INNOVUS PHARMACEUTICALS, INC.
Form 10-K
April 01, 2019

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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, 2018

Commission file number: 000-52991

INNOVUS PHARMACEUTICALS, INC.

(Name of registrant as specified in its charter)

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

Registrant's telephone number: 858-964-5123

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

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

Common Stock $0.001 par value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes 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 every Interactive Data File required to be submitted 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 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:

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, 2018, 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 $16.3 million, based on the closing price of $11.55 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 April 1, 2019, the registrant had 2,355,737 shares of common stock outstanding.

Documents Incorporated by Reference

The registrant incorporates information required by Part III (Items 10, 11, 12, 13, and 14) of this report by reference to portions of the registrant’s definitive proxy statement with respect to its 2019 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year ended December 31, 2018, pursuant to Regulation 14A.

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PART I

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

"Zestra®," "Zestra Glide®," "EjectDelay®," "Sensum+®," "Vesele®," "Beyond Human®," "Androferti®," "RecalMax™," "
"FlutiCare®," "Xyralid®," "AllerVarx®," "Apeaz®," "ArthriVarx®," "Diabasens®," "Musclin®," "Regenerum™" and other
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.

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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 medical devices to improve men's and women's health and vitality. Our products currently focus in six main categories, including sexual health, pain management, general muscle health, respiratory, sleep, and diabetic care. We deliver innovative and unique health solutions of OTC medicines, devices, consumer and health products, and clinical supplements through four general channels including Direct to Consumer Marketing, E-Commerce, Retail/Wholesale, and International Distribution. Collectively these channels make up our proprietary Beyond Human® Sales & Marketing Platform which was acquired in 2016 and significantly expanded through the development of proprietary algorithms to target consumers and improve efficiency and return in 2018. We are dedicated to being a leader in developing and marketing new OTC and branded Abbreviated New Drug Application ("ANDA") products, supplements and medical 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, Walmart.com®, and Walgreens.com on-line stores and our own product websites and platforms among other e-commerce business platforms) channels to tap new markets and drive demand for such products and to establish physician relationships.

Corporate Structure

We are incorporated in the State of Nevada and have five wholly-owned subsidiaries including Novalere, Inc., Semprae Laboratories, Inc., FasTrak Pharmaceuticals, Inc., Supplement Hunt, Inc., and Prime Savings Club, Inc.

Our Strategy

Our corporate strategy focuses on three 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;

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 and Supplement Hunt™ platform, the addition of new online platforms such as Amazon®, eBay®, Wish.com, Walmart.com® and Walgreens.com, through our own websites both nationally and internationally and commercial partnerships with established international complementary partners that: (a) generates revenue, and (b) requires a lower cost structure compared to traditional pharmaceutical companies, thereby increasing our gross margins; and

3. Developing and acquiring the assets of on-line marketplaces such as Supplementhunt.com and Primesavingsclub.com that focus on certain market segments such as lower priced, soon to expire supplement business with the Supplementhunt.com asset acquisition and with the select consumer product business through Primesavingsclub.com among others in which we sell third party, brand or non-branded products.

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We believe that our proven ability to market, license, acquire and develop brand name non-prescription pharmaceutical and consumer health products and devices and sell third party products on our platforms uniquely positions us to commercialize our products, expand our platforms 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, respiratory and other diseases and conditions. 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 and expand 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 Trôphikôs, 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, (10) Musclin® from the University of Iowa, and (11) HealthiFeet®, ThermoMax® and BreastLift™ from Boston Topicals;

Increasing the number of U.S. non-exclusive distribution channel partners for print media, direct mailing and online sales. One of our goals is to increase the number of our own and third-party U.S. distribution channel partners that sell our products and make them more efficient and profitable through our proprietary consumer targeting algorithms. To do this, we have devised a three-pronged approach. First, we have developed a proprietary consumer targeting algorithm that allows us 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, Walmart.com® and Walgreens.com, among other stores, in addition to our own product websites;

Developing or acquiring products or developing or acquiring proprietary product ingredients that may prove to be more profitable in the long run for the Company. We are currently exploring the acquisition and development of proprietary product ingredients that we can use to develop our own products through our various channels and to sell product ingredients to third parties that they can use to develop their own products;

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 developed 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 introduce 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 currently have 12 active commercial partnerships covering our products in 45 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 arthritis 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 4 issued U.S. patents, 12 U.S. patent applications, 12 foreign patents, and 10 foreign patent applications. We also currently have 33 U.S. trademark registrations, 38 U.S. trademark applications, 50 foreign trademark registrations and 47 foreign trademark applications;

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; and

Building or acquiring additional on-line marketplaces for our and third party products. We believe that we can achieve higher profit margins from building our own or purchasing niche on-line marketplaces that can achieve relatively high gross margins and be profitable over the long run.

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Our Products

Marketed Products

We currently market and sell over 35 products in the U.S. and more than 10 in multiple countries around the world through our 12 international commercial partners. We currently have seven core products which we define as recognizing more than $1.0 million in annual sales or projected to recognize more than $1.0 million in sales over the next twelve months. The following represents these core products:

1. Vesele®;
2. UriVarx®;
3. FlutiCare®;
4. Apeaz®;
5. Diabasens®;
6. Prostagorx®; and
7. Sensum®.

In addition, we currently expect to launch the following products in the U.S. in 2019, subject to the applicable regulatory approvals, if required:

1. ThermoMax® is a hand cream with two strengths that provides up to eight hours of hand warming relief (second quarter of 2019);
2. BreastLift™ is a clinically tested cream to provide safe and natural way to firm sagging breasts (second quarter of 2019);
3. HealthiFeet® is a foot cream that provides foot warming relief (second quarter of 2019);
4. MZS Sleeping Aid™ with Hemp-Derived THC-free oil and melatonin and is in tincture form (launched in first quarter of 2019);
5. Trexar™ is a supplement to provide enhanced sensation (second quarter of 2019);
6. Musclin® is a proprietary supplement made of two FDA Generally Recognized As Safe (GRAS) approved ingredients designed to increase muscle mass, endurance and activity (second half of 2019). 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;
7. Regenerum™ is a proprietary product containing two natural molecules; the first 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 2020 pending successful clinical trials in patients with muscle wasting or cachexia; and
8. Octiq™ is an expected FDA ophthalmic OTC monograph compliant product for the treatment of eye redness and eye lubrication (late 2019/early 2020).

In addition to the above product pipeline, we currently intend to license and acquire other products that we may launch in 2019.

Sales and Marketing Channels

As discussed, we currently have four main sales and marketing channels making up the Beyond Human® sales and marketing platform acquired in March 2016, which has resulted in the significant revenue growth to $24.0 million in the year ended December 31, 2018 compared with $8.8 million in the year ended December 31, 2017. We feel that these channels complement each other to enhance the Innovus Pharmaceuticals, Inc. brand and awareness of our customers and provide us with the ability to use our sales and marketing in the most efficient way possible in acquiring new customers and maintaining those current customers for longer periods of time.

Print and Direct Mail Marketing

Through our Beyond Human® sales and marketing platform, we have access to advertise in the vast majority of newspapers and magazines on a regular basis. We have developed our own proprietary algorithms that allow us to target customers looking for specific health products allowing us to increase the return on our investment and reduce the cost to acquire new customers. During 2018, we have been able to expand our reach to Canada with the approval of twelve of our products by Health Canada and successfully expand our Beyond Human® sales and marketing platform.

E-Commerce

We have an extensive number of on-line channels through our Amazon®, NewEgg®, Walmart.com®, eBay®, Wish.com and Walgreens.com sites in addition to our own InnovusPharma.com site along with sites for each of our products individually. Our expertise allows us to successfully drive product sales through proper marketing campaigns through third party sites as well as through email marketing campaigns to increase traffic to our own sites. Additionally, we have recognized that maintaining a proper e-commerce presence allows those customers who read our advertisements in the newspapers and magazine or receive our direct mail another avenue to purchase products. We also have acquired additional on-line marketplaces such as Supplementhunt.com and Primesavingsclub.com that allow us to expand the number of products that we sell through our e-commerce channels.

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Retail/Wholesale

We are continuously introducing our products to varieties of retail and wholesale partners to enhance the brand and product awareness for our customers. In 2018, we significantly increased our advertising expenses specifically in the Print and Direct Mail Marketing channel which, in turn, has had a direct positive impact to the success of products in retail. We intend to continue to demonstrate to our retail and wholesale partners the advantages of incorporating our products in their stores especially due to our proprietary consumer targeted marketing approach that our print advertising and e-commerce business allows us to achieve.

International Distribution

We continue to work with our exclusive commercial partners outside of the U.S. that would be responsible for sales and marketing in those territories. We evaluate the performance of each of these partners to ensure a steady flow of consumer activity for each of our products. 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.

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. 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, 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 and advertisement requirements. Unlike pharmaceutical companies who primarily sell prescription products, we currently sell drug or health products into the OTC market. While prescription products normally must

progress from pre-clinical to clinical to FDA approval and then can be marketed and sold, our products are normally subject to conformity to FDA monograph requirements and similar requirements in other countries, which requires a shorter time frame for us to satisfy regulatory requirements and permits us to begin commercialization.

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

U.S. Food and Drug Administration

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

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

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

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

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

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

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

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

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

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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.

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.

Bioequivalence 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 provides 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.

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Federal Trade Commission/State and County Attorney Generals

With respect to FTC matters, if the FTC has reason to believe the law is being violated (e.g. failure to possess adequate substantiation for product claims), it can initiate an enforcement action. The FTC has a variety of processes and remedies available to it for enforcement, both administratively and judicially, including compulsory process authority, cease and desist orders, and injunctions. FTC enforcement could result in orders requiring, among other things, limits on advertising, consumer redress, divestiture of assets, rescission of contracts, or such other relief as may be deemed necessary. Violation of these orders could result in substantial financial or other penalties. Any action against us by the FTC could materially and adversely affect our ability to successfully market our products.

In addition, we may be subject, from time to time, to state and county attorneys general regulations, administrative actions and enforcement proceedings that attempt to protect the public in their states and jurisdictions from untrue claims by various supplement or other products.

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.

Research and Development

We have used outside contract research organizations to carry out our research and development activities. During the years ended December 31, 2018 and 2017, we incurred research and development costs totaling $160,000 and $39,000, respectively. The increase was a result in additional research of new products, quality testing of products, and additional clinical trials expense incurred in 2018 primarily related to Musclin®.

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Employees

We currently have 27 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 4 patents in the U.S. and 12 patents registered outside the U.S. We currently have 12 patent applications pending in the U.S. and 10 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 33 trademark registrations in the U.S. and have 38 trademark applications pending in the U.S. We also own 50 trademarks registered outside of the U.S., with 47 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 investing in 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 Annual 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, 2018, we had an accumulated deficit of approximately $43.9 million. In addition, we incurred net losses of approximately $8.3 million and $6.5 million for the years ended December 31, 2018 and 2017, respectively. These losses may continue in the future. We expect to continue to incur significant sales and marketing, research and development, and general and administrative expense. As a result, we will need to generate significant revenue to achieve profitability, and we may never achieve profitability. Revenue and profit, if any, will depend upon various factors, including (1) growing the current sales of our products, (2) the successful acquisition of additional commercial products, (3) raising capital to implement our growth strategy, (4) obtaining any applicable regulatory approvals of our proposed product candidates, (5) the successful licensing and commercialization of our proposed product candidates, and (6) growth and development of our operations. We may not achieve our business objectives and the failure to achieve such goals would have an adverse impact on us.

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

We have not been profitable since inception. As of December 31, 2018, we had approximately $1.2 million in cash. We had a net loss of approximately $8.3 million and $6.5 million for the years ended December 31, 2018 and 2017, 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, 2020, 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 or preferred 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 or preferred stock may result in a decrease in value of your investment. If we do issue any such additional shares of common stock or preferred stock with voting rights, 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.

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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.

Our internal control over financial reporting may not be effective, which could have a significant and adverse effect on our business.

Section 404 of the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, which we collectively refer to as Section 404, require us to evaluate our internal control over financial reporting and require management to report on the effectiveness of this internal control as of the end of each fiscal year. In addition, if and when we are no longer a "small reporting company" under applicable SEC rules, Section 404 will require us to obtain an attestation report from our independent registered public accounting firm as to our internal control over financial reporting.

Effective internal control is necessary for us to produce accurate and reliable financial reports and is important in our efforts to prevent financial fraud. In the course of our Section 404 evaluations, we or our independent registered public accounting firm may identify significant deficiencies or material weaknesses in our internal control over financial reporting. If we fail to maintain an effective system of internal control over financial reporting or if management or our independent registered public accounting firm discover significant deficiencies or material weaknesses, we may be unable to produce accurate and reliable financial report or prevent fraud, which could result in a loss of customer or inventor confidence in us or our public disclosures and negatively impact our stock price. Any of these outcomes could harm our financial condition and results of operations.

Further, our Section 404 evaluations may lead us to conclude that enhancements, modifications or changes to our internal control over financial reporting are necessary or desirable. Implementing any such changes would divert the attention of management, involve significant time and costs and negatively impact our financial reporting functions during the transition, any of which could have a material negative effect on our results of operations and financial condition.

Risks Associated with Our Business Model

We 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.

While we have been in existence for a number of years, we only generated approximately $736,000 in net revenue in 2015, approximately $4.8 million in 2016 and approximately $8.8 million and $24.0 million in net revenue for the years ended December 31, 2017 and 2018, respectively, and our operations have not yet been profitable. No assurances can be given that we will generate any significant revenue in the future. 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. Investors must consider our business and prospects in light of the risks and difficulties we will encounter as an early-stage company. We may not be able to successfully address these risks and difficulties, which could significantly harm our business, operating results and financial condition.

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

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

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

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

Changes in government regulation or in practices relating to the pharmaceutical industry could change the need for the products we provide.

Governmental and regulatory agencies throughout the world, but particularly in the United States, strictly regulate the drug development and sales process. Changes in regulation, such as regulatory submissions to meet the internal research and development standards of pharmaceutical research, a relaxation in existing regulatory requirements, the introduction of simplified drug approval procedures or an increase in regulatory requirements that we may have difficulty satisfying or that make our products less competitive, could substantially change the demand for our products and the prices at which we are able to sell our products.

Possible yet unanticipated changes in federal and state law could cause any products we intend to launch containing hemp-derived oil to be illegal, or could otherwise prohibit, limit or restrict any potential products we may launch containing hemp-derived oil.

We currently intend to launch certain products containing hemp-derived oil. Until 2014 when 7 U.S. Code §5940 became federal law as part of the Agricultural Act of 2014 (the "2014 Farm Act"), products containing oils derived from hemp, notwithstanding a minimal or non-existing THC content, were classified as Schedule I illegal drugs. The 2014 Farm Act expired on September 30, 2018, and was thereafter replaced by the Agricultural Improvement Act of 2018 on December 20, 2018 (the "2018 Farm Act"), which amended various sections of the U.S. Code, thereby removing hemp, defined as cannabis with less than 0.3% THC, from Schedule 1 status under the Controlled Substances Act, and legalizing the cultivation and sale of industrial-hemp at the federal level, subject to compliance with certain federal requirements and state law, amongst other things. THC is the psychoactive component of plants in the cannabis family generally identified as marihuana or marijuana. There is no assurance that the 2018 Farm Act will not be repealed or amended such that our intended products containing hemp-derived oil would once again be deemed illegal under federal law. The 2018 Farm Act delegates the authority to the states to regulate and limit the production of hemp and hemp derived products within their territories. Although a majority of states have adopted laws and regulations that allow for the production and sale of hemp and hemp derived products under certain circumstances, no assurance can be given that such state laws may not be repealed or amended such that our intended products containing

hemp-derived oil would once again be deemed illegal under the laws of one or more states now permitting such products, which in turn would render such intended products illegal in those states under federal law even if the federal law is unchanged. In the event of either repeal of federal or of state laws and regulations, or of amendments thereto that are adverse to our intended products, we may be restricted or limited with respect to those products that we may sell or distribute, which could adversely impact on our intended business plan with respect to such intended products.

Sources of oil from hemp plants depend upon legality of cultivation, processing, marketing and sales of products derived from those plants under state law.

Oils derived from hemp plants can only be legally produced in states that have laws and regulations that allow for such production and that comply with the 2018 Farm Act, apart from state laws legalizing and regulating medical and recreational cannabis or marijuana, which remains illegal under federal law and regulations. We intend to purchase all of our hemp-derived oils from licensed growers and processors in states where such production is legal. As described in the preceding risk factor, in the event of repeal or amendment of laws and regulations which are now favorable to the cannabis/hemp industry in such states, we would be required to locate new suppliers in states with laws and regulations that qualify under the 2018 Farm Act. If we were to be unsuccessful in arranging new sources of supply of our raw ingredients, or if our raw ingredients were to become legally unavailable, our intended business plan with respect to such intended products could be adversely impacted.

Because we may only sell and ship our intended products containing hemp-derived oil in states that have adopted laws and regulations qualifying under the 2018 Farm Act, a reduction in the number of states having such qualifying laws and regulations could limit, restrict or otherwise preclude the sale of intended products containing hemp-derived oil.

The interstate shipment of hemp-derived oils from one state to another is legal only where both states have laws and regulations that allow for the production and sale of such products and that qualify under the 2018 Farm Act. Therefore, the marketing and sale of our intended products containing hemp-derived oil will limited by such factor and is restricted to such states. Although we believe we may lawfully sell any finished products we intend to launch in a majority of states, a repeal or adverse amendment of laws and regulations that are now favorable to the distribution, marketing and sale of finished products we intend to sell could significantly limit, restrict or prevent us from generating revenue related to such intended products. Any such repeal or adverse amendment of now favorable laws and regulations could have an adverse impact on our intended business plan with respect to such intended products.

In the event we offer products containing hemp-derived oil through a website available in all states, we may be found to violate the laws of states in which all or certain uses of any cannabis containing products are illegal, which could have an adverse impact on our reputation and ability to offer to sell our intended products containing hemp-derived oil.

We currently offer our products for sale through our website. In the event that we choose to sell products containing hemp-derived oil through our website, the mere visibility of such a website in states where the sale of intended products containing hemp-derived oil is illegal could result in a finding that we have violated the criminal laws of one or more of such states. Any criminal investigation, prosecution and conviction could significantly harm our business, operating results and financial condition.

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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 functions are 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 $8.8 million in net revenue in 2017, and approximately $24.0 million during the year ended December 31, 2018. 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.

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 marketing and advertising are regulated by the Federal Trade Commission and State and County Attorneys General

With respect to Federal Trade Commission (“FTC”) matters, if the FTC has reason to believe the law is being violated (e.g. failure to possess adequate substantiation for product claims), it can initiate an enforcement action. The FTC has a variety of processes and remedies available to it for enforcement, both administratively and judicially, including compulsory process authority, cease and desist orders, and injunctions. FTC enforcement could result in orders requiring, among other things, limits on advertising, consumer redress, divestiture of assets, rescission of contracts, or such other relief as may be deemed necessary. Violation of these orders could result in substantial financial or other penalties. Any action against us by the FTC could materially and adversely affect our ability to successfully market our products.

In addition, our marketing and advertising is regulated by regulations, administrative actions and legal proceeding of various State and County Attorneys General across the United States. Any regulation, administrative actions or legal proceeding against us by any of these entities could materially and adversely affect our ability to successfully market our products.

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.

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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.

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 issuance 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.

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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.

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.

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

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

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

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

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

Also, a third party may assert that our patents are invalid and/or unenforceable. There are no unresolved communications, allegations, complaints or threats of litigation related to the possibility that our patents are invalid or unenforceable. Any litigation or claims against us, whether 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 more than 35 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 from certain regulatory agencies such as the Federal Trade Commission, Attorney General, Better Business Bureau, among others 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, 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.

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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.

Risks Related to Ownership of our Common Stock

There is currently limited public trading market for our common stock and we cannot assure you that an active trading market will develop in the near future.

Our common stock is currently quoted under the symbol “INNV” in the over-the-counter markets, including the OTCQB tier of the OTC Markets Group, Inc. Although we have submitted an application to have our shares traded on the Nasdaq Capital Market, it is currently not listed on a national exchange, there is currently very limited trading in our securities, and no assurances can be given that our shares will ever by traded on the Nasdaq Capital market or any other national exchange. There may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer that has a large and steady volume of trading activity that will generally support continuous sales. We cannot give you any assurance that an active public trading market for our common stock will develop or be sustained. You may not be able to liquidate your shares quickly or at the market price if trading in our common stock is not active.

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

As of December 31, 2018, we had 2,101,284 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;
- Changes in state and federal laws and regulations with respect to the sale and production of hemp-derived oils;
- 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.

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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 Charter 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 provides 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 Charter gives our Board of Directors the right to create new series of preferred stock. As a result, our 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.

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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.

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Item 1B. Unresolved Staff Comments.

There are no unresolved staff comments at December 31, 2018.

Item 2. Properties.

In October 2017, we entered into a commercial lease agreement for 16,705 square feet of office and warehouse space located in San Diego, California that commenced on December 1, 2017 and continues until April 30, 2023. The initial monthly base rent is $21,000 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.

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 filed a response to the Amended Complaint and we and the Plaintiffs began limited discovery. We have a scheduled mediation in this litigation scheduled for April 2019. 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.

On January 23, 2019 we filed a complaint in the U.S. Federal District Court for the Southern District located in San Diego, California against Dr. Yeager, Servet Buyuktimken and Nadir Buyuktimkin (the "021 Patent Claimed Inventors"), who are all the inventors names on the US issued patent number 9,821,021 entitled Sensitization

Composition and Methods of Action (the "021 Patent"), for copyright infringement relating to a clinical study table (the "Innovus Pharm Clinical Study Table") included in the 021 Patent. We claim that the 021 Patent Claimed Inventors illegally stole and used the Innovus Pharm Clinical Study Table and the suit requests certain damages and injunctive relief described therein.

Marin County District Attorney's Letter. On August 24, 2018, the Company received a letter from the Marin County District Attorney's Office requesting substantiation for certain advertising claims made for certain of the Company's products, DiabaSens® and Apeaz® that were marketed and sold to customers in that County. The Marin County District Attorney's Office is part of a larger ten county Northern California Task Force of district attorneys to handle consumer protection matters. In November 2018, the Company responded through its regulatory attorneys, Olshan, to the Marin County's District Attorney's letter. In March 2019, the Company received a response from the Marin County District Attorney and is preparing its response thereto.

From time to time, in addition to the matters 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.

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PART II

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

Market Information

Our common stock is available for quotation on the OTCQB 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.

On March 15, 2019, the Company's Board of Directors approved to amend and restate the Company's Charter to affect a one-for-105 reverse stock split of its issued and outstanding shares of common stock, but not the number of shares of common stock authorized for issuance under our Charter nor the par value of common stock and preferred stock (the "Reverse Split"). The Annual Report, financial statements and accompanying footnotes have been retroactively restated to reflect the reverse stock split.

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.

	2018		**2017**	
	High	**Low**	**High**	**Low**
First Quarter	$22.05	$8.40	$40.95	$10.50
Second Quarter	$17.33	$10.82	$15.75	$8.61
Third Quarter	$19.43	$9.77	$14.60	$9.14
Fourth Quarter	$13.13	$5.78	$12.29	$8.19

As of April 1, 2019, we had 557 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.

Equity Compensation Plan Information

The following table provides information as of December 31, 2018 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	93,082	$ 14.513	(1) 139,911
Equity Compensation Plans Not Approved by Security Holders:			
2013 Equity Incentive Plan	9,904	$ 16.452	(1) -
2014 Equity Incentive Plan	77,277	$ 13.718	(1) 86
Total	180,263	$ 14.631	(1) 139,997

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

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Recent Sales of Unregistered Securities

In January 2017, we entered into a securities purchase agreement with an unrelated third-party investor pursuant to which the investor loaned us gross proceeds of $150,000, and we issued to such investor (i) a promissory note in the aggregate principal amount of $165,000, and (ii) 3,143 restricted shares of our common stock. In September 2017, the investor converted the remaining principal and interest balance of the promissory note of $170,221 into 20,265 restricted shares of common stock through an exchange agreement.

In January 2017, we issued 2,143 shares of common stock valued at $44,662 in connection with the amendment to the in-license agreement for Sensum+®.

In January 2017, we issued 3,191 shares of common stock to a third-party firm as compensation for services rendered to us.

In February 2017, we issued 7,848 shares of common stock to certain third-party firms as compensation for services rendered to us.

In March 2017, certain 2016 Notes holders elected to convert $350,610 in principal and interest into 13,357 shares of common stock.

In April and May 2017, we issued 3,985 shares of common stock to certain third-party firms as compensation for services rendered to us.

In September 2017, we entered into a securities purchase agreement with an unrelated third-party investor pursuant to which the investor loaned us gross proceeds of $150,000, and we issued to such investor (i) a promissory note in the aggregate principal amount of $165,000, and (ii) 8,524 restricted shares of our common stock. In April 2018, this investor converted the remaining principal and interest balance of the promissory note of $169,543 into 14,041 restricted shares of common stock through an exchange agreement.

During the three months ended September 30, 2017, we issued 6,138 shares of our common stock in exchange for services under existing consulting and service agreements with third parties.

In October 2017, we entered into securities purchase agreements with two unrelated third-party investors pursuant to which the investors loaned us gross proceeds of $500,000, and we issued to such investors (i) promissory notes in the aggregate principal amount of $600,000, and (ii) 5,715 restricted shares of common stock. In March 2018, one of the investors converted the remaining principal and interest balance of the promissory note of $166,667 into 21,429 restricted shares of common stock through an exchange agreement.

During the three months ended December 31, 2017 we issued 17,041 shares of our common stock to certain third-party firms as compensation for services rendered to us.

In December 2017, we entered into securities purchase agreements with three unrelated third-party investors pursuant to which the investors loaned us gross proceeds of $850,000, and we issued to such investors (i) promissory notes in the aggregate principal amount of $950,000, and (ii) 15,239 restricted shares of common stock. In July 2018, one of the investors converted the remaining principal and interest balance of the promissory note of $402,433 into 36,502 restricted shares of common stock through an exchange agreement. In August 2018, two of the investors converted the remaining principal and interest balance of the promissory notes of $250,000 into 22,676 restricted shares of common stock through an exchange agreement.

In January 2018 we issued 8,361 shares of common stock to certain third-party consulting firms for services rendered.

In January and March 2018, we entered into securities purchase agreements with three unrelated third-party investors pursuant to which the investors loaned us gross proceeds of $1,227,500, and we issued to such investors (i) promissory notes in the aggregate principal amount of $1,496,875, and (ii) 12,210 restricted shares of common stock. In July 2018, two of the investors converted the remaining principal and interest balance of the promissory notes of $300,000 into 27,211 restricted shares of common stock through an exchange agreement. In November 2018, one of the investors converted the remaining principal and interest balance of the promissory note of $100,000 into 11,905 restricted shares of common stock through an exchange agreement.

In February and March 2018, we entered into securities purchase agreements with two unrelated third-party investors pursuant to which the investors loaned us gross proceeds of $650,000, and we issued to such investors (i) promissory notes in the aggregate principal amount of $720,000, and (ii) 14,143 restricted shares of common stock. In October 2018, one of the investors converted the remaining principal and interest balance of the promissory note of $340,036 into 40,481 restricted shares of common stock through an exchange agreement. In November 2018, one of the investors converted the remaining principal and interest balance of the promissory note of $142,915 into 20,940 restricted shares of common stock through an exchange agreement.

In March 2018, we issued 2,998 restricted shares of common stock to a third-party consultant for services rendered.

In April 2018, we issued 159 restricted shares of common stock to a third-party consultant for services rendered.

In July 2018, we entered into a securities purchase agreement with an unrelated third-party investor pursuant to which the investor loaned us gross proceeds of $500,000, and we issued to such investor (i) the July 2018 5% Notes Payable, in the aggregate principal amount of $550,000, and (ii) 15,239 restricted shares of our common stock.

In August 2018, we entered into securities purchase agreements with two unrelated third-party investors pursuant to which the investors loaned us gross proceeds of $1.0 million, and we issued to such investors (i) the August 2018 Notes payable, in the aggregate principal amount of $1.2 million, and (ii) 9,524 restricted shares of our common stock.

In August 2018, we issued 6,086 restricted shares of common stock to a third-party consultant for services rendered.

In September 2018, we entered into a securities purchase agreement with an unrelated third-party investor pursuant to which the investor loaned us gross proceeds of $350,000, and we issued to such investor (i) the September 2018 5% Notes Payable, in the aggregate principal amount of $390,000, and (ii) 9,524 restricted shares of our common stock.

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In October 2018, we entered into a securities purchase agreement with an unrelated third-party investor pursuant to which the investor loaned us gross proceeds of $500,000, and we issued to such investor (i) a promissory note in the principal amount of $550,000, and (ii) 15,239 restricted shares of our common stock.

In November 2018, we entered into securities purchase agreements with three unrelated third-party investors pursuant to which the investors loaned us gross proceeds of $900,000, and we issued to such investors (i) promissory notes in the aggregate principal amount of $1.1 million, and (ii) 11,429 restricted shares of our common stock.

In November 2018, we acquired the assets of Boston Topicals, LLC. As part of the purchase consideration we issued an aggregate of 6,869 shares of common stock to the sellers of the assets.

On December 2018, we entered into a securities purchase agreement with an unrelated third-party investor pursuant to which the investor loaned us gross proceeds of $350,000, and we issued to such investor (i) a promissory note in the principal amount of $420,000, and (ii) 3,334 restricted shares of our common stock.

In December 2018, we issued 8,192 shares of common stock to certain third-party consultant for services rendered.

We believe that each of the offers, sales and issuances of securities described were exempt from registration under the Securities Act pursuant to Regulation D under the Securities Act or pursuant to Section 4(a)(2) or Section 3(a)(9) of the Securities Act regarding transactions not involving a public offering. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the stock certificates and instruments issued in such transactions. All recipients had adequate access, through their relationships with us, to information about us.

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 244,445 shares of our common stock at an offering price of $15.75 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).

On February 12, 2019, our registration statement on Form S-1 (File No. 333-229223) was declared effective by the SEC for our public offering pursuant to which we sold an aggregate of 230,853 shares of our common stock at an offering price of $7.53 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 February 13, 2019 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.

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

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

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

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 medical devices to improve men's and women's health and vitality. Our products currently focus in six main categories including sexual health, pain management, general muscle health, respiratory, sleep, and

diabetic care. We deliver innovative and unique health solutions of OTC medicines, devices, consumer and health products, and clinical supplements through four general channels including Direct to Consumer Marketing, E-Commerce, Retail/Wholesale, and International Distribution. Collectively these channels make up our proprietary Beyond Human® Sales & Marketing Platform, which was acquired 2016, and significantly expanded through the development of proprietary algorithms to target consumers and improve efficiency and return in 2018. We are dedicated to being a leader in developing and marketing new OTC and branded Abbreviated New Drug Application ("ANDA") products, supplements and medical 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, Walmart.com®, and Walgreens.com on-line stores and our own product websites and platforms among other e-commerce business platforms) channels to tap new markets and drive demand for such products and to establish physician relationships.

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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 complementary partners that: (a) generates revenue, and (b) requires a lower cost structure compared to traditional pharmaceutical companies, thereby increasing our gross margins.

3. Developing and acquiring on-line marketplaces such as Supplementhunt.com and Primesavingsclub.com that focus on certain market segments such as lower priced, soon to expire supplement business with the Supplementhunt.com acquisition and with the select consumer product business through Primesavingsclub.com among others in which we sell third party, brand or non-branded products.

Our Products

Marketed Products

We currently market and sell over 35 products in the U.S. and more than 10 in multiple countries around the world through our 12 international commercial partners. We have five core products which we define as having more than $1.0 million in annual sales or rapidly growing product. The following represents these core products:

1. Vesele®
2. UriVarx®
3. FlutiCare®
4. Apeaz®
5. Diabasens®
6. Prostagorx®
7. Sensum®

In addition, we currently expect to launch in the U.S. the following products in 2019, subject to the applicable regulatory approvals, if required:

1. ThermoMax® is a hand cream with two strengths that provides up to eight hours of hand warming relief (second quarter of 2019);
2. BreastLift™ is a clinically tested cream to provide safe and natural way to firm sagging breasts (second quarter of 2019);
3. HealthiFeet® is a foot cream that provides foot warming relief (second quarter of 2019);
4. MZS Sleeping Aid™ with Hemp-Derived THC-free oil and melatonin is in tincture form (launched in first quarter of 2019);
5. Trexar™ is a supplement to provide neuropathy support and enhanced sensation (second quarter of 2019);
6. Musclin® is a proprietary supplement made of two FDA Generally Recognized As Safe (GRAS) approved ingredients designed to increase muscle mass, endurance and activity (second half of 2019). 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;
7. Regenerum™ is a proprietary product containing two natural molecules: the first 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 2020 pending successful clinical trials in patients with muscle wasting or cachexia; and
8. Octiq™ is an expected FDA ophthalmic OTC monograph compliant product for the treatment of eye redness and eye lubrication (late 2019/early 2020).

Sales and Marketing Channels

As discussed, we currently have four main sales and marketing channels making up the Beyond Human® sales and marketing platform acquired in March 2016, which has resulted in the significant revenue growth to $24.0 million in the year ended December 31, 2018 compared with $8.8 million in the year ended December 31, 2017. We feel that these channels complement each other to enhance the Innovus Pharmaceuticals, Inc. brand and awareness of our customers and provide us with the ability to use our sales and marketing in the most efficient way possible in acquiring new customers and maintaining those current customers.

Print and Direct Mail Marketing

Through our Beyond Human® sales and marketing platform, we have access to advertise in the vast majority of newspapers and magazines on a regular basis. We have developed our own proprietary algorithm which allows us to target customers looking for specific health products allowing us to increase the return on our investment and reduce the cost to acquire new customers. During 2018, we were able to expand our reach to Canada with the approval of twelve of our products by Health Canada and successfully expand our Beyond Human® sales and marketing platform.

E-Commerce

We have an extensive on-line media channel through our Amazon®, NewEgg®, Walmart.com®, eBay®, Wish.com, and Walgreens.com sites in addition to our own InnovusPharma.com site along with sites for each of our products individually. Our expertise allows us to successfully drive product sales through proper marketing campaigns through third-party sites as well as through email marketing campaigns to increase traffic to our own sites. Additionally, we have recognized that maintaining a proper e-commerce presence allows those customers who read our advertisements in the newspapers and magazine or receive our direct mail another avenue to purchase products.

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Retail/Wholesale

We are continuously introducing our products to varieties of retail and wholesale partners to enhance the brand and product awareness for our customers. In 2018, we significantly increased our advertising expenses specifically in the Print and Direct Mail Marketing channel which, in turn, has had a direct positive impact to the success of products in retail. We intend to continue to demonstrate to our retail and wholesale partners the advantages of incorporating our products in their stores, especially due to our proprietary consumer targeted marketing approach that our print advertising allows us to achieve.

International Distribution

We continue to work with our exclusive commercial partners outside of the U.S. that would be responsible for sales and marketing in those territories. We evaluate the performance of each of these partners to ensure a steady flow of consumer activity for each of our products. 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.

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. In the first quarter of 2019 we placed another purchase order and are currently in compliance with our minimum product batch purchase requirements required to maintain the agreement.

Reverse Stock Split

On March 15, 2019, the Company's Board of Directors approved to amend and restate the Company's Charter to affect a one-for-105 reverse stock split of its issued and outstanding shares of common stock, but not the number of shares of common stock authorized for issuance under our Charter (the "Reverse Split"). The Annual Report, financial statements and accompanying footnotes have been retroactively restated to reflect the reverse stock split.

Private Placement

On January 3, 2019, the Company completed a sale of common stock and warrants under a Securities Purchase Agreement with an accredited investor, pursuant to which the Company sold an aggregate of 431,490 units ("*Units*") for $7.35 per unit, with each Unit consisting of (i) one share of common stock ("*Shares*"), (ii) one warrant to purchase one share of common stock at an exercise price of $7.35 per share ("*Series A Warrant*"), and (iii) one warrant to purchase one share of Common Stock at an exercise price of $8.40 per share ("*Series B Warrant*") (the "*Private Placement*"); provided, however, that in order to ensure that the Investor's beneficial ownership did not exceed 9.99% of the outstanding shares of our common stock, the Investor elected to exercise its right to purchase 200,637 prefunded warrants ("*Series C Warrants*," and together with the Series A Warrants and Series B Warrants, the "*Investor Warrants*") in lieu of Shares as part of the Units, which Series C Warrants have a nominal exercise price of $0.105 per share. In addition, the Company issued Series B Warrants to purchase 32,362 shares of common stock, an amount equal to 7.5% of the aggregate number of Shares, including Series C Warrants, sold in the Private Placement, at an exercise price of $9.19 per share (the "*Placement Agent Warrants*") to the designees of H.C. Wainwright & Co., LLC (the "*Placement Agent*"), the Company's sole placement agent, as compensation for its services in connection with the Private Placement.

The Investor Warrants and Placement Agent Warrants are exercisable immediately upon issuance, subject to an issuance limitation set forth therein equal to the number of authorized and unreserved shares of our common stock available for issuance on the date thereof, and shall terminate as follows: (i) the Series A Warrants shall terminate 18-months from the date of the Reverse Split, (ii) the Series B Warrants shall terminate five and a half years from the date of the Reverse Split, and (iii) the Series C Warrants shall terminate at such time that they are exercised in full. In addition, each of the Investor Warrants contains a 4.99% beneficial ownership limitation, which may be increased up to 9.99% at the sole option of the Investor upon 61 day prior notice to the Company (the "*Beneficial Ownership Limitation*"), and which prevents the Investor from exercising the Investor Warrants in the event such exercise would cause the Investor's beneficial ownership of the Company's outstanding shares of Common Stock to exceed the Beneficial Ownership Limitation.

In connection with the sale of the Units, the Company granted certain registration rights with respect to the Shares and shares of common stock issuable upon exercise of the Investor Warrants, pursuant to a Registration Rights Agreement by and between us and the Investor (the "*Registration Rights Agreement*"). Under the terms of the Registration Rights Agreement, we agreed to file a registration statement no later than 30 days after the Closing Date in order to register the Shares and shares of common stock underlying the Investor Warrants sold and issued in connection with the Private Placement which was filed on January 14, 2019 and declared effective on February 12, 2019. We also agreed to register the shares of common stock underlying the Placement Agent Warrants issued to the Placement Agent's designees as compensation for its services in connection with the Private Placement.

Asset Purchase Agreement

On January 1, 2019, the Company completed an Asset Purchase Agreement ("APA"), pursuant to which the Company agreed to purchase substantially all of the assets of Prime Consultants, LLC for a total cash payment of $343,000 (the "Purchase Price"). Of the total Purchase Price, the Company acquired $313,000 of inventory. Prime Consultants, LLC is an e-commerce business with sales of products primarily through the Amazon platform generating approximately $2.8 million in revenue in 2018.

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Results of Operations

Year Ended December 31, 2018 Compared to Year Ended December 31, 2017 (dollars in thousands)

	Year Ended December 31, 2018	Year Ended December 31, 2017	Increase (Decrease)	% Increase (Decrease)
NET REVENUE:				
Product sales, net	$ 22,879	$ 8,806	$ 14,073	159.8 %
License revenue	9	10	(1)	(10.0)%
Service revenue	509	-	509	100.0 %
Cooperative marketing revenue	593	-	593	100.0 %
Net revenue	23,990	8,816	15,174	172.1 %
OPERATING EXPENSE:				
Cost of product sales	4,325	1,848	2,477	134.0 %
Research and development	160	39	121	310.3 %
Sales and marketing	17,206	6,853	10,353	151.1 %
General and administrative	7,991	5,175	2,816	54.4 %
Total operating expense	29,682	13,915	15,767	113.3 %
LOSS FROM OPERATIONS	(5,692)	(5,099)	(593)	11.6 %
OTHER INCOME (EXPENSE):				
Interest expense	(1,446)	(872)	(574)	(65.8)%
Loss on extinguishment of debt	(1,332)	(700)	(632)	(90.3)%
Other income (expense), net	(13)	(7)	(6)	(85.7)%
Fair value adjustment for contingent consideration	204	194	10	5.2 %
Change in fair value of derivative liabilities	-	(17)	17	100.0 %
Total other expense, net	(2,587)	(1,402)	(1,185)	(84.5)%
LOSS BEFORE PROVISION FOR INCOME TAXES	(8,279)	(6,501)	(1,778)	(27.3)%
Provision for income taxes	-	3	(3)	(100.0)%
NET LOSS	$ (8,279)	$ (6,504)	$ (1,775)	(27.3)%

Net Revenue

We recognized net revenue of approximately $24.0 million and $8.8 million for the years ended December 31, 2018 and 2017, respectively. The increase in net revenue in 2018 was primarily the result of new product launches in late 2017 and 2018 as well as an increase in marketing spend through the sales and marketing platform acquired in the

Beyond Human® asset acquisition in March 2016. Diabasens® was launched in the first quarter of 2018, and we recognized net sales of approximately $5.5 million during the fiscal year and established a subscription base of approximately $108,000 monthly as of December 31, 2018. During the fourth quarter of 2016 we launched UriVarx® and during 2017 we launched ProstaGorx®, Apeaz® and ArthriVarx®, three of the four of which were core products in fiscal 2018 and collectively recognized net sales of approximately $9.5 million during the year ended December 31, 2018 compared with $4.3 million during the year ended December 31, 2017 and established a subscription base of approximately $137,000 monthly as of December 31, 2018. Two of our historical products, Vesele® and Sensum+®, also recognized continued growth in the year ended December 31, 2018, generating net revenue of $5.4 million compared with $3.4 million during the year ended December 31, 2017.

The following represents the number of units of our top products shipped in North America during the years ended December 31, 2018 and 2017:

	Year Ended December 31, 2018	**Year Ended December 31, 2017**	**# Increase (Decrease)**	**% Increase (Decrease)**	
NUMBER OF UNITS:					
Diabasens®	180,411	-	180,411	100.0	%
Urivarx®	107,853	62,837	45,016	71.6	%
Apeaz®	90,370	11,763	78,607	668.3	%
Vesele®	84,844	59,418	25,426	42.8	%
Fluticare®	57,909	1,101	56,808	5,159.7	%
Sensum®	25,117	24,073	1,044	4.3	%

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Cost of Product Sales

We recognized cost of product sales of approximately $4.3 million and $1.8 million for the years ended December 31, 2018 and 2017, respectively. The cost of product sales includes the cost of inventory, shipping, internal and external fulfillment expenses and royalties. The increase in cost of product sales by 134% is a direct result in the overall percentage increase in product sales of 160% in comparing the fiscal 2018 and 2017. The increase in the gross margin of product sales to 81.1% in 2018 compared to 79.0% in 2017 is due to the transition of our fulfillment services from utilizing third party providers in 2017 to managing the process internally in 2018 as well as improvements in the cost of products negotiated with our manufacturers during the period. Additionally, the increase in our print and direct mail marketing spend during fiscal 2018 resulted in customers purchasing more units per order when compared to the typical purchases that occur on e-commerce platforms which results in a decrease in shipping expense per unit on average.

Research and Development

We recognized research and development expense of approximately $160,000 and $39,000 for the years ended December 31, 2018 and 2017, respectively. The increase was a result in additional cost for research of new products, quality testing of products, and additional clinical trials expense incurred in 2018 primarily related to Musclin.

Sales and Marketing

We recognized sales and marketing expense of approximately $17.2 million and $6.9 million for the years ended December 31, 2018 and 2017, respectively. Sales and marketing expense consists primarily of print advertisements, direct mail marketing and sales and marketing support. The increase in sales and marketing expense during the year ended December 31, 2018 when compared to the same period in 2017 is due to the increase in the number of products we integrated into the Beyond Human® sales and marketing platform. Additionally, our expansion of sales into the Canadian market, specifically in the second half of 2018, resulted in an increase in marketing expenses, as we introduced new products to that market.

General and Administrative

We recognized general and administrative expense of approximately $8.0 million and $5.2 million for the years ended December 31, 2018 and 2017, respectively. General and administrative expense consists primarily of employee compensation, investor relation expense, legal, accounting, public reporting costs and other infrastructure expense

related to the launch of our products. Additionally, our general and administrative expense includes professional fees, insurance premiums and general corporate expense. The increase is primarily due to the increase in employee headcount from 12 full-time employees as of December 31, 2017 to 27 full-time employees as of December 31, 2018 resulting in an increase in compensation expenses of approximately $1.1 million, an increase of approximately $1.0 million in merchant fees and third-party e-commerce fees as result of the significant increase in revenues during the fiscal year ended December 31, 2018 compared to 2017, and general increases in insurance premiums, legal expenses, rent expense due to our larger office space lease.

Other Income and Expense

We recognized interest expense of approximately $1.4 million and $0.9 million for the years ended December 31, 2018 and 2017, 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 in 2017 (see Note 5 to the accompanying consolidated financial statements included elsewhere in this Annual Report). Due to the shares, warrants and cash discounts provided to our lenders, the effective interest rate is significantly higher than the coupon rate. The increase in interest expense during the year ended December 31, 2018 is due to the increase in the note agreements entered into during the year to enable us to increase the sales and marketing throughout the period.

We recognized a loss on extinguishment of debt of approximately $1.3 million during the year ended December 31, 2018. The loss on debt extinguishment was the result of the securities exchange agreements entered into with certain Notes Payable holders. In exchange for the settlement of approximately $1.9 million in principal and interest, we issued 195,185 shares of our common stock to such holders, with an aggregate fair value of $2.9 million. As a result, the remaining unamortized debt discount of approximately $0.3 million and the fair value of the common stock issued in excess of the debt settled of approximately $1.0 million were recorded as a loss on debt extinguishment during the year ended December 31, 2018.

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 108,884 shares of our common stock to such holder with an aggregate 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 Payable, 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 both the years ended December 31, 2018 and 2017. 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.

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Income Taxes

We recognized a provision for income taxes of $0 for the year ended December 31, 2018 compared to $3,000 for the year ended December 31, 2017.

Net Loss

Net loss for the year ended December 31, 2018 was approximately $8.3 million, or $(4.16) basic and diluted net loss per share, compared to a net loss for the same period in 2017 of $6.5 million, or $(4.32) 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, 2018, we had an accumulated deficit of $43.9 million and a working capital deficit of $2.3 million.

As of March 29, 2019, we had approximately $1.7 million in cash and $0.6 million held by processors. 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 private placement offering and issuance of notes payable in the first quarter of 2019 totaling $2.7 million (see Note 11 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, the Company’s CEO, who is also a significant shareholder, has deferred the remaining payment of his salary earned through June 30, 2016 of $1.2 million and will continue to defer such compensation if payment would jeopardize the ability of the Company to continue its operations.

Our principle debt instruments include the following:

January and March 2018 Notes Payable

On January 8, 2018, January 30, 2018, March 1, 2018 and March 2, 2018, the Company entered into a securities purchase agreement with three unrelated third-party investors, pursuant to which the investors loaned the Company gross proceeds of $678,000 in January 2018 and $550,000 in March 2018 pursuant to 0% promissory notes ("January and March 2018 Notes Payable"). The notes have an Original Issue Discount ("OID") of $269,000 and bear interest at the rate of 0% per annum. The principal amount of $1.5 million is to be repaid in twelve equal monthly installments. Monthly installments of $68,000 began in February 2018 and are due through January 2019 and monthly installments of $56,000 began in April 2018 and are due through March 2019. The effective interest rate is 22% per annum for the January and March 2018 Notes Payable.

In connection with the January and March 2018 Notes Payable, we issued the investors restricted shares of our common stock totaling 27,211 shares. 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 January and March 2018 Notes Payable. 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 $227,000 in January 2018 and $188,000 in March 2018. In connection with the financing, we issued 5,918 restricted shares of our common stock in January 2018, and 2,998 restricted shares of common stock in March 2018 to a third-party consultant. The fair value of the restricted shares of common stock issued of $68,000 in January 2018 and $55,000 in March 2018 was recorded as a debt discount to the carrying value of the January and March 2018 Notes Payable. The discount is being amortized to interest expense using the effective interest method over the term of the January and March 2018 Notes Payable.

On July 31, 2018, the Company entered into a securities exchange agreement with two of the January and March 2018 Notes Payable holders. In connection with the securities exchange agreement, the Company issued a total of 27,211 shares of common stock in exchange for the settlement of principal due totaling $300,000. 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 was determined to be $440,000. Due to the settlement of the principal balance of $300,000 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 balance totaling $140,000 and the unamortized debt discount as of the date of settlement of $100,000 were recorded as a loss on debt extinguishment in the accompanying condensed consolidated statement of operations.

On November 6, 2018, the Company entered into a securities exchange agreement with one of the January and March 2018 Notes Payable holders. In connection with the securities exchange agreement, the Company issued a total of 11,905 shares of common stock in exchange for the settlement of principal due totaling $100,000. 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, and was determined to be $133,000. Due to the settlement of the principal balance of $100,000 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 balance totaling $33,000 and the unamortized debt discount as of the date of settlement of $24,000 were recorded as a loss on debt extinguishment in the accompanying condensed consolidated statement of operations.

February and March 2018 5% Notes Payable

On February 28, 2018 and March 28, 2018, the Company entered into a securities purchase agreement with two unrelated third-party investors, pursuant to which the investors loaned the Company gross proceeds of $650,000 pursuant to 5% promissory notes ("February and March 2018 5% Notes Payable"). The notes have an OID of $70,000 and require aggregate payments 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 2018 and in three installments on October 1, 2018, January 1, 2019 and April 1, 2019 for the note issued in March 2018.

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In connection with the February and March 2018 5% Notes Payable, we issued the investors restricted shares of our common stock totaling 14,143 shares. 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 February and March 2018 5% Notes Payable. 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 $94,000 in February 2018 and $129,000 in March 2018. The discount is being amortized to interest expense using the effective interest method over the term of the February and March 2018 5% Notes Payable.

On October 8, 2018, the Company entered into a securities exchange agreement with one of the February and March 2018 5% Notes Payable holders. In connection with the securities exchange agreement, the Company issued a total of 40,481 shares of common stock in exchange for the settlement of principal due totaling $340,000. 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 was determined to be $485,000. Due to the settlement of the principal balance of $340,000 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 balance totaling $145,000 and the unamortized debt discount as of the date of settlement of $3,000 were recorded as a loss on debt extinguishment in the accompanying condensed consolidated statement of operations.

On November 30, 2018, the Company entered into a securities exchange agreement with one of the February and March 2018 5% Notes Payable holders. In connection with the securities exchange agreement, the Company issued a total of 20,940 shares of common stock in exchange for the settlement of principal due totaling $143,000. 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 was determined to be $231,000. Due to the settlement of the principal balance of $143,000 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 balance totaling $88,000 was recorded as a loss on debt extinguishment in the accompanying condensed consolidated statement of operations.

July 2018 5% Note Payable

On July 19, 2018, the Company entered into a securities purchase agreement with an unrelated third-party investor in which the investor loaned the Company gross proceeds of $500,000 pursuant to 5% promissory notes (“July 2018 5% Notes Payable”). The notes have an OID of $50,000 and require payments of $550,000 in principal. The notes bear interest at the rate of 5% per annum and the principal amount and interest are payable at maturity on February 19, 2019.

In connection with the note, the Company issued the investor restricted shares of common stock totaling 15,239 shares. 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 the Company recording a debt discount of $226,000. The discount is being amortized to interest expense using the effective interest method over the term of the note.

August 2018 Notes Payable

On August 1, 2018, the Company entered into a securities purchase agreement with two unrelated third-party investors in which the investors loaned the Company gross proceeds of $1.0 million pursuant to a 0% promissory note ("August 2018 Notes Payable"). The notes have an OID of $200,000 and require twelve payments of $100,000 in principal per month through August 2019. The August 2018 Notes Payable bear no interest per annum. The effective interest rate is 20% per annum for the notes.

In connection with the August 2018 Notes Payable, we issued the investors restricted shares of common stock totaling 9,524 shares. 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 August 2018 Notes Payable. 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 $435,000. In connection with the financing, we issued 6,086 restricted shares to a third-party consultant. The fair value of the restricted shares of common stock issued of $100,000 was recorded as a debt discount to the carrying value of the August 2018 Notes Payable. The discount is being amortized to interest expense using the effective interest method over the term of the August 2018 Notes Payable.

September 2018 5% Notes Payable

On September 12, 2018, the Company entered into a securities purchase agreement with an unrelated third-party investor in which the investor loaned the Company gross proceeds of $350,000 pursuant to 5% promissory notes ("September 2018 5% Notes Payable"). The notes have an OID of $40,000 and require payments of $390,000 in principal. The notes bear interest at the rate of 5% per annum and the principal amount and interest are payable in three installments on March 12, 2019, June 12, 2019 and September 12, 2019 for the note.

In connection with the September 2018 5% Notes Payable, the Company issued the investor restricted shares of common stock totaling 9,524 shares. 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 September 2018 5% Notes Payable. 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 $130,000. The discount is being amortized to interest expense using the effective interest method over the term of the Note.

October 2018 5% Notes Payable

On October 22, 2018, the Company entered into a securities purchase agreement with an unrelated third-party investor in which the investor loaned the Company gross proceeds of $500,000 pursuant to 5% promissory notes ("October 2018 5% Notes Payable"). The notes have an OID of $50,000 and require payments of $550,000 in principal. The notes bear interest at the rate of 5% per annum and the principal amount and interest are payable at maturity on May 1, 2019.

In connection with the October 2018 5% Notes Payable, the Company issued the investor restricted shares of common stock totaling 15,239 shares. 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 2018 5% Notes Payable. 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 $176,000. The discount is being amortized to interest expense using the effective interest method over the term of the Note.

November and December 2018 Notes Payable

On November 6, 2018, November 8, 2018 and December 12, 2018, the Company entered into a securities purchase agreement with three unrelated third-party investors, pursuant to which the investors loaned the Company gross proceeds of $1.25 million pursuant to 0% promissory notes ("November and December 2018 Notes Payable"). The notes have an OID of $270,000 and require aggregate payments of $1.52 million in principal. The notes bear interest at the rate of 0% per annum.

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In connection with the November and December 2018 Notes Payable, the Company issued the investors restricted shares of our common stock totaling 14,763 shares. 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 November and December 2018 Notes Payable. 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 $374,000 in November 2018 and $125,000 in December 2018. The discount is being amortized to interest expense using the effective interest method over the term of the November and December 2018 Notes Payable.

Net Cash Flows (dollars in thousands)

	For the Year Ended December 31, 2018	**For the Year Ended December 31, 2017**
Net cash used in operating activities	$ (6,121)	$ (2,361)
Net cash used in investing activities	(494)	(58)
Net cash provided by financing activities	6,298	3,154
Net change in cash	(317)	735
Cash at beginning of the year	1,565	830
Cash at the end of the year	$ 1,248	$ 1,565

Operating Activities

For the year ended December 31, 2018, cash used in operating activities was approximately $6.1 million compared with cash used in operating activities of approximately $2.4 million for the year ended December 31, 2017. The increase in the cash used by operating activities of approximately $3.7 million is due primarily from an increase in the net loss of $1.8 million, a net reduction in working capital of $2.4 million and a reduction in stock compensation expenses issued to employees, the board of directors and consultants of $0.6 million offset by increases of $1.2 million consisting primarily from additional loss on the extinguishment of debt and the amortization of debt discount both relating to our issued notes payable.

Investing Activities

For the year ended December 31, 2018, cash used in investing activities was approximately $494,000, which consisted of the purchase of property and equipment for the corporate office as well as the cash used for the acquisitions in

2018. Cash used in investing activities in 2017 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.

Financing Activities

For the year ended December 31, 2018, cash provided by financing activities was approximately $6.3 million, consisting primarily of the net proceeds from the exercise of warrants of $2.9 million and notes payable and short-term loans payable of $5.8 million, offset by the repayment of notes payable and short-term loans payable of approximately $2.3 million. Cash provided by financing activities in 2017 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.

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, 2018, we had an accumulated deficit of approximately $43.9 million and a working capital deficit of $2.3 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, 2018, we received approximately $2.9 million in funds from the exercise of warrants and an aggregate of $5.8 million from the issuance of notes payable and short-term loans payable. These funds were primarily utilized for working capital purposes. The outstanding notes payable and short-term loans payable principal balance at December 31, 2018 was approximately $3.3 million.

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

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

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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

On January 1, 2018, we adopted Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). The new guidance sets forth a new five-step revenue recognition model, which replaces the prior revenue recognition guidance in its entirety and is intended to eliminate numerous industry-specific pieces of revenue recognition guidance that have historically existed in U.S. GAAP. The underlying principle of the new standard is that a business or other organization will recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects what it expects to receive in exchange for the goods or services. The standard also requires more detailed disclosures and provides additional guidance for transactions that were not addressed completely in the prior accounting guidance.

We reviewed all contracts at the date of initial application and elected to use the modified retrospective transition method, where the cumulative effect of the initial application is recognized as an adjustment to opening retained earnings at January 1, 2018. Therefore, comparative prior periods have not been adjusted and continue to be reported under FASB ASC Topic 605, *Revenue Recognition*, ("ASC 605"). The adoption of the new revenue recognition guidance was immaterial to our condensed consolidated statements of operations, balance sheet, and cash flows as of and for the year ended December 31, 2018.

Revenue is measured based on consideration specified in a contract with a customer. A contract with a customer exists when we enter into an enforceable contract with a customer. A performance obligation is a promise in a contract to transfer a distinct product or service to the customer. Performance obligations promised in a contract are identified based on the goods or service that will be transferred to the customer that are both capable of being distinct and are distinct in the context of the contract. The transaction price of a contract is allocated to each distinct performance obligation and recognized as revenue when or as the customer receives the benefit of the performance obligation. The transaction price is determined based on the consideration to which we will be entitled to receive in exchange for transferring goods or service to the customer.

Product Sales: Our principal activities from which we generate our revenue are 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. The contract is based on either the acceptance of standard terms and conditions on the websites for e-commerce customers and via telephone with our third-party call center for our print media and direct mail customers, or the execution of terms and conditions contracts with retailers, distributors and wholesalers. These contracts define each party's rights, payment terms and other contractual terms and conditions of the sale. Consideration is typically paid prior to shipment via credit card or check when our products are sold direct to consumers or approximately 30 days from the time control is transferred when sold to wholesalers, distributors and retailers. We apply judgment in determining the customer's ability and intention to pay, which is based on a variety of factors including the customer's historical payment experience and, in some circumstances, published credit and financial information pertaining to the customer. We have concluded the sale of bottled finished goods and related shipping and handling are accounted for as the single performance obligation. The transaction price of a contract is allocated to each distinct performance obligation and recognized as revenue when or as the customer receives the benefit of the performance obligation. The transaction price is determined based on the consideration to which we will be entitled to receive in exchange for transferring goods to the customer. We issue refunds to e-commerce and print media customers, upon request, within 30 days of delivery. We estimate the amount of potential refunds at each reporting period using a portfolio approach of historical data, adjusted for changes in expected customer experience, including seasonality and changes in economic factors. For retailers, distributors and wholesalers, we do not offer a right of return or refund and revenue is recognized at the time products are shipped to customers. In all cases, judgment is required in estimating these reserves. Actual claims for returns could be materially different from the estimates. We recognize revenue when we satisfy a performance obligation in a contract by transferring control over a product to a customer when product is shipped. Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction, that are collected by us from a customer, are excluded from revenue. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost and are included in cost of product sales.

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 nonrefundable payments or licensing fee is recognized when all required conditions are met. If the consideration for the initial license fee is for the right to sell the licensed product in the respective territory with no other required conditions to be met, such type of nonrefundable license fee arrangement for the right to sell the licensed product in the territory is recognized ratably over the term of the license agreement. For arrangements with licenses that include sales-based royalties, including sales-based milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize royalty revenue and sales-based milestones at the later of (i) when the related sales

occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied. The achievement of the sales-based milestone underlying the payment to be received predominantly relates to the licensee's performance of future commercial activities.

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Service Revenue: During the year ended December 31, 2018, we entered into a contract with a customer to provide sales, marketing, customer service, fulfillment, and storage services for a certain product which they have the rights to sell in Canada. The contract indicates that each of the services are provided as needed or as requested by the customer. The performance obligation is a promise to perform each of these services individually and therefore each service is considered to be distinct in the context of the contract. The transaction price is allocated to each distinct performance obligation and therefore revenue is recognized as the services are performed.

Cooperative Marketing Revenue: During the year ended December 31, 2018, we entered into a contract with a broker to allow other companies to rent addresses from our list for their own marketing purposes. These companies do not obtain access to such lists, but rather the process is managed by a third-party broker. Only upon an individual purchasing a customer’s product would the customer have visibility of the individual's information. In accordance with the contract, the broker will present an offer to us to rent certain lists from us. Upon our written approval, the broker will execute the rental and arrange for the requested marketing materials to be sent, which we consider the performance obligation. We recognize revenue when the rental is executed as indicated by the broker. Collection is managed by the broker and we apply judgment in determining the customer’s ability and intention to pay.

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. 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.

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.

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Goodwill and Intangible Assets

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

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

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

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

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

Long-Lived Assets

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

Derivative Liabilities

Certain of our embedded conversion features on debt and issued and outstanding common stock purchase warrants, which have exercise price reset features and other anti-dilution protection clauses, were 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 were 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.

On January 1, 2018, we adopted Financial Accounting Standards Board (“FASB”) Accounting Standards Update (“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*. This ASU requires that 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 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. The Company elected to use the modified retrospective transition method, where the cumulative effect of the initial application is recognized as an adjustment to opening retained earnings at January 1, 2018. As a result of the adoption of this ASU, we recorded a cumulative-effect adjustment to the consolidated statement of financial position as of January 1, 2018 of $59,000 for the warrants previously classified as a derivative liability due to a down round provision included in the terms of the warrant agreement. Therefore, the cumulative-effect adjustment was recorded as a reduction in accumulated deficit and derivative liabilities in the accompanying condensed consolidated balance sheet as of January 1, 2018. The adoption of this ASU did not have an impact on our condensed consolidated results of operations.

Recent Accounting Pronouncements

See Note 1 to our consolidated financial statements for the years ended December 31, 2018 and 2017 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.

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

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

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer ("CEO"), our principal executive officer, and our Chief Financial Officer ("CFO"), our principal financial and accounting officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2018, the end of the period covered by this Annual Report, pursuant to Rules 13a-15(b) and 15d-15(b) under the Securities Exchange Act of 1934, as amended ("Exchange Act").

In connection with that evaluation, our CEO and CFO concluded that, as of December 31, 2018, our disclosure controls and procedures were effective. For the purpose of this review, disclosure controls and procedures means controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. These disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal accounting and financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its

judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Management’s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, our CEO and CFO and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with accepted accounting principles generally accepted in the United States of America. Our management, under the supervision and with the participation of our CEO and CFO, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations (“COSO”). Based on such evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2018.

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, 2018 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 CFO, do not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override

of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Item 9B. Other Information.

None.

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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.