

INNOVUS PHARMACEUTICALS, INC.

Form 10-Q

November 14, 2018

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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

(Mark One)

Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the Quarterly Period ended September 30, 2018

or

Transition Report Pursuant to Section 13 or 15(d) of the Exchange Act.

For the transition period from \_\_\_ to \_\_\_\_.

Commission File Number: 000-52991

**INNOVUS PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Nevada

(State or Other Jurisdiction of

90-0814124

(IRS Employer

Incorporation or Organization) Identification No.)

**8845 Rehco Road**

**92121**

**San Diego, CA**

(Address of Principal Executive Offices) (Zip Code)

**858-964-5123**

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant Rule 405 of Regulation S-T (Sec.232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

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

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

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

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

As of November 14, 2018, the registrant had 216,469,857 shares of common stock outstanding.

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**TABLE OF CONTENTS**

|  | Page |
|--|------|
| <b><u>PART I—FINANCIAL INFORMATION</u></b>   |      |
| <u>Item 1. Financial Statements</u>  | 3    |
| <u>Condensed Consolidated Balance Sheets at September 30, 2018 (Unaudited) and December 31, 2017</u>                               | 3    |
| <u>Condensed Consolidated Statements of Operations (Unaudited) for the Three and Nine Months Ended September 30, 2018 and 2017</u> | 4    |
| <u>Condensed Consolidated Statements of Cash Flows (Unaudited) for the Nine Months Ended September 30, 2018 and 2017</u>           | 5    |
| <u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>  | 6    |
| <u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>                               | 17   |
| <u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>  | 25   |
| <u>Item 4. Controls and Procedures</u>   | 25   |
| <b><u>PART II—OTHER INFORMATION</u></b>  |      |
| <u>Item 1. Legal Proceedings</u>   | 26   |
| <u>Item 1A. Risk Factors</u>   | 26   |
| <u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>   | 26   |
| <u>Item 3. Defaults Upon Senior Securities</u>   | 27   |
| <u>Item 4. Mine Safety Disclosures</u>   | 27   |
| <u>Item 5. Other Information</u>   | 27   |
| <u>Item 6. Exhibits</u>  | 27   |
| <u>Signatures</u>  | 28   |

**INNOVUS PHARMACEUTICALS, INC.****Condensed Consolidated Balance Sheets**

|  | <b>September<br/>30,<br/><br/>2018<br/>(Unaudited)</b> | <b>December<br/>31,<br/><br/>2017</b> |
|--|--|---------------------------------------|
| <b>ASSETS</b>  |  |                                       |
| Assets:  |  |                                       |
| Cash   | \$703,012  | \$1,564,859                           |
| Accounts receivable, net   | 356,347  | 68,259                                |
| Prepaid expense and other current assets                                     | 1,265,474  | 363,080                               |
| Inventories  | 2,198,045  | 1,725,698                             |
| Total current assets   | 4,522,878  | 3,721,896                             |
| Property and equipment, net  | 206,425  | 62,454                                |
| Deposits   | 20,881   | 20,881                                |
| Goodwill   | 952,576  | 952,576                               |
| Intangible assets, net   | 3,800,674  | 4,273,099                             |
| Total assets   | \$9,503,434  | \$9,030,906                           |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>                                  |  |                                       |
| Liabilities:   |  |                                       |
| Accounts payable and accrued expense   | \$2,530,687  | \$2,607,121                           |
| Accrued compensation   | 1,027,068  | 1,118,293                             |
| Deferred revenue and customer deposits                                       | 95,372   | 24,690                                |
| Accrued interest payable   | 24,232   | 3,648                                 |
| Derivative liabilities – warrants  | -  | 58,609                                |
| Contingent consideration   | -  | 28,573                                |
| Short-term loan payable  | 138,048  | 65,399                                |
| Notes payable, net of debt discount of \$830,610 and \$437,355, respectively | 2,340,849  | 1,239,296                             |
| Total current liabilities  | 6,156,256  | 5,145,629                             |
| Accrued compensation – less current portion                                  | 1,227,554  | 1,531,904                             |
| Contingent consideration – less current portion                              | 1,261,455  | 1,450,430                             |
| Total non-current liabilities  | 2,489,009  | 2,982,334                             |
| Total liabilities  | 8,645,265  | 8,127,963                             |
| Commitments and contingencies  |  |                                       |

Stockholders' equity:

|  |              |              |
|--|--------------|--------------|
| Preferred stock: 7,500,000 shares authorized, at \$0.001 par value, no shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively                         | -            | -            |
| Common stock: 292,500,000 shares authorized, at \$0.001 par value, 208,169,412 and 167,420,605 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively | 208,169      | 167,421      |
| Additional paid-in capital   | 42,350,286   | 36,375,359   |
| Accumulated deficit  | (41,700,286) | (35,639,837) |
| Total stockholders' equity   | 858,169      | 902,943      |
| <br>   |              |              |
| Total liabilities and stockholders' equity   | \$9,503,434  | \$9,030,906  |

See accompanying notes to these condensed consolidated financial statements.

**INNOVUS PHARMACEUTICALS, INC.****Condensed Consolidated Statements of Operations****(Unaudited)**

|   | <b>For the</b>            |                | <b>For the</b>           |                |
|---|---------------------------|----------------|--------------------------|----------------|
|   | <b>Three Months Ended</b> |                | <b>Nine Months Ended</b> |                |
|   | <b>September 30,</b>      |                | <b>September 30,</b>     |                |
|   | <b>2018</b>               | <b>2017</b>    | <b>2018</b>              | <b>2017</b>    |
| Net revenue:  |                           |                |                          |                |
| Product sales, net  | \$6,956,861               | \$2,218,343    | \$18,469,199             | \$6,426,790    |
| License revenue   | 582                       | 2,500          | 5,737                    | 10,000         |
| Service revenue   | 189,462                   | -              | 345,110                  | -              |
| Cooperative marketing revenue   | 233,074                   | -              | 416,710                  | -              |
| Net revenue   | 7,379,979                 | 2,220,843      | 19,236,756               | 6,436,790      |
| Operating expense:  |                           |                |                          |                |
| Cost of product sales   | 1,536,792                 | 480,076        | 3,739,837                | 1,329,131      |
| Research and development  | 59,201                    | 8,736          | 93,093                   | 26,982         |
| Sales and marketing   | 5,263,533                 | 1,626,630      | 14,094,203               | 4,869,717      |
| General and administrative  | 2,023,030                 | 1,321,001      | 5,638,352                | 4,207,899      |
| Total operating expense   | 8,882,556                 | 3,436,443      | 23,565,485               | 10,433,729     |
| Loss from operations  | (1,502,577 )              | (1,215,600 )   | (4,328,729 )             | (3,996,939 )   |
| Other income (expense):   |                           |                |                          |                |
| Interest expense  | (381,663 )                | (104,276 )     | (949,533 )               | (771,885 )     |
| Loss on extinguishment of debt  | (745,439 )                | (89,341 )      | (1,039,711 )             | (394,169 )     |
| Other income (expense), net   | 290                       | (4,800 )       | 665                      | (5,622 )       |
| Fair value adjustment for contingent consideration                                | 179,451                   | 69,305         | 198,250                  | 195,459        |
| Change in fair value of derivative liabilities                                    | -                         | 16,055         | -                        | (32,138 )      |
| Total other expense, net  | (947,361 )                | (113,057 )     | (1,790,329 )             | (1,008,355 )   |
| Provision for income taxes  | -                         | -              | -                        | 3,200          |
| Net loss  | \$(2,449,938 )            | \$(1,328,657 ) | \$(6,119,058 )           | \$(5,008,494 ) |
| Net loss per share of common stock – basic and diluted                            | \$(0.01 )                 | \$(0.01 )      | \$(0.03 )                | \$(0.03 )      |
| Weighted average number of shares of common stock outstanding – basic and diluted | 214,527,261               | 161,587,934    | 202,290,341              | 152,325,196    |

See accompanying notes to these condensed consolidated financial statements.



**INNOVUS PHARMACEUTICALS, INC.****Condensed Consolidated Statements of Cash Flows****(Unaudited)**

|  | <b>For the</b>           |                      |
|--|--------------------------|----------------------|
|  | <b>Nine Months Ended</b> |                      |
|  | <b>September 30,</b>     | <b>September 30,</b> |
|  | <b>2018</b>              | <b>2017</b>          |
| Cash flows from operating activities:  |                          |                      |
| Net loss   | \$(6,119,058)            | \$(5,008,494)        |
| Adjustments to reconcile net loss to net cash used in operating activities:  |                          |                      |
| Depreciation & amortization  | 32,093                   | 8,258                |
| (Recovery of) Allowance for doubtful accounts  | (179 )                   | 5,090                |
| Common stock, restricted stock units and stock options issued to employees, board of directors and consultants for compensation and services | 356,058                  | 997,030              |
| Loss on extinguishment of debt   | 1,039,712                | 394,169              |
| Change in fair value of contingent consideration   | (198,250 )               | (195,459 )           |
| Change in fair value of derivative liabilities   | -                        | 32,138               |
| Amortization of debt discount  | 898,895                  | 687,598              |
| Amortization of intangible assets  | 472,425                  | 472,675              |
| Changes in operating assets and liabilities, net of acquisition amounts  |                          |                      |
| Accounts receivable  | (287,909 )               | 959                  |
| Prepaid expense and other current assets   | (764,346 )               | 177,297              |
| Inventories  | (472,347 )               | (40,199 )            |
| Accounts payable and accrued expense   | (257,647 )               | 506,007              |
| Accrued compensation   | (395,575 )               | 433,498              |
| Accrued interest payable   | 37,560                   | (6,094 )             |
| Deferred revenue and customer deposits   | 70,682                   | (11,000 )            |
| Net cash used in operating activities  | (5,587,887)              | (1,546,527)          |
| Cash flows used in investing activities:   |                          |                      |
| Purchase of property and equipment   | (176,064 )               | (10,131 )            |
| Contingent consideration payment   | (19,298 )                | -                    |
| Net cash used in investing activities  | (195,362 )               | (10,131 )            |
| Cash flows from financing activities:  |                          |                      |
| Payments on short-term loans payable   | (245,383 )               | (7,199 )             |
| Proceeds from short-term loans payable   | 125,000                  | -                    |
| Proceeds from notes payable  | 3,722,499                | 300,000              |
| Payments on notes payable  | (1,535,416)              | (214,000 )           |

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|   |             |             |
|---|-------------|-------------|
| Proceeds from warrant and stock option exercises  | 2,852,701   | 4,879       |
| Issuance of common stock for services   | 2,000       | -           |
| Proceeds from sale of common stock and warrants, net of offering costs  | -           | 3,307,773   |
| Payments on convertible debentures  | -           | (1,222,422) |
| Prepayment penalty on extinguishment of convertible debentures  | -           | (127,247 )  |
| Net cash provided by financing activities   | 4,921,401   | 2,041,784   |
| Net change in cash  | (861,847 )  | 485,126     |
| Cash at beginning of period   | 1,564,859   | 829,933     |
| Cash at end of period   | \$703,012   | \$1,315,059 |
| Supplemental disclosures of cash flow information:  |             |             |
| Cash paid for income taxes  | \$-         | \$5,600     |
| Cash paid for interest  | \$4,519     | \$80,344    |
| Supplemental disclosures of non-cash investing and financing activities:  |             |             |
| Common stock issued for conversion of convertible debentures and accrued interest   | \$1,288,172 | \$577,835   |
| Reclassification of the fair value of the embedded conversion features from derivative liability to additional paid-in capital upon conversion                | \$-         | \$203,630   |
| Relative fair value of common stock issued in connection with notes payable recorded as debt discount   | \$693,911   | \$99,386    |
| Fair value of non-forfeitable common stock issued to consultant included in accounts payable and accrued expense  | \$-         | \$360,000   |
| Offering costs in connection with warrant exercises included in accounts payable and accrued expenses   | \$181,213   | \$-         |
| Cumulative adjustment to accumulated deficit for the fair value of the warrant derivative liability upon adoption of ASU 2017-11 on January 1, 2018           | \$58,609    | \$-         |
| Issuance of shares of common stock for vested restricted stock units  | \$-         | \$92        |
| Fair value of common stock issued for prepayment of future royalties due under the CRI License Agreement included in prepaid expense and other current assets | \$-         | \$44,662    |
| Fair value of common stock issued as financing fees in connection with notes payable recorded as debt discount  | \$222,500   | \$-         |

See accompanying notes to these condensed consolidated financial statements.

**INNOVUS PHARMACEUTICALS, INC.**

**Notes to Condensed Consolidated Financial Statements**

**September 30, 2018**

**(Unaudited)**

**NOTE 1 – ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Organization**

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

We generate revenue from 31 commercial products in the United States, including 12 of these commercial products in multiple countries around the world through our 16 international commercial partners. While 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.

**Basis of Presentation**

The condensed consolidated balance sheet as of December 31, 2017, which has been derived from audited consolidated financial statements, and these unaudited condensed consolidated financial statements have been prepared by management in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”), and include all assets, liabilities, revenues and expenses of the Company and its wholly owned subsidiaries: FasTrack Pharmaceuticals, Inc., Semprae Laboratories, Inc. (“Semprae”) and Novalere, Inc. (“Novalere”). All material intercompany transactions and balances have been eliminated. These interim unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with Management’s Discussion and Analysis of Financial Condition and Results of Operations and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2017. Certain information required by U.S. GAAP has been condensed or omitted in accordance with the rules and regulations of the U.S. Securities and

Exchange Commission (“SEC”). The results for the period ended September 30, 2018 are not necessarily indicative of the results to be expected for the entire fiscal year ending December 31, 2018 or for any future period.

### **Change in Accounting Principle**

On January 1, 2018, we adopted Financial Accounting Standards Board (“FASB”) Accounting Standards Update (“ASU”) No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features*. This ASU requires that when determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity’s own stock. As a result, a freestanding equity-linked financial instrument no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic earnings per share. The Company elected to use the modified retrospective transition method, where the cumulative effect of the initial application is recognized as an adjustment to opening retained earnings at January 1, 2018. As a result of the adoption of this ASU, we recorded a cumulative-effect adjustment to the consolidated statement of financial position as of January 1, 2018 of \$58,609 for the warrants previously classified as a derivative liability due to a down round provision included in the terms of the warrant agreement. Therefore, the cumulative-effect adjustment was recorded as a reduction in accumulated deficit and derivative liabilities in the accompanying condensed consolidated balance sheet as of January 1, 2018. The adoption of this ASU did not have an impact on our condensed consolidated results of operations.

### **Liquidity**

Our operations have been financed primarily through proceeds from convertible debentures and notes payable, sales of our common stock and revenue generated from our products domestically and internationally by our partners. These funds have provided us with the resources to operate our business, sell and support our products, attract and retain key personnel and add new products to our portfolio. We have experienced net losses and negative cash flows from operations each year since our inception. As of September 30, 2018, we had an accumulated deficit of \$41,700,286 and negative working capital of \$1,633,378.

During the nine months ended September 30, 2018, we received net cash proceeds of \$2.7 million from the exercise of warrants (see Note 5). Additionally, during the period we raised \$3.7 million in gross proceeds from the issuance of notes payable to six investors (see Note 4). We have also raised \$1.5 million in gross proceeds from the issuance of notes payable to four investors subsequent to September 30, 2018 (see Note 7). We have also issued equity securities in certain circumstances to pay for services from vendors and consultants.

As of September 30, 2018, we had \$703,012 in cash and \$453,675 held by merchant processors reported in other current assets and as of November 13, 2018 we had \$1,528,293 in cash and \$387,062 held by merchant processors reported in other current assets. During the nine months ended September 30, 2018, we had net cash used in operating activities of approximately \$5.6 million. We expect that our existing capital resources, together with revenue from sales of our products and expected upcoming sales milestone payments from the commercial partners signed for our products will be sufficient to allow us to continue our operations, commence the product development process and launch selected products through at least the next 12 months. In addition, our CEO, who is also a significant shareholder, has deferred the remaining payment of his salary earned through June 30, 2016 totaling \$1,227,554 and has agreed to refrain from receipt of any funds which may jeopardize the ability of the Company to operate. Our actual needs will depend on numerous factors, including timing of introducing our products to the marketplace, our ability to attract additional international distributors for our products and our ability to in-license in non-partnered territories and/or develop new product candidates. Although no assurances can be given, we currently intend to raise additional capital through the sale of debt or equity securities to provide additional working capital, pay for further expansion and development of our business, and to meet current obligations. Such capital may not be available to us when we need it or on terms acceptable to us, if at all.

### **Use of Estimates**

The preparation of these condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. Such management estimates include the allowance for doubtful accounts, sales returns and chargebacks, realizability of inventories, valuation of deferred tax assets, goodwill and intangible assets, valuation of contingent acquisition consideration, recoverability of long-lived assets and goodwill and the valuation of equity-based instruments. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from these estimates under different assumptions or conditions.

### **Fair Value Measurement**

Our financial instruments are cash, accounts receivable, accounts payable, accrued liabilities, contingent consideration and debt. The recorded values of cash, accounts receivable, accounts payable and accrued liabilities approximate their fair values based on their short-term nature. The fair value of the contingent acquisition consideration is based upon the present value of expected future payments under the terms of the agreements and is a Level 3 measurement. Based on borrowing rates currently available to us, the carrying values of the notes payable and short-term loans payable approximate their respective fair values.

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

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

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

Level 3 measurements are unobservable inputs.

## **Revenue Recognition**

Our principal activities from which we generate our revenue are product sales.

Revenue is measured based on consideration specified in a contract with a customer. A contract with a customer exists when we enter into an enforceable contract with a customer. The contract is based on either the acceptance of standard terms and conditions on the websites for e-commerce customers and via telephone with our third-party call center for our print media and direct mail customers, or the execution of terms and conditions contracts with retailers and wholesalers. These contracts define each party's rights, payment terms and other contractual terms and conditions of the sale. Consideration is typically paid prior to shipment via credit card or check when our products are sold direct to consumers or approximately 30 days from the time control is transferred when sold to wholesalers, distributors and retailers. We apply judgment in determining the customer's ability and intention to pay, which is based on a variety of factors including the customer's historical payment experience and, in some circumstances, published credit and financial information pertaining to the customer.

A performance obligation is a promise in a contract to transfer a distinct product to the customer, which for us is transfer of over-the-counter drug and consumer care products to our customers. Performance obligations promised in a contract are identified based on the goods that will be transferred to the customer that are both capable of being distinct and are distinct in the context of the contract, whereby the transfer of the goods is separately identifiable from other promises in the contract. We have concluded the sale of bottled finished goods and related shipping and handling are accounted for as the single performance obligation.

The transaction price of a contract is allocated to each distinct performance obligation and recognized as revenue when or as the customer receives the benefit of the performance obligation. The transaction price is determined based on the consideration to which we will be entitled to receive in exchange for transferring goods to the customer. We issue refunds to e-commerce and print media customers, upon request, within 30 days of delivery. We estimate the amount of potential refunds at each reporting period using a portfolio approach of historical data, adjusted for changes in expected customer experience, including seasonality and changes in economic factors. For retailers, distributors and wholesalers, we do not offer a right of return or refund and revenue is recognized at the time products are shipped to customers. In all cases, judgment is required in estimating these reserves. Actual claims for returns could be materially different from the estimates. The estimated reserve for sales returns and allowances, which is included in accounts payable and accrued expense, was approximately \$213,000 and \$53,000 at September 30, 2018 and December 31, 2017, respectively.

We recognize revenue when we satisfy a performance obligation in a contract by transferring control over a product to a customer when product is shipped. Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction, that are collected by us from a customer, are excluded from revenue. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost and are included in cost of product sales.

We enter into exclusive distributor and license agreements that are within the scope of ASC Topic 606. The license agreements we enter into normally generate three separate components of revenue: (1) an initial nonrefundable payment due on signing or when certain specific conditions are met; (2) royalties that are earned on an ongoing basis as sales are made or a pre-agreed transfer price; and (3) sales-based milestone payments that are earned when cumulative sales reach certain levels. Revenue from the initial nonrefundable payments or licensing fee is recognized when all required conditions are met. If the consideration for the initial license fee is for the right to sell the licensed product in the respective territory with no other required conditions to be met, such type of nonrefundable license fee arrangement for the right to sell the licensed product in the territory is recognized ratably over the term of the license agreement. For arrangements with licenses that include sales-based royalties, including sales-based milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied. The achievement of the sales-based milestone underlying the payment to be received predominantly relates to the licensee's performance of future commercial activities.

## Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding and vested but deferred RSUs during the period presented. Diluted net loss per share is computed using the weighted average number of common shares outstanding and vested plus deferred RSUs during the periods plus the effect of dilutive securities outstanding during the periods. For the three and nine months ended September 30, 2018 and 2017, basic net loss per share is the same as diluted net loss per share as a result of our common stock equivalents being anti-dilutive. See Note 5 for more details.

## Recent Accounting Pronouncements

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting*. This ASU expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The amendments in this ASU will become effective for us beginning January 1, 2019, and early adoption is permitted. We do not anticipate that this ASU will have a material effect on our consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, *Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*. The update simplifies how an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount. This update is effective for annual and interim periods beginning after December 15, 2019, and interim periods within that reporting period. While we are still in the process of completing our analysis on the impact this guidance will have on the consolidated financial statements and related disclosures, we do not expect the impact to be material.



In January 2017, the FASB issued ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*. The update provides that when substantially all the fair value of the assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This update is effective for annual and interim periods beginning after December 15, 2017, and interim periods within that reporting period. We adopted this ASU on January 1, 2018 and the impact on our consolidated financial statements will depend on the facts and circumstances of any specific future transactions.

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

## NOTE 2 – INVENTORY

Inventories consist of the following:

|                            | <b>September<br/>30,<br/>2018</b> | <b>December<br/>31,<br/>2017</b> |
|----------------------------|-----------------------------------|----------------------------------|
| Raw materials and supplies | \$317,070                         | \$164,469                        |
| Work in process            | 126,883                           | 152,935                          |
| Finished goods             | 1,754,092                         | 1,408,294                        |
| Total                      | \$2,198,045                       | \$1,725,698                      |

**NOTE 3 – INTANGIBLE ASSETS AND GOODWILL**

Amortizable intangible assets consist of the following:

**September 30, 2018**

|                                       | <b>Amount</b> | <b>Accumulated<br/>Amortization</b> | <b>Net<br/>Amount</b> | <b>Useful<br/>Lives<br/><br/>(years)</b> |
|---------------------------------------|---------------|-------------------------------------|-----------------------|--|
| Patent & Trademarks                   | \$417,597     | \$(150,018 )                        | \$267,579             | 7– 15                                    |
| Customer Contracts                    | 611,119       | (295,374 )                          | 315,745               | 10                                       |
| Sensum+® License (from CRI)           | 234,545       | (125,056 )                          | 109,489               | 10                                       |
| Vesele® Trademark                     | 25,287        | (12,578 )                           | 12,709                | 8  |
| Beyond Human® Website and Trade Name  | 222,062       | (101,744 )                          | 120,318               | 5– 10                                    |
| Novalere Manufacturing Contract       | 4,681,000     | (1,706,615 )                        | 2,974,385             | 10                                       |
| Other Beyond Human® Intangible Assets | 4,730         | (4,281 )                            | 449                   | 1– 3                                     |
| Total                                 | \$6,196,340   | \$(2,395,666 )                      | \$3,800,674           |  |

**December 31, 2017**

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

Amortization expense for the three and nine months ended September 30, 2018 and 2017 was \$157,475 and \$157,477 and \$472,425 and \$472,675, respectively. The following table summarizes the approximate expected future amortization expense as of September 30, 2018 for intangible assets:

|                   |             |
|-------------------|-------------|
| Remainder of 2018 | \$ 157,475  |
| 2019              | 629,001     |
| 2020              | 628,527     |
| 2021              | 599,598     |
| 2022              | 591,834     |
| 2023              | 558,150     |
| Thereafter        | 636,089     |
|                   | \$3,800,674 |

#### NOTE 4 – NOTES PAYABLE

The following table summarizes the outstanding notes payable at September 30, 2018 and December 31, 2017:

|  | <b>2018</b> | <b>2017</b> |
|--|-------------|-------------|
| Notes payable:                           |             |             |
| February 2016 Note Payable               | \$-         | \$ 54,984   |
| September 2017 5% Note Payable           | -           | 165,000     |
| October and December 2017 Notes Payable  | -           | 1,066,667   |
| December 2017 5% Note Payable            | -           | 390,000     |
| January and March 2018 Notes Payable     | 411,459     | -           |
| February and March 2018 5% Notes Payable | 720,000     | -           |
| July 2018 5% Note Payable                | 550,000     | -           |
| August 2018 Notes Payable                | 1,100,000   | -           |
| September 2018 3.8% Note Payable         | 390,000     | -           |
| Total notes payable                      | 3,171,459   | 1,676,651   |
| Less: Debt discount                      | (830,610 )  | (437,355 )  |
| Carrying value                           | 2,340,849   | 1,239,296   |
| Less: Current portion                    | (2,340,849) | (1,239,296) |
| Notes payable, net of current portion    | \$-         | \$-         |

The following table summarizes the future minimum payments as of September 30, 2018 for the notes payable:

|                   |             |
|-------------------|-------------|
| Remainder of 2018 | \$1,004,004 |
| 2019              | 2,167,455   |
|                   | \$3,171,459 |

*September 2017 5% Note Payable*

On September 20, 2017, we entered into a securities purchase agreement with an unrelated third-party investor in which the investor loaned us gross proceeds of \$150,000 pursuant to a 5% promissory note. The note has an Original Issue Discount (“OID”) of \$15,000 and requires payment of \$165,000 in principal upon maturity. The note bears interest at the rate of 5% per annum and the principal amount and interest are payable at maturity on May 20, 2018.

In connection with the note, we issued the investor restricted shares of common stock totaling 895,000 shares. The fair value of the restricted shares of common stock issued was based on the market price of our common stock on the date of issuance of the note. The allocation of the proceeds received to the restricted shares of common stock based on their relative fair value and the OID resulted in us recording a debt discount of \$70,169. The discount is being amortized to interest expense using the effective interest method over the term of the note.

In April 2018, we entered into a securities purchase agreement with the September 2017 5% Note holder. In connection with the securities exchange agreement, we issued a total of 1,474,287 shares of common stock in exchange for the settlement of principal and interest due totaling \$169,543. The fair value of the shares of common stock issued was based on the market price of our common stock on the date of the securities exchange agreements was determined to be \$196,080. Due to the settlement of the principal and interest balance of \$169,543 into shares of common stock, the transaction was recorded as a debt extinguishment and the fair value of the shares of common stock issued in excess of the settled principal balance totaling \$26,537 and the unamortized debt discount as of the date of settlement of \$12,050 were recorded as a loss on debt extinguishment in the accompanying condensed consolidated statement of operations.

#### *December 2017 5% Note Payable*

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

On July 23, 2018, we entered into a securities exchange agreement with the December 2017 5% Note Payable holder. In connection with the securities exchange agreement, we issued a total of 3,832,695 shares of common stock in exchange for the settlement of principal and interest due totaling \$402,433. The fair value of the shares of common stock issued was based on the market price of our common stock on the date of the securities exchange agreements was determined to be \$682,220. Due to the settlement of the principal and interest balance of \$402,433 into shares of common stock, the transaction was recorded as a debt extinguishment and the fair value of the shares of common stock issued in excess of the settled principal and interest balance totaling \$279,787 and the unamortized debt discount as of the date of settlement of \$42,594 were recorded as a loss on debt extinguishment in the accompanying condensed consolidated statement of operations.

#### *October and December 2017 Notes Payable*

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

On March 1, 2018, we entered into a securities exchange agreement with certain of the October and December 2017 Notes Payable holders. In connection with the securities exchange agreement, we issued a total of 2,250,000 shares of common stock in exchange for the settlement of principal due under the October and December 2017 Notes Payable totaling \$166,667. The fair value of the shares of common stock issued, based on the market price of our common stock on the date of the securities exchange agreements, was determined to be \$384,750. Due to the settlement of the principal balance of \$166,667 into shares of common stock, the transaction was recorded as a debt extinguishment and the fair value of the shares of common stock issued in excess of the settled principal balance totaling \$218,083 and the unamortized debt discount as of the date of settlement of \$37,602 were recorded as a loss on debt extinguishment in the accompanying condensed consolidated statement of operations.

On July 31, 2018, we entered into a securities exchange agreement with the October and December 2017 Notes Payable holders. In connection with the securities exchange agreement, we issued a total of 2,380,954 shares of common stock in exchange for the settlement of principal due totaling \$250,000. The fair value of the shares of common stock issued was based on the market price of our common stock on the date of the securities exchange agreements was determined to be \$366,667. Due to the settlement of the principal balance of \$250,000 into shares of common stock, the transaction was recorded as a debt extinguishment and the fair value of the shares of common stock issued in excess of the settled principal balance totaling \$116,667 and the unamortized debt discount as of the date of settlement of \$66,753 were recorded as a loss on debt extinguishment in the accompanying condensed consolidated statement of operations.

#### *January and March 2018 Notes Payable*

On January 8, 2018, January 30, 2018, March 1, 2018 and March 2, 2018, we entered into a securities purchase agreement with three unrelated third-party investors, pursuant to which the investors loaned us gross proceeds of \$677,500 in January 2018 and \$550,000 in March 2018 pursuant to 0% promissory notes (“January and March 2018 Notes Payable”). The notes have an OID of \$269,375 and bear interest at the rate of 0% per annum. The principal amount of \$1,496,875 is to be repaid in twelve equal monthly installments. Monthly installments of \$68,490 began in February 2018 and are due through January 2019 and monthly installments of \$56,250 begin in April 2018 and are due through March 2019. The effective interest rate is 22% per annum for the January and March 2018 Notes Payable.

In connection with the January and March 2018 Notes Payable, we issued the investors restricted shares of our common stock totaling 1,282,000 shares. The fair value of the restricted shares of common stock issued was based on the market price of our common stock on the date of issuance of the January and March 2018 Notes Payable. The allocation of the proceeds received to the restricted shares of common stock based on their relative fair value and the OID resulted in us recording a debt discount of \$226,669 in January 2018 and \$187,574 in March 2018. In connection with the financing, we issued 621,317 restricted shares of our common stock in January 2018 and 314,737 restricted shares of common stock in March 2018 to a third-party consultant. The fair value of the restricted shares of common stock issued of \$67,500 in January 2018 and \$55,000 in March 2018 was recorded as a debt discount to the carrying value of the January and March 2018 Notes Payable. The discount is being amortized to interest expense using the effective interest method over the term of the January and March 2018 Notes Payable.

On July 31, 2018, we entered into a securities exchange agreement with the January and March 2018 Notes Payable holders. In connection with the securities exchange agreement, we issued a total of 2,857,144 shares of common stock in exchange for the settlement of principal due totaling \$300,000. The fair value of the shares of common stock issued was based on the market price of our common stock on the date of the securities exchange agreements was determined to be \$440,000. Due to the settlement of the principal balance of \$300,000 into shares of common stock, the transaction was recorded as a debt extinguishment and the fair value of the shares of common stock issued in excess of the settled principal balance totaling \$140,000 and the unamortized debt discount as of the date of settlement of \$99,638 were recorded as a loss on debt extinguishment in the accompanying condensed consolidated statement of operations.

*February and March 2018 5% Notes Payable*

On February 28, 2018 and March 28, 2018, we entered into a securities purchase agreement with two unrelated third-party investors, pursuant to which the investors loaned us gross proceeds of \$650,000 pursuant to 5% promissory notes (“February and March 2018 5% Notes Payable”). The notes have an OID of \$70,000 and require aggregate payments of \$720,000 in principal. The notes bear interest at the rate of 5% per annum and the principal amount and interest are payable at maturity on October 28, 2018 for the note issued in February 2018 and in three installments on October 1, 2018, January 1, 2019 and April 1, 2019 for the note issued in March 2018.

In connection with the February and March 2018 5% Notes Payable, we issued the investors restricted shares of our common stock totaling 1,485,000 shares. The fair value of the restricted shares of common stock issued was based on the market price of our common stock on the date of issuance of the February and March 2018 5% Notes Payable. The allocation of the proceeds received to the restricted shares of common stock based on their relative fair value and the OID resulted in us recording a debt discount of \$93,566 in February 2018 and \$128,695 in March 2018. The discount is being amortized to interest expense using the effective interest method over the term of the February and March 2018 5% Notes Payable.

#### *July 2018 5% Note Payable*

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

In connection with the note, we issued the investor restricted shares of common stock totaling 1,600,000 shares. The fair value of the restricted shares of common stock issued was based on the market price of our common stock on the date of issuance of the note. The allocation of the proceeds received to the restricted shares of common stock based on their relative fair value and the OID resulted in us recording a debt discount of \$176,166. The discount is being amortized to interest expense using the effective interest method over the term of the note.

#### *August 2018 Notes Payable*

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

In connection with the August 2018 Notes Payable, we issued the investors restricted shares of common stock totaling 1,000,000 shares. The fair value of the restricted shares of common stock issued was based on the market price of our common stock on the date of issuance of the August 2018 Notes Payable. The allocation of the proceeds received to the restricted shares of common stock based on their relative fair value and the OID resulted in us recording a debt discount of \$435,322. In connection with the financing, we issued 638,978 restricted shares to a third-party consultant.



The fair value of the restricted shares of common stock issued of \$100,000 was recorded as a debt discount to the carrying value of the August 2018 Notes Payable. The discount is being amortized to interest expense using the effective interest method over the term of the August 2018 Notes Payable.

#### *September 2018 5% Notes Payable*

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

In connection with the September 2018 5% Notes Payable, we issued the investor restricted shares of common stock totaling 1,000,000 shares. The fair value of the restricted shares of common stock issued was based on the market price of our common stock on the date of issuance of the September 2018 5% Notes Payable. The allocation of the proceeds received to the restricted shares of common stock based on their relative fair value and the OID resulted in us recording a debt discount of \$130,296. The discount is being amortized to interest expense using the effective interest method over the term of the Note.

#### *Interest Expense*

We recognized interest expense on notes payable of approximately \$14,497 and \$17,750 and \$48,275 and \$64,463 for the three and nine months ended September 30, 2018 and 2017, respectively. Amortization of the debt discount to interest expense during the three and nine months ended September 30, 2018 and 2017 approximated \$364,804 and \$86,250 and \$898,896 and \$687,598, respectively.

## NOTE 5 – STOCKHOLDERS' EQUITY

### Issuances of Common Stock

In the first quarter of 2018, eleven of our warrant holders exercised their Series B Warrants to purchase shares of common stock totaling 18,925,002 at an exercise price of \$0.15 per share. We received net cash proceeds of \$2,657,538. The remaining Series B Warrants totaling 6,741,667 expired on March 21, 2018. Per the terms of the engagement letter with H.C. Wainwright & Co. (“HCW”) in connection with the public offering in March 2017 and as a result of the Series B Warrant exercises, we paid HCW \$181,213 and issued a warrant to purchase 862,917 shares of common stock at an exercise price of \$0.1875 per share (125% of the price of the common stock sold in the public offering in March 2017) which expires on March 21, 2023. The fair value of the warrants issued to HCW totaled \$136,729 and was determined using Black-Scholes. The fair value of the warrants was recorded as an offering cost but has no net impact to additional paid-in capital in stockholders' equity in the accompanying condensed consolidated balance sheet. In the third quarter of 2018, a warrant holder exercised their Series A Warrants to purchase shares of common stock totaling 100,000 at an exercise price of \$0.15 per share. We received net cash proceeds of \$13,950.

On October 10, 2017, we entered into a service agreement with a third party pursuant to which we agreed to issue, over the term of the agreement, 2,000,000 shares of common stock in exchange for services to be rendered. We have terminated this agreement effective January 30, 2018. During the three months ended March 31, 2018, we issued 166,666 shares of restricted common stock under the agreement related to services provided and recognized the fair value of the shares issued of \$13,917 in general and administrative expense in the accompanying consolidated statement of operations. The shares of common stock vested on the date of issuance and the fair value of the shares of common stock was based on the market price of our common stock on the date of vesting.

During the three and nine months ended September 30, 2018, we issued 0 and 106,486 shares of restricted common stock, respectively, for services and recorded expense of \$0 and \$10,500 which is included in general and administrative expense in the accompanying condensed consolidated statement of operations. The 106,486 shares of common stock vested on the date of issuance and the fair value of the shares of common stock was based on the market price of our common stock on the date of vesting.

During the three and nine months ended September 30, 2018, we issued 3,600,000 and 6,367,000 shares of restricted common stock, respectively, to note holders in connection with their notes payable. The relative fair value of the shares of restricted common stock issued was determined to be \$401,782 and \$693,911, respectively, and was recorded as a debt discount (see Note 4).

In connection with the January and March 2018 Notes, we issued 621,317 restricted shares of common stock in January 2018 and 314,737 restricted shares of common stock in March 2018 to a third-party consultant. The fair value of the restricted shares of common stock issued of \$67,500 in January 2018 and \$55,000 in March 2018 was recorded as a debt discount to the carrying value of the notes payable during the nine months ended September 30, 2018 (see Note 4).

In connection with the August 2018 Notes, we issued 638,978 restricted shares of common stock in March 2018 to a third-party consultant. The fair value of the restricted shares of common stock issued of \$100,000 in August 2018 was recorded as a debt discount to the carrying value of the notes payable during the nine months ended September 30, 2018 (see Note 4).

In March 2018, certain October and December 2017 Notes Payable holders elected to exchange \$166,667 in principal for 2,250,000 shares of common stock (see Note 4). The fair value of the shares of common stock of \$384,750 was based on the market price of our common stock on the date of issuance.

In April 2018, certain September 2017 5% Notes Payable holders elected to exchange \$169,543 in principal and interest for 1,474,287 shares of common stock (see Note 4). The fair value of the shares of common stock of \$196,080 was based on the market price of our common stock on the date of issuance.

In July 2018, certain December 2017 5% Notes Payable holders elected to exchange \$402,433 in principal and interest for 3,832,695 shares of common stock (see Note 4). The fair value of the shares of common stock of \$682,220 was based on the market price of our common stock on the date of issuance.

In July 2018, certain January and March 2018 Notes Payable holders elected to exchange \$300,000 in principal for 2,857,144 shares of common stock (see Note 4). The fair value of the shares of common stock of \$440,000 was based on the market price of our common stock on the date of issuance.

In July 2018, certain October and December 2017 Notes Payable holders elected to exchange \$250,000 in principal for 2,380,954 shares of common stock (see Note 4). The fair value of the shares of common stock of \$366,667 was based on the market price of our common stock on the date of issuance.

### **2013 Equity Incentive Plan**

We have issued common stock, restricted stock units and stock option awards to employees, non-executive directors and outside consultants under the 2013 Equity Incentive Plan (“2013 Plan”), which was approved by our Board of

Directors in February of 2013. The 2013 Plan allows for the issuance of up to 10,000,000 shares of our common stock to be issued in the form of stock options, stock awards, stock unit awards, stock appreciation rights, performance shares and other share-based awards. As of September 30, 2018, there were no shares available under the 2013 Plan.

### **2014 Equity Incentive Plan**

We have issued common stock, restricted stock units and stock options to employees, non-executive directors and outside consultants under the 2014 Equity Incentive Plan (“2014 Plan”), which was approved by our Board of Directors in November 2014. The 2014 Plan allows for the issuance of up to 20,000,000 shares of our common stock to be issued in the form of stock options, stock awards, stock unit awards, stock appreciation rights, performance shares and other share-based awards. As of September 30, 2018, there were 63 shares were available under the 2014 Plan.

## 2016 Equity Incentive Plan

We have issued common stock, restricted stock units and stock options to employees, non-executive directors and outside consultants under the 2016 Equity Incentive Plan (“2016 Plan”), which was approved by our Board of Directors in March 2016. The 2016 Plan allows for the issuance of up to 25,663,199 shares of our common stock to be issued in the form of stock options, stock awards, stock unit awards, stock appreciation rights, performance shares and other share-based awards. As of September 30, 2018, 15,506,569 shares were available under the 2016 Plan.

## Stock Options

For the nine months ended September 30, 2018 and 2017, the following weighted average assumptions were utilized for the calculation of the fair value of the stock options granted during the period using Black-Scholes:

|                                 | <b>2018</b> | <b>2017</b> |
|---------------------------------|-------------|-------------|
| Expected life (in years)        | 6.23        | 8.6         |
| Expected volatility             | 200.6%      | 217.0%      |
| Average risk-free interest rate | 2.81 %      | 2.28 %      |
| Dividend yield                  | 0 %         | 0 %         |
| Grant date fair value           | \$0.15      | \$0.17      |

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

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

| <b>Weighted<br/>average<br/>exercise<br/>price</b> | <b>Weighted<br/>remaining<br/>contractual<br/>life (years)</b> | <b>Aggregate<br/>intrinsic<br/>value</b> |
|--|--|--|
|--|--|--|

|   | <b>Options</b> |         |     |          |
|---|----------------|---------|-----|----------|
| Outstanding at December 31, 2017                  | 88,000         | \$ 0.17 | 8.2 | \$ 1,590 |
| Granted   | 282,000        | 0.15    | 9.6 | 280      |
| Exercised   | -              | -       | -   | -        |
| Cancelled   | -              | -       | -   | -        |
| Forfeited   | -              | -       | -   | -        |
| Outstanding at September 30, 2018                 | 370,000        | \$ 0.15 | 9.3 | \$ 1,870 |
| Vested and Expected to Vest at September 30, 2018 | 370,000        | \$ 0.15 | 9.3 | \$ 1,870 |

The aggregate intrinsic value is calculated as the difference between the exercise price of all outstanding stock options and the quoted price of our common stock at September 30, 2018. During the three and nine months ended September 30, 2018 and 2017, the Company recognized stock-based compensation from stock options of \$4,820 and \$904 and \$9,218 and \$6,310, respectively.

The weighted average grant date fair value of outstanding stock options for the nine months ended September 30, 2018 is \$0.15 per share.

### Restricted Stock Units

The following table summarizes the restricted stock unit activity for the nine months ended September 30, 2018:

|                                   | <b>Restricted</b>  |
|-----------------------------------|--------------------|
|                                   | <b>Stock Units</b> |
| Outstanding at December 31, 2017  | 13,191,835         |
| Granted                           | 6,805,772          |
| Exchanged                         | (713,541 )         |
| Cancelled                         | (1,536,459 )       |
| Outstanding at September 30, 2018 | 17,747,607         |
| Vested at September 30, 2018      | 10,950,904         |

The vested restricted stock units at September 30, 2018 have not settled and are not showing as issued and outstanding shares of ours but are considered outstanding for earnings per share calculations. Settlement of these vested restricted stock units will occur on the earliest of (i) the date of termination of service of the employee or consultant, (ii) change of control of us, or (iii) 7-10 years from date of issuance. Settlement of vested restricted stock units may be made in the form of (i) cash, (ii) shares, or (iii) any combination of both, as determined by the board of directors and is subject to certain criteria having been fulfilled by the recipient.

We calculate the fair value of the restricted stock units based upon the quoted market value of the common stock at the date of grant. The grant date fair value of restricted stock units issued during the three and nine months ended September 30, 2018 was \$39,000 and \$982,292. For the three and nine months ended September 30, 2018 and 2017, we recognized \$128,008 and \$80,125 and \$325,442 and \$248,804, respectively, of stock-based compensation expense for the vested units. As of September 30, 2018, compensation expense related to unvested shares not yet recognized in the condensed consolidated statement of operations was approximately \$878,289 and will be recognized over a remaining weighted-average term of 2.55 years.

## **Warrants**

During the year ended December 31, 2014, we issued warrants in connection with notes payable (which were repaid in 2013). The remaining warrants of 135,816 have an exercise price of \$0.10 and expire December 6, 2018.

In January 2015, we issued 250,000 warrants with an exercise price of \$0.30 per share to a former executive in connection with the January 2015 debenture. The warrants expire on January 21, 2020. The warrants contain anti-dilution protection, including protection upon dilutive issuances. In connection with the convertible debentures issued in 2015, the exercise price of these warrants was reduced to \$0.0896 per share and an additional 586,705 warrants were issued per the anti-dilution protection afforded in the warrant agreement during the year ended December 31, 2015.

In connection with the convertible debentures in 2015, we issued warrants with an exercise price of \$0.30 per share and expiration in 2020 to investors and placement agents. Warrants to purchase 774,533 shares of common stock remain outstanding as of September 30, 2018.

In connection with the convertible debentures in 2016, we issued warrants to the investors and placement agents with an exercise price of \$0.40 per share and expire in 2021. Warrants to purchase 4,220,000 shares of common stock remain outstanding as of September 30, 2018.

In connection with the public equity offering in March 2017, we issued Series A Warrants to purchase 25,666,669 shares of common stock at \$0.15 per share and Series B Warrants to purchase 25,666,669 shares of common stock at \$0.15 per share. The Series A Warrants expire in 2022. In the first quarter of 2018, certain investors elected to exercise 18,925,002 Series B Warrants and the remaining Series B Warrants expired in March 2018. We also issued warrants to purchase 1,283,333 shares of common stock to our placement agent with an exercise price of \$0.1875 per share and expire in 2022 in connection with the Series B Warrants exercised, as well as in March 2018 we issued our placement agent warrants to purchase 862,917 shares of common stock with an exercise price of \$0.1875 per share and expire in 2023 in connection with the Series B Warrants exercised.

For the nine months ended September 30, 2018, the following weighted average assumptions were utilized for the calculation of the fair value of the warrants issued during the period using Black-Scholes:

|                                 | <b>2018</b> |
|---------------------------------|-------------|
| Expected life (in years)        | 5.0         |
| Expected volatility             | 183.8 %     |
| Average risk-free interest rate | 2.69 %      |
| Dividend yield                  | 0 %         |

At September 30, 2018, there are 33,679,973 fully vested warrants outstanding. The weighted average exercise price of outstanding warrants at September 30, 2018 is \$0.19 per share, the weighted average remaining contractual term is 3.3 years and the aggregate intrinsic value of the outstanding warrants is \$27,817.

### **Net Loss per Share**

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



The weighted average shares of common stock outstanding used in the basic and diluted net loss per share calculation for the three and nine months ended September 30, 2018 and 2017 was 203,576,357 and 152,250,793 and 191,530,885 and 143,192,157, respectively.

The weighted average restricted stock units vested but issuance of the common stock is deferred until there is a change in control, a specified date in the agreement or the employee or director resigns used in the basic and diluted net loss per share calculation for the three and nine months ended September 30, 2018 and 2017 was 10,950,904 and 9,337,141 and 10,759,456 and 9,133,039, respectively.

The total weighted average shares outstanding used in the basic and diluted net loss per share calculation for the three and nine months ended September 30, 2018 and 2017 was 214,527,261 and 161,587,934 and 202,290,341 and 152,325,196, respectively.

The following table shows the anti-dilutive shares excluded from the calculation of basic and diluted net loss per common share as of September 30, 2018 and 2017:

|   | <b>As of September 30,</b> |             |
|---|----------------------------|-------------|
|   | <b>2018</b>                | <b>2017</b> |
| <b>Gross number of shares excluded:</b> |                            |             |
| Restricted stock units – unvested       | 6,796,703                  | 3,437,500   |
| Stock options                           | 370,000                    | 79,000      |
| Warrants                                | 33,679,973                 | 58,583,725  |
| Total                                   | 40,846,676                 | 62,100,225  |

The above table does not include the ANDA Consideration Shares related to the Novalere acquisition totaling 138,859 at September 30, 2018 and 2017, respectively, as they are considered contingently issuable.

## **NOTE 6 – COMMITMENTS AND CONTINGENCIES**

In May 2017, we entered into a commercial agreement with West-Ward Pharmaceuticals International Limited (“WWPIL”), a wholly-owned subsidiary of Hikma Pharmaceuticals PLC (“Hikma”) (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY). Pursuant to the commercial agreement, WWPIL provided us with the rights to launch our branded, fluticasone propionate nasal spray USP, 50 mcg per spray (FlutiCare®), under WWPIL’s FDA approved ANDA No. 207957 in the U.S. in mid-November 2017. The initial term of the commercial agreement is for two years, and upon

expiration of the initial term, the agreement will automatically renew for subsequent one-year terms unless either party notifies the other party in writing of its desire not to renew at least 90 days prior to the end of the then current term. The agreement requires us to meet certain minimum product batch purchase requirements in order for the agreement to continue to be in effect. We have met the annual minimum product batch purchase requirements to date.

### *Litigation*

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

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

### **NOTE 7 – SUBSEQUENT EVENTS**

In October 2018, we entered into a promissory note agreement and securities purchase agreement with an unrelated third-party investor in which the investor loaned us gross proceeds of \$500,000 in consideration for the issuance of a 5% promissory note. The note has an OID of \$50,000 and requires payment of \$550,000 in principal. The note bears interest at the rate of 5% per annum and the principal amount and interest are payable at maturity on May 1, 2019. As additional consideration for the purchase of the note, we issued 1,600,000 shares of restricted common stock to the investor.

In October 2018, we entered into an exchange agreement with a note holder of the February and March 2018 5% Notes Payable to convert the principal and interest balance of \$340,036 to 4,250,445 shares of common stock.

In November 2018, we entered into a promissory note agreement and securities purchase agreement with three unrelated third-party investors in which the investors loaned us gross proceeds of \$898,000 in consideration for the issuance of a 0% promissory note. The notes have an OID of \$202,000 and requires payment of \$1,100,000 in principal. The note bears interest at the rate of 0% per annum and the principal amount and interest are payable at maturity on November 6, 2019. As additional consideration for the purchase of the note, we issued 1,200,000 shares of restricted common stock to the investors.

In November 2018, we entered into an exchange agreement with a note holder of the February and March 2018 Notes Payable to convert the principal balance of \$100,000 to 1,250,000 shares of common stock.

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

## **ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*Innovus Pharmaceuticals, Inc., together with its subsidiaries, are collectively referred to as "Innovus", the "Company", "us", "we", or "our". The following information should be read in conjunction with the condensed consolidated financial statements and notes thereto appearing elsewhere in this report. For additional context with which to understand our financial condition and results of operations, see the discussion and analysis included in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission ("SEC") on April 2, 2018, as well as the consolidated financial statements and related notes contained therein.*

### **Forward Looking Statements**

Certain statements in this report, including information incorporated by reference, are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking

statements reflect current views about future events and financial performance based on certain assumptions. They include opinions, forecasts, intentions, plans, goals, projections, guidance, expectations, beliefs or other statements that are not statements of historical fact. Words such as “may,” “should,” “could,” “would,” “expects,” “plans,” “believes,” “anticipates,” “intends,” “estimates,” “approximates,” “predicts,” or “projects,” or the negative or other variation of such words and similar expressions may identify a statement as a forward-looking statement. Any statements that refer to projections of our future financial performance, our anticipated growth and trends in our business, our goals, strategies, focus and plans, and other characterizations of future events or circumstances, including statements expressing general optimism about future operating results and the development of our products, are forward-looking statements.

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

## Overview

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

Our business model leverages our ability to (a) develop and build our current pipeline of proprietary products, and (b) to 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 31 products marketed in the United States with 12 of those being marketed and sold in multiple countries around the world through some of our 16 international commercial partners. We currently expect to launch an additional four products in the U.S. in 2018 and we currently have approvals to launch certain of our already marketed products in at least six additional countries.

## **Our Strategy**

Our corporate strategy focuses on two primary objectives:

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:

1. the introduction of line extensions and reformulations of either our or third-party currently marketed products;
2. the development of new proprietary OTC products, supplements and devices; and
3. the acquisition of products or obtaining exclusive licensing rights to market such products; and

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:

1. generates revenue, and
2. requires a lower cost structure compared to traditional pharmaceutical companies, thereby increasing our gross margins.

## **Our Products**

We currently market and sell 31 products in the U.S. and 12 in multiple countries around the world through our 16 international commercial partners. While 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 in 2018, subject to the applicable regulatory approvals, if required:

- GlucoGorx™ Supplement, Glucometer, Lancing Device and GlucoGorx™ Strips. GlucoGorx™ is a supplement designed
1. to help diabetics and others control their levels of blood sugar. The Glucometer, Lancing Device and GlucoGorx™ Strips are part of an FDA approved kit that we will co-market with GlucoGorx™ (second half of 2018);
  2. Carvanum™ for indications for muscle soreness (fourth quarter 2018);
  3. MZS Sleeping Aid with CBD oil (fourth quarter 2018);
  4. Trexar™ for neuropathy support and enhanced sensation (fourth quarter 2018);
  5. Musclin™ for muscle growth (first quarter 2019);
  6. Regenerum™ for muscle wasting or cachexia (first quarter 2019);
  7. Optik for vision support (first quarter 2019).

### **Sales and Marketing Strategy U.S. and Internationally**

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

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

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

|  | <b>Three<br/>Months<br/>Ended</b> | <b>Three<br/>Months<br/>Ended</b> | <b>\$ Change</b>   | <b>%<br/>Change</b> |           |
|--|-----------------------------------|-----------------------------------|--------------------|---------------------|-----------|
|  | <b>September<br/>30, 2018</b>     | <b>September<br/>30, 2017</b>     |                    |                     |           |
| <b>NET REVENUE:</b>                                |                                   |                                   |                    |                     |           |
| 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               | %         |
| <b>OPERATING EXPENSE:</b>                          |                                   |                                   |                    |                     |           |
| 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               | %         |
| <b>LOSS FROM OPERATIONS</b>                        | <b>(1,502,577)</b>                | <b>(1,215,600)</b>                | <b>(286,977 )</b>  | <b>(23.6</b>        | <b>)%</b> |
| <b>OTHER INCOME (EXPENSE):</b>                     |                                   |                                   |                    |                     |           |
| 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               | %         |
| <b>NET LOSS</b>                                    | <b>\$(2,449,938)</b>              | <b>\$(1,328,657)</b>              | <b>(1,121,281)</b> | <b>(84.4</b>        | <b>)%</b> |
|  | <b>Nine<br/>Months<br/>Ended</b>  | <b>Nine<br/>Months<br/>Ended</b>  | <b>\$ Change</b>   | <b>%<br/>Change</b> |           |

|  | <b>September<br/>30, 2018</b> | <b>September<br/>30, 2017</b> |                     |              |           |
|--|-------------------------------|-------------------------------|---------------------|--------------|-----------|
| <b>NET REVENUE:</b>                                |                               |                               |                     |              |           |
| 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        | %         |
| <b>OPERATING EXPENSE:</b>                          |                               |                               |                     |              |           |
| 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        | %         |
| <b>LOSS FROM OPERATIONS</b>                        | <b>(4,328,729 )</b>           | <b>(3,996,939 )</b>           | <b>(331,790 )</b>   | <b>(8.3</b>  | <b>)%</b> |
| <b>OTHER INCOME (EXPENSE):</b>                     |                               |                               |                     |              |           |
| 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       | )%        |
| <b>NET LOSS</b>                                    | <b>\$(6,119,058 )</b>         | <b>\$(5,008,494 )</b>         | <b>(1,110,564 )</b> | <b>(22.2</b> | <b>)%</b> |



*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 Apezaz® and ArthriVarx® in mid-2017. The following represents the number of units shipped of our top products during the periods:

|                         | <b>Three<br/>Months<br/>Ended</b> | <b>Three<br/>Months<br/>Ended</b> | <b>#</b>      | <b>%</b>      |   |
|-------------------------|-----------------------------------|-----------------------------------|---------------|---------------|---|
|                         | <b>September<br/>30,</b>          | <b>September<br/>30,</b>          | <b>Change</b> | <b>Change</b> |   |
|                         | <b>2018</b>                       | <b>2017</b>                       |               |               |   |
| <b>Number of units</b>  |                                   |                                   |               |               |   |
| Diabasens™              | 70,363                            | -                                 | 70,363        | 100.0         | % |
| Vesele®                 | 40,359                            | 11,896                            | 28,463        | 239.3         | % |
| Fluticare®              | 35,813                            | -                                 | 35,813        | 100.0         | % |
| Apezaz®                 | 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       | % |

|                         | <b>Nine<br/>Months<br/>Ended</b> | <b>Nine<br/>Months<br/>Ended</b> | <b>#</b>      | <b>%</b>      |   |
|-------------------------|----------------------------------|----------------------------------|---------------|---------------|---|
|                         | <b>September<br/>30,</b>         | <b>September<br/>30,</b>         | <b>Change</b> | <b>Change</b> |   |
|                         | <b>2018</b>                      | <b>2017</b>                      |               |               |   |
| <b>Number of units</b>  |                                  |                                  |               |               |   |
| 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          | % |
| Apezaz®                 | 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.

*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 (see Note 4 to the accompanying condensed consolidated financial statements). 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.

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 Sempra.

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 (see Note 1 to the accompanying condensed consolidated financial statements).

### *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.

### **Liquidity and Capital Resources**

Historically, we have funded losses from operations through the sale of equity and issuance of debt instruments. Combined with revenue, these funds have provided us with the capital to operate our business, to sell and support our products, attract and retain key personnel, and add new products to our portfolio. To date, we have experienced net losses each year since our inception. As of September 30, 2018, we had an accumulated deficit of \$41.7 million and working capital deficit of \$1.6 million.

As of September 30, 2018, we had approximately \$0.7 million in cash and \$453,675 held by merchant processors reported in other current assets and as of November 13, 2018 we had approximately \$1,528,293 million in cash and \$387,062 held by merchant processors reported in other current assets. Although no assurances can be given, we currently plan to raise additional capital through the sale of equity or debt securities. We expect, however, that our existing capital resources, revenue from sales of our products and upcoming new product launches and sales milestone payments from the commercial partners signed for our products, and equity instruments available to pay certain vendors and consultants, will be sufficient to allow us to continue our operations, commence the product development process and launch selected products through at least the next 12 months. In addition, our CEO, who is also a significant shareholder, has deferred the remaining payment of his salary earned through June 30, 2016 totaling \$1.2 million for at least the next 12 months.

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

We currently intend to raise additional capital through the sale of debt or equity securities to provide additional working capital, for further expansion and development of our business, and to meet current obligations, although no assurances can be given. If we issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience substantial dilution, and the newly issued equity or debt securities may have more

favorable terms or rights, preferences and privileges senior to those of our existing stockholders. If we raise funds by incurring additional debt, we may be required to pay significant interest expense and our leverage relative to our earnings or to our equity capitalization may increase. Obtaining commercial loans, assuming they would be available, would increase our liabilities and future cash commitments and may impose restrictions on our activities, such as financial and operating covenants. Further, we may incur substantial costs in pursuing future capital and/or financing transactions, including investment banking fees, legal fees, accounting fees, printing and distribution expense and other costs. We may also be required to recognize non-cash expense in connection with certain securities we may issue, such as convertible notes and warrants, which would adversely impact our financial results. We may be unable to obtain financing when necessary as a result of, among other things, our performance, general economic conditions, conditions in the pharmaceuticals industries, or our operating history. In addition, the fact that we are not and have never been profitable could further impact the availability or cost to us of future financings. As a result, sufficient funds may not be available when needed from any source or, if available, such funds may not be available on terms that are acceptable to us. If we are unable to raise funds to satisfy our capital needs when needed, then we may need to forego pursuit of potentially valuable development or acquisition opportunities, we may not be able to continue to operate our business pursuant to our business plan, which would require us to modify our operations to reduce spending to a sustainable level by, among other things, delaying, scaling back or eliminating some or all of our ongoing or planned investments in corporate infrastructure, business development, sales and marketing and other activities, or we may be forced to discontinue our operations entirely.

The Company's principle debt instruments include the following:

In the first quarter of 2018, we entered into a securities purchase agreement with three unrelated third-party investors, pursuant to which the investors loaned us gross proceeds of \$1,222,500 pursuant to 0% promissory notes ("January and March 2018 Notes Payable"). The January and March 2018 Notes Payable have an OID of \$269,375 and bear interest at the rate of 0% per annum. The principal amount of \$1,496,875 is to be repaid in twelve equal monthly installments. Monthly installments of \$68,490 began in February 2018 and are due through January 2019 and monthly installments of \$56,250 begin in April 2018 and are due through March 2019. In connection with the January and March 2018 Notes Payable, we issued 1,282,000 restricted shares of common stock to the investors. The remaining principal balance under these notes was \$411,459 at September 30, 2018. In July 2018, we entered into a securities exchange agreement with two of the note holders. In connection with the securities exchange agreement, we issued a total of 2,857,144 shares of common stock in exchange for the settlement of the remaining principal due under the notes payable to those investors, totaling \$300,000.

In February and March 2018, we entered into securities purchase agreements with two unrelated third-party investors, pursuant to which the investors loaned us gross proceeds of \$650,000 pursuant to 5% promissory notes (“February and March 2018 5% Notes Payable”). The February and March 2018 5% Notes Payable have an OID of \$70,000 and require payment of \$720,000 in principal. The February and March 2018 5% Notes Payable bear interest at the rate of 5% per annum and the principal amount and accrued interest are payable at maturity on October 28, 2018 for the note issued in February 2018 and in three installments on October 1, 2018, January 1, 2019 and April 1, 2019 for the note issued in March 2018. In connection with the February and March 2018 5% Notes Payable, we issued the investors restricted shares of common stock totaling 1,485,000. The remaining principal balance under these notes was \$720,000 at September 30, 2018.

In July 2018, we entered into a securities purchase agreement with an unrelated third-party investor, pursuant to which the investor loaned us gross proceeds of \$500,000 pursuant to 5% promissory notes (“July 2018 5% Notes Payable”). The July 2018 5% Notes Payable have an OID of \$50,000 and require aggregate payments of \$550,000 in principal. The July 2018 5% Notes Payable bear interest at the rate of 5% per annum and the principal amount and accrued interest are payable at maturity on February 19, 2019. In connection with the July 2018 5% Notes Payable, we issued the investor restricted shares of common stock totaling 1,600,000. The remaining principal balance under these notes was \$550,000 at September 30, 2018.

In August 2018, we entered into securities purchase agreements with two unrelated third-party investors, pursuant to which the investors loaned us gross proceeds of \$1,000,000 pursuant to 0% promissory notes (“August 2018 Notes Payable”). The August 2018 Notes Payable have an OID of \$200,000 and require twelve payments of \$100,000 in principal per month through August 2019. The August 2018 Notes Payable bear no interest per annum. In connection with the August 2018 Notes Payable, we issued the investors restricted shares of common stock totaling 1,000,000. The remaining principal balance under these notes was \$1,100,000 at September 30, 2018.

In September 2018, we entered into a securities purchase agreement with an unrelated third-party investor, pursuant to which the investor loaned us gross proceeds of \$350,000 pursuant to 5% promissory notes (“September 2018 5% Notes Payable”). The September 2018 5% Notes Payable have an OID of \$40,000 and require aggregate payments of \$390,000 in principal. The September 2018 5% Notes Payable bear interest at the rate of 5% per annum and the principal amount and accrued interest are payable in three installments on March 12, 2019, June 12, 2019 and September 12, 2019. In connection with the September 2018 5% Notes Payable, we issued the investor restricted shares of common stock totaling 1,000,000. The remaining principal balance under these notes was \$390,000 at September 30, 2018.

### *Net Cash Flows*

|   | <b>Nine<br/>Months<br/>Ended<br/>September<br/>30, 2018</b> | <b>Nine<br/>Months<br/>Ended<br/>September<br/>30, 2017</b> |
|---|---|---|
| Net cash used in operating activities     | \$(5,587,887)   | \$(1,546,527)   |
| Net cash used in investing activities     | (195,362 )  | (10,131 )   |
| Net cash provided by financing activities | 4,921,401   | 2,041,784   |
| Net change in cash                        | (861,847 )  | 485,126   |
| Cash at beginning of period               | 1,564,859   | 829,933   |
| Cash at end of period                     | \$703,012   | \$1,315,059   |

### *Operating Activities*

For the nine months ended September 30, 2018, cash used in operating activities was approximately \$5.6 million consisting primarily of the net loss for the period of approximately \$6.1 million as well as the purchase of additional inventory, \$0.5 million, to support the significant growth in sales during the period and merchant processor holdback, \$0.8 million, which was primarily offset by non-cash common stock, restricted stock units and stock options issued for services and compensation of approximately \$356,000, amortization of debt discount of \$899,000, loss on debt extinguishment of \$1.0 million, and amortization of intangible assets of \$472,000. The increase in net cash used in operating activities during 2018 is primarily the result of increased marketing spending in launching a number of new products and the introduction of direct mail advertising which has been the main cause for the increase in revenues during the period, expansion of our operations which include hiring personnel and product commercialization activities.



### *Investing Activities*

For the nine months ended September 30, 2018, cash used in investing activities was approximately \$0.2 million which consisted of the purchase of property and equipment for our expanded corporate and fulfillment office location.

### *Financing Activities*

For the nine months ended September 30, 2018, cash provided by financing activities was approximately \$4.9 million, consisting primarily of the gross proceeds from the exercise of Series B Warrants of \$2.7 million and notes payable of \$3.7 million, offset by the repayment of notes payable and short-term loans payable of \$1.5 million. Cash provided by financing activities in 2017 was primarily related to the net proceeds from the public equity offering in March 2017 of \$3.3 million and notes payable of \$300,000, offset by the repayment of convertible debentures of approximately \$1.2 million, notes payable of \$214,000, and the prepayment penalty on the repayment of the convertible debentures of \$127,000.

### **Critical Accounting Policies and Estimates**

On January 1, 2018, we adopted Financial Accounting Standards Board (“FASB”) ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features*. This ASU requires that when determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity’s own stock. As a result, a freestanding equity-linked financial instrument no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic earnings per share. As a result of the adoption of this ASU, we recorded a cumulative-effect adjustment to the consolidated statement of financial position as of January 1, 2018 of \$58,609 for the warrants previously classified as a derivative liability due to a down round provision included in the terms of the warrant agreement. Therefore, the cumulative-effect adjustment was recorded as a reduction in accumulated deficit and derivative liabilities in the accompanying condensed consolidated balance sheet as of January 1, 2018. The adoption of this ASU did not have an impact on our condensed consolidated results of operations.

On January 1, 2018, we adopted FASB Accounting Standards Codification (“ASC”) Topic 606, *Revenue from Contracts with Customers* (“ASC 606”). The new guidance sets forth a new five-step revenue recognition model which replaces the prior revenue recognition guidance in its entirety and is intended to eliminate numerous industry-specific pieces of

revenue recognition guidance that have historically existed in U.S. GAAP. The underlying principle of the new standard is that a business or other organization will recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects what it expects to receive in exchange for the goods or services. The standard also requires more detailed disclosures and provides additional guidance for transactions that were not addressed completely in the prior accounting guidance.

We reviewed all contracts at the date of initial application and elected to use the modified retrospective transition method, where the cumulative effect of the initial application is recognized as an adjustment to opening retained earnings at January 1, 2018. Therefore, comparative prior periods have not been adjusted and continue to be reported under FASB ASC Topic 605, Revenue Recognition, (“ASC 605”). The adoption of the new revenue recognition guidance was immaterial to our condensed consolidated statements of operations, balance sheet, and cash flows as of and for the three and nine months ended September 30, 2018.

Our principal activities from which we generate our revenue are product sales. We have one reportable segment of business.

Revenue is measured based on consideration specified in a contract with a customer. A contract with a customer exists when we enter into an enforceable contract with a customer. The contract is based on either the acceptance of standard terms and conditions on the websites for e-commerce customers and via telephone with our third-party call center for our print media and direct mail customers, or the execution of terms and conditions contracts with retailers and wholesalers. These contracts define each party's rights, payment terms and other contractual terms and conditions of the sale. Consideration is typically paid prior to shipment via credit card when our products are sold direct to consumers or approximately 30 days from the time control is transferred when sold to wholesalers, distributors and retailers. We apply judgment in determining the customer's ability and intention to pay, which is based on a variety of factors including the customer's historical payment experience and, in some circumstances, published credit and financial information pertaining to the customer.

A performance obligation is a promise in a contract to transfer a distinct product to the customer, which for us is transfer of over-the-counter drug and consumer care products to our customers. Performance obligations promised in a contract are identified based on the goods that will be transferred to the customer that are both capable of being distinct and are distinct in the context of the contract, whereby the transfer of the goods is separately identifiable from other promises in the contract. We have concluded the sale of bottled finished goods and related shipping and handling are accounted for as the single performance obligation.

The transaction price of a contract is allocated to each distinct performance obligation and recognized as revenue when or as the customer receives the benefit of the performance obligation. The transaction price is determined based on the consideration to which we will be entitled to receive in exchange for transferring goods to the customer. We issue refunds to e-commerce and print media customers, upon request, within 30 days of delivery. We estimate the amount of potential refunds at each reporting period using a portfolio approach of historical data, adjusted for changes in expected customer experience, including seasonality and changes in economic factors. For retailers, distributors and wholesalers, we do not offer a right of return or refund and revenue is recognized at the time products are shipped to customers. In all cases, judgment is required in estimating these reserves. Actual claims for returns could be materially different from the estimates.

We recognize revenue when we satisfy a performance obligation in a contract by transferring control over a product to a customer when product is shipped. Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction, that are collected by us from a customer, are excluded from revenue. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost and are included in cost of product sales.

We enter into exclusive distributor and license agreements that are within the scope of ASC Topic 606. The license agreements we enter into normally generate three separate components of revenue: 1) an initial nonrefundable payment due on signing or when certain specific conditions are met; 2) royalties that are earned on an ongoing basis as sales are made or a pre-agreed transfer price and 3) sales-based milestone payments that are earned when cumulative sales reach certain levels. Revenue from the initial nonrefundable payments or licensing fee is recognized when all required conditions are met. If the consideration for the initial license fee is for the right to sell the licensed product in the respective territory with no other required conditions to be met, such type of nonrefundable license fee arrangement for the right to sell the licensed product in the territory is recognized ratably over the term of the license agreement. For arrangements with licenses that include sales-based royalties, including sales-based milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied. The achievement of the sales-based milestone underlying the payment to be received predominantly relates to the licensee's performance of future commercial activities.

For the three and nine months ended September 30, 2018, there were no other material changes to the "Critical Accounting Policies" discussed in Part II, Item 7 (Management's Discussion and Analysis of Financial Condition and

Results of Operations) of our Annual Report on Form 10-K for the year ended December 31, 2017.

### **Off- Balance Sheet Arrangements**

None.

### **Recent Accounting Pronouncements**

See Note 1 to our condensed consolidated financial statements included in this Quarterly Report.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not applicable.

### **ITEM 4. CONTROLS AND PROCEDURES**

*Evaluation of disclosure controls and procedures.*

As of September 30, 2018, we evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")).

Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2018, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including chief executive officer and vice president, finance, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, but not absolute, assurance that the objectives of the disclosure controls and procedures are met. The design of any disclosure control and procedure also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

*Changes in internal control over financial reporting.*

During the quarter ended September 30, 2018, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II—OTHER INFORMATION**

### **ITEM 1. 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 actions. We believe that the Plaintiffs’ allegations and claims are wholly without merit, and we intend to defend the case vigorously and assert counterclaims against the Plaintiffs. More specifically, we believe that we secured and paid for all of the rights claimed by Dr. Yeager from his company Centric Research Institute (“CRI”) pursuant to agreements with CRI (the “CRI Agreements”) and that CRI has indemnification obligations under the CRI Agreements for all expenses and losses associated with the claims made by the Plaintiffs.

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

## ITEM 1A. RISK FACTORS

The risks described in *Part I, Item 1A, Risk Factors*, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, could materially and adversely affect our business, financial condition and results of operations. These risk factors do not identify all of the risks that we face. Our business, financial condition and results of operations could also be affected by factors that are not presently known to us or that we currently consider to be immaterial. There have been no material changes to the “Risk Factors” section included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

## ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

During the three months ended September 30, 2018, we entered into a Settlement Agreement and General Release with an unrelated note holder to convert the outstanding principal and interest balance of \$169,543 into 1,474,287 restricted shares of our common stock.

On July 19, 2018, we entered into a securities purchase agreement with an unrelated third-party investor in which the investor loaned us gross proceeds of \$500,000, pursuant to which we issued to such investor (i) the July 2018 5% Notes Payable, in the aggregate principal amount of \$550,000, and (ii) 1,600,000 restricted shares of our common stock.

On July 23, 2018, we entered into a securities and exchange agreement with the December 2017 5% Note Payable holder, pursuant to which we issued a total of 3,832,695 shares of our common stock in exchange for the settlement of principal and interest due totaling \$402,433. The fair value of the shares of common stock issued, based on the market price of our common stock on the date of the securities exchange agreements, was determined to be \$682,220.

On August 1, 2018, we entered into a securities purchase agreement with two unrelated third-party investors in which the investors loaned us gross proceeds of \$1,000,000, pursuant to which we issued to such investors (i) the August 2018 Notes Payable, in the aggregate principal amount of \$1,200,000, and (ii) 1,000,000 restricted shares of our common stock. In addition, in connection with the transaction, we issued 638,978 restricted shares of our common stock to a third-party consultant for services rendered.

On August 5, 2018, we entered into a securities and exchange agreement with certain of the October and December 2017 Notes Payable holders, pursuant to which we issued a total of 5,238,098 shares of our common stock in exchange for the settlement of principal due totaling \$550,000. The fair value of the shares of common stock issued, based on the market price of our common stock on the date of the securities exchange agreements, was determined to be \$885,239.

On September 12, 2018, we entered into a securities purchase agreement with an unrelated third-party investor in which the investor loaned us gross proceeds of \$350,000, pursuant to which we issued to such investor (i) the September 2018 5% Notes Payable, in the aggregate principal amount of \$390,000, and (ii) 1,000,000 restricted shares of our common stock.

Proceeds from each of the above issuances were used for general corporate purposes. All of the above sales and issuances were made in reliance on Section 4(a)(2) of the Securities Act of 1933, as amended, as transactions by and issuer not involving any public offering, Regulation D of the Securities Act, and/or Section 3(a)(9) under the Securities Act. In all such transactions, certain inquiries were made by the Company to establish that such sales qualified for such exemption from the registration requirements.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

### **ITEM 5. OTHER INFORMATION**

None.

### **ITEM 6. EXHIBITS**

**Exhibit No. Description**

- 10.1 Employment Agreement between Registrant and Ryan Selhorn, dated April 27, 2018 filed as Exhibit 10.1 to Registrant's Current Report on Form 8-K filed with the SEC on April 23, 2018 and incorporated herein by reference.
- 31.1\* Certification of Bassam Damaj, Ph.D., principal executive officer, pursuant to Rule 13-a-14(a) or 15d-14(a) of the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2\* Certification of Ryan Selhorn, CPA, principal financial officer, pursuant to Rule 13-a-14(a) or 15d-14(a) of the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1\*\* Certification of Bassam Damaj, Ph.D., principal executive officer, and Ryan Selhorn, CPA, principal financial officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101.INS\* XBRL Instance Document
- 101.SCH\* XBRL Taxonomy Extension Schema Document
- 101.CAL\* XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF\* XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB\* XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE\* XBRL Taxonomy Extension Presentation Linkbase Document

\*Filed herewith.

This certification is being furnished solely to accompany this report pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and is not being filed for purposes of Section 18 of the \*\*Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation by reference language of such filing.



## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Innovus Pharmaceuticals, Inc.  
(Registrant)

Date: November 14, 2018 /s/ Bassam Damaj  
Bassam Damaj, Ph.D.  
President, Chief Executive Officer and Director  
(Principal Executive Officer)

/s/ Ryan Selhorn  
Ryan Selhorn, CPA  
Vice President, Chief Financial Officer  
(Principal Financial Officer)