 and 2016 are entirely related to wages owed to our President and Chief Executive Officer. Under the terms of his employment agreement, wages are to be accrued but no payment made for, so long as payment of such salary would jeopardize our ability to continue as a going concern. The President and Chief Executive Officer started to receive payment of salary in July 2016. Our President and Chief Executive Officer has agreed to not receive payment on his remaining accrued wages and related payroll tax amounts within the next 12 months and thus the remaining balance is classified as a long-term liability. In April 2017, our Board of Directors approved for payment the accrued fiscal year 2016 bonus of $33,442 to our former Executive Vice President and Chief Financial Officer in accordance with his employment agreement and the bonus amount was paid upon his departure. The fiscal year 2017 and 2016 bonus for our President and Chief Executive Officer has not yet been approved by our Board of Directors but is included in accrued compensation in the accompanying consolidated balance sheets as of December 31, 2017 and 2016 in accordance with the terms of his employment agreement.

Table of Contents

NOTE 8 – STOCKHOLDERS' EQUITY

Capital Stock

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

Issuances of Common Stock

Public Equity Offering

On March 21, 2017, we completed a sale of common stock and warrants under a registered public offering. The gross proceeds to us from the offering were $3,850,000, before underwriting discounts and commissions and other offering expenses ($3,307,773 after underwriting discounts, commissions and expenses).

The public offering price per share of common stock sold was $0.15. Each investor who purchased a share of common stock in the offering received a five-year warrant to purchase one share of common stock at an exercise price of $0.15 per share ("Series A Warrants") and a one-year warrant to purchase one share of common stock at an exercise price of $0.15 per share ("Series B Warrants"). Under the terms of the offering, we issued 25,666,669 shares of common stock, Series A Warrants to purchase up to an aggregate of 25,666,669 shares of common stock and Series B Warrants to purchase up to an aggregate of 25,666,669 shares of common stock. The Series A Warrants and Series B Warrants are exercisable immediately. We allocated the net proceeds received of $3,307,773 to the shares of common stock, Series A Warrants and Series B Warrants sold in the offering based on their relative fair values. The fair value of the Series A Warrants and Series B Warrants was determined using Black-Scholes. Based on their relative fair values, we allocated net of proceeds of $1,593,233 to the shares of common stock, $1,075,995 to the Series A Warrants and $638,545 to the Series B Warrants.

In connection with this offering, we issued to H.C. Wainwright & Co. ("HCW"), the underwriter in the offering, a warrant to purchase up to 1,283,333 shares of common stock and HCW received total cash consideration, including the reimbursement of public offering-related expenses, of $443,000. If such warrant is exercised, each share of common stock may be purchased at $0.1875 per share (125% of the price of the common stock sold in the offering), commencing on March 21, 2017 and expiring March 21, 2022. The fair value of the warrants issued to HCW totaled $129,755 and was determined using Black-Scholes. The fair value of the warrants was recorded as an offering cost but has no net impact to additional paid-in capital in stockholders' equity in the accompanying consolidated balance sheet.

In connection with this offering, we incurred $99,227 in other offering costs that have been offset against the proceeds from this offering.

Other Stock Issuances and Related Stock-Based Compensation

On October 10, 2017, we entered into a service agreement with a third party pursuant to which we agreed to issue, over the term of the agreement, 2,000,000 shares of common stock in exchange for services to be rendered. We have terminated this agreement effective January 30, 2018. During the year ended December 31, 2017, we issued 333,332

shares of restricted common stock under the agreement related to services provided and recognized the fair value of the shares issued of $28,767 in general and administrative expense in the accompanying consolidated statement of operations. The shares of common stock vested on the date of issuance and the fair value of the shares of common stock was based on the market price of our common stock on the date of vesting. There were 1,666,668 shares of restricted common stock remaining to be issued under this service agreement as of December 31, 2017, of which we issued 166,666 prior to termination.

On September 1, 2016, we entered into a service agreement with a third party pursuant to which we agreed to issue, over the term of the agreement, 2,000,000 shares of common stock in exchange for services to be rendered. The agreement was extended on July 20, 2017 through December 31, 2017. In connection with the extension, we agreed to issue 1,200,000 shares of common stock in exchange for services to be rendered. We have terminated this agreement effective November 9, 2017. During the years ended December 31, 2017 and 2016, we issued 1,489,512 shares and 1,330,000 shares, respectively, under the agreement related to services provided and recognized the fair value of the shares issued of $206,276 and $332,970, respectively, in general and administrative expense in the accompanying consolidated statements of operations. The shares of common stock vested on the date of issuance and the fair value of the shares of common stock was based on the market price of our common stock on the date of vesting. There are no shares of common stock to be issued under this service agreement as of December 31, 2017.

Table of Contents

On August 23, 2016, we entered into a consulting agreement with a third party pursuant to which we agreed to issue 1,600,000 restricted shares of common stock, payable in four equal installments, in exchange for services to be rendered over the agreement which ended on August 23, 2017. The shares were considered fully-vested and non-refundable at the execution of the agreement. In 2016, we issued 800,000 shares of common stock and during the year ended December 31, 2017, we issued a total of 800,000 shares of common stock under the agreement. The fair value of the shares issued during 2017 of $360,000 was based on the market price of our common stock on the date of agreement. During the years ended December 31, 2017 and 2016, we recognized $465,000 and $255,000, respectively, in general and administrative expense in the accompanying consolidated statements of operations.

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

In July 2016, we issued 100,000 shares of common stock to CRI pursuant to the Amended CRI Asset Purchase Agreement (see Note 2). The fair value of the restricted shares of common stock of $23,000 was based on the market price of our common stock on the date of issuance and is included in research and development expense in the accompanying consolidated statement of operations during the year ended December 31, 2016. Additionally, in January 2017, we issued 225,000 shares of common stock to CRI pursuant to the Amended CRI Asset Purchase Agreement for the prepayment of future royalties due on net profit of Sensum+® in the U.S. in 2017. The fair value of the restricted shares of common stock of $44,662 was based on the market price of our common stock on the date of issuance and is included in prepaid expense and other current assets in the accompanying consolidated balance sheet at December 31, 2017.

On June 16, 2016, we entered into a consulting agreement with a third party pursuant to which we agreed to issue 250,000 restricted shares of common stock in exchange for services to be rendered. In July 2016, we issued 250,000 fully-vested shares under the agreement related to services to be provided over the term of the agreement which ended on December 16, 2016. The fair value of the shares issued of $47,500 was based on the market price of our common stock on the date of vesting. On December 16, 2016, we amended the consulting agreement to extend the term to June 16, 2017 and in connection with the amendment issued 80,000 fully-vested shares for services to be provided over the remaining term of the amended agreement. The fair value of the shares issued of $14,640 was based on the market price of our common stock on the date of vesting. On January 19, 2017, we further amended the agreement to expand the scope of service performed by the consultant and as a result issued an additional 78,947 shares of fully vested common stock for services to be provided through June 16, 2017. The fair value of the shares issued of $15,000 was based on the market price of our common stock on the date of vesting. During the years ended December 31, 2017 and 2016, we recognized $28,420 and $48,720, respectively, in general and administrative expense in the accompanying consolidated statements of operations.

In 2017 and 2016, we issued a total of 189,314 shares and 1,012,500 shares of common stock, respectively, for services and recorded an expense of $18,960 and $192,043 for the years ended December 31, 2017 and 2016, respectively, which is included in general and administrative expense in the accompanying consolidated statements of operations. The shares of common stock vested on the date of issuance and the fair value of the shares of common

stock was based on the market price of our common stock on the date of vesting.

In 2017 and 2016, we issued 2,825,000 shares and 2,361,111 shares of restricted common stock, respectively, to note holders in connection with their notes payable. The relative fair value of the shares of restricted common stock issued was determined to be $216,905 and $276,167, respectively, and was recorded as a debt discount during the years ended December 31, 2017 and 2016 (see Note 5).

In connection with the October and December 2017 Notes, we issued 576,373 restricted shares of common stock in October 2017 and 543,478 restricted shares of common stock in December 2017 to a third-party consultant. The fair value of the restricted shares of common stock issued of $48,761 in October 2017 and $50,000 in December 2017 was recorded as a debt discount to the carrying value of the notes payable during the year ended December 31, 2017 (see Note 5).

In 2017 and 2016, certain 2016 Notes holders elected to convert $350,610 and $1,749,070 in principal and interest into 1,402,440 shares and 6,996,280 shares of common stock, respectively (see Note 5). Upon conversion, the fair value of the embedded conversion feature derivative liability on the date of conversion was reclassified to additional paid-in capital (see Note 9).

In September and October 2017, certain 2016 and 2017 Notes Payable holders elected to exchange $742,771 in principal and interest for 11,432,747 shares of common stock (see Note 5). The fair value of the shares of common stock of $1,120,828 was based on the market price of our common stock on the date of issuance.

Table of Contents

In March 2017 and July 2017, we issued shares of common stock totaling 71,500 upon the exercise of stock options for total cash proceeds of $4,879.

In 2017 and 2016, we issued 92,000 shares and 19,315,994 shares of common stock, respectively, in exchange for vested restricted stock units.

2016 Issuances

In connection with the issuance of the 2016 Notes, we issued restricted shares of common stock totaling 7,500,000 to the Investors. The relative fair value of the restricted shares of common stock totaling $1,127,225 was recorded as a debt discount during the year ended December 31, 2016 (see Note 5).

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

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

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

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

During the year ended December 31, 2016, the Q3 2015 Notes holders elected to convert all principal and interest outstanding of $1,515,635 into 10,104,228 shares of common stock at a conversion price of $0.15 per share (see Note 8). As a result of the conversion of the outstanding principal and interest balance into shares of common stock, the fair value of the embedded conversion feature derivative liabilities of $2,018,565 on the date of conversion was reclassified to additional paid-in capital (see Note 9) and the remaining unamortized debt discount was amortized to interest expense during the year ended December 31, 2016.

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

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

based on the market price of our common stock on the date of vesting.

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

On February 19, 2016, we entered into a consulting agreement with a third party, pursuant to which we agreed to issue, over the term of the agreement, 1,750,000 shares of common stock in exchange for services to be rendered. During the year ended December 31, 2016, we issued 1,750,000 shares under the agreement related to services provided in connection with the acquisition of Beyond Human® (see Note 3) and recognized the fair value of the shares issued of $181,013 in general and administrative expense in the accompanying consolidated statement of operations. The 1,750,000 shares of common stock vested on the date of issuance and the fair value of the shares of common stock was based on the market price of our common stock on the date of vesting.

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

Table of Contents

2013 Equity Incentive Plan

We have issued common stock, restricted stock units and stock option awards to employees, non-executive directors and outside consultants under the 2013 Equity Incentive Plan ("2013 Plan"), which was approved by our Board of Directors in February of 2013. The 2013 Plan allows for the issuance of up to 10,000,000 shares of our common stock to be issued in the form of stock options, stock awards, stock unit awards, stock appreciation rights, performance shares and other share-based awards. The exercise price for all equity awards issued under the 2013 Plan is based on the fair market value of the common stock. Currently, because our common stock is quoted on the OTCQB, the fair market value of the common stock is equal to the last-sale price reported by the OTCQB as of the date of determination, or if there were no sales on such date, on the last date preceding such date on which a sale was reported. Generally, each vested stock unit entitles the recipient to receive one share of our common stock which is eligible for settlement at the earliest of their termination, a change in control of us or a specified date. Restricted stock units can vest according to a schedule or immediately upon award. Stock options generally vest over a three-year period, first year cliff vesting with quarterly vesting thereafter on the three-year awards, and have a ten-year life. Stock options outstanding are subject to time-based vesting as described above and thus are not performance-based. As of December 31, 2017, 89,516 shares were available under the 2013 Plan.

2014 Equity Incentive Plan

We have issued common stock, restricted stock units and stock options to employees, non-executive directors and outside consultants under the 2014 Equity Incentive Plan ("2014 Plan"), which was approved by our Board of Directors in November 2014. The 2014 Plan allows for the issuance of up to 20,000,000 shares of our common stock to be issued in the form of stock options, stock awards, stock unit awards, stock appreciation rights, performance shares and other share-based awards. The exercise price for all equity awards issued under the 2014 Plan is based on the fair market value of the common stock. Generally, each vested stock unit entitles the recipient to receive one share of our common stock which is eligible for settlement at the earliest of their termination, a change in control of us or a specified date. Restricted stock units can vest according to a schedule or immediately upon award. Stock options generally vest over a three-year period, first year cliff vesting with quarterly vesting thereafter on the three-year awards and have a ten-year life. Stock options outstanding are subject to time-based vesting as described above and thus are not performance-based. As of December 31, 2017, 49,367 shares were available under the 2014 Plan.

2016 Equity Incentive Plan

On March 21, 2016, our Board of Directors approved the adoption of the 2016 Equity Incentive Plan and on October 20, 2016 adopted the Amended and Restated 2016 Equity Incentive Plan ("2016 Plan"). The 2016 Plan was then approved by our stockholders in November 2016. The 2016 Plan allows for the issuance of up to 20,000,000 shares of our common stock to be issued in the form of stock options, stock awards, stock unit awards, stock appreciation rights, performance shares and other share-based awards. The 2016 Plan includes an evergreen provision in which the number of shares of common stock authorized for issuance and available for future grants under the 2016 Plan will be increased each January 1 after the effective date of the 2016 Plan by a number of shares of common stock equal to the lesser of: (a) 4% of the number of shares of common stock issued and outstanding on a fully-diluted basis as of the close of business on the immediately preceding December 31, or (b) a number of shares of common stock set by our Board of Directors. In March 2017, our Board of Directors approved an increase of 5,663,199 shares of common stock to the shares authorized under the 2016 Plan in accordance with the evergreen provision in the 2016 Plan. The exercise price for all equity awards issued under the 2016 Plan is based on the fair market value of the common stock. Generally, each vested stock unit entitles the recipient to receive one share of our common stock which is eligible for settlement at the earliest of their termination, a change in control of the us or a specified date. Restricted

stock units can vest according to a schedule or immediately upon award. Stock options generally vest over a three-year period, first year cliff vesting with quarterly vesting thereafter on the three-year awards and have a ten-year life. Stock options outstanding are subject to time-based vesting as described above and thus are not performance-based. As of December 31, 2017, 21,008,882 shares were available under the 2016 Plan.

Stock Options

For the years ended December 31, 2017 and 2016, the following weighted average assumptions were utilized for the calculation of the fair value of the stock options granted during the period using Black-Scholes:

	2017	2016
Expected life (in years)	9.1	10.0
Expected volatility	213.6%	227.2%
Average risk-free interest rate	2.30%	1.76%
Dividend yield	0%	0%
Grant date fair value	$0.15	$0.18

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

Table of Contents

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, 2015	196,000	$0.31	9.0	$-
Granted	91,500	$0.17	-	-
Exercised	-	-	-	-
Cancelled	(50,000)	$0.31	-	-
Forfeited	-	-	-	-
Outstanding at December 31, 2016	237,500	$0.22	8.6	14,293
Granted	46,000	0.15	-	-
Exercised	(71,500)	0.07	-	-
Cancelled	(124,000)	0.31	-	-
Forfeited	-	-	-	-
Outstanding at December 31, 2017	88,000	$0.17	9.0	$377
Vested and Expected to Vest at December 31, 2017	88,000	$0.17	9.0	$377
Vested and Expected to Vest at December 31, 2016	237,500	$0.22	8.6	$14,293

The aggregate intrinsic value is calculated as the difference between the exercise price of all outstanding stock options and the quoted price of our common stock at December 31, 2017 and 2016. During the years ended December 31, 2017 and 2016, the Company recognized stock-based compensation from stock options of $7,078 and $20,390, respectively. The intrinsic value of the stock options exercised during the year ended December 31, 2017 on the dates of exercise was $7,133.

Restricted Stock Units

The following table summarizes the restricted stock unit activity for the years ended December 31, 2017 and 2016:

	Restricted Stock Units
Outstanding at December 31, 2015	17,554,736
Granted	14,636,106
Exchanged	(19,315,994)
Outstanding at December 31, 2016	12,874,848
Granted	2,908,987
Exchanged	(92,000)

Cancelled	(2,500,000)
Outstanding at December 31, 2017	13,191,835
Vested at December 31, 2017	9,871,523
Vested at December 31, 2016	8,493,600

The vested restricted stock units at December 31, 2017 and 2016 have not settled and are not showing as issued and outstanding shares of ours but are considered outstanding for earnings per share calculations. Settlement of these vested restricted stock units will occur on the earliest of (i) the date of termination of service of the employee or consultant, (ii) change of control of us, or (iii) 10 years from date of issuance. Settlement of vested restricted stock units may be made in the form of (i) cash, (ii) shares, or (iii) any combination of both, as determined by the board of directors and is subject to certain criteria having been fulfilled by the recipient.

We calculate the fair value of the restricted stock units based upon the quoted market value of the common stock at the date of grant. The grant date fair value of restricted stock units issued during the years ended December 31, 2017 and 2016 was $515,500 and $1,499,268, respectively. For the years ended December 31, 2017 and 2016, we recognized $328,929 and $934,363, respectively, of stock-based compensation expense for the vested units. As of December 31, 2017, compensation expense related to unvested shares not yet recognized in the consolidated statement of operations was approximately $518,000 and will be recognized over a remaining weighted-average term of 1.9 years.

Table of Contents

Warrants

Outstanding Warrants

During the year ended December 31, 2014, we issued warrants in connection with notes payable (which were repaid in 2013). The remaining warrants of 135,816 have an exercise price of $0.10 and expire December 6, 2018. Warrants to purchase 245,157 shares of common stock were exercised under the cashless exercise provisions of the warrant agreement in July 2016, which resulted in the issuance of 191,908 shares of common stock. The intrinsic value of the warrants on the date of exercise was $86,359.

In January 2015, we issued 250,000 warrants with an exercise price of $0.30 per share to a former executive 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 convertible debentures issued in 2015, 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.

In connection with the Q3 2015 Notes, we issued warrants to purchase 1,808,333 shares of common stock with an exercise price of $0.30 per share and expire in 2020 to investors and placement agents. Warrants to purchase 1,033,800 shares of common stock were exercised during the year ended December 31, 2016. The intrinsic value of the warrants on the dates of exercise was $150,200. Warrants to purchase 774,533 shares of common stock remain outstanding as of December 31, 2017.

In connection with the 2016 Notes, we issued warrants to the Investors and placement agents with an exercise price of $0.40 per share and expire in 2021. Warrants to purchase 4,220,000 shares of common stock remain outstanding as of December 31, 2017.

In connection with the public equity offering in March 2017, we issued Series A Warrants to purchase 25,666,669 shares of common stock at $0.15 per share and Series B Warrants to purchase 25,666,669 shares of common stock at $0.15 per share. The Series A Warrants expire in 2022 and the Series B Warrants expire in 2018. We also issued warrants to purchase 1,283,333 shares of common stock to our placement agent with an exercise price of $0.1875 per share and expire in 2022.

For the year ended December 31, 2017, the following weighted average assumptions were utilized for the calculation of the fair value of the warrants issued during the period using Black-Scholes:

	2017
Expected life (in years)	3.1
Expected volatility	203.3%
Average risk-free interest rate	1.49%
Dividend yield	0%

At December 31, 2017, there are 58,583,725 fully vested warrants outstanding. The weighted average exercise price of outstanding warrants at December 31, 2017 is $0.17 per share, the weighted average remaining contractual term is 2.4 years and the aggregate intrinsic value of the outstanding warrants is $0.

2016 Activity

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

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

Table of Contents

Net Loss per Share

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

The weighted average shares of common stock outstanding used in the basic and diluted net loss per share calculation for the years ended December 31, 2017 and 2016 was 148,640,929 and 85,436,145, respectively.

The weighted average restricted stock units vested but issuance of the common stock is deferred until there is a change in control, a specified date in the agreement or the employee or director resigns used in the basic and diluted net loss per share calculation for the years ended December 31, 2017 and 2016 was 9,292,529 and 8,670,237, respectively.

The total weighted average shares outstanding used in the basic and diluted net loss per share calculation for the years ended December 31, 2017 and 2016 was 157,933,458 and 94,106,382, respectively.

The following table shows the anti-dilutive shares excluded from the calculation of basic and diluted net loss per common share as of December 31, 2017 and 2016:

	As of December 31,	
	2017	2016
Gross number of shares excluded:		
Restricted stock units – unvested	3,320,312	4,381,248
Stock options	88,000	237,500
Convertible debentures and accrued interest	-	6,414,132
Warrants	58,583,725	5,967,054
Total	61,992,037	16,999,934

The above table does not include the ANDA Consideration Shares related to the Novalere acquisition totaling 138,859 at December 31, 2017 and 2016 as they are considered contingently issuable (see Note 3).

Table of Contents

NOTE 9 – DERIVATIVE LIABILITIES

The warrants issued in connection with the January 2015 Non-Convertible Debenture to a former executive and the February 2014 Convertible Debenture are measured at fair value and classified as a liability because these warrants contain anti-dilution protection and therefore, cannot be considered indexed to our own stock which is a requirement for the scope exception as outlined under FASB ASC 815. The estimated fair value of the warrants was determined using the Probability Weighted Black-Scholes Model, resulting in a value of $226,297 at the date of issuance. The fair value will be affected by changes in inputs to that model including our stock price, expected stock price volatility, the contractual term and the risk-free interest rate. We will continue to classify the fair value of the warrants as a liability until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability, whichever comes first. The anti-dilution protection for the warrants survives for the life of the warrants which ends in January 2020. Certain of these warrants were exercised under the cashless exercise provisions of the warrant agreement in April 2016 and, as a result, the fair value of the warrant derivative liability on the date of exercise totaling $518,224 was reclassified to additional paid-in capital (see Note 8).

The derivative liabilities are a Level 3 fair value measure in the fair value hierarchy and the assumptions for the Probability Weighted Black-Scholes Option-Pricing Model for the years ended December 31, 2017 and 2016 are represented in the table below:

	2017	2016
Expected life (in years)	2.1 – 3.0	3.1 – 4.0
Expected volatility	167% – 187%	188% – 230%
Average risk-free interest rate	1.33% – 1.89%	0.86% – 1.47%
Dividend yield	0%	0%

We had determined the embedded conversion features of the Q3 2015 Notes and 2016 Notes (see Note 5) to be derivative liabilities because the terms of the embedded conversion features contained anti-dilution protection and therefore, could not be considered indexed to our own stock which was a requirement for the scope exception as outlined under FASB ASC 815. The embedded conversion features were to be measured at fair value and classified as a liability with subsequent changes in fair value recorded in earnings at the end of each reporting period. We had determined the fair value of the derivative liabilities using a Path-Dependent Monte Carlo Simulation Model. The fair value of the derivative liabilities using such model was affected by changes in inputs to that model and was based on the individual characteristics of the embedded conversion features on the valuation date as well as assumptions for volatility, remaining expected life, risk-free interest rate, credit spread, probability of default by us and acquisition of us. During the years ended December 31, 2017 and 2016, the Q3 2015 Notes and 2016 Notes were either converted into shares of common stock or repaid in full. The conversion of the Q3 2015 and 2016 Notes during the years ended December 31, 2017 and 2016 resulted in the fair value of the embedded conversion feature derivative liability on the dates of conversion of $203,630 and $3,111,828, respectively, to be reclassified to additional paid-in capital (see Note 8). Upon repayment of the remaining 2016 Notes in March 2017 (see Note 5), the fair value of the embedded conversion features on date of repayment of $238,101 was extinguished and included in loss on debt extinguishment in the accompanying consolidated statement of operations during the year ended December 31, 2017.

F-37

Table of Contents

The derivative liabilities are a Level 3 fair value measurement in the fair value hierarchy and a summary of quantitative information with respect to valuation methodology and significant unobservable inputs used for our embedded conversion feature derivative liabilities that are categorized within Level 3 of the fair value hierarchy during the years ended December 31, 2017 and 2016 is as follows:

	2017	2016
Stock price	$ 0.10 – 0.31	$ 0.05 – 0.50
Strike price	$ 0.25	$ 0.15 – 0.25
Expected life (in years)	0.4	0.3 – 1.1
Expected volatility	130% – 168%	121% – 274%
Average risk-free interest rate	0.78% – 0.87%	0.28% – 0.69%
Dividend yield	0%	0%

At December 31, 2017 and 2016, the estimated Level 3 fair values of the embedded conversion feature and warrant derivative liabilities measured on a recurring basis are as follows:

At December 31, 2017

	Fair value	Level 1	Level 2	Level 3	Total
Warrant derivative liabilities	$58,609	$-	$-	$58,609	$58,609

At December 31, 2016

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

The following table presents the activity for the Level 3 embedded conversion feature and warrant derivative liabilities measured at fair value on a recurring basis for the years ended December 31, 2017 and 2016:

Fair Value Measurements Using Level 3 Inputs

Warrant derivative liabilities:	
Beginning balance December 31, 2015	$432,793
Reclassification of fair value of warrant derivative liability to additional paid-in capital upon cashless exercise of warrants	(518,224)
Change in fair value	249,501
Ending balance December 31, 2016	164,070
Change in fair value	(105,461)
Ending balance December 31, 2017	$58,609
Embedded conversion feature derivative liabilities:	
Beginning balance December 31, 2015	$301,779
Initial fair value of embedded conversion feature derivative liabilities with the 2016 Notes	3,444,284
Reclassification of fair value of embedded conversion feature derivative liability to additional paid-in capital upon conversions of Q3 2015 Notes	(2,018,565)
Reclassification of fair value of embedded conversion feature derivative liability to additional paid-in capital upon conversions of 2016 Notes	(1,093,263)
Change in fair value	(314,561)
Ending balance December 31, 2016	319,674
Reclassification of fair value of embedded conversion feature derivative liability to additional paid-in capital upon conversions of 2016 Notes	(203,630)
Extinguishment of embedded conversion feature upon repayment of 2016 Notes	(238,101)
Change in fair value	122,057
Ending balance December 31, 2017	$-

Table of Contents

NOTE 10 – INCOME TAXES

We are subject to taxation in the United States and California, Colorado and South Carolina. The provision for income taxes for the years ended December 31, 2017 and 2016 are summarized below:

	2017	2016
Current:		
Federal	$-	$(800)
State	3,200	3,200
Total current	3,200	2,400
Deferred:		
Federal	1,055,730	(2,552,758)
State	(614,230)	(650,597)
Change in valuation allowance	(441,500)	3,203,355
Total deferred	-	-
Income tax provision	$3,200	$2,400

At December 31, 2017, we had federal net operating loss carry forwards of approximately $24,259,000 which may be offset against future taxable income through 2037, and a California net operating loss carryforward of approximately $23,419,000. No net deferred tax assets are recorded at December 31, 2017 and 2016, as all deferred tax assets and liabilities have been fully offset by a valuation allowance due to the uncertainty of future utilization.

On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act (the "Act"). The Act amends the Internal Revenue Code to reduce tax rates and modify policies, credits, and deductions for individuals and businesses. For businesses, the Act reduces the corporate tax rate from a maximum of 35% to a flat 21% rate. The rate reduction is effective on January 1, 2018. As a result of the rate reduction, we have reduced the deferred tax asset balance as of December 31, 2017 by $3.1 million. Due to our full valuation allowance position, there was no net impact on our income tax provision during the year ended December 31, 2017 as the reduction in the deferred tax asset balance was fully offset by a corresponding decrease in the valuation allowance.

In conjunction with the Act, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. We have recognized the provisional tax impacts related to the revaluation of deferred tax assets and liabilities at December 31, 2017. There was no net impact on our consolidated financial statements as of and for the year ended December 31, 2017 as the corresponding adjustment was made to the valuation allowance. The ultimate impact may differ from these provisional amounts, possibly materially, due to, among other things, additional analysis, changes in interpretations and assumptions we have made, additional regulatory guidance that may be issued, and actions we may take as a result of the Act.

Table of Contents

At December 31, 2017 and 2016, the approximate deferred tax assets (liabilities) consist of the following:

	2017	2016
Net operating loss carry-forwards	$6,730,000	$8,108,000
State taxes	1,000	1,000
Equity based instruments	324,000	374,000
Deferred compensation	813,000	916,000
Intangibles	-	-
Derivative liabilities	-	127,000
Other	191,000	125,000
Total deferred tax assets	8,059,000	9,651,000
Intangibles	(825,000)	(1,572,000)
Derivative liabilities	(5,000)	-
Warrants	(2,000)	(170,000)
Debt discount	(16,000)	(252,000)
Other	-	(4,000)
Total deferred tax liabilities	(848,000)	(1,998,000)
Less: valuation allowance	(7,211,000)	(7,653,000)
Net deferred tax assets	$-	$-

At December 31, 2017 and 2016, we have recorded a full valuation allowance against its net deferred tax assets of approximately $7,211,000 and $7,653,000 respectively. The change in the valuation allowance during the years ended December 31, 2017 and 2016 was a decrease of approximately $442,000 and an increase of approximately $3,203,000, respectively, and a full valuation allowance has been recorded since, in the judgment 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.

Table of Contents

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

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

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

A reconciliation of the statutory federal income tax rate for the years ended December 31, 2017 and 2016 to the effective tax rate is as follows:

	2017	2016
Expected federal tax	34.00%	34.00%
State tax (net of federal benefit)	(0.03)%	(0.02)%
Contingent consideration	0.86%	(3.15)%
Fair value of embedded conversion feature in excess of allocated debt proceeds	-%	(5.01)%
Loss on extinguishment of debt	(3.52)%	-%
Restricted stock units	(0.18)%	(7.34)%
Stock options	(0.21)%	-%
Change in federal tax rate	(45.59)%	-%
Release of valuation allowance	45.59%	-%
Other	(0.12)%	0.86%
Valuation allowance	(30.85)%	(19.36)%
Total	(0.05)%	(0.02)%

We follow FASB ASC 740-10, Uncertainty in Income Taxes. We recognize interest and penalties associated with uncertain tax positions as a component of income tax expense. We do not have any unrecognized tax benefits or a liability for uncertain tax positions at December 31, 2017 and 2016. We do not expect to have any unrecognized tax benefits within the next twelve months. We recognize accrued interest and penalties associated with uncertain tax positions, if any, as part of income tax expense. There were no tax related interest and penalties recorded for 2017 and 2016. Since we incurred net operating losses in every tax year since inception, all of its income tax returns are subject to examination and adjustments by the IRS for at least three years following the year in which the tax attributes are utilized.

NOTE 11 – COMMITMENTS AND CONTINGENCIES

Royalties and Other Obligations

As described more fully in Note 2, we have several licensing agreements which could result in substantial payments for royalties and upon the obtainment of contractual milestones, as well as, certain minimum purchase order requirements. In October 2017, the royalty obligation due for net product sales of Vesele® ended as the royalty term was for three years from October 2014. The outstanding royalty obligation under such arrangement is $132,316 and $73,675 as of December 31, 2017 and 2016 and is included in accounts payable and accrued expense in the accompanying consolidated balance sheets.

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

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

In May 2017, we entered into a commercial agreement with West-Ward Pharmaceuticals International Limited ("WWPIL"), a wholly-owned subsidiary of Hikma Pharmaceuticals PLC ("Hikma") (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY). Pursuant to the commercial agreement, WWPIL provided us with the rights to launch our branded, fluticasone propionate nasal spray USP, 50 mcg per spray (FlutiCare®), under WWPIL's FDA approved ANDA No. 207957 in the U.S. in mid-November 2017. The initial term of the commercial agreement is for two years, and upon expiration of the initial term, the agreement will automatically renew for subsequent one-year terms unless either party notifies the other party in writing of its desire not to renew at least 90 days prior to the end of the then current term. The agreement requires us to meet certain minimum product batch purchase requirements in order for the agreement to continue to be in effect. We have met the minimum product batch purchase requirements through May 2018.

Table of Contents

Operating Lease

In December 2013, we entered into a lease agreement for 2,578 square feet of office space in San Diego, CA that commenced on December 10, 2013 and continued until January 31, 2019. Monthly rent was in the amount of $7,347, with an approximate 4% increase in the base rent amount on an annual basis. In August 2017, we entered into a lease termination agreement with the landlord in which we were released from any future commitments under the lease, were not subject to any penalties and were to vacate the office space by November 1, 2017. In connection with the termination agreement, we received reimbursement of our lease deposit of $14,958, as well as, a moving expense reimbursement of $22,000 which was recorded as a reduction in general and administrative expense during the year ended December 31, 2017.

In October 2017, we entered into a commercial lease agreement for 16,705 square feet of office and warehouse space in San Diego, CA that commenced on December 1, 2017 and continues until April 30, 2023. The initial monthly base rent is $20,881 with an approximate 3% increase in the base rent amount on an annual basis, as well as, rent abatement for rent due from January 2018 through May 2018. We hold an option to extend the lease an additional 5 years at the end of the initial term. Under the terms of the lease we are also entitled to a tenant improvement allowance of $100,000 in which completion of the tenant improvements and receipt of the allowance was in 2018.

Rent expense for the years ended December 31, 2017 and 2016 was $77,983 and $88,513, respectively. The following represents future annual minimum lease payments as of December 31, 2017:

2018	$146,794
2019	258,741
2020	266,501
2021	274,500
2022	282,024
Thereafter	94,008
Total	$1,322,568

Employment Agreements

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

Litigation

James L. Yeager, Ph.D., and Midwest Research Laboratories, LLC v. Innovus Pharmaceuticals, Inc. On January 18, 2018, Dr. Yeager and Midwest Research Laboratories (the “Plaintiffs”) filed a complaint in the Illinois Northern District Court in Chicago, Illinois, which Plaintiffs amended on February 26, 2018 (“Amended Complaint”). The Amended Complaint alleges that the Company violated Dr. Yeager’s right of publicity and made unauthorized use of his name, likeness and identity in advertising materials for its product Sensum+®. Plaintiffs seek actual and punitive damages, costs and attorney’s fees, an injunction and corrective advertising. We intend to file a response to the Amended Complaint by May 21, 2018. We believe that the Plaintiffs’ allegations and claims are wholly without merit, and we intend to defend the case vigorously and assert counterclaims against the Plaintiffs. More specifically, we believe that we secured and paid for all of the rights claimed by Dr. Yeager from his company Centric Research Institute (“CRI”) pursuant to agreements with CRI (the “CRI Agreements”) and that CRI has indemnification obligations under the CRI

Agreements for all expenses and losses associated with the claims made by the Plaintiffs.

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

Indemnities

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

Table of Contents

NOTE 12 – SUBSEQUENT EVENTS

On January 5, 2018, we entered into an exclusive ten-year license agreement with Acerus Pharmaceuticals Corporation, a Canadian company ("Acerus"), under which we granted to Acerus an exclusive license to market and sell UriVarx® in Canada. Under the agreement, we received a non-refundable upfront payment, we will be eligible to receive up to CAD$1.65 million (USD$1.31 million at December 31, 2017) in milestone payments based on Acerus achieving certain sales targets and we will sell UriVarx® to Acerus at an agreed-upon transfer price. Acerus also has minimum annual purchase requirements for UriVarx® during the term of the agreement.

On January 18, 2018, we entered into an exclusive ten-year license agreement with Lavasta Pharma FZ-LLC, a Dubai company ("Lavasta"), under which we granted to Lavasta an exclusive license to market and sell Zestra® and Zestra Glide® in Iran and ProstaGorx® in the Kingdom of Saudi Arabia, Algeria, Egypt, the United Arab Emirates, Lebanon, Jordan, Kuwait, Morocco, Tunisia, Bahrain, Oman, Qatar, and Turkey, among other countries. If any country in the territory under this agreement is ever listed on the U.S. Department of Treasury's restricted OFAC List or other list of countries that a U.S. OTC pharma company cannot do business with, then such country shall be removed from the list of countries included in the territory in this agreement for such applicable restricted period. Under the agreement, we received a non-refundable upfront payment and we will sell products to Lavasta at an agreed-upon transfer price. Lavasta also has minimum annual purchase requirements for the products during the term of the agreement.

In the first quarter of 2018, eleven of our warrant holders exercised their Series B Warrants to purchase shares of common stock totaling 18,925,002 at an exercise price of $0.15 per share. We received net cash proceeds of approximately $2.7 million. The remaining Series B Warrants totaling 6,741,667 expired on March 21, 2018. Per the terms of the engagement letter with HCW in connection with the public offering in March 2017 and as a result of the Series B Warrant exercises, we paid HCW approximately $181,000 and issued a warrant to purchase 862,917 shares of common stock at an exercise price of $0.1875 per share (125% of the price of the common stock sold in the public offering in March 2017) which expires on March 21, 2023.

In January 2018, we issued 256,486 shares of common stock to consultants for services rendered. The fair value of the common stock issued was approximately $21,000.

On March 1, 2018, we entered into a securities exchange agreement with certain of the October and December 2017 Notes Payable holders. In connection with the securities exchange agreement, we issued a total of 2,250,000 shares of common stock in exchange for the settlement of principal due under the October and December 2017 Notes Payable totaling $166,667. The fair value of the shares of common stock issued was based on the market price of our common stock on the date of the securities exchange agreements. Due to the settlement of the principal balance of $166,667 into shares of common stock, the transaction was recorded as a debt extinguishment and the fair value of the shares of common stock issued in excess of the settled principal and interest balance totaling approximately $218,000 was recorded as a loss on debt extinguishment.

In the first quarter of 2018, we entered into a securities purchase agreement with three unrelated third-party investors in which the investors loaned us gross proceeds of $1,227,500. The promissory notes have an OID of $269,375 and bear interest at the rate of 0% per annum. The principal amount of $1,496,875 is to be repaid in twelve equal monthly installments. Monthly installments of $68,490 began in February 2018 and are due through January 2019 and monthly installments of $56,250 begin in April 2018 and are due through March 2019. In connection with the promissory notes, we issued 1,282,000 restricted shares of common stock to the investors. The allocation of the proceeds received to the restricted shares of common stock based on their relative fair value and the OID resulted in us recording a debt

discount of approximately $409,000. In connection with this financing in the first quarter of 2018, we issued 936,054 restricted shares of common stock to a third-party consultant. The fair value of the restricted shares of common stock issued of $122,500 was recorded as a debt discount to the carrying value of the notes payable. The discount is being amortized to interest expense using the effective interest method over the term of the promissory notes.

In February and March 2018, we entered into securities purchase agreements with two unrelated third-party investors in which the investors loaned us gross proceeds of $650,000 pursuant to 5% promissory notes. The notes have an OID of $70,000 and requires payment of $720,000 in principal. The notes bear interest at the rate of 5% per annum and the principal amount and interest are payable at maturity on October 28, 2018 for the note issued in February and in three installments on October 1, 2018, January 1, 2019 and April 1, 2019 for the note issued in March. In connection with the notes, we issued the investors restricted shares of common stock totaling 1,485,000. The fair value of the restricted shares of common stock issued was based on the market price of our common stock on the date of issuance of the note. The allocation of the proceeds received to the restricted shares of common stock based on their relative fair value and the OID resulted in us recording a debt discount of approximately $222,000. The discount is being amortized to interest expense using the effective interest method over the term of note.

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