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.