INNOVUS PHARMACEUTICALS, INC.
Form 424B3
February 13, 2019

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Filed Pursuant to Rule 424(b)(3)

Registration No. 333-229223

PROSPECTUS

139,317,017 Shares

Common Stock

This prospectus relates to the sale from time to time of up to 139,317,017 shares of common stock, par value $0.001 per share, of Innovus Pharmaceuticals, Inc. ("*we*," "*us*," or the "*Company*") by the selling stockholders identified in this prospectus. All of the shares of being offered, when sold, will be sold by the selling stockholders. The shares of common stock registered for resale pursuant to this prospectus include:

24,239,503 shares of Company common stock issued to the selling stockholders in a private placement transaction, consummated on January 3, 2019 (the "*Private Placement*");

111,679,538 shares of Company common stock that may be issued upon exercise of certain common stock purchase warrants issued to the selling stockholders in connection with the Private Placement (the "*Investor Warrants*"); and

3,397,976 shares of Company common stock that may be issued upon exercise of common stock purchase warrants issued as compensation to the designees of H.C. Wainwright & Co., LLC, the Company's sole placement agent in connection with the Private Placement (the "*Placement Agent Warrants*").

We are registering the shares of common stock to provide the selling stockholders with freely tradable securities. This prospectus does not necessarily mean that the selling stockholders will exercise their warrants and/or offer or sell their shares. Up to 139,317,017 shares of common stock may be sold from time to time after the effectiveness of the registration statement of which this prospectus forms a part; *provided, however*, that the sale of such shares by the selling stockholders is subject to certain limitations discussed in the section entitled "*Description of Private Placement*" beginning on page 24 of this prospectus.

We will not receive proceeds from the sale of the shares of common stock by the selling stockholders. However, we may receive proceeds of up to approximately $7.1 million from the exercise of the Investor Warrants and Placement Agent Warrants by the selling stockholders, once the registration statement, of which this prospectus is a part, is declared effective; *provided, however*, that the exercise of certain of the Investor Warrants and Placement Agent Warrants by the selling stockholders is subject to certain limitations discussed in the section of the prospectus entitled "*Description of Private Placement*." All selling and other expenses incurred by the selling stockholders will be paid by the selling stockholders, except for certain legal fees and expenses, which will be paid by us.

Our common stock is currently quoted on the OTCQB Marketplace under the symbol "INNV." The last reported sale price of our Common Stock on January 11, 2019 was $0.067 per share.

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We have submitted an application to have our common stock listed on the Nasdaq Capital Market under the symbol INNV, although no assurances may be given with respect to if or when our application will be approved. In order to facilitate the listing of our common stock on the Nasdaq Capital Market and to ensure that we have a sufficient number of authorized shares of common stock available for issuance upon the conversion and exercise of all of our derivative securities, we intend, subject to stockholder approval, to effect a reverse stock split of our issued and outstanding shares common stock, but not the number of shares authorized for issuance under our Amended and Restated Articles of Incorporation ("*Charter*") (the "*Reverse Split*"). On January 7, 2019, we filed a preliminary consent solicitation statement pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission in order to solicit the consent of our stockholders to approve an amendment to our Charter to effect the Reverse Split. Assuming we obtain the requisite stockholder consent, the exact ratio of the Reverse Split shall be determined by our Board of Directors, in its sole discretion, but it shall not exceed a ratio of 1-for-200. The Reverse Split will not be effected prior to at least 30 days after the registration statement, of which this prospectus forms a part, is declared effective, if at all. Therefore, in this prospectus, all share and per share amounts have been calculated on a pre-split basis.

An investment in our securities involves a high degree of risk. We urge you to read carefully the section entitled "Risk Factors" beginning on page 7 of this prospectus, where we describe specific risks associated with an investment in our securities, before you make your investment decision.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is February 13, 2019.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 that we filed with the Securities and Exchange Commission (the "*SEC*"). Under the registration statement, the selling stockholders may, from time to time, sell up to an aggregate of 139,317,017 shares of our common stock, par value $0.001 per share ("*Common Stock*"), which includes up to 115,077,514 shares of Common Stock that may be issued upon the exercise of warrants. The registration statement we filed with the SEC, of which this prospectus forms a part, includes exhibits that provide more detail of the matters discussed in this prospectus. You should read this prospectus and the related exhibits filed with the SEC before making your investment decision. The registration statement and the exhibits can be obtained from the SEC, as indicated under the section entitled "*Where You Can Find More Information*."

You should rely only on the information contained in this prospectus. Neither we nor the selling stockholders have authorized anyone to provide you with different or additional information. If anyone provides you with different or inconsistent information, you should not rely on it. Neither we nor the selling stockholders are making an offer to sell our Common Stock in any jurisdiction where the offer or sale thereof is not permitted. You should not assume that the information appearing in this prospectus or the documents incorporated by reference herein is accurate as of any date other than their respective dates. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read carefully the entirety of this prospectus before making an investment decision.

Unless the context otherwise requires, the words "*Innovus Pharmaceuticals, Inc.,*" "*Innovus Pharma*," "*Innovus*," "*we*," "*the Company*," "*us*" and "*our*" refer to Innovus Pharmaceuticals, Inc., a Nevada corporation.

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PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision in our securities. Before deciding to invest in our securities, you should read this entire prospectus carefully, including our financial statements and the related notes included in this prospectus and the information set forth under the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

In order to facilitate the listing of our Common Stock on the Nasdaq Capital Market and to ensure that we have a sufficient number of authorized shares of Common Stock available for issuance upon the conversion and exercise of all of our derivative securities, we intend, subject to stockholder approval, to effect a reverse stock split of our issued and outstanding shares Common Stock, but not the number of shares authorized for issuance under our Amended and Restated Articles of Incorporation ("Charter") (the "Reverse Split"). On January 7, 2019, we filed a preliminary consent solicitation statement pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, with the SEC in order to solicit the consent of our stockholders to approve an amendment to our Charter to effect the Reverse Split. Assuming we obtain the requisite stockholder consent, the exact ratio of the Reverse Split shall be determined by our Board of Directors, in its sole discretion, but it shall not exceed a ratio of 1-for-200. The Reverse Split will not be effected prior to at least 30 days after the registration statement, of which this prospectus forms a part, is declared effective, if at all. Therefore, in this prospectus, all share and per share amounts have been calculated on a pre-split basis.

Our Company

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

Our business model leverages our ability to (i) develop and build our current pipeline of proprietary products, and (ii) to acquire outright or in-license commercial products that are supported by scientific and/or clinical evidence, place

them through our existing supply chain, retail and on-line (including our Amazon®, eBay®, Wish.com, Sears.com, Walmart.com®, Newegg.com, Bonanza.com, Alibaba.com and Walgreens.com on-line stores and other e-commerce business platforms) channels to tap new markets and drive demand for such products and to establish physician relationships. We currently have 34 products marketed in the United States with 12 of those being marketed and sold in multiple countries around the world through some of our 15 international commercial partners.

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: (i) the introduction of line extensions and reformulations of either our or third-party currently marketed products; (ii) the development of new proprietary OTC products, supplements and devices; and (iii) 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®, Newegg.com, eBay®, Wish.com, Sears.com, Walmart.com®, Bonanza.com, Alibaba.com and Walgreens.com, and commercial partnerships with established international complimentary partners that: (i) generate revenue, and (ii) require a lower cost structure compared to traditional pharmaceutical companies, thereby increasing our gross margins.

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Our Products

We currently market and sell 34 products in the U.S. and 12 in multiple countries around the world through our 15 international commercial partners. Although we generate revenue from the sale of all of our commercial products, most revenue is currently generated by UriVarx®, Apeaz®, Vesele®, Diabasens™, Sensum+®, ProstaGorx®, Zestra®, Zestra® Glide, RecalMax™, FlutiCare®, AllerVarx®, ArthriVarx®, Xyralid®, PEVarx®, and Beyond Human® Testosterone Booster and related products.

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

1. Carvanum™ for indications for muscle soreness (first quarter 2019);
2. MZS Sleeping Aid™ with hemp-derived oil (first quarter 2019);
3. Trexar™ for neuropathy support and enhanced sensation (first quarter 2019);
4. Musclin™ for muscle growth (second half 2019 pending clinical trial data);
5. Optik, an OTC monograph compliant ophthalmic product for eye redness and dryness (second half 2019);
6. Regenerum™ for muscle wasting or cachexia (second half 2020 pending clinical trial data); and
7. ThermoMax® for hand warming relief (first half 2019).

On October 18, 2018, we announced our plans to expand our product line into the hemp-derived oil-based products market commencing with the introduction of MZS Sleeping Aid™, a supplement in tincture form containing hemp-derived oil. This product does not contain any THC (Tetrahydrocannabinol) and is designed to be compliant with applicable U.S. state and federal laws. We expect to launch the product in certain states within the United States initially, and eventually, pending regulatory approval, expand into the Canadian market, although no assurances can be given. Further, we may expand into other products using hemp-derived oil in the future, although we do not currently have any specific plans to do so.

Sales and Marketing Strategy U.S. and Internationally

Our sales and marketing strategy is based on (i) the use of direct to consumer advertisements in print and online media through our proprietary Beyond Human™ sales and marketing platform acquired in March 2016, which in addition to the print and direct mail includes extensive on-line media channels through our Amazon®, eBay®, Wish.com, Sears.com, Walgreens.com and Walmart.com® sites, over 170 websites and over 2.5 million subscribers, (ii) working with direct retail and wholesale commercial channel partners in the U.S. and also directly marketing the products ourselves to physicians, urologists, gynecologists and therapists and to other healthcare providers, and (iii) working with exclusive commercial partners outside of the U.S. that would be responsible for sales and marketing in those

territories. We have now fully integrated most of our existing line of products such as Diabasens™, Vesele®, Sensum+®, UriVarx®, Zestra®, RecalMax™, Xyralid®, FlutiCare®, Apeaz® and other products into the Beyond Human™ sales and marketing platform. We plan to integrate other products upon their commercial launches in 2019. We also market and distribute our products in the U.S. through retailers, wholesalers and other online channels. Our strategy outside the U.S. is to partner with companies who can effectively market and sell our products in their countries through their direct marketing and sales teams. The strategy of using our partners to commercialize our products is designed to limit our expenses and fix our cost structure, enabling us to increase our reach while minimizing our incremental spending.

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Our current OTC, Rx-to-OTC ANDA switch drugs and consumer care products marketing strategy is to focus on five main U.S. markets, each of which we believe to be in excess of $1.0 billion: (i) sexual health (female and male sexual dysfunction and health); (ii) urology (bladder and prostate health); (iii) respiratory disease; (iv) brain health; and (v) pain. We will focus our current efforts on these five markets and will seek to develop, acquire or license products that we can sell through our sales channels in these fields.

Acquisition and Licensing Strategy

Our acquisition and licensing strategy is to acquire or in-license products that fit our commercialization strategy that are branded, with growing market shares, that can be sold direct to consumers and through our on-line partnerships and that can then be sold internationally through our commercial partnerships.

The following represents products and product candidates we have successfully acquired:

1. Zestra® and Zestra Glide® (acquired Semprae Laboratories, Inc. in 2013 - current Innovus subsidiary);
2. Vesele® (from Trophikos, Inc. in 2014);
3. Sensum+® (from Centric Research Institute in 2013);
4. FlutiCare™ (acquired Novalere, Inc. in 2015, current Innovus Pharma subsidiary);
   Beyond Human® Testosterone Booster; Beyond Human® Human Growth Agent; Beyond Human® Ketones;
5. Beyond Human® Krill Oil; Beyond Human® Omega 3 Fish Oil; Beyond Human® Vision Formula; Beyond Human® Blood Sugar; and Beyond Human® Colon Cleanse (acquired Beyond Human™ assets in 2016); and
6 HealthiFeet®, ThermoMax® (two strengths) and Breastlift™ (from Boston Topicals, LLC in 2018).

The following represents the products we have in-licensed from third parties:

1. Androferti® (from Q Pharma in 2015);
2. AllerVarx™ (from NTC Pharma in 2016); and
3. UriVaRx® (from Seipel Pty. Ltd. 2015).

In addition, we have developed and repurposed Xyralid®™ for the relief of the pain and symptoms caused by hemorrhoids.

We currently have 15 partnerships that have the rights to sell certain of our current products in approximately 49 countries. Our international partners include the following companies:

1. Orimed Pharma, the OTC subsidiary of Jamp Pharma (Canada);
2. Acerus Pharmaceuticals, Inc. (Canada);
3. DanaLife ApS (Denmark and in alternative markets);
4. Tramorgan (U.K.);
5. Sothema Laboratories (MENA);
6. Ovation Pharma (Morocco);
7. LaVasta Pharmaceuticals (MENA);
8. BroadMed (Lebanon);
9. Elis Pharmaceuticals (Lebanon);
10. BioTask (Malaysia);
11. Oz Biogenics (Myanmar and Vietnam);
12. Khandelwal Laboratories (India);
13. PT Resources (Select Asian Countries);
14. BroadMed (Lebanon); and
15. J&H Co. LTD (South Korea).

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Corporate Information

We are incorporated in the state of Nevada. Our principal place of business is located at 8845 Rehco Road, San Diego, California 92121. Our telephone number is (858) 964-5123. We maintain a corporate website at https://innovuspharma.com/. The information contained on our website is not, and should not be interpreted to be, a part of this prospectus.

Risks Related to our Business

Our ability to implement our business strategy is subject to numerous risks, as more fully described in the section entitled "*Risk Factors*" immediately following this prospectus summary. These risks include, among others:

We have a short operating history and have not produced significant revenues from our operations;

We have a history of operating losses, including an accumulated deficit of approximately $41.7 million at September 30, 2018, which will likely continue in the future;

The success of our business currently depends on market acceptance of all 34 of our products, but also on our top revenue generating products: UriVarx®, Apeaz®, Vesele®, Diabasens™, Sensum+®, ProstaGorx®, Zestra®, Zestra® Glide, RecalMax™, FlutiCare®, AllerVarx®, ArthriVarx®, Xyralid®, PEVarx®, and Beyond Human® Testosterone Booster and related products™, that accounted for approximately 95% of our annual net revenue during the nine months ended September 30, 2018. No customer accounted for more than 10% of total net revenue during that period;

We have no commercial manufacturing capacity and rely on third-party contract manufacturers to produce commercial quantities of our products;

We face significant competition and have limited resources compared to many of our competitors;

If we fail to protect our intellectual property rights, such as patents and trademarks, our ability to pursue the development of our technologies and products would be negatively affected;

We may not be able to raise the levels of financing required to market and sell many of our products;

We may not be able to grow effectively and retain or hire the necessary talent to increase our sales;

We may not be able to grow internationally to the extent we would like due to regulatory, political, or economic changes in such countries;

We are currently very reliant on the experience, knowledge, skills and actions of our President and Chief Executive Officer, Dr. Bassam Damaj;

We may not be able to acquire or license the necessary products required for us to grow effectively and increase our product revenue;

We may face an uncertain U.S. regulatory, political and economic environment;

Changes in federal and state law and regulations regarding the sale and production of products containing hemp-derived oil could impact our ability to produce and sell products containing hemp-derived oil in the future, including by making such activities illegal; and

Our liquidity.

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Private Placement

On December 30, 2018, we entered into a Securities Purchase Agreement ("*SPA*") with an accredited investor (the "*Investor*"), pursuant to which, on January 3, 2019 (the "*Closing Date*"), we sold an aggregate of 45,306,347 units ("*Units*") for $0.07 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 $0.07 per share ("*Series A Warrant*"), and (iii) one warrant to purchase one share of Common Stock at an exercise price of $0.08 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 Common Stock, the Investor elected to exercise its right to purchase 21,066,844 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 $0.001 per share. In addition, we issued Series B Warrants to purchase 3,397,976 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 $0.0875 per share (the "*Placement Agent Warrants*") to the designees of H.C. Wainwright & Co., LLC (the "*Placement Agent*"), our 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 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, we 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. We have also agreed to register the shares of Common Stock underling the Placement Agent Warrants issued to the Placement Agent's designees as compensation for its services in connection with the Private Placement.

Our Reverse Stock Split

We have submitted an application to have our Common Stock listed on the Nasdaq Capital Market under the symbol INNV, although no assurances may be given with respect to if or when our application will be approved. On January 4, 2019, our Board of Directors approved the consummation of a reverse stock split of our issued and outstanding shares Common Stock, but not the number of shares authorized for issuance under our Charter, at a ratio of up to 1-for-200 in order to facilitate the listing of our Common Stock on the Nasdaq Capital Market and to provide us with additional authorized shares of Common Stock, which is currently necessary in order to ensure that we have sufficient shares of Common Stock available for issuance upon the conversion and exercise of our outstanding derivative securities, including the Investor Warrants and Placement Agent Warrants. On January 7, 2019, we filed a preliminary consent solicitation statement pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, with the SEC in order to solicit the consent of our stockholders to approve an amendment to our Charter to effect the Reverse Split. Assuming we obtain the requisite stockholder consent, the exact ratio of the Reverse Split shall be determined by our Board of Directors, in its sole discretion, but it shall not exceed a ratio of 1-for-200. No fractional shares of Common Stock will be issued in connection with the Reverse Split, and all such fractional interests will be rounded up to the nearest whole number. Issued and outstanding stock options and warrants will be split on the same basis and exercise prices will be adjusted accordingly.

Pursuant to the SPA executed in connection with the Private Placement, the Reverse Split will not be effected prior to at least 30 days after the registration statement, of which this prospectus forms a part, is declared effective, if at all. Therefore, in this prospectus, all share and per share amounts have been calculated on a pre-split basis.

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The Offering

The following summary contains general information about this offering. The summary is not intended to be complete. You should read the full text and more specific details contained elsewhere in this prospectus.

Common Stock being offered by the selling stockholders	Up to 139,317,017 shares.
Common Stock outstanding as of January 14, 2019 (1)	244,839,264 shares
Use of Proceeds	The selling stockholders will receive all of the proceeds from the sale of the shares of Common Stock offered for sale under this prospectus. We will not receive any proceeds from the sale of shares of our Common Stock by the selling stockholders. However, we may receive approximately $7.1 million in proceeds from the exercise of the warrants sold and issued in the Private Placement, including the Investor Warrants and Placement Agent Warrants. We anticipate that proceeds that we receive from the exercise of such warrants, if any, will be used for working capital and general corporate purposes.
Plan of Distribution	The selling stockholders may sell the shares of Common Stock from time to time on the principal market on which the shares of Common Stock are traded at the prevailing market price or in negotiated transactions. See "*Plan of Distribution*."
Risk Factors	An investment in our securities involves a high degree of risk. See the section entitled "*Risk Factors*" for a discussion of factors you should consider carefully before making an investment decision.
OTCQB Marketplace Symbol	INNV

(1) The number of shares of our Common Stock outstanding is based on 244,839,264 shares of Common Stock outstanding as of January 14, 2019, and excludes:

115,077,514 shares of Common Stock issuable upon the exercise of the Investor Warrants and Placement Agent Warrants issued in connection with the Private Placement;
33,544,157 shares of Common Stock issuable upon the exercise of warrants outstanding as of January 14, 2019 at a weighted average exercise price of $0.19 per share;
449,000 shares of Common Stock issuable upon the exercise of options outstanding as of January 14, 2019 at a weighted average exercise price of $0.14 per share;
18,787,607 shares of Common Stock issuable upon the exercise of restricted stock units as of January 14, 2019; and

an aggregate of 13,869,424 shares of Common Stock reserved for issuance under our Amended and Restated 2016 Equity Incentive Plan, 2014 Equity Incentive Plan and 2013 Equity Incentive Plan.

Unless otherwise indicated, all information in this prospectus assumes no exercise of the outstanding warrants or outstanding stock options, as described above.

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RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our securities. The occurrence of any of the events or developments described below could harm our business, financial condition, operating results, and growth prospects. In such an event, the market price of our securities could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

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 September 30, 2018, we had an accumulated deficit of approximately $41.7 million. In addition, we incurred net losses of approximately $6.1 million for the nine months ended September 30, 2018, and $6.5 million and $13.7 million for the years ended December 31, 2017 and 2016, respectively. These losses may continue in the future. We expect to continue to incur significant sales and marketing, research and development, and general and administrative expense. As a result, we will need to generate significant revenue to achieve profitability, and we may never achieve profitability. Revenue and profit, if any, will depend upon various factors, including, among other things, (i) growing the current sales of our products, (ii) the successful acquisition of additional commercial products, (iii) raising capital to implement our growth strategy, (iv) obtaining any applicable regulatory approvals of our proposed product candidates, (v) the successful licensing and commercialization of our proposed product candidates, and (vi) 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 September 30, 2018, we had $703,012 in cash. We had a net loss of approximately $6.1 million for the nine months ended September 30, 2018, and $6.5 million and $13.7 million for the years ended December 31, 2017 and 2016, respectively. Additionally, sales of our existing products are significantly below the levels necessary to achieve positive cash flow. Although we expect that our existing capital resources and revenue from sales of our products will be sufficient to allow us to continue our operations, commence the product development process and launch selected products through at least January 14, 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 Charter currently authorizes 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.

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

We have historically funded our operations partly through the issuance of debt and equity 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.

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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.

Risks Associated with Our Business Model

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

We have a short operating history with our current business model, which involves the commercialization, licensing and development of over-the-counter healthcare products. Although we have been in existence for many years, we only began our current business model in 2013 and only generated approximately $1.0 million in net revenue in 2014, approximately $736,000 in 2015, approximately $4.8 million in 2016, $8.8 million in 2017, and approximately $19.2 million for the nine months ended September 30, 2018, and our operations have not yet been profitable. No assurances can be given that we will generate any significant revenue in the future. As a result, we have a very limited operating history for you to evaluate in assessing our future prospects. Our operations have not produced significant revenue over a period of time and may not produce significant revenue in the near term, which may harm our ability to obtain additional financing and may require us to reduce or discontinue our operations. You must consider our business and prospects in light of the risks and difficulties we will encounter as an early-stage company. We may not be able to successfully address these risks and difficulties, which could significantly harm our business, operating results and financial condition.

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 within the U.S.

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

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

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

Governmental 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.

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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.

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

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

Our sales and marketing function is currently 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 had approximately $4.8 million in net revenue in 2016, approximately $8.8 million during the year ended December 31, 2017 and approximately $19.2 million during the nine months ended September 30, 2018. While we are growing our revenue and our distribution channels, 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.

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

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

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

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

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.

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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 securities, 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 affects us, such as unknown or contingent liabilities and liabilities related to compliance with applicable laws. Any such liabilities, individually or in the aggregate, could have a material adverse effect on our business.

Failure to successfully manage the operational challenges and risks associated with, or resulting from, acquisitions could adversely affect our results of operations, cash flows and liquidity. Borrowings or issuances of convertible

securities associated with these acquisitions may also result in higher levels of indebtedness, which could impact our ability to service our debt within the scheduled repayment terms.

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

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

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

Successfully grow our marketing, distribution and sales infrastructure; and

Continue to improve our operational, manufacturing, financial and management controls, reporting systems and procedures.

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If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

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

Our success depends to a significant extent upon the continued services of Dr. Bassam Damaj, our President and Chief Executive Officer. Dr. Damaj has overseen our current business strategy since inception and provides leadership for our growth and operations strategy as well as being our sole employee with any significant scientific or pharmaceutical experience. Loss of the services of Dr. Damaj would have a material adverse effect on our growth, 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.

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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. Although extensions of patent term due to regulatory delays may be available, it is possible that, before any of our products candidates can be commercialized, any related patent, even with an extension, may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent.

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

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

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

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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/or forced to 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.

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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 34 products on the market in the U.S. and have growing revenue, from time to time, we may face product liability litigation and/or other litigation owing to the manner that we market and sell certain of our products, such as through nationwide newspaper advertisements, direct mailing or other direct to consumer campaigns. If we are unsuccessful in defending claims brought against us, such as those brought in the case described in the section entitled "*Legal Proceedings*" located in "*Management's Discussion and Analysis of Financial Condition and Results of Operation*," the result could have a material impact on the profit and losses of the Company.

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

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

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

The FDA regulates most of our OTC or non-prescription drugs using its OTC Monograph, which when final, is published in the Code of Federal Regulations at 21 CFR Parts 330-358. Those of our products that meet each of the 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 no active 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.

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Sales of additional shares of our Common Stock could cause the price of our Common Stock to decline.

As of January 14, 2019, we had 244,839,264 shares of Common Stock outstanding. A substantial number of those shares are restricted securities and such shares may be sold under Rule 144 of the Securities Act of 1933, as amended ("*Securities Act*"), subject to any applicable holding period. As such, sales of the above shares or other substantial amounts of our Common Stock in the public or private markets, or the availability of such shares for sale by us, including the issuance of Common Stock upon conversion and/or exercise of outstanding convertible securities, warrants and options, could adversely affect the price of our Common Stock. We may sell additional shares or securities convertible into shares of Common Stock, which could adversely affect the market price of shares of our Common Stock. In addition, the sale of a substantial number of shares of our Common Stock, or anticipation of such sales, could make it more difficult for us to obtain future financing. To the extent the trading price of our Common Stock at the time of exercise of any of our outstanding options or warrants exceeds their exercise price, such exercise will have a dilutive effect on our stockholders.

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

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

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

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

Changes in state and federal laws and regulations with respect to the sale and production of hemp-derived oils;

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;

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- Developments involving corporate collaborators, if any;

- Changes in accounting principles; and

- The loss of any of our key management personnel.

In the past, securities class action litigation has often been brought against companies that experience volatility in the market price of their securities. Whether 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 holders of our Common Stock.

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.

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In addition, the acquisition of controlling interest provisions of the Nevada Revised Statutes provide that a stockholder acquiring a controlling interest in our Company, and those acting in association with that stockholder, obtain no voting rights in the control shares unless voting rights are conferred by stockholders holding a majority of our voting power (exclusive of the control shares). For purposes of these provisions, “controlling interest” means the ownership of outstanding voting shares enabling the acquiring person to exercise (either directly or indirectly or in association with others) one-fifth or more but less than one-third, one-third or more but less than a majority, or a majority or more of the voting power in the election of our directors, and “control shares” means those shares the stockholder acquired on the date it obtained a controlling interest or in the 90-day period preceding that date.

Accordingly, the provisions could require multiple votes with respect to voting rights in share acquisitions effected in separate stages, and the effect of these provisions may be to discourage, delay or prevent a change in control of our Company.

The rights of the holders of Common Stock may be impaired by the potential issuance of preferred stock.

Our 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.

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.

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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.

Risks Relating to the Reverse Split

If we are unable to obtain sufficient consents from our stockholders to approve the Reverse Split, we will continue to have an insufficient number of shares of Common Stock available for issuance upon the conversion of our outstanding securities and will be limited in our ability to issue additional equity securities in the future.

Our Charter currently authorizes the issuance of up to 292.5 million shares of Common Stock and up to 7.5 million shares of preferred stock. As of January 14, 2019, we had 244,839,264 shares of Common Stock outstanding, and were obligated to reserve an additional 168,376,486 shares of Common Stock for issuance upon our outstanding derivative securities. As a result, the number of shares of Common Stock currently outstanding in addition to the number of shares of Common Stock that we are obligated to reserve for issuance exceed our authorized Common Stock by approximately 120,715,750 shares. Therefore, we currently do not have sufficient authorized but unissued shares of Common Stock to permit the conversion and exercise of all of our outstanding derivative securities, and unless we are able to effect the Reverse Split or increase the number of shares that we have authorized for issuance through other means, we will continue to have insufficient shares authorized to do so. In addition, in the event that we are unable to obtain sufficient stockholder consent to effectuate the Reverse Split, we will not be able to issue any additional shares of Common Stock in the future, preventing us from taking advantage of any opportunities to raise additional working capital or otherwise consummate strategic or other transactions that require the issuance of Common Stock.

Our planned Reverse Split may not increase our stock price sufficiently to enable us to list our Common Stock on the Nasdaq Capital Market.

We currently expect that the Reverse Split of our outstanding Common Stock will increase the market price of our Common Stock sufficiently so that we will be able to meet the minimum bid price requirement portion of listing requirements of the Nasdaq Capital Market. However, the effect of the Reverse Split upon the market price of our Common Stock cannot be predicted with certainty, and the results of reverse stock splits by companies in similar circumstances have been varied. It is possible that the market price of our Common Stock following the Reverse Split will not increase sufficiently for us to be in compliance with the minimum bid price requirement, or if it does, that such price will be sustained. If we are unable meet the minimum listing requirements, we will be unable to list our shares on the Nasdaq Capital Market.

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Even if the Reverse Split achieves the requisite increase in the market price of our Common Stock, we cannot assure you that we will be able to continue to comply with the minimum bid price requirement of the Nasdaq Capital Market.

Even if the Reverse Split achieves the requisite increase in the market price of our Common Stock to be in compliance with the minimum bid price of the Nasdaq Capital Market, we cannot assure you that the market price of our Common Stock following the Reverse Split will remain at the level required for continuing compliance with that requirement. It is not uncommon for the market price of a company's common stock to decline in the period following a reverse stock split. If the market price of our Common Stock declines following the effectuation of the Reverse Split, the percentage decline may be greater than would occur in the absence of a reverse stock split. In any event, other factors unrelated to the number of shares of our Common Stock outstanding, such as negative financial or operational results, could adversely affect the market price of our Common Stock and jeopardize our ability to meet or maintain the Nasdaq Capital Market's minimum bid price requirement. In addition to specific listing and maintenance standards, the Nasdaq Capital Market has broad discretionary authority over the initial and continued listing of securities, which it could exercise with respect to the listing of our Common Stock.

Even if the Reverse Split increases the market price of our Common Stock, there can be no assurance that we will be able to comply with other continued listing standards of the Nasdaq Capital Market.

Even if the market price of our Common Stock increases sufficiently so that we comply with the minimum bid price requirement, we cannot assure you that we will be able to comply with the other standards that we are required to meet in order to maintain a listing of our Common Stock on the Nasdaq Capital Market. Assuming that our listing application is approved after the Reverse Stock Split, our failure to meet these other requirements may result in our Common Stock being delisted from the Nasdaq Capital Market, irrespective of our compliance with the minimum bid price requirement.

The Reverse Split may decrease the liquidity of the shares of our Common Stock.

The liquidity of the shares of our Common Stock may be affected adversely by the Reverse Split given the reduced number of shares that will be outstanding following the Reverse Split, especially if the market price of our Common Stock does not increase following the Reverse Split. In addition, the Reverse Split may increase the number of stockholders who own odd lots (less than 100 shares) of our Common Stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales.

Following the Reverse Split, the resulting market price of our Common Stock may not attract new investors, including institutional investors, and may not satisfy the investing requirements of those investors. Consequently,

the trading liquidity of our Common Stock may not improve.

Although we believe that a higher market price of our Common Stock may help generate greater or broader investor interest, there can be no assurance that the Reverse Split will result in a share price that will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of our Common Stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of our Common Stock may not necessarily improve.

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SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION

This prospectus includes forward-looking statements. All statements, other than statements of historical fact, contained in this prospectus, including statements regarding our future operating results, financial position and cash flows, our business strategy and plans and our objectives for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "believe," "may," "will," "estimate," "continue," "anticipate," "plan," "target," "project," "contemplate," "predict," "potential," "would," "could," "should," "intend" and "expect" or the negative of these terms or other similar expressions.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, operating results, business strategy, short-term and long-term business operations and objectives. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions, including those described under sections in this prospectus entitled "*Risk Factors*" and "*Management's Discussion and Analysis of Financial Condition and Results of Operations,*" and elsewhere in this prospectus. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors and uncertainties may emerge from time to time. It is not possible for our management to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance and events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assume responsibility for the accuracy and completeness of the forward-looking statements. Except as required by applicable law, we undertake no obligation to update publicly or revise any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations, whether as a result of any new information, future events, changed circumstances or otherwise.

This prospectus contains estimates and statistical data that we obtained from industry publications and reports. These publications generally indicate that they have obtained their information from sources believed to be reliable, but do not guarantee the accuracy and completeness of their information, and you are cautioned not to give undue weight to such estimates. Although we believe the publications are reliable, we have not independently verified their data. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

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DESCRIPTION OF PRIVATE PLACEMENT TRANSACTION

On December 30, 2018, we entered into a Securities Purchase Agreement ("*SPA*") with an accredited investor (the "*Investor*"), pursuant to which, on January 3, 2019 (the "*Closing Date*"), we sold an aggregate of 45,306,347 units ("*Units*") for $0.07 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 $0.07 per share ("*Series A Warrant*"), and (iii) one warrant to purchase one share of Common Stock at an exercise price of $0.08 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 Common Stock, the Investor elected to exercise its right to purchase 21,066,844 prefunded warrants ("*Series C Warrants*," and together with the Series A 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 $0.001 per share. In addition, we issued Series B Warrants to purchase 3,397,976 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 $0.0875 per share (the "*Placement Agent Warrants*") to the designees of H.C. Wainwright & Co., LLC (the "*Placement Agent*"), our 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 (the "*Issuance Restrictions*") equal to the number of authorized and unreserved shares of 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. Pursuant to the Issuance Restrictions, until the Reverse Split has been effected, the Investor may not require the Company to issue upon exercise of the Investor Warrants a number of shares of Common Stock, which, when aggregated with any shares of Common Stock issued (i) pursuant to the SPA, (ii) upon prior exercise of any Investor Warrants, and (iii) pursuant to any Placement Agent Warrants issued as a fee in connection with the Private Placement would exceed 45,306,347 shares (the "*Issuable Maximum*"). 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 days 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.

The Private Placement resulted in gross proceeds to the Company of approximately $3.17 million, and net proceeds to the Company of approximately $2.79 million, after deducting the Placement Agent's commissions, fees and expenses and the Company's offering expenses. We currently expect to use the proceeds for, among other purposes, general working capital purposes.

In connection with the sale of the Units, we 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. We have also agreed to register the shares of Common Stock underling the Placement Agent Warrants issued to the designees of the Placement Agent as compensation for its services in connection with the Private Placement.

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USE OF PROCEEDS

The Common Stock to be offered and sold using this prospectus will be offered and sold by the selling stockholders named in this prospectus. Accordingly, we will not receive any proceeds from any sale of shares of our Common Stock in this offering. A portion of the shares covered by this prospectus may be issued upon exercise of the Investor Warrants and Placement Agent Warrants. Upon any exercise of Investor Warrants and the Placement Agent Warrants, the selling stockholders will pay us the applicable exercise price, and we currently anticipate that any such proceeds would be used primarily for working capital and general corporate purposes. We will pay all of the fees and expenses incurred by us in connection with this registration. We will not be responsible for fees and expenses incurred by the selling stockholders or any underwriting discounts or agent’s commissions.

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SELLING STOCKHOLDERS

This prospectus relates to the sale from time to time by the selling stockholders of up to 139,317,017 shares of our Common Stock, which consists of up to (i) 24,239,503 shares of Common Stock issued in the Private Placement; (ii) 111,679,538 shares of Common Stock issuable upon exercise of the Investor Warrants issued in connection with the Private Placement, which includes 45,306,347, 45,306,347 and 21,066,844 shares of Common Stock issuable upon exercise of the Series A Warrants, Series B Warrants and Series C Warrants, respectively; and (iii) up to 3,397,976 shares of Common Stock issuable upon exercise of the Placement Agent Warrants issued to the designees of H.C. Wainwright & Co., LLC, the Placement Agent, as compensation for its services in connection with the Private Placement. When we refer to the "selling stockholders" in this prospectus, we mean the persons and entities listed in the table below, and their respective pledgees, donees, permitted transferees, assignees, successors and others who later come to hold any of the selling stockholders' interests in shares of our Common Stock other than through a public sale.

Selling Stockholders Table

The table below presents information as of January 14, 2019, regarding the selling stockholders and the shares of Common Stock that the selling stockholders may offer and sell from time to time under this prospectus. More specifically, the following table sets forth as to the selling stockholders:

- the number of shares of our Common Stock that the selling stockholders beneficially owned prior to this offering;
- the total number of shares of our Common Stock that the selling stockholders may offer for resale pursuant to this prospectus; and
- the number and percent of shares of our Common Stock beneficially held by the selling stockholders after this offering, assuming all of the resale shares of Common Stock are sold by the selling stockholders and that the selling stockholders do not acquire any additional shares of our Common Stock prior to their assumed sale of all of the resale shares.

The table was prepared based on information supplied to us by the selling stockholders. Although we have assumed for purposes of the table below that the selling stockholders will sell all of the securities offered by this prospectus, because the selling stockholders may offer from time to time all or some of their securities covered under this prospectus, or in another permitted manner, no assurances can be given as to the actual number of securities that will be resold by the selling stockholders or that will be held by the selling stockholders after completion of the resales. The selling stockholders may sell all, some or none of their securities offered by this prospectus. In addition, the selling stockholders may have sold, transferred or otherwise disposed of the securities in transactions exempt from the registration requirements of the Securities Act of 1933, as amended (the "*Securities Act*"), since the date the selling

stockholders provided the information regarding their securities holdings. Information covering the selling stockholders may change from time to time and changed information will be presented in a supplement to this prospectus if and when necessary and required.

Except as described above, including with respect to the Issuance Restrictions and Beneficial Ownership Limitation, there are currently no agreements, arrangements or understandings with respect to the resale of any of the securities covered by this prospectus.

The applicable percentages of ownership are based on an aggregate of 244,839,264 shares of our Common Stock issued and outstanding on January 14, 2019. The number of shares Common Stock beneficially owned by the selling stockholders is determined under rules promulgated by the SEC.

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Name of Selling Security Holder	Shares Beneficially Owned Prior to Offering (2) (3)	Maximum Number of Shares Being Offered Pursuant to this Prospectus				Shares Beneficially Owned After Offering (1)		
		Common Stock	Shares Issuable Upon Exercise of Series A Warrants	Shares Issuable Upon Exercise of Series B Warrants	Shares Issuable Upon Exercise of Series C Warrants	Number	Percent	
Armistice Capital Master Fund Ltd. (4)	24,239,503(5)	24,239,503	45,306,347	45,306,347	21,066,844	8,000,000	2.1	%
Charles Worthman (6)	52,013	-	-	33,980	-	18,033	*	
Mark Viklund (7)	140,439	-	-	101,939	-	38,500	*	
Michael Vasinkevich (8)	3,151,965	-	-	2,191,695	-	960,270	*	
Noam Rubinstein (9)	1,474,612	-	-	1,070,362	-	404,250	*	

* Less than 1%.

(1) Beneficial ownership of the selling stockholders after the offering assumes (i) the selling stockholders have the ability to exercise all Investor Warrants and Placement Agent Warrants, despite the Beneficial Ownership Limitation and Issuance Restrictions, as more specifically set forth in the section of this prospectus entitled "*Description of Private Placement*," (ii) the exercise of all Investor Warrants or Placement Agent Warrants held by the selling stockholders, and (iii) that each selling stockholder will sell all of the shares of Common Stock offered by it under this prospectus, including all shares of Common Stock that may be issued upon the exercise of the Investor Warrants and Placement Agent Warrants identified herein. In calculating the percent of shares beneficially owned by each selling stockholder after the offering, it also assumes that only such selling stockholder's derivative securities, including the Investor Warrants and/or Placement Agent Warrants, were exercised, and as a consequence, the number of issued and outstanding shares used to calculate percent ownership was increased by the number of shares of Common Stock issuable upon the exercise of such derivative securities held by such selling stockholder.

(2) Includes shares of Common Stock owned prior to the Private Placement, including shares of Common Stock issuable upon the exercise of certain derivative securities, which shares are not being offered pursuant to this prospectus.

(3) Includes shares of Common Stock and shares of Common Stock issuable upon exercise of the Placement Agent Warrants, including those that may not currently be exercised as a result of the Issuance Restrictions, issued in connection with the Private Placement.

(4) Armistice Capital, LLC, the investment manager of Armistice Capital Master Fund Ltd. ("*Armistice*"), and Steven J. Boyd, the managing member of Armistice Capital, LLC, hold shared voting and dispositive power over the shares of Common Stock held by Armistice. The principal business address of Armistice is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY, 10022.

(5) Includes 24,239,503 shares of Common Stock issued to Armistice in the Private Placement. Does not include 119,679,538 shares of Common Stock underlying warrants held by Armistice as of January 14, 2019, consisting of (i) 8,000,000 shares of Common Stock issuable upon a warrant that was previously issued to Armistice, and which shares are not being offered pursuant to this prospectus; (ii) 45,306,347 shares of Common Stock issuable upon exercise of Series A Warrants; (iii) 45,306,347 shares of Common Stock issuable upon exercise of Series B Warrants; (iv) and 21,066,844 shares of Common Stock issuable upon exercise of Series C Warrants. Each of the warrants included in this footnote contains a 4.99% beneficial ownership limitation, which may be increased up to 9.99% at the sole option of Armistice upon 61 days prior notice to the Company, and which prevents Armistice from exercising such warrants in the event such exercise would cause Armistice's beneficial ownership of the Company's outstanding shares of Common Stock to exceed the Beneficial Ownership Limitation. In addition, each of the warrants is subject to the Issuance Restrictions, as set forth in the section of this prospectus entitled "*Description of Private Placement Transaction.*" As a result, the warrants included herein may not be exercised within 60 days from January 14, 2019, and therefore are not included in the shares beneficially owned by Armistice prior to the offering.

(6) Mr. Worthman, a designee of the Placement Agent, received Placement Agent Warrants in connection with the Private Placement. Mr. Worthman's address is c/o H.C. Wainwright & Co., LLC, 430 Park Avenue, New York, New York 10022.

(7) Mr. Viklund, a designee of the Placement Agent, received Placement Agent Warrants in connection with the Private Placement. Mr. Viklund's address is c/o H.C. Wainwright & Co., LLC, 430 Park Avenue, New York, New York 10022.

(8) Mr. Vasinkevich, a designee of the Placement Agent, received Placement Agent Warrants in connection with the Private Placement. Mr. Vaseinkevich's address is c/o H.C. Wainwright & Co., LLC, 430 Park Avenue, New York, New York 10022.

(9) Mr. Rubinstein, a designee of the Placement Agent, received Placement Agent Warrants in connection with the Private Placement. Mr. Rubinstein's address is c/o H.C. Wainwright & Co., LLC, 430 Park Avenue, New York, New York 10022.

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PLAN OF DISTRIBUTION

Each selling stockholder of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the OTCQB Marketplace or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the selling stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The selling stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

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We are required to pay certain fees and expenses incurred by us incident to the registration of the securities. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the selling stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

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MARKET PRICE OF OUR COMMON STOCK AND OTHER STOCKHOLDER MATTERS

Market Information

Our Common Stock is currently quoted on the OTCQB Marketplace under the symbol "INNV." The last reported sale price of our Common Stock on January 11, 2019 was $0.067 per share.

The high and low sales prices of our Common Stock for the periods indicated are set forth below. These prices do not reflect retail mark-up, markdown or commissions. Such OTCQB Marketplace quotations reflect inter-dealer prices, without markup, markdown or commissions and, particularly because our Common Stock is traded infrequently, may not necessarily represent actual transactions or a liquid trading market.

	High	Low
Year Ending December 31, 2019		
First quarter ended March 31, 2018 (through January 11, 2019)	$0.08	$0.06
Year Ending December 31, 2018		
First quarter ended March 31, 2018	$0.21	$0.08
Second quarter ended June 30, 2018	$0.17	$0.10
Third quarter ended September 30, 2018	$0.18	$0.09
Fourth quarter ended December 31, 2018	$0.12	$0.06
Year Ended December 31, 2017		
First quarter ended March 31, 2017	$0.39	$0.10
Second quarter ended June 30, 2017	$0.15	$0.08
Third quarter ended September 30, 2017	$0.14	$0.09
Fourth quarter ended December 31, 2017	$0.12	$0.08
Year Ended December 31, 2016		
First quarter ended March 31, 2016	$0.10	$0.03
Second quarter ended June 30, 2016	$0.37	$0.05
Third quarter ended September 30, 2016	$0.66	$0.21
Fourth quarter ended December 31, 2016	$0.33	$0.16

Holders

As of January 14, 2019, we had 244,839,264 shares of Common Stock, par value $0.001 per share, issued and outstanding held by approximately 35,000 shareholders of record. Our transfer agent is Issuer Direct Corporation and is located at 1981 Murray Holladay Road, Suite 100 Salt Lake City, UT 84117.

Dividends

We have never declared or paid cash dividends on our Common Stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our Board of Directors and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our Board of Directors may deem relevant.

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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, RSUs and Rights	Weighted-Average Exercise Price of Outstanding Options, RSUs 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	10,604,967	$0.141	(1) 13,869,361
Equity Compensation Plans Not Approved by Security Holders:			
2013 Equity Incentive Plan	1,036,849	$0.157	(1) -
2014 Equity Incentive Plan	8,122,999	$0.31	(1) 63
Total	19,754,815	$0.141	(1) 13,869,424

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

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DESCRIPTION OF SECURITIES

Reverse Stock Split

We have submitted an application to have our Common Stock listed on the Nasdaq Capital Market under the symbol INNV, although no assurances may be given with respect to if or when our application will be approved. In order to facilitate the listing of our Common Stock on the Nasdaq Capital Market and to ensure that we have a sufficient number of authorized shares of Common Stock available for issuance upon the conversion and exercise of all of our derivative securities, we intend, subject to stockholder approval, to effect a reverse stock split of our issued and outstanding shares Common Stock, but not the number of shares authorized for issuance under our Charter. On January 7, 2019, we filed a preliminary consent solicitation statement pursuant to Regulation 14A of the Securities Exchange Act of 1934 with the SEC in order to solicit the consent of our stockholders to approve an amendment to our Charter to effect the Reverse Split. Assuming we obtain the requisite stockholder consent, the exact ratio of the Reverse Split shall be determined by our Board of Directors, in its sole discretion, but it shall not exceed a ratio of 1-for-200. The Reverse Split will not be effected prior to at least 30 days after the registration statement, of which this prospectus forms a part, is declared effective, if at all. Therefore, in this section, all share and per share amounts have been calculated on a pre-split basis.

Common Stock

Our Charter currently authorizes the issuance of 292,500,000 shares of Common Stock, par value $0.001 per share. As of January 14, 2019, 244,839,264 shares of Common Stock were issued and outstanding.

Holders of shares of Common Stock are entitled to one vote for each share on all matters to be voted on by our stockholders, and do not have any cumulative voting rights. Holders of shares of Common Stock are entitled to share ratably in dividends, if any, as may be declared, from time to time by our Board of Directors in its discretion, from funds legally available to be distributed. In the event of a liquidation, dissolution or winding up of the Company, the holders of shares of Common Stock are entitled to share pro rata all assets remaining after payment in full of all liabilities and the prior payment to the preferred stockholders, if any. Holders of Common Stock have no preemptive rights to purchase our Common Stock. There are no conversion rights or redemption or sinking fund provisions with respect to the Common Stock.

Preferred Stock

Our Charter currently authorizes the issuance of 7,500,000 shares of preferred stock, par value $0.001 per share. As of January 14, 2019, we had no shares of preferred stock issued and outstanding.

Our Charter gives our Board of Directors the right to create a new series of preferred stock. In addition, our Board of Directors, subject to the provisions of our Charter and limitations imposed by law, is authorized to: adopt resolutions, issue shares, fix the number of shares, change the number of shares constituting any series, and to provide for the following: (i) voting power; (ii) designations; (iii) preferences; and (iv) relative, participating, optional or other special rights, qualifications, limitations or restrictions, including the following: dividend rights (including whether dividends are cumulative), dividend rates, terms of redemption (including sinking fund provisions), redemption prices, conversion rights, and liquidation preferences of the shares constituting any class or series of the preferred stock. In each of the listed cases, we will not need any further action or vote by the stockholders.

One of the effects of undesignated preferred stock may be to enable the Board of Directors to render more difficult or to discourage an attempt to obtain control of us by means of a tender offer, proxy contest, merger or otherwise, and thereby to protect the continuity of our management. The issuance of shares of preferred stock pursuant to the Board of Director’s authority described above may adversely affect the rights of holders of Common Stock. For example, preferred stock issued by us may rank prior to the Common Stock as to dividend rights, liquidation preference or both, may have full or limited voting rights and may be convertible into shares of Common Stock. Accordingly, the issuance of shares of preferred stock may discourage bids for the Common Stock at a premium or may otherwise adversely affect the market price of the Common Stock.

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Anti-Takeover Provisions and Nevada Laws

The Nevada Revised Statutes contains a provision governing "*Acquisition of Controlling Interest*." A corporation is subject to Nevada's control share law if it has more than 200 shareholders, at least 100 of whom are shareholders of record and residents of Nevada, conduct business in Nevada, or do so through an affiliated corporation. The law focuses on the acquisition of a "controlling interest," which means the ownership of outstanding voting shares sufficient, but for the control share law, to enable the acquiring person to exercise the following proportions of the voting power of the corporation in the election of directors: (i) one-fifth or more, but less than one-third, (ii) one-third or more, but less than a majority, or (iii) a majority or more. The ability to exercise such voting power may be direct or indirect, as well as individual or in association with others.

The effect of the control share law is that the acquiring entity, and those acting in association with it, obtains only such voting rights in the control shares as are conferred by a resolution of the shareholders of the corporation, approved at a special or annual meeting of shareholders. The control share law contemplates that voting rights will be considered only once by the other shareholders. Thus, there is no authority to strip voting rights from the control shares of an acquiring entity once those rights have been approved. If the shareholders do not grant voting rights to the control shares acquired by an acquiring entity, then those shares do not become permanent non-voting shares. The acquiring entity is free to sell its shares to others.

If the buyers of those shares themselves do not acquire a controlling interest, then the control share law does not govern their shares. If control shares are accorded full voting rights and the acquiring entity has acquired control shares with a majority or more of the voting power, then any shareholders of record (other than an acquiring entity) who has not voted in favor of approval of voting rights is entitled to demand fair value for such shareholder's shares. Nevada's control share law may have the effect of discouraging takeovers of the Company.

Our Charter and Bylaws exempt our Common Stock from the control share acquisition act.

In addition to the control share law, Nevada has a business combination law that prohibits certain business combinations between Nevada corporations and "interested shareholders" for three years after the "interested shareholders" first become "interested shareholders," unless the corporation's board of directors approves the combination in advance.

For purposes of Nevada law, an "interested shareholders" is any person who is: (i) the beneficial owner, directly or indirectly, of 10% or more of the voting power of the outstanding voting shares of the corporation, or (ii) an affiliate or associate of the corporation, and at any time within the three previous years was the beneficial owner, directly or indirectly, of 10% or more of the voting power of the then-outstanding shares of the corporation. The definition of the

term “business combination” is sufficiently broad to cover virtually any kind of transaction that would allow a potential acquirer to use the corporation’s assets to finance the acquisition, or otherwise to benefit its own interests rather than the interests of the corporation and its other shareholders.

The effect of Nevada’s business combination law is to discourage parties potentially interested in taking control of our Company from doing so if it cannot obtain the approval of our board of directors.

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BUSINESS

Overview

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

Our business model leverages our ability to (i) develop and build our current pipeline of proprietary products, and (ii) to 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 channels (including our Amazon®, eBay®, Wish.com, Sears.com, Walmart.com®, Newegg.com, Bonanza.com, Alibaba.com and Walgreens.com on-line stores and other e-commerce business platforms) to tap new markets and drive demand for such products and to establish physician relationships. We currently have 34 products marketed in the United States with 12 of those being marketed and sold in multiple countries around the world through some of our 15 international commercial partners. We currently expect to launch an additional six products in the U.S. in 2019 and we currently have approvals to launch certain of our already marketed products in at least six additional countries.

Corporate Structure

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

Our Reverse Stock Split

We have submitted an application to have our Common Stock listed on the Nasdaq Capital Market under the symbol INNV, although no assurances may be given with respect to if or when our application will be approved. On January 4, 2019, our Board of Directors approved the consummation of a reverse stock split of our issued and outstanding shares Common Stock, but not the number of shares authorized for issuance under our Charter at a ratio of up to 1-for-200 in order to facilitate the listing of our Common Stock on the Nasdaq Capital Market and to provide us with additional authorized shares of Common Stock, which is currently necessary in order to ensure that we have sufficient shares of Common Stock available for issuance upon the conversion and exercise of our outstanding derivative securities. On January 7, 2019, we filed a preliminary consent solicitation statement pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, with the SEC in order to solicit the consent of our stockholders to approve an amendment to our Charter to effect the Reverse Split. Assuming we obtain the requisite stockholder consent, the exact ratio of the Reverse Split shall be determined by our Board of Directors, in its sole discretion, but the ratio shall not exceed 1-for-200. No fractional shares of Common Stock will be issued in connection with the Reverse Split, and all such fractional interests will be rounded up to the nearest whole number. Issued and outstanding stock options and warrants will be split on the same basis and exercise prices will be adjusted accordingly.

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: (i) the introduction of line extensions and reformulations of either our or third-party currently marketed products; (ii) the development of new proprietary OTC products, supplements and devices; and (iii) the acquisition of products or obtaining exclusive licensing rights to market such products; and

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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®, Newegg.com, eBay®, Wish.com, Sears.com, Walmart.com®, Bonanza.com, Alibaba.com and Walgreens.com and commercial partnerships with established international complimentary partners that: (i) generate revenue, and (ii) require a lower cost structure compared to traditional pharmaceutical companies, thereby increasing our gross margins.

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

Focusing on acquisition and licensing of commercial, non-prescription pharmaceutical and consumer health products, supplements and certain related devices that are well aligned with current therapeutic areas of male and female sexual health, urology, pain, vitality and respiratory diseases. In general, we seek non-prescription pharmaceutical (OTC monograph, Rx to OTC ANDA switched drugs) and consumer health products, supplements and certain related devices that are already marketed with scientific and/or clinical data and evidence that are aligned with our therapeutic areas, which we then can grow through promotion to physicians and expanding sales through our existing retail and online channels and commercial partners on a worldwide basis. We have done this through our acquisitions and licensing of (i) Sensum+® from Centric Research Institute, or CRI, (ii) Zestra® and Zestra Glide® from Semprae, (iii) Vesele® from Trôphikôs, LLC, (iv) U.S. and Canada rights to Androferti® from Laboratorios Q Pharma (Spain), (v) FlutiCare® from Novalere, (vi) UriVarx® from Seipel Group, (vii) Can-C® eye drops and supplement from International AntiAging Systems, (viii) our nine Beyond Human® supplements from Beyond Human, LLC, (ix) MZS™, melatonin from International AntiAging Systems, and (x) Musclin™ from the University of Iowa, and (xi) HealthiFeet®, ThermoMax™ (for two strengths) and BreastLift™ Cream from Boston Topicals, LLC;

Increasing the number of U.S. non-exclusive distribution channel partners for print media, direct mailing and online sales and also open more channels directly to physicians, urologists, gynecologists and therapists. One of our goals is to increase the number of U.S. distribution channel partners that sell our products. To do this, we have devised a four-pronged approach. First, we are seeking to increase our print media and direct to consumer mailings for our products. Second, we are seeking to expand the number of OTC direct selling partners, such as the larger in-store retail and wholesale distributors for selected products, and to expand sales to the more regional, statewide and local distributors, such as regional pharmacy chains, large grocery stores and supplement and health stores for selected products. Third, we are working to expand our online presence through relationships with well-known online sellers and the building of our own platforms such as established Amazon®, eBay®, Wish.com, Sears.com, Walmart.com® and Walgreens.com, among other stores. In addition, we announced in December 2018 the acquisition of all of the assets of SupplementHunt.com, an on-line retailer that specializes in selling brand name supplement and muscle-building products. Fourth, we are seeking to expand sales of our OTC products directly through sampling programs and detailing to physicians, urologists, gynecologists, therapists and to other healthcare providers who generally are used to recommending products that are supported by strong scientific and/or clinical data and evidence to their patients;

Seeking commercial partnerships outside the U.S. and developing consistent international commercial and distribution systems. We seek to develop a strong network of international distribution partners outside of the U.S.

To do so, we are relying in part on past relationships that Dr. Bassam Damaj, our President and Chief Executive Officer, has had with certain commercial partners globally. In addition, we believe we have the ability to develop new relationships with commercial distributors who can demonstrate they have leading positions in their regions and can provide us with effective marketing and sales efforts and teams to detail our products to physicians and therapists. Our commercial partners outside the U.S. are responsible for storing, distributing and promoting our products to physicians, urologists, gynecologists, therapists and to other healthcare providers. We have already entered into 15 commercial partnerships covering our products in 49 countries outside the U.S.; and

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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.

Our Products

On October 18, 2018, we announced our plans to expand our product line into the hemp-derived oil-based products market with the introduction of MZS Sleeping Aid™, a supplement in tincture form containing hemp-derived oil. The product does not contain any THC (Tetrahydrocannabinol) and is designed to be compliant with applicable U.S. state and federal laws. We expect to launch the product in certain states within the United States initially, and eventually, pending regulatory approval, expand into the Canadian market, although no assurances can be given. Further, we may expand into other products using hemp-derived oil in the future, although we do not currently have any specific plans to do so.

We currently market and sell 34 products in the U.S. and 12 in multiple countries around the world through our 15 international commercial partners:

1. Vesele® for promoting sexual health (U.S. and U.K.);
2. Vesele™ Nitric Oxide Strips, measures levels of nitric oxide;
3. Zestra® for female arousal (U.S., U.K., Denmark, Belgium, France, Malaysia, India, Monaco, Canada, Morocco, the UAE, Hong Kong, South Africa and South Korea);
4. Zestra Glide® (U.S., Canada and the MENA countries);
5. EjectDelay® indicated for the treatment of premature ejaculation (U.S. and Canada);
6. Sensum+® to alleviate reduced penile sensitivity (U.S., U.K. and Morocco);
7. Beyond Human® Testosterone Booster;
8. Beyond Human® Ketones;
9. Beyond Human® Krill Oil;
10. Beyond Human® Omega 3 Fish Oil;
11. Beyond Human® Eagle Vision Formula;
12. Beyond Human® Blood Sugar;

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13. Beyond Human® Colon Cleanse;
14. Beyond Human® Green Coffee Extract;
15. Beyond Human® Growth Agent;
16. RecalMax™ for brain health;
17. RecalMax™ Nitric Oxide Strips;
18. Androferti® (U.S. and Canada) supports overall male reproductive health and sperm quality;
19. UriVarx® for overactive bladder and urinary incontinence in Canada and for bladder health in the U.S.;
20. PEVarx® to support peak sexual performance and stamina;
21. ProstaGorx® for prostate support in the U.S. and for BPH in Canada;
22. FlutiCare® and FDA OTC approved drugs for allergy symptom relief;
23. Apeaz® for pain relief;
24. AllerVarx® for allergy relief;
25. ArthriVarx® for joint pain;
26. Xyralid® an FDA OTC monograph compliant drug for hemorrhoid pain relief;
27. Can-C® Eye Drops;
28. MZS™ Sleep Aid, a sleep aid supplement;
29. Diabasens™, a cream to increase blood flow and sensation in the legs and hands;
30. UriVarx™ UTI Urine Strips, diagnostic strips for detecting urinary tract infections;
31. Xyralid® Suppositories, relief of both internal & external hemorrhoidal symptoms;
32. Glucometer, GlocuGorx™, FDA cleared device to test blood sugar levels; and
33. Breastlift™; and
34. HealthiFeet®, a cream to relieve foot discomfort

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

(1) Vesele®

Vesele® is a proprietary oral supplement of Arginine with high absorption backed with clinical use data in men and women for sexual dysfunction. Vesele® contains a patented formulation of L-Arginine and L-Citrulline in combination with the natural absorption enhancer Bioperine®. The beneficial effects of Vesele® on sexual and cognitive functions were confirmed in a four-month U.S. clinical survey study involving 152 patients (69 men and 83 women). Results from the clinical survey indicated (i) improvement of erectile hardness and maintenance in men and increased sexual intercourse frequency with their partners, and (ii) lubrication in women, when taken separately by each.

(2) Vesele™ Nitric Oxide Strips

Vesele™ Nitric Oxide Strips are developed to be used with our supplement Vesele® to measure saliva levels of nitric oxide and help consumers monitor the effect of Vesele® real time on their nitric oxide levels.

(3) Zestra®

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

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

(4) Zestra Glide®

Zestra Glide® is a clinically tested water-based longer lasting lubricant. We acquired Zestra Glide® in our acquisition of Semprae in December 2013. In a 57 patient safety clinical study, Zestra Glide® proved to be safe and caused no irritation or skin side effects during the six week trial. To our knowledge, Zestra Glide® is the only water-based lubricant clinically tested for safety and has a viscosity of over 16000cps on the market. Increased viscosity usually translates into longer effects. The lubricant market is estimated to be approximately $200.0 million in the U.S. (Symphony IRI Group Study, 2012).

(5) EjectDelay®

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

(6) Sensum+®

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

(7) Beyond Human® Testosterone Booster ("BHT")

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

(8) Beyond Human® Ketones

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

(9) Beyond Human® Krill Oil

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

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(10)Beyond Human® Omega 3 Fish Oil

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

(11)Beyond Human® Eagle Vision Formula

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

(12)Beyond Human® Blood Sugar

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

(13)Beyond Human® Colon Cleanse

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

(14)Beyond Human® Green Coffee Extract

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

(15) Beyond Human® Growth Agent

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

(16)RecalMax™

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

(17)RecalMax™ Nitric Oxide Strips

RecalMax™ Nitric Oxide Strips are developed to be used with our supplement RecalMax™ to measure saliva levels of nitric oxide and help consumers monitor the effect of RecalMax™ real time on their nitric oxide levels.

(18)Androferti®

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

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(19) UriVarx®

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

(20) PEVarx®

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

(21) ProstaGorx®

ProstaGorx® is a clinical strength, multi-response prostate supplement, scientifically formulated to effectively maintain good prostate health in the U.S. and is an approved Natural Health Product for BPH by Health Canada.

(22) FlutiCare® (Fluticasone propionate nasal spray)

FlutiCare® is an FDA approved OTC nasal spray containing fluticasone propionate indicated for allergy relief symptoms.

(23) Apeaz®

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

(24) AllerVarx®

AllerVarx® is a patented formulation produced in bilayer tablets with a technology that allows a controlled release of the ingredients. The fast-release layer allows the rapid antihistaminic activity of perilla. The sustained-release layer

enhances quercetin and vitamin D3 bioavailability, thanks to its lipidic matrix, and exerts antiallergic activity spread over time. AllerVarx® was studied in a clinical trial assessing the reduction of both nasal and ocular symptoms in allergic patients, and daily consumption of anti-allergic drugs, over a period of 30 days. AllerVarx® showed a reduction of approximately 70% in total symptom scores and a reduction of approximately 73% in the use of anti-allergic drugs. There were no side effects noted during the administration of AllerVarx® and all the patients enrolled finished the study with good compliance.

(25)ArthriVarx®

A supplement for joint health.

(26)Xyralid®

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

(27)Can-C® Eye Drops

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

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(28) MZS™ Sleep Aid

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

(29) Diabasens™

Diabasens™ is a proprietary cream designed to increase blood flow and sensation in the hands and legs.

(30) UriVarx™ UTI Urine Strips

UriVarx™ UTI Urine Strips are FDA cleared diagnostic strips for home use that a man or woman can use to determine if they have a urinary tract infection.

(31) Xyralid® Suppositories

Xyralid® Suppositories are OTC FDA monograph compliant suppositories indicated for the relief of both internal and external hemorrhoidal symptoms. The drug works by constricting or shrinking swollen hemorrhoidal tissues and gives prompt soothing relief from painful burning, itching and discomfort.

(32) Glucometer GlucoGorx™

The Glucometer, Lancing Device and GlucoGorx™ Strips are FDA cleared devices that are sold individually or as a kit for the measurement of blood glucose levels.

(33) Breastlift™

BreastLift™ offers a safe and natural way to enhance women's breasts, increasing lift and improving firmness.

(34) HealthiFeet®

HealthiFeet® foot cream is a podiatrist-recommended topical cream clinically proven to relieve foot discomfort associated with cold feet. HealthiFeet® contains L-Arginine, a naturally occurring amino acid, which helps restore temperature to cold feet, keeping them warm and comfortable.

Pipeline Products

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

(1) Carvanum™

Carvanum™ is a proprietary cream designed to help muscle soreness and leg health.

(2) MZS™ Sleeping Aid with Hemp-Derived Oil

MZS™ Sleeping Aid with Hemp-Derived Oil is in tincture form containing hemp-derived oil.

(3) Trexar™

Trexar™ is a supplement to provide neuropathy support and enhanced sensation.

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(4) Musclin™

Musclin™ is a proprietary supplement made of two FDA Generally Recognized As Safe ("*GRAS*") approved ingredients designed to increase muscle mass, endurance and activity. The main ingredient in Musclin™ is a natural activator of the transient receptor potential cation channel, subfamily V, member 3 (TRPV3) channels on muscle fibers responsible to increase fibers width resulting in larger muscles. We currently expect to launch this product in the second half of 2019.

(5) Regenerum™

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

(6) Optik™

Optik™ is an expected FDA ophthalmic OTC monograph compliant product for the treatment of eye redness and eye lubrication.

(7) ThermoMax®

ThermoMax® is a hand cream with two strengths that provides up to eight hours of hand warming relief.

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

Sales and Marketing Strategy U.S. and Internationally

Our sales and marketing strategy is based on (i) the use of direct to consumer advertisements in print and online media through our proprietary Beyond Human™ sales and marketing platform acquired in March 2016, which in addition to the print and direct mail includes extensive on-line media channels through our Amazon®, eBay®, Wish.com, Sears.com, Walgreens.com and Walmart.com® sites, over 170 websites and over 2.5 million subscribers, (ii) working

with direct retail and wholesale commercial channel partners in the U.S. and also directly marketing the products ourselves to physicians, urologists, gynecologists and therapists and to other healthcare providers, and (iii) working with exclusive commercial partners outside of the U.S. that would be responsible for sales and marketing in those territories. We have now fully integrated most of our existing line of products such as Diabasens™, Sensum+®, UriVarx®, Zestra®, RecalMax™, Xyralid®, FlutiCare®, Apeaz® and other products into the Beyond Human™ sales and marketing platform. We plan to integrate other products upon their commercial launches in 2019. We also market and distribute our products in the U.S. through retailers, wholesalers and other online channels. Our strategy outside the U.S. is to partner with companies who can effectively market and sell our products in their countries through their direct marketing and sales teams. The strategy of using our partners to commercialize our products is designed to limit our expenses and fix our cost structure, enabling us to increase our reach while minimizing our incremental spending.

Our current OTC, Rx-to-OTC ANDA switch drugs and consumer care products marketing strategy is to focus on five main U.S. markets each of which we believe to be in excess of $1.0 billion: (i) sexual health (female and male sexual dysfunction and health); (ii) urology (bladder and prostate health); (iii) respiratory disease; (iv) brain health; and (v) pain. We will focus our current efforts on these five markets and will seek to develop, acquire or license products that we can sell through our sales channels in these fields.

Manufacturers and Single Source Suppliers

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

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Government Regulation

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

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

US Food and Drug Administration

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

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

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

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

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

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

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

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

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

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

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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.

BioEquivalency Studies

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

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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. Those of our 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 ("*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.

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;

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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 nine months ended September 30, 2018, we recognized research and development expense of approximately $93,000. During the years ended December 31, 2017 and 2016, we incurred research and development costs totaling $38,811 and $77,804, respectively. Research and development expenses include costs for stability testing and other development related costs for our products.

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Employees

We currently have 21 full-time employees, including Dr. Bassam Damaj, who serves as our President and Chief Executive Officer. We also rely on a number of consultants. Our employees are not represented by a labor union or by a collective bargaining agreement. Subject to the availability of financing, we intend to expand our staff to implement our growth strategy.

Intellectual Property Protection

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

We currently hold four patents in the U.S. and eleven patents registered outside the U.S. We currently have nine patent applications pending in the U.S. and eight 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 currently have one pending U.S. Copyright application.

We currently own 33 trademark registrations in the U.S. and have 35 trademark applications pending in the U.S. We also own 48 trademarks registered outside of the U.S., with 45 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.

Description of Property

We maintain our principal office at 8845 Rehco Road, San Diego, California 92121. Our telephone number at that office is (858) 964-5123. In October 2017, we entered into a commercial lease agreement for 16,705 square feet of office and warehouse space in San Diego, CA that commenced on December 1, 2017 and continues until April 30, 2023. The initial monthly base rent is $20,881 with an approximate 3% increase in the base rent amount on an annual basis, as well as rent abatement for rent due from January 2018 through May 2018. We hold an option to extend the lease an additional five 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; 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.

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. In October 2018, we filed a motion to dismiss the action. In December 2018, the judge in this case ruled that limited discovery in the case around the issue of jurisdiction of the court can move forward on that issue and the parties may submit briefs relating to that issue. The Company believes 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, the Company believes that it 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.

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 and the Company has not heard back from that entity since that time.

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

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MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION

AND RESULTS OF OPERATIONS

Historical results and trends should not be taken as indicative of future operations. Management's statements contained in this report that are not historical facts are forward-looking statements. Forward-looking statements, which are based on certain assumptions and describe future plans, strategies and expectations of the Company, are generally identifiable by use of the words "believe," "expect," "intend," "anticipate," "estimate," "project," "prospects," or similar expressions. The Company's ability to predict results or the actual effect of future plans or strategies is inherently uncertain. Factors which could have a material adverse effect on the operations and future prospects of the Company on a consolidated basis include, but are not limited to: changes in economic conditions, legislative/regulatory changes, availability of capital, interest rates, competition and generally accepted accounting principles. These risks and uncertainties should be considered in evaluating forward-looking statements and undue reliance should not be placed on such statements.

Overview

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

Our business model leverages our ability to (i) develop and build our current pipeline of proprietary products, and (ii) to acquire outright or in-license commercial products that are supported by scientific and/or clinical evidence, place them through our existing supply chain, retail and on-line (including our Amazon®, eBay®, Wish.com, Sears.com, Walmart.com®, Newegg.com, Bonanza.com, Alibaba.com and Walgreens.com on-line stores and other e-commerce business platforms) channels to tap new markets and drive demand for such products and to establish physician relationships. We currently have 34 products marketed in the United States with 12 of those being marketed and sold in multiple countries around the world through some of our 15 international commercial partners. We currently expect to launch an additional six products in the U.S. in 2019 and we currently have approvals to launch certain of our already marketed products in at least six additional countries.

Our Strategy

Our corporate strategy focuses on two primary objectives:

1. Developing a diversified product portfolio of exclusive, unique and patented non-prescription OTC and branded ANDA drugs, devices, consumer health products, and clinical supplements through: (i) the introduction of line extensions and reformulations of either our or third-party currently marketed products; (ii) the development of new proprietary OTC products, supplements and devices; and (iii) 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®, Newegg.com, eBay®, Wish.com, Sears.com, Walmart.com®, Bonanza.com, Alibaba.com and Walgreens.com and commercial partnerships with established international complimentary partners that: (i) generate revenue, and (ii) require a lower cost structure compared to traditional pharmaceutical companies, thereby increasing our gross margins.

Our Products

We currently market and sell 34 products in the U.S. and 12 in multiple countries around the world through our 15 international commercial partners. Although we generate revenue from the sale of our commercial products, most revenue is currently generated by UriVarx®, Apeaz®, Vesele®, Diabasens™, Sensum+®, ProstaGorx®, Zestra®, Zestra® Glide, RecalMax™, FlutiCare®, AllerVarx®, ArthriVarx®, Xyralid®, PEVarx®, and Beyond Human® Testosterone Booster and related products.

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

1. Carvanum™ for indications for muscle soreness (first quarter 2019);
2. MZS Sleeping Aid with hemp-derived oil (first quarter 2019);
3. Trexar™ for neuropathy support and enhanced sensation (first quarter 2019);
4. Musclin™ for muscle growth (second half 2019 pending clinical trial results);
5. Optik for eye lubrication and redness (second half 2019);
6. Regenerum™ for muscle wasting or cachexia (second half 2020 pending clinical results); and
7. ThermoMax® for hand warming relief (first half 2019).

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On October 18, 2018, we announced our plans to expand our product line into the hemp-derived oil-based products market with the introduction of MZS Sleeping Aid™, a supplement in tincture form containing hemp-derived oil. The product does not contain any THC (Tetrahydrocannabinol) and is designed to be compliant with applicable U.S. state and federal laws. We expect to launch the product in certain states within the United States initially, and eventually, pending regulatory approval, expand into the Canadian market, although no assurances can be given. Further, we may expand into other products using hemp-derived oil in the future, although we do not currently have any specific plans to do so.

Sales and Marketing Strategy U.S. and Internationally

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

Our current OTC, Rx-to-OTC ANDA switch drugs and consumer care products marketing strategy is to focus on four main U.S. markets each of which we believe to be in excess of $1.0 billion: (i) sexual health (female and male sexual dysfunction and health); (ii) urology (bladder and prostate health); (iii) respiratory disease; (iv) brain health; and (v) pain. We will focus our current efforts on these four markets and will seek to develop, acquire or license products that we can sell through our sales channels in these fields.

Acquisition and Licensing Strategy

Our acquisition and licensing strategy is to acquire or in-license products that fit our commercialization strategy that are branded, with growing market shares, that can be sold direct to consumers and through our on-line partnerships and that can then be sold internationally through our commercial partnerships.

The following represents products and product candidates we have successfully acquired:

1. Zestra® and Zestra Glide® (acquired Semprae Laboratories, Inc. in 2013 - current Innovus subsidiary);
2. Vesele® (from Trophikos, Inc. in 2014);
3. Sensum+® (from Centric Research Institute in 2013);
4. FlutiCare™ (acquired Novalere, Inc. in 2015, current Innovus Pharma subsidiary);
   Beyond Human® Testosterone Booster; Beyond Human® Human Growth Agent; Beyond Human® Ketones;
5. Beyond Human® Krill Oil; Beyond Human® Omega 3 Fish Oil; Beyond Human® Vision Formula; Beyond Human® Blood Sugar; and Beyond Human® Colon Cleanse (acquired Beyond Human™ assets in 2016); and
6. HealthiFeet®, ThermoMax™ (two strengths) and Breastlift™ (from Boston Topicals, LLC in 2018).

The following represents the products we have in-licensed from third parties:

1. Androferti® (from Q Pharma in 2015);
2. AllerVarx™ (from NTC Pharma in 2016); and
3. UriVaRx® (from Seipel Pty. Ltd. 2015).

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In addition, we have developed and repurposed Xyralid®™ for the relief of the pain and symptoms caused by hemorrhoids.

We currently have 15 partnerships that have the rights to sell certain of our current products in approximately 49 countries. Our international partners include the following companies:

1. Orimed Pharma, the OTC subsidiary of Jamp Pharma (Canada)
2. Acerus Pharmaceuticals, Inc. (Canada);
3. DanaLife ApS (Denmark and in alternative markets);
4. Tramorgan (U.K.);
5. Sothema Laboratories (MENA);
6. Ovation Pharma (Morocco);
7. LaVasta Pharmaceuticals (MENA);
8. BroadMed (Lebanon);
9. Elis Pharmaceuticals (Lebanon);
10. BioTask (Malaysia);
11. Oz Biogenics (Myanmar and Vietnam);
12. Khandelwal Laboratories (India);
13. PT Resources (Select Asian Countries);
14. BroadMed (Lebanon); and
15. J&H Co. LTD (South Korea).

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Results of Operations for the Three and Nine Months Ended September 30, 2018 Compared with the Three and Nine Months Ended September 30, 2017

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	$ Change	% Change
NET REVENUE:				
Product sales, net	$6,956,861	$2,218,343	$4,738,518	213.6 %
License revenue	582	2,500	(1,918)	(76.7)%
Service revenue	189,462	-	189,462	100.0 %
Cooperative marketing revenue	233,074	-	233,074	100.0 %
Net revenue	7,379,979	2,220,843	5,159,136	232.3 %
OPERATING EXPENSE:				
Cost of product sales	1,536,792	480,076	1,056,716	220.1 %
Research and development	59,201	8,736	50,465	577.7 %
Sales and marketing	5,263,533	1,626,630	3,636,903	223.6 %
General and administrative	2,023,030	1,321,001	702,029	53.1 %
Total operating expense	8,882,556	3,436,443	5,446,113	158.5 %
LOSS FROM OPERATIONS	(1,502,577)	(1,215,600)	(286,977)	(23.6)%
OTHER INCOME (EXPENSE):				
Interest expense	(381,663)	(104,276)	277,387	266.0 %
Loss on extinguishment of debt	(745,439)	(89,341)	656,098	100.0 %
Other income (expense), net	290	(4,800)	(5,090)	(106.0)%
Fair value adjustment for contingent consideration	179,451	69,305	(110,146)	(158.9)%
Change in fair value of derivative liabilities	-	16,055	16,055	100.0 %
Total other expense, net	(947,361)	(113,057)	834,304	738.0 %
NET LOSS	$(2,449,938)	$(1,328,657)	(1,121,281)	(84.4)%

	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017	$ Change	% Change
NET REVENUE:				
Product sales, net	$18,469,199	$6,426,790	$12,042,409	187.4 %
License revenue	5,737	10,000	(4,263)	(42.6)%

Service revenue	345,110	-	345,110	100.0	%
Cooperative marketing revenue	416,710	-	416,710	100.0	%
Net revenue	19,236,756	6,436,790	12,799,966	198.9	%
OPERATING EXPENSE:					
Cost of product sales	3,739,837	1,329,131	2,410,706	181.4	%
Research and development	93,093	26,982	66,111	245.0	%
Sales and marketing	14,094,203	4,869,717	9,224,486	189.4	%
General and administrative	5,638,352	4,207,899	1,430,453	34.0	%
Total operating expense	23,565,485	10,433,729	13,131,756	125.9	%
LOSS FROM OPERATIONS	(4,328,729)	(3,996,939)	(331,790)	(8.3	)%
OTHER INCOME (EXPENSE):					
Interest expense	(949,533)	(771,885)	177,648	23.0	%
Loss on extinguishment of debt	(1,039,711)	(394,169)	645,542	163.8	%
Other income (expense), net	665	(5,622)	(6,287)	(111.8	)%
Fair value adjustment for contingent consideration	198,250	195,459	(2,791)	(1.4	)%
Change in fair value of derivative liabilities	-	(32,138)	(32,138)	(100.0	)%
Total other expense, net	(1,790,329)	(1,008,355)	781,974	77.6	%
Provision for income taxes	-	3,200	(3,200)	(100.0	)%
NET LOSS	$(6,119,058)	$(5,008,494)	(1,110,564)	(22.2	)%

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Net Revenue

We recognized net revenue of approximately $7.4 million and $19.2 million for the three and nine months ended September 30, 2018, respectively, compared to $2.2 million and $6.4 million for the three and nine months ended September 30, 2017, respectively. The increase in net revenue in 2018 was primarily the result of the expansion of the Beyond Human Sales and Marketing platform into direct mail marketing including catalogs, postcards, and tear sheets introduced in the middle of the first quarter of 2018 in addition to the newspaper and magazine advertisements previously utilized as well as the introduction of new products including Diabasens™ in the first quarter of 2018 and Apeaz® and ArthriVarx® in mid-2017. The following represents the number of units shipped of our top products during the periods:

	Three Months Ended September 30, 2018	**Three Months Ended September 30, 2017**	**# Change**	**% Change**	
Number of units					
Diabasens™	70,363	-	70,363	100.0	%
Vesele®	40,359	11,896	28,463	239.3	%
Fluticare®	35,813	-	35,813	100.0	%
Apeaz®	32,850	3,126	29,724	950.9	%
UriVarx®	32,429	15,004	17,425	116.1	%
Zestra® & Zestra Glide®	30,243	2,515	27,728	1,102.5	%

	Nine Months Ended September 30, 2018	**Nine Months Ended September 30, 2017**	**# Change**	**% Change**	
Number of units					
Diabasens™	94,778	-	94,778	100.0	%

UriVarx®	86,783	26,528	60,255	227.1 %
Zestra® & Zestra Glide®	58,247	3,938	54,309	1,379.5 %
Vesele®	56,411	34,417	21,994	63.9 %
Apeaz®	53,943	3,126	50,817	1,625.6 %
Fluticare®	44,348	-	44,348	100.0 %

Cost of Product Sales

We recognized cost of product sales of approximately $1.5 million and $3.7 million for the three and nine months ended September 30, 2018, respectively compared to $0.4 million and $1.3 million for the three and nine months ended September 30, 2017, respectively. The cost of product sales includes the cost of inventory, shipping and warehouse costs, royalties and salaries and benefits for our warehouse employees. The increase in cost of product sales is a result of higher shipping costs due to an increase in the number of units shipped. The increase in the gross margin to 80.6% in 2018 compared to 79.4% in 2017 is due to the higher margins earned on the increased volume of our product sales through the Beyond Human™ sales and marketing platform, as well as the efforts in the first half of 2018 to bring our fulfillment and shipping process in-house to our facility in San Diego.

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Research and Development

We recognized research and development expense of approximately $59,000 and $93,000 for the three and nine months ended September 30, 2018, respectively, compared to $9,000 and $27,000 for the three and nine months ended September 30, 2017, respectively. Research and development expenses include costs for stability testing and other development related costs for our products.

Sales and Marketing

We recognized sales and marketing expense of approximately $5.3 million and $14.1 million for the three and nine months ended September 30, 2018, respectively, compared to $1.6 million and $4.9 million for the three and nine months ended September 30, 2017, respectively. Sales and marketing expense consists primarily of print advertisements and sales and marketing support. The increase in sales and marketing expense during the three and nine months ended September 30, 2018 when compared to the same period in 2017 is due to the increase in the number of products integrated into the Beyond Human™ sales and marketing platform, an increase in the distribution of direct mail and print advertisements, as well as the costs of our third-party customer service call center due to the higher volume of sales orders received as a result of the Beyond Human® asset acquisition. Also, initial product launches require larger advertising spends in an effort to increase brand awareness. Total direct advertising costs for the three and nine months ended September 30, 2018 was $4.3 million and $11.5 million, respectively, compared to $1.4 million and $4.0 million for the three and nine months ended September 30, 2017.

General and Administrative

We recognized general and administrative expense of approximately $2.0 million and $5.6 million for the three and nine months ended September 30, 2018, respectively, compared to $1.3 million and $4.2 million for the three and nine months ended September 30, 2017, respectively. The increase in general and administrative expense over the periods is primarily due to the growth of the Company which has resulted in the need for additional employees from 6 employees as of September 30, 2017 to 26 employees as of September 30, 2018 as well as the additional occupancy costs relating to a lease agreement entered into in November 2017 for a fulfillment and corporate office building. General and administrative expense consists primarily of salaries expense, 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.

Other Income and Expense

We recognized interest expense of approximately $382,000 and $950,000 for the three and nine months ended September 30, 2018, respectively, and $104,000 and $772,000 for the three and nine months ended September 30, 2017, respectively. Interest expense primarily includes interest related to our debt and amortization of debt discounts. 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 three and nine months ended September 30, 2018 is due to the larger amount of debt discount amortization in 2018 compared to 2017 due to the notes issued in the first and third quarter of 2018.

We recognized a loss on extinguishment of debt of approximately $745,000 and $1,040,000 during the three and nine months ended September 30, 2018, respectively, compared to a loss of $89,000 and $394,000 during the three and nine months ended September 30, 2017, respectively. The loss on debt extinguishment in 2018 was the result of the securities exchange agreements entered into with certain note payable holders during 2018. In exchange for the issuance of 12,795,080 shares of Common Stock with a fair value of approximately $2,070,000, we settled the principal and interest balances totaling $1,289,000 with the noteholders. The remaining loss on debt extinguishment was the write-off of the remaining unamortized debt discount as of the date of settlement of $259,000. The loss on debt extinguishment in 2017 was due to a settlement of notes payable as well as the required prepayment of the 2016 convertible notes from the cash proceeds received through the public equity offering in March 2017.

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We recognized a gain from the fair value adjustment for contingent consideration of approximately $179,000 and $198,000 for the three and nine months ended September 30, 2018, respectively, compared to a gain of $69,000 and $195,000 for the three and nine months ended September 30, 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.

We recognized a gain (loss) from the change in fair value of derivative liabilities of approximately $16,000 and $(32,000) for the three and nine months ended September 30, 2017. Change in fair value of derivative liabilities primarily includes the change in the fair value of the warrants and embedded conversion features classified as derivative liabilities. The loss on change in fair value of derivative liabilities during the nine months ended September 30, 2017 is primarily due to the increase in our stock price from December 31, 2016 through the date of conversion of certain of the convertible debentures in 2017, which resulted in the fair value of the embedded conversion features at the conversion date to be higher than the fair value at December 31, 2016. There was no change in fair value during the three and nine months ended September 30, 2018, respectively, as we adopted ASU 207-11, which resulted in our warrants derivative liability being reclassified to equity as of the date of adoption on January 1, 2018.

Net Loss

Net loss for the three and nine months ended September 30, 2018 was approximately $2.5 million or $0.01 basic and diluted net loss per share and $6.1 million or $0.03 basic and diluted net loss per share, respectively, compared to a net loss of $1.3 million or $0.01 basic and diluted net loss per share and $5.0 million or $0.03 basic and diluted net loss per share for the three and nine months ended September 30, 2017, respectively.

Results of Operations for the Fiscal Year Ended December 31, 2017 Compared with the Fiscal Year Ended December 31, 2016

	Year Ended December 31, 2017	**Year Ended December 31, 2016**	**$ Increase (Decrease)**	**% Increase (Decrease)**	
NET REVENUE:					
Product sales, net	$8,806,300	$4,817,603	$3,988,697	82.8	%
License revenue	10,000	1,000	9,000	900.0	%
Net revenue	8,816,300	4,818,603	3,997,697	83.0	%

OPERATING EXPENSE:					
Cost of product sales	1,848,325	1,083,094	765,231	70.7	%
Research and development	38,811	77,804	(38,993)	(50.1)	%
Sales and marketing	6,853,559	3,621,045	3,232,514	89.3	%
General and administrative	5,174,827	5,870,572	(695,745)	(11.9)	%
Total operating expense	13,915,522	10,652,515	3,263,007	30.6	%
LOSS FROM OPERATIONS	(5,099,222)	(5,833,912)	(734,690)	(12.6)	%
OTHER INCOME (EXPENSE):					
Interest expense	(872,166)	(6,661,694)	(5,789,528)	(86.9)	%
Loss on extinguishment of debt	(700,060)	-	700,060	100.0	%
Other income (expense), net	(6,878)	1,649	(8,527)	(517.1)	%
Fair value adjustment for contingent consideration	194,034				