

ELBIT SYSTEMS LTD

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ZE=2>1,957,629 \$2.86 5.67 \$

Options vested and expected to vest September 30, 2017

2,707,075 \$2.47 6.56 \$

Table of Contents**JAGUAR HEALTH, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. Stock Incentive Plans (Continued)**

There was no option activity related to the 2013 Equity Incentive Plan in the nine months ended September 30, 2017.

The weighted average grant date fair value of stock options granted (excluding the options issued in the Napo Merger) was \$0.44 and \$0.89 during the nine months ended September 30, 2017 and 2016.

The number of option shares that vested in the nine months ended September 30, 2017 and 2016 was 533,348 shares and 480,377 shares. The grant date weighted average fair value of option shares that vested in the nine months ended September 30, 2017 and 2016 was \$549,453 and \$542,999, respectively.

No options were exercised in the nine months ended September 30, 2017 or 2016.

The intrinsic value is computed as the options granted multiplied by the difference between the fair market value of the Company's common stock of \$0.20 on September 30, 2017 and the grant date stock option exercise price.

The Company granted RSUs in 2014 and 2015 under the 2013 Equity Incentive Plan. The units granted vest upon the occurrence of both a liquidity event and satisfaction of the service-based requirement. The time-based vesting provided that 50% of the RSU vested on January 1, 2016 and the remaining 50% vested on July 1, 2017. The Company began recording stock-based compensation expense relating to the RSU grants effective May 18, 2015, the date of the Company's initial public offering, and the date the liquidity condition was met. The stock-based compensation expense is based on the grant date fair value which is the equivalent to the fair market value on the date of grant, and is amortized over the vesting period using the straight-line method, net of estimated forfeitures. On January 1, 2016, the Company issued 17,546 shares of its common stock in exchange for 27,768 vested and released RSUs, net of 10,172 RSU shares used to pay withholding taxes. On July 3, 2017, the Company issued 13,307 shares of its common stock in exchange for 20,789 vested and released RSUs, net of 7,086 RSU shares used to pay withholding taxes. The Company granted 5,893,849 RSUs to replace Napo RSUs upon the consummation of the Napo Merger.

**Stock-Based Compensation**

The following table summarizes stock-based compensation expense related to stock options and RSUs for the three and nine months ended September 30, 2017 and 2016, and are included in the statements of operations and comprehensive loss as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development expense	\$ 45,009	\$ 53,935	\$ 168,981	\$ 116,552
Sales and marketing expense	7,938	50,052	23,307	58,733
General and administrative expense	133,807	145,391	438,636	303,157
Total	\$ 186,754	\$ 249,378	\$ 630,924	\$ 478,442

As of September 30, 2017, the Company had \$761,710 of unrecognized stock-based compensation expense for options and restricted stock units outstanding, which is expected to be recognized over a weighted-average period of 1.59 years.

Table of Contents**JAGUAR HEALTH, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. Stock Incentive Plans (Continued)**

The estimated grant-date fair value of employee stock options was calculated using the Black-Scholes-Merton option-pricing model using the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Weighted-average volatility	76.92%	69.39 - 71.38%	74.26 - 76.92%	66.25 - 71.38%
Weighted-average expected term (years)	5.82	5.00 - 5.82	5.82	5.00 - 5.82
Risk-free interest rate	1.95%	1.10 - 1.29%	1.95 - 1.98%	1.10 - 1.49%
Expected dividend yield				

The estimated grant-date fair value of non-employee stock options was calculated using the Black-Scholes-Merton option-pricing model was revalued using the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Weighted-average volatility		78.30 - 80.02%		78.30 - 80.04%
Weighted-average expected term (years)		9.17 - 10.00		9.17 - 10.00
Risk-free interest rate		1.32 - 1.67%		1.32 - 1.74%
Expected dividend yield				

**11. Net Income (Loss) Per Share Attributable to Common Stockholders**

The following table presents the calculation of basic and diluted net loss per common share for the three and nine months ended September 30, 2017 and 2016:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net income (loss) attributable to common shareholders basic	\$ 4,759,844	\$ (3,415,490)	\$ (1,761,156)	\$ (11,057,169)
Interest on convertible debt, net of tax		209,149		
Net income attributable to common shareholders diluted	\$ 4,968,993	\$ (3,415,490)	\$ (1,761,156)	\$ (11,057,169)
Shares used to compute net income (loss) per common share basic	55,434,898	11,264,886	28,246,721	10,298,987
Dilutive effect of warrants	675,383			
Dilutive effect of convertible debt	11,093,249			
Shares used to compute net income (loss) per common share diluted	67,203,530	11,264,886	28,246,721	10,298,987
Net loss per share attributable to common shareholders basic	\$ 0.09	\$ (0.30)	\$ (0.06)	\$ (1.07)

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Net loss per share attributable to common stock diluted	\$	0.07	\$	(0.30)	\$	(0.06)	\$	(1.07)
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Table of Contents**JAGUAR HEALTH, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****11. Net Income (Loss) Per Share Attributable to Common Stockholders (Continued)**

The Company's basic net income (loss) per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration of potentially dilutive securities. Restricted stock units are considered in the calculation of the Company's basic net income (loss) per share as they are fully vested. Diluted net income (loss) per share is the same as basic net income (loss) per share since the effect of potentially dilutive securities is anti-dilutive. In the three months ended September 30, 2017, certain warrant shares were dilutive. The rights of the holders of voting common stock and non-voting common stock are identical, except with respect to voting and conversion. Shares of Jaguar non-voting common stock have the same rights to dividends and other distributions and are convertible into shares of Jaguar common stock on a one-for-one basis upon transfers to non-affiliates of Nantucket, upon the release from escrow of certain non-voting shares held by a former creditors of Napo to the legacy stockholders of Napo under specified conditions and at any time on or after April 1, 2018 at the option of the respective holders thereof.

The following outstanding common stock equivalents have been excluded from diluted net loss per common share for the nine months ended September 30, 2017 and 2016 because their inclusion would be anti-dilutive:

	September 30, 2017	September 30, 2016
Options issued and outstanding	2,984,304	2,444,375
Warrants to purchase common stock	6,656,333	715,539
Restricted stock units		20,789
Total	9,640,637	3,180,703

**12. 401(k) Plan**

The Company sponsors a 401(k) defined contribution plan covering all employees. There were no employer contributions to the plan from plan inception through September 30, 2017.

**13. Income Taxes**

The forecasted effective tax rate for the nine months ended September 30, 2017 and 2016 was zero percent, primarily as a result of the estimated tax loss for the year and the change in valuation allowance. However, as a result of the acquisition of Napo in July 2017, the Company recorded a tax benefit of \$12.2 million as a discrete item in the current quarter. This tax benefit is a result of the partial release of its existing valuation allowance since the acquired deferred tax liabilities from Napo will provide a source of income for the Company to realize a portion of its deferred tax assets, for which a valuation allowance is no longer needed.

**14. Subsequent Events**

The Company completed an evaluation of the impact of subsequent events through November 20, 2017, the date these financial statements were issued.

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**JAGUAR HEALTH, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**14. Subsequent Events (Continued)**

***Follow-On Public Offering***

In October 2017, we completed a follow-on registered offering ("offering") of our Common Stock. In connection with the offering, we issued 21,250,000 shares of our Common Stock at a price to the public of \$0.20 per share. As a result of the follow-on offering, we received \$3.55 million in net proceeds, after deducting underwriting discounts and commissions of \$297,500 and estimated offering expenses of \$400,000.

On November 1, 2017, the underwriters of our previously announced offering exercised their over-allotment option (the "Over-Allotment Option") to purchase an additional 437,500 shares of our voting common stock, par value \$0.0001 per share at a public offering price of \$0.20 per share. We received additional gross proceeds of approximately \$87,500 from the exercise of the Over-Allotment Option, increasing the aggregate gross proceeds to us from the offering to approximately \$4.3 million, before deducting offering expenses, underwriting discounts and commissions payable by us.

***Termination of Elanco Agreement***

On November 1, 2017, we received a letter (the "Notice") from Elanco serving as formal notice of Elanco's decision to terminate the Elanco Agreement by giving us 90 days written notice. Pursuant to the terms of the Elanco Agreement, termination of the Agreement will become effective on January 30, 2018, which is 90 days after the date of the Notice. On the effective date of termination of the Elanco Agreement, all licenses granted to Elanco by us under the Elanco Agreement will be revoked and the rights granted thereunder revert back to us.

***Registered Direct Offering and Equity Line***

On November 24, 2017, we entered into a share purchase agreement (the "Share Purchase Agreement") with L2 Capital, LLC, a Kansas limited liability company ("L2 Capital"), pursuant to which we agreed to sell 2,000,000 shares of our Common Stock to L2 Capital for a purchase price of \$0.25 per share in a registered direct offering (the "Registered Direct Offering"), without an underwriter or placement agent. Net proceeds to us from the Registered Direct Offering were approximately \$0.49 million and transaction expenses were approximately \$9,000. We used the net proceeds from the Registered Direct Offering for the commercialization of Mytesi, our lead prescription drug product, and for working capital and general corporate purposes.

Concurrently with the Registered Direct Offering, we entered into a common stock purchase agreement (the "CSPA") with L2 Capital relating to an offering (the "Equity Line Offering") of an aggregate of up to 12,100,000 shares of our common stock, of which 10,000,000 of such shares are being offered in an indirect primary offering consisting of an equity line of credit. We initially issued 2,100,000 shares of Common Stock (the "Commitment Shares") to L2 Capital as an inducement to enter into the CSPA. Additionally, under the terms of the CSPA, the Company has the right to "put," or sell, up to 10,000,000 shares of Common Stock (the "Purchase Shares") to L2 Capital at a fixed price of \$0.52 per share or such other price to be agreed upon between L2 Capital and us.

On December 27, 2017, we delivered a notice to L2 Capital of our decision to exercise the option to increase the number of shares of our Common Stock, available for issuance under the equity line from 10,000,000 shares to 17,808,142 shares of Common Stock at a fixed price of \$0.52 per share (or such other

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**JAGUAR HEALTH, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**14. Subsequent Events (Continued)**

price agreed upon between L2 Capital and us) (the "Upsize Option"). In consideration for our exercise of the Upsize Option, we issued 1,000,000 shares of Common Stock to L2 Capital as a commitment fee.

***CVP Secured Promissory Note***

On December 8, 2017, we entered into a securities purchase agreement (the "Securities Purchase Agreement") with Chicago Venture Partners, L.P. ("CVP"), pursuant to which we issued to CVP a promissory note (the "Note") in the aggregate principal amount of \$1,587,500 for an aggregate purchase price of \$1,100,000. The Note carries an original issue discount of \$462,500, and the initial principal balance also includes \$25,000 to cover CVP's transaction expenses. We used proceeds for the note issuance for general corporate purposes. The Note bears interest at the rate of 8% per annum and matures on September 8, 2018.

***PIPE Financing***

On December 27 2017, we entered into a share purchase agreement with several investors for the purchase of up to \$1.97 million shares of Common Stock at a purchase price equal to the lesser of (i) \$0.10 and (ii) the product equal to (x) eighty percent (80%) multiplied by (y) the average volume-weighted average price of the Common Stock for the five consecutive trading days ending on the date immediately preceding the date of the share purchase agreement.

***Riverside/MEF Notes***

On December 29, 2017, Napo Pharmaceuticals, Inc. ("Napo"), our wholly-owned subsidiary, entered into an amendment (the "First Amendment") to the Note Purchase Agreement and Notes (each as defined below) with each of the purchasers (the "Purchasers") party to the Note Purchase Agreement, dated March 1, 2017, by and among the Napo and the Purchasers (as amended, the "Note Purchase Agreement"). In connection with the First Amendment, Napo amended the original issue discount exchangeable promissory notes previously issued to the Purchasers on March 1, 2017 (the "First Tranche Notes") and April 27, 2017 (the "Second Tranche Notes" and together with the First Tranche Notes, the "Notes") pursuant to the Note Purchase Agreement to, among other things, (a) increase the principal amount outstanding under the First Tranche Notes and the Second Tranche Notes by twelve percent (12%), (b) lower the price at which the Notes are exchangeable for shares (the "Exchange Shares") of our Common Stock (the "Common Stock") from \$0.56 per share to \$0.20 per share, and (c) extend the maturity date of the First Tranche Notes from December 1, 2017 to February 15, 2018 and the Second Tranche Notes from January 27, 2018 to April 1, 2018.

In connection with the First Amendment, we also issued 2,492,084 shares of Common Stock to the Purchasers as repayment of \$299,050.08 principal amount of the First Tranche Notes. Following such repayment and the 12% increase to the outstanding balance of the Notes described above, \$435,949.92 and \$735,000.00 principal amount remain outstanding under the First Tranche Notes and Second Tranche Notes, respectively.

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**Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The following discussion and analysis should be read together with our financial statements and the related notes appearing elsewhere in this report.*

**For the years ended December 31, 2016 and 2015**

**Overview**

We are an animal health company focused on developing and commercializing first-in-class gastrointestinal products for companion and production animals, foals, and high value horses. Canalevia is our lead prescription drug product candidate, intended for treatment of various forms of diarrhea in dogs. We achieved statistically significant results in a multicenter canine proof-of-concept study completed in February 2015, supporting the conclusion that Canalevia treatment is superior to placebo. As we announced in December 2015, the pivotal clinical field study to evaluate the safety and effectiveness of Canalevia for acute diarrhea in dogs is underway. Two-hundred dogs were enrolled in the Canalevia pivotal study, which completed enrollment in January 2017. Jaguar has received Minor Use in a Minor Species (MUMS) designation for Canalevia for Chemotherapy-Induced Diarrhea (CID) in dogs. Canalevia is a canine-specific formulation of crofelemer, an active pharmaceutical ingredient isolated and purified from the *Croton lechleri* tree, which is sustainably harvested. A human-specific formulation of crofelemer, Mytesi (formerly known as Fulyzaq), was approved by the FDA in 2012 for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. Members of our management team developed crofelemer while at Napo Pharmaceuticals, Inc. or Napo, which was Jaguar's parent company until May 13, 2015. The reception among users of our lead non-prescription products Neonorm Calf and Neonorm Foal, an anti-diarrheal product we launched for newborn horses in early 2016 has been quite positive. The clinically-proven performance of Neonorm Foal, in combination with our heightened understanding of market needs within the global equine space, is driving our increased focus on equine product development. Equilevia (formerly referred to as SB-300) is Jaguar's prescription drug product candidate for treatment of gastrointestinal ulcers in horses. Equilevia is a pharmaceutical formulation of a standardized botanical extract. Neonorm is a standardized botanical extract derived from the *Croton lechleri* tree. We launched Neonorm Calf in the United States at the end of 2014 for preweaned dairy calves. Canalevia, Equilevia and Neonorm are distinct products formulated to address specific species and market channels. We have filed nine investigational new animal drug applications, or INADs, with the FDA and intend to develop species-specific formulations of Neonorm in six additional target species, and Canalevia for both cats and dogs. In July 2016 we released data from two China-based studies sponsored by Fresno, California-based Integrated Animal Nutrition and Health Inc. showing remarkable resolution of diarrhea and cure of piglets afflicted with diarrhea following treatment with a *Croton lechleri* botanical extract administered in water.

As we announced in December 2016, Jaguar has signed a distribution agreement with Henry Schein, Inc., the world's largest provider of health care products and services to office-based dental, animal health and medical practitioners, for exclusive distribution of Neonorm Foal product to all segments of the U.S. equine market. Henry Schein's animal health business, Dublin, Ohio-based Henry Schein Animal Health, employs approximately 900 team members and had 2015 net sales of \$2.9 billion. The agreement became effective on December 9, 2016, and, subject to provisions specified in the agreement, shall continue in force for an initial period of one year. Thereafter, unless either party notifies the other of its intent not to renew the term of the agreement at least 30 days prior to the end of the then current term, the term shall be automatically renewed upon expiration for successive renewal terms of one year.

As we announced in September 2016, we have signed an exclusive supply and distribution agreement for this botanical extract with Integrated Animal Nutrition and Health Inc. for dairy cattle and pigs in the Chinese marketplace. According to the Minnesota-based Institute for Agriculture and Trade Policy, swine production was expected to reach 723 million head in 2014 in China, where pork is still the main protein



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source for many consumers. In 2015 there were an estimated 15.6 million dairy cattle in China, according to Index Muni. Integrated Animal Nutrition and Health, Inc. has minimum purchase requirements of the botanical extract to maintain their exclusivity.

Since inception, we have been primarily focused on designing and conducting studies of Canalevia to treat diarrhea in dogs and of Neonorm to help retain fluid in calves and to function as an anti-diarrheal in foals. We are also focused on developing a full suite of equine products to support and improve gastrointestinal health in foals and adult horses. Gastrointestinal conditions such as acute diarrhea, ulcers and diarrhea associated with acute colitis can be extremely debilitating for horses, and present a significant economic and emotional burden for veterinarians and owners around the world. A portion of our activities has also been focused on other efforts associated with being a recently formed company, including securing necessary intellectual property, recruiting management and key employees, and financing activities.

On February 8, 2017, we entered into a binding agreement of terms for our acquisition of Napo. Following the merger, Napo will operate as our wholly-owned subsidiary, focused on human health. The binding financial terms of the merger include a 3-to-1 Napo-to-Jaguar value ratio to calculate the relative ownership of the combined entity. As of January 31, 2017, Napo owned approximately 19% of the outstanding shares of our common stock.

The Binding Agreement of Terms sets forth the financial terms of the merger and customary conditions to closing, which include but are not limited to completion of due diligence, receipt of a fairness opinion, and stockholder and other approvals. Additionally, the financial terms of the merger and conditions to closing include provisions that (i) Napo's secured convertible debt shall not exceed \$10.0 million and its unsecured debt shall not exceed \$3.0 million, and (ii) a third party will invest \$3.0 million in us for approximately four million shares of our newly issued common stock with the investment proceeds loaned to Napo immediately prior to the consummation of the merger. The Binding Agreement of Terms also provides that if the merger fails to close for any reason on or prior to July 31, 2017, other than as a result directly or indirectly of (x) lack of stockholder approval by either party or (y) Napo (i) failing to perform in accordance with the terms and conditions of the agreement or (ii) failing to abide by or breaching the provisions or representations, warranties and covenants of the agreement or the merger documents, then, on or before the close of business on August 7, 2017, we will be required to issue 2,000,000 shares of our restricted common stock to Napo.

We expect to incur significant expenses in connection with the merger. While we have assumed that a certain level of expenses will be incurred, there are many factors that could affect the total amount or the timing of the merger expenses, and many of the expenses that will be incurred are, by their nature, difficult to estimate. These expenses could result in the combined company taking significant charges against earnings following the completion of the merger. The ultimate amount and timing of such charges are uncertain at the present time. We incurred approximately \$100,000 in professional and other fees associated with the proposed merger during the year ended December 31, 2016.

On January 27, 2017, we entered into a licensing, development, co-promotion and commercialization agreement with Elanco to license, develop and commercialize Canalevia, our drug product candidate under investigation for treatment of acute and chemotherapy-induced diarrhea in dogs, and other drug product formulations of crofelemer for treatment of gastrointestinal diseases, conditions and symptoms in cats and other companion animals. The Elanco Agreement grants Elanco exclusive global rights to Canalevia, a product whose active pharmaceutical ingredient is sustainably isolated and purified from the Croton lechleri tree, for use in companion animals. Pursuant to the Elanco Agreement, Elanco will have exclusive rights globally outside the U.S. and co-exclusive rights with us in the U.S. to direct all marketing, advertising, promotion, launch and sales activities related to the Licensed Products.

Under the terms of the Elanco Agreement, we received a \$1.5 million upfront payment and will receive additional payments upon achievement of certain development, regulatory and sales milestones in an aggregate amount of up to \$61.0 million payable throughout the term of the Elanco Agreement, as well

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as product development expense reimbursement, and royalty payments on global sales. The Elanco Agreement specifies that we will supply the Licensed Products to Elanco, and that the parties will agree to set a minimum sales requirement that Elanco must meet to maintain exclusivity. Elanco will also reimburse us for Canalevia-related expenses, including reimbursement for Canalevia-related expenses in Q4 2016, certain development and regulatory expenses related to our planned target animal safety study and the completion of our field study of Canalevia for acute diarrhea in dogs.

**Financial Operations Overview**

We were incorporated in June 2013 in Delaware. Napo formed our company to develop and commercialize animal health products. Prior to our incorporation, the only activities of Napo related to animal health were limited to the retention of consultants to evaluate potential strategic alternatives. We were previously a majority-owned subsidiary of Napo. However, following the closing of our May 2015 initial public offering, we are no longer majority-owned by Napo.

We have not generated any material revenue to date and expect to continue to incur significant research and development and other expenses. Our net loss attributable to common stockholders was \$14.7 million and \$16.6 million for the years ended December 31, 2016 and 2015. As of December 31, 2016, we had total stockholders' deficit of \$2.5 million and cash and cash equivalents of \$950,979. We expect to continue to incur losses for the foreseeable future as we expand our product development activities, seek necessary approvals for our product candidates, conduct species-specific formulation studies for our non-prescription products, establish API manufacturing capabilities and begin commercialization activities. As a result, we expect to experience increased expenditures for 2017.

**Revenue**

We sell our primary commercial product Neonorm to distributors under agreements that may provide distributor price adjustments and rights of return under certain circumstances. Until we have sufficient sales history and pipeline visibility, we will defer revenue and costs of distributor sales until products are sold by the distributor to the distributor's customers. Revenue recognition depends on notification either directly from the distributor that product has been sold to the distributor's customer, when we have access to the data. We maintain system controls to verify that the reported distributor and third party data is accurate. Deferred revenue on shipments to distributors will reflect the estimated effects of distributor price adjustments, if any, and the estimated amount of gross margin expected to be realized when the distributor sells through product purchased from the Company. Accounts receivable from distributors will be recognized and included in deferred revenue when we ship product to the distributor. We relieve inventory and recognize revenue typically upon shipment by the distributor to their customer. We recognized \$141,523 and \$258,381 in revenue for the years ended December 31, 2016 and 2015, respectively.

**Cost of Revenue**

Cost of revenue expenses consist of costs to manufacture, package and distribute Neonorm that distributors have sold through to their customers.

**Research and Development Expense**

Research and development expenses consist primarily of clinical and contract manufacturing expense, personnel and related benefit expense, stock-based compensation expense, employee travel expense, reforestation expenses. Clinical and contract manufacturing expense consists primarily of costs to conduct stability, safety and efficacy studies, and manufacturing startup expenses at an outsourced API provider in Italy.

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We typically use our employee and infrastructure resources across multiple development programs. We track outsourced development costs by prescription drug product candidate and non-prescription product but do not allocate personnel or other internal costs related to development to specific programs or development compounds.

The timing and amount of our research and development expenses will depend largely upon the outcomes of current and future trials for our prescription drug product candidates as well as the related regulatory requirements, the outcomes of current and future species-specific formulation studies for our non-prescription products, manufacturing costs and any costs associated with the advancement of our line extension programs. We cannot determine with certainty the duration and completion costs of the current or future development activities.

The duration, costs and timing of trials, formulation studies and development of our prescription drug and non-prescription products will depend on a variety of factors, including:

the scope, rate of progress, and expense of our ongoing, as well as any additional clinical trials, formulation studies and other research and development activities;

future clinical trial and formulation study results;

potential changes in government regulations; and

the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a prescription drug product candidate or non-prescription product could mean a significant change in the costs and timing associated with our development activities.

We expect research and development expense to increase significantly as we add personnel, commence additional clinical studies and other activities to develop our prescription drug product candidates and non-prescription products.

**Sales and Marketing Expense**

Sales and marketing expenses consist of personnel and related benefit expense, stock-based compensation expense, direct sales and marketing expense, employee travel expense, and management consulting expense. We currently incur sales and marketing expenses to promote Neonorm calf and foal sales.

We expect sales and marketing expense to increase significantly as we develop and commercialize new products and grow our existing Neonorm market. We will need to add sales and marketing headcount to promote the sales of existing and new products.

**General and Administrative Expense**

General and administrative expenses consist of personnel and related benefit expense, stock-based compensation expense, employee travel expense, legal and accounting fees, rent and facilities expense, and management consulting expense.

We expect general and administrative expense to increase in order to enable us to effectively manage the overall growth of the business. This will include adding headcount, enhancing information systems and potentially expanding corporate facilities.

**Interest Expense**

Interest expense consists primarily of interest on convertible promissory notes, the standby bridge financing commitment and the loan and security agreement (long-term debt arrangement). It also includes

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interest expense and the amortization of a beneficial conversion feature related to convertible promissory notes issued in June and December 2014 and in February and March 2015.

**Results of Operations***Comparison of the years ended December 31, 2016 and 2015*

The following table summarizes the Company's results of operations with respect to the items set forth in such table for the years ended December 31, 2016 and 2015 together with the change in such items in dollars and as a percentage:

	Years Ended December 31,		Variance	
	2016	2015	(\$)	(%)
<b>Revenue</b>	\$ 141,523	\$ 258,381	\$ (116,858)	(45.2)%
<b>Operating Expenses</b>				
Cost of revenue	51,966	123,457	(71,491)	(57.9)%
Research and development expense	7,206,864	6,475,851	731,013	11.3%
Sales and marketing expense	485,440	765,091	(279,651)	(36.6)%
General and administrative expense	5,983,238	5,339,351	643,887	12.1%
<b>Total operating expenses</b>	<b>13,727,508</b>	<b>12,703,750</b>	<b>1,023,758</b>	<b>8.1%</b>
<b>Loss from operations</b>	<b>(13,585,985)</b>	<b>(12,445,369)</b>	<b>(1,140,616)</b>	<b>9.2%</b>
Interest expense, net	(985,549)	(3,317,287)	2,331,738	(70.3)%
Other expense	(11,046)	(27,277)	16,231	(59.5)%
Change in fair value of warrants	(43,200)	(501,617)	458,417	(91.4)%
Loss on extinguishment of debt	(108,000)		(108,000)	N/A
<b>Net loss and comprehensive loss</b>	<b>\$ (14,733,780)</b>	<b>\$ (16,291,550)</b>	<b>\$ 1,557,770</b>	<b>(9.6)%</b>

*Revenue and Cost of Revenue*

Revenue and related cost of revenue for the years ended December 31, 2016 and 2015 reflects sell-through of our Neonorm Calf and Neonorm Foal products to our distributors. We defer recognizing revenue and cost of revenue until products are sold by the distributor to the distributor's end customers and recognition depends on notification from the distributor that product has been sold to the distributor's end customer. In 2016, we began selling the botanical extract to a distributor for use exclusively in China. The revenue from these sales, which totaled \$24,000 in the year ended December 31, 2016, is recognized upon shipment to the distributor as no return rights are provided to this distributor. We experienced a reduction in Neonorm Calf unit sales in the year ended December 31, 2016 compared to 2015 resulting in the decrease in revenue. The decrease in cost of revenue was consistent with the decrease in revenue. We are increasing our efforts to promote sales growth.

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The following table presents the components of research and development expense for the years ended December 31, 2016 and 2015 together with the change in such components in dollars and as a percentage:

	Years Ended December 31,		Variance	Variance %
	2016	2015		
<b>R&amp;D:</b>				
<b>Personnel and related benefits</b>	\$ 2,546,220	\$ 1,891,954	\$ 654,266	34.6%
<b>Materials expense and tree planting</b>	113,394	187,876	(74,482)	(39.6)%
<b>Travel, other expenses</b>	400,846	360,362	40,484	11.2%
<b>Clinical and contract manufacturing</b>	2,254,122	3,093,193	(839,071)	(27.1)%
<b>Stock-based compensation</b>	181,489	472,145	(290,656)	(61.6)%
<b>Other</b>	1,710,793	470,321	1,240,472	263.8%
<b>Total</b>	\$ 7,206,864	\$ 6,475,851	\$ 731,013	11.3%

We increased research and development expense \$731,000 from \$6.5 million in the year ended December 31, 2015 to \$7.2 million for the same period in 2016. We added headcount to enable us to make significant progress in the development of certain drug candidates that resulted in the increase of \$654,000 in personnel and related benefit expenses, while carefully controlling spend in clinical trials and contract manufacturing. Clinical trial expenses increased due to our dog safety and efficacy study and our horse dose determination study both of which began in fiscal year 2016. These expenses were offset by a reduction of contract manufacturing expenses associated with the setup of manufacturing in Italy, which was completed in March 2016. Stock-based compensation decreased \$291,000 from \$472,000 in the year ended December 31, 2015 to \$181,000 in the same period in 2016 primarily due to the reduction in the fair market value of our common stock. Other expenses, consisting primarily of consulting and formulation expenses, increased \$1.2 million from \$470,000 in the year ended December 31, 2015 to \$1.7 million in the same period in 2016. Consulting expenses increased \$940,000 from \$135,000 in the year ended December 31, 2015 to \$1.1 million in the same period in 2016 due to a substantial increase in contractor utilization to assist in our clinical trials and in chemistry, manufacturing and controls ("CMC") activities. Formulation expenses increased \$250,000 from \$170,000 in the year ended December 31, 2015 to \$420,000 for the same period in 2016 due to an increase in work needed to supply clinical operations with active and placebo product for use in clinical trials. We plan to increase our research and development expense as we continue developing our drug candidates.

We also continued our reforestation efforts, although our expense decreased \$74,000 from \$188,000 in the year ended December 31, 2015 to \$113,000 for the same period in 2016. We value and take to heart the responsibility to replenish trees consumed in order to extract the raw material to manufacture our primary commercial product and the drug product for use in clinical trials.

Table of Contents**Sales and Marketing Expense**

The following table presents the components of sales and marketing expense for the years ended December 31, 2016 and 2015 together with the change in such components in dollars and as a percentage:

	Years Ended December 31,		Variance	Variance %
	2016	2015		
<b>S&amp;M:</b>				
Personnel and related benefits	\$ 198,100	\$ 347,944	\$ (149,844)	(43.1)%
Stock-based compensation	73,679	54,115	19,564	36.2%
Direct Marketing Fees	116,417	196,910	(80,493)	(40.9)%
Other	97,244	166,122	(68,878)	(41.5)%
<b>Total</b>	<b>\$ 485,440</b>	<b>\$ 765,091</b>	<b>\$ (279,651)</b>	<b>(36.6)%</b>

Sales and marketing expense decreased \$280,000 from \$765,000 in the year ended December 31, 2015 to \$485,000 in the same period in 2016 primarily due to a decrease in average monthly headcount for most of the fiscal year and a decrease in direct marketing expense. Personnel costs decreased \$150,000 from \$348,000 for the year ended December 31, 2015 to \$198,000 for the same period in 2016. Stock based compensation expense increased \$20,000 from \$54,000 in the year ended December 31, 2015 to \$74,000 in the same period in 2016 due primarily to expense associated with options granted to a consultant in 2016. Direct marketing and sales expense decreased \$81,000 from \$197,000 in the year ended December 31, 2015 to \$116,000 for the same period in 2016 due to a reduction in marketing programs to promote our Neonorm products. Other expenses, consisted primarily of travel expense, consulting expense and royalty expense. Travel expenses decreased \$42,000 from \$66,000 in the year ended December 31, 2015 to \$25,000 in the same period in 2016 consistent with the reduction in headcount. Consulting expense increased \$7,000 from \$47,000 in the year ended December 31, 2015 to \$54,000 in the same period in 2016. Royalty expenses decreased \$39,000 from \$40,000 in the year ended December 31, 2015 to \$1,000 in the same period in 2016 due to a reduction in the royalty rate upon going public and also due to the decrease in sales of our Neonorm products. We plan to expand sales and marketing spend to promote our Neonorm products.

**General and Administrative Expense**

The following table presents the components of general and administrative expense for the years ended December 31, 2016 and 2015 together with the change in such components in dollars and as a percentage:

	Years Ended December 31,		Variance	Variance %
	2016	2015		
<b>G&amp;A:</b>				
Personnel and related benefits	\$ 2,104,809	\$ 2,025,339	\$ 79,470	3.9%
Accounting fees	311,693	351,743	(40,050)	(11.4)%
Third-party consulting fees and Napo service fees	374,852	200,758	174,094	86.7%
Legal fees	824,288	611,237	213,051	34.9%
Travel	310,066	442,095	(132,029)	(29.9)%
Stock-based compensation	462,759	465,905	(3,146)	(0.7)%
Rent and lease expense	384,147	280,753	103,394	36.8%
Public company expenses	291,253	234,247	57,006	24.3%
Other	919,371	727,274	192,097	26.4%
<b>Total</b>	<b>\$ 5,983,238</b>	<b>\$ 5,339,351</b>	<b>\$ 643,887</b>	<b>12.1%</b>

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Our general and administrative expenses increased \$644,000 from \$5.3 million in the year ended December 31, 2015 to \$6.0 million for the same period in 2016. In 2015, we became a public company and added headcount that has resulted in increases of \$79,000 in personnel expense. Stock-based compensation was flat at \$466,000 in the year ended December 31, 2015 compared to \$463,000 in the same period in 2016 due to expense associated with new grants to existing employees offsetting the reduction in our stock price. Our public company expenses increased \$57,000 due primarily to a full year of expense in 2016 versus only seven months of expense in 2015 as we filed our IPO in May 2015. We controlled our professional services expenses, reducing our audit fees by \$40,000. However, our legal fees increased \$213,000 from \$611,000 in the year ended December 31, 2015 compared to \$824,000 in the same period in 2016 due to increased public filings with the SEC, and we increased consulting expenses by \$174,000 from \$201,000 in the year ended December 31, 2015 to \$375,000 in the same period in 2016 primarily due to placement agent fees related to the 2016 private placement financing in 2016. Rent expense increased \$103,000 due to moving into our new San Francisco headquarters facility in July of 2015. Other expenses, including insurance costs also increased as a result of becoming a public company in May 2015. We expect to incur additional general and administrative expense as a result of operating as a public company and as we grow our business, including expenses related to compliance with the rules and regulations of the SEC, additional insurance expenses, investor relations activities and other administrative and professional services.

**Liquidity and Capital Resources**

*Sources of Liquidity*

We had an accumulated deficit of \$40.4 million as a result of incurring net losses since our inception as we have not generated significant revenue through the current fiscal year. Our net loss and comprehensive loss was \$801,000 for the period from inception to December 31, 2013, \$8.6 million for the year ended December 31, 2014, \$16.3 million for the year ended December 31, 2015, and \$14.7 million for the year ended December 31, 2016. We expect to continue to incur additional losses through the end of fiscal year 2017 and in future years due to expected significant expenses for toxicology, safety and efficacy clinical trials of our products and product candidates, for establishing contract manufacturing capabilities, and for the commercialization of one or more of our product candidates, if approved.

We had cash and cash equivalents of \$951,000 as of December 31, 2016 compared to \$7.7 million as of December 31, 2015. We do not believe our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements for the next 12 months. Our independent registered public accounting firm has included an explanatory paragraph in its audit report included in our Form 10-K regarding our assessment of substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty.

To date, we have funded our operations primarily through the issuance of equity securities, short-term convertible promissory notes, and long-term debt, in addition to sales of Neonorm, our commercial product:

In 2013, we received \$400 from the issuance of 2,666,666 shares of common stock to our parent Napo Pharmaceuticals, Inc. We also received \$519,000 of net cash from the issuance of convertible promissory notes in an aggregate principal amount of \$525,000. These notes were all converted to common stock in 2014.

In 2014, we received \$6.7 million in proceeds from the issuance of convertible preferred stock. Effective as of the closing of our initial public offering, the 3,015,902 shares of outstanding convertible preferred stock were automatically converted into 2,010,596 shares of common stock. Following our initial public offering, there were no shares of preferred stock outstanding.

In 2014, we received \$1.1 million from the issuance of convertible promissory notes in an aggregate principal amount of \$1.1 million. These notes were converted to common stock upon the

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effectiveness of the initial public offering in May of 2015. In August 2014, we entered into a standby line of credit with an individual, who is an accredited investor, for up to \$1.0 million. To date, we had not made any drawdowns under this facility. Also, in October of 2014, as amended and restated in December 2014, we entered into a \$1.0 million standby bridge loan which was repaid in 2015.

In 2015, we received \$1.25 million in exchange for \$1.25 million of convertible promissory notes, of which \$1.0 million was converted to common stock in 2015, and \$100,000 was repaid in 2015. The remaining \$150,000 remains outstanding.

In May 2015, we received net proceeds of \$15.9 million upon the closing of our initial public offering, gross proceeds of \$20.0 million (2,860,000 shares at \$7.00 per share) net of \$1.2 million of underwriting discounts and commissions and \$3.3 million of offering expenses, including \$0.4 million of non-cash expense. These shares began trading on The NASDAQ Capital Market on May 13, 2015.

In 2015, we received net proceeds of \$5.9 million from the issuance of long-term debt. We entered into a loan and security agreement with a lender for up to \$8.0 million, which provided for an initial loan commitment of \$6.0 million. Under the loan agreement we are required to maintain \$4.5 million of the proceeds in cash, which amount may be reduced or eliminated on the achievement of certain milestones. An additional \$2.0 million is available contingent on the achievement of certain further milestones. The agreement has a term of three years, with interest only payments through February 29, 2016. Thereafter, principal and interest payments will be made with an interest rate of 9.9%. Additionally, there will be a balloon interest payment of \$560,000 on August 1, 2018. This amount is being recognized over the term of the loan agreement and the effective interest rate, considering the balloon payment, is 15.0%. Our proceeds are net of a \$134,433 debt discount under the terms of such agreement.

In 2014 and 2015, we received \$24,000 and \$531,000, respectively, in cash from sales of Neonorm to distributors.

In 2015, we received approximately \$13,000 in proceeds from the exercise of stock options.

In 2016, we received net proceeds of \$4.1 million upon the closing of our follow-on public offering, reflecting gross proceeds of \$5.0 million (2.0 million shares at \$2.50 per share) net of \$373,011 of underwriting discounts and commissions and \$496,887 of offering expenses.

In June 2016, we entered into the CSPA with a private investor. Under the terms of the agreement, we may sell up to \$15.0 million in common stock to the investor during the approximately 30-month term of the agreement. Upon execution of the CSPA, we sold 222,222 shares of our common stock to the investor at \$2.25 per share for net proceeds of \$448,732, reflecting gross proceeds of \$500,000 and offering expenses of \$51,268. In consideration for entering into the CSPA, we issued 456,667 shares of our common stock to the investor. We issued 1,348,601 shares in exchange for net proceeds of \$2,122,570, reflecting gross proceeds of \$2,176,700 net of \$54,130 offering expenses under the CSPA in the year ended December 31, 2016.

In October 2016, we entered into a Common Stock Purchase Agreement with an existing private investor. Upon execution of the agreement we sold 170,455 shares of our common stock in exchange for \$150,000 in cash proceeds.

On November 22, 2016, we entered into a Securities Purchase Agreement, or the 2016 Purchase Agreement, with certain institutional investors, pursuant to which we sold securities to such investors in a private placement transaction, which we refer to herein as the 2016 Private Placement. In the 2016 Private Placement, we sold an aggregate of 1,666,668 shares of our common stock at a price of \$0.60 per share for gross proceeds of approximately \$1.0 million. The investors in the 2016 Private Placement also received (i) warrants to purchase up to an aggregate of 1,666,668





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shares of our common stock, at an exercise price of \$0.75 per share, or the Series A Warrants, (ii) warrants to purchase up to an aggregate 1,666,668 shares of our common stock, at an exercise price of \$0.90 per share, or the Series B Warrants, and (iii) warrants to purchase up to an aggregate 1,666,668 shares of our common stock, at an exercise price of \$1.00 per share, or the Series C Warrants and, together with the Series A Warrants and the Series B Warrants, the 2016 Warrants.

On January 27, 2017, we entered into a licensing, development, co-promotion and commercialization agreement with Elanco to license, develop and commercialize Canalevia, our drug product candidate under investigation for treatment of acute and chemotherapy-induced diarrhea in dogs, and other drug product formulations of crofelemer for treatment of gastrointestinal diseases, conditions and symptoms in cats and other companion animals. The Elanco Agreement grants Elanco exclusive global rights to Canalevia, a product whose active pharmaceutical ingredient is sustainably isolated and purified from the *Croton lechleri* tree, for use in companion animals. Pursuant to the Elanco Agreement, Elanco will have exclusive rights globally outside the U.S. and co-exclusive rights with us in the U.S. to direct all marketing, advertising, promotion, launch and sales activities related to the Licensed Products. Under the terms of the Elanco Agreement, we received a \$1.5 million upfront payment and will receive additional payments upon achievement of certain development, regulatory and sales milestones in an aggregate amount of up to \$61.0 million payable throughout the term of the Elanco Agreement, as well as product development expense reimbursement, and royalty payments on global sales. The Elanco Agreement specifies that we will supply the Licensed Products to Elanco, and that the parties will agree to set a minimum sales requirement that Elanco must meet to maintain exclusivity. Elanco will also reimburse us for Canalevia-related expenses, including reimbursement for Canalevia-related expenses in Q4 2016, certain development and regulatory expenses related to our planned target animal safety study and the completion of our field study of Canalevia for acute diarrhea in dogs.

We expect our expenditures will continue to increase as we continue our efforts to develop animal health products, expand our commercially available Neonorm product and continue development of Canalevia in the near term. We have agreed to pay Indena S.p.A. fees of approximately €2.1 million under a memorandum of understanding relating to the establishment of our commercial API manufacturing arrangement in Italy. As of June 30, 2016, we remitted €1.95 million of the €2.1 million. We paid the final €150,000 on July 15, 2016.

We do not believe our current capital is sufficient to fund our operating plan through December 2017. We will need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. We may also not be successful in entering into partnerships that include payment of upfront licensing fees for our products and product candidates for markets outside the United States, where appropriate. If we do not generate upfront fees from any anticipated arrangements, it would have a negative effect on our operating plan. The Company plans to finance its operations and capital funding needs through equity and/or debt financing as well as revenue from future product sales. However, there can be no assurance that additional funding will be available to the Company on acceptable terms on a timely basis, if at all, or that the Company will generate sufficient cash from operations to adequately fund operating needs or ultimately achieve profitability. If the Company is unable to obtain an adequate level of financing needed for the long-term development and commercialization of its products, the Company will need to curtail planned activities and reduce costs. Doing so will likely have an adverse effect on the Company's ability to execute on its business plan.

Table of Contents**Cash Flows for Year Ended December 31, 2016 Compared to the Year Ended December 31, 2015**

The following table shows a summary of cash flows for the years ended December 31, 2016 and 2015:

	Years Ended December 31,	
	2016	2015
<b>Total cash used in operations</b>	\$ (14,413,718)	\$ (14,315,863)
<b>Total cash provided by/(used in) investing activities</b>	2,384,500	(3,002,700)
<b>Total Cash Provided by Financing Activities</b>	5,282,666	24,170,902
	\$ (6,746,552)	\$ 6,852,339

**Cash Used in Operating Activities**

During the year ended December 31, 2016, cash used in operating activities of \$14.4 million resulted from our net loss of \$14.7 million, offset by non-cash accretion of end of term payment, debt discounts and debt issuance costs of \$510,000, stock-based compensation of \$718,000, loss on extinguishment of debt of \$108,000, depreciation expense of \$47,000, net of changes in operating assets and liabilities of \$1.1 million.

During the year ended December 31, 2015, cash used in operating activities of \$14.3 million resulted from our net loss of \$16.3 million, offset by non-cash accretion of debt discounts of \$2.5 million, non-cash revaluation of warrant liability of \$502,000 and stock-based compensation of \$992,000, amortization of debt issuance costs of \$130,000, accretion of the balloon payment on the long-term debt of \$116,000, loss on the sale of property and equipment of \$35,000, depreciation expense of \$5,000, net of changes in operating assets and liabilities of \$2.3 million.

**Cash Provided By/Used In Investing Activities**

During the year ended December 31, 2016, cash provided by investing activities of \$2.4 million primarily consisted of \$2.5 million of a release of restricted cash that resulted from a reduction in our long-term debt, net of \$104,000 in purchases of property and equipment.

During the year ended December 31, 2015, cash used in investing activities of \$3.0 million primarily consisted of \$3.0 million in restricted cash that resulted from our issuance of long-term debt, \$23,000 from the purchase of property and equipment, net of \$21,000 from the sale of property and equipment.

**Cash Provided by Financing Activities**

During the year ended December 31, 2016, cash provided by financing activities of \$5.3 million primarily consisted of \$4.1 million in net cash received in our secondary public offering, net of commissions and certain offering expenses, \$2.6 million in net proceeds received in the CSPA, \$150,000 in net proceeds from an additional common stock purchase agreement, and \$903,000 in net cash received in the sale of common stock to various investors as part of the 2016 Private Placement offset by \$2.5 million in principal payments on our long-term debt.

During the year ended December 31, 2015, cash provided by financing activities 24.2 million primarily consisted of the gross proceeds from the issuance of \$5.6 million in long-term debt, net of discounts and debt issuance costs, \$1.3 million in convertible promissory notes, offset by \$1.1 million in repayments thereof, and \$18.4 million in net cash was provided related to our initial public offering, net of commissions and certain deferred offering costs, offset by the repayment of the \$1.0 million bridge loans and \$100,000 in convertible notes.

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**Description of Indebtedness**

*Convertible Notes and Warrants*

*2013 Convertible Notes*

From July through September 2013, we issued four convertible promissory notes (collectively the "Notes") for gross aggregate proceeds of \$525,000 to various third-party lenders. The Notes bore interest at 8% per annum. The Notes automatically matured and the entire outstanding principal amount, together with accrued interest, was due and payable in cash at the earlier of July 8, 2015 (the "Maturity Date") or ten business days after the date of consummation of the initial closing of a first equity round of financing. We consummated a first equity round of financing prior to the Maturity Date with a pre-money valuation of greater than \$3.0 million, and, accordingly, principal and accrued interest was converted into shares of common stock at 75% of the purchase price paid by such equity investors. These notes were all converted to common stock in February 2014 upon the issuance of the convertible preferred stock. In February 2014, in connection with the first equity round of financing and issuance of the Series A convertible preferred stock, the noteholders exercised their option to convert their Notes into 207,664 shares of common stock and accrued interest was paid in cash to the noteholders. The accreted interest expense related to the discount on the Notes was \$1,443 for the period from January 1, 2014 to the conversion date of the Notes. Upon conversion, the entire remaining debt discount of \$4,071 was recorded as interest expense.

In connection with the Notes, we issued warrants to the noteholders, which became exercisable to purchase an aggregate of 207,664 shares of common stock as of the issuance of the first equity round of financing (the "Warrants"). The Warrants have a \$2.53 exercise price, are fully exercisable from the initial date of the first equity round of financing, and have a five-year term subsequent to that date. The warrants were fully expensed prior to 2016.

*2014 Convertible Notes*

On June 2, 2014, pursuant to a convertible note purchase agreement, we issued convertible promissory notes in the aggregate principal amount of \$300,000 to two accredited investors, including a convertible promissory note for \$200,000 to a board member to which Series A preferred stock was sold. These notes accrued interest at 3% per annum and automatically were to mature on June 1, 2015. Interest expense for the year ended December 31, 2015 was \$3,237 and is included in interest expense in the statement of operations and comprehensive loss. Accrued interest is \$8,507 and is included in accrued liabilities in the balance sheet. All interest was to be paid in cash upon maturity. Upon the closing of the IPO, the outstanding principal amount automatically converted into 53,571 shares common stock at \$5.60, as amended in March 2015. Upon issuance, we analyzed the beneficial nature of the conversion terms and determined that a beneficial conversion feature, or BCF, existed because the effective conversion price on issuance of the notes was less than the fair value at the time of the issuance. We calculated the value of the BCF using the intrinsic method and recorded a BCF of \$75,000 as a discount to notes payable and to additional paid-in capital. For the year ended December 31, 2015, we amortized \$31,250 of the discount as interest expense in the statements of operations and comprehensive loss.

On July 16, 2014, pursuant to a convertible note purchase agreement, we issued a convertible promissory note in the principal amount of \$150,000 to an accredited investor. This note accrued interest at 3% per annum and automatically was to mature on June 1, 2015. Interest expense for the year ended December 31, 2015 was \$1,627 and is included in interest expense in the statements of operations and comprehensive loss. Accrued interest is \$3,711 and is included in accrued liabilities in the balance sheet. All interest was to be paid in cash upon maturity. Upon the closing of the IPO, the outstanding principal amount automatically converted into 26,785 shares of common stock at \$5.60, as amended in March 2015. Upon issuance, we analyzed the beneficial nature of the conversion terms and determined that a BCF existed because the effective conversion price was less than the fair value at the time of the issuance. We calculated the value of the BCF using the intrinsic method and recorded a BCF of \$37,500 as a discount to

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the notes payable and to additional paid-in capital. For the year ended December 31, 2015, we amortized \$17,857 of the discount as interest expense in the statements of operations and comprehensive loss.

In connection with the Transfer Agreement (Note 6) we issued fully vested and immediately exercisable warrants to the Manufacturer to purchase 16,666 shares of common stock at 90% of the IPO price, amended to \$6.30 in March 2015, for a period of five years. The fair value of the warrants, \$37,840, was recorded as research and development expense and additional paid-in capital in June 2014. The warrants were originally valued using the Black-Scholes model with the following assumptions: stock price of \$4.83, exercise price of \$4.35, term of five years, volatility of 49%, dividend yield of 0%, and risk-free interest rate of 1.64%.

On December 23, 2014, pursuant to a convertible note purchase agreement, we issued convertible promissory notes in the aggregate principal amount of \$650,000 to three accredited investors, including a convertible promissory note for \$250,000 to the same board member to which the June 2, 2014 \$200,000 convertible promissory note was issued and to which Series A preferred stock was sold. These notes accrued interest at 12% per annum and became payable within thirty days following the IPO. Interest expense for the year ended December 31, 2015 was \$28,210 and is included in interest expense in the statements of operations and comprehensive loss. Accrued interest is \$30,132 and is included in accrued liabilities in the balance sheet. All interest was to be paid in cash upon maturity. Upon consummation of our IPO, the noteholders converted the notes into 116,070 shares of common stock at a conversion price equal to 80% of the IPO price, amended to \$5.60 in March 2015. In connection with these notes, we also issued the lenders a fully vested warrant to purchase shares of our common stock at an exercise price equal to 80% of the IPO price, amended to \$5.60 in March 2015. These warrants entitle the noteholders to purchase 58,035 shares of common stock. The fair value of the warrants, \$147,943, was recorded as a debt discount and liability at December 23, 2014. We amortized \$141,890 of this discount in the year ended December 31, 2015 which has been recorded as interest expense in the statements of operations and comprehensive loss. The warrants were originally valued using the Black-Scholes model with the following assumptions: stock price of \$4.59, exercise price of \$4.15, term of three years expiring December 2017, volatility of 49%, dividend yield of 0%, and risk-free interest rate of 1.10%. Based on the circumstances, the value derived using the Black-Scholes model approximated that which would be obtained using a lattice model. The debt discount was amortized as interest expense over the one hundred ninety days from issuance of the notes through their first maturity date of July 31, 2015, beginning in January 2015. We analyzed the beneficial nature of the conversion terms and determined that a BCF existed because the effective conversion price was less than the fair value at the time of the issuance. We calculated the value of the BCF using the intrinsic method. A BCF of \$502,057 was recorded as a discount to the notes payable and to additional paid-in capital. For the years ended December 31, 2016 and 2015, we amortized \$0 and \$484,329 of the BCF as interest expense in the statements of operations and comprehensive loss.

***2015 Convertible Notes***

In February 2015, we issued convertible promissory notes to two accredited investors in the aggregate principal amount of \$250,000. These notes were issued pursuant to the convertible note purchase agreement dated December 23, 2014. In connection with the issuance of the notes, we issued the lenders warrants to purchase 22,320 shares at \$5.60 per share, which expire December 31, 2017. Principal and interest of \$103,912 was paid in May 2015 for \$100,000 of these notes. The Company analyzed the beneficial nature of the conversion terms and determined that a BCF existed because the effective conversion price was less than the fair value at the time of the issuance. We calculated the value of the BCF using the intrinsic method. A BCF for the full face value was recorded as a discount to the notes payable and to additional paid-in capital. For the years ended December 31, 2016 and 2015, we amortized \$0 and \$250,000 of the BCF as interest expense in the Company's statement of operations and comprehensive income.

Table of Contents***Extinguishment of debt***

The remaining outstanding note of \$150,000 is payable to the investor at an effective simple interest rate of 12% per annum, and was due in full on July 31, 2016. On July 28, 2016, we entered into an amendment to extend the repayment of the principal and related interest under the terms of the remaining note from July 31, 2016 to October 31, 2016. On November 8, 2016, we entered into an amendment to further extend the maturity date of the remaining note from October 31, 2016 to January 1, 2017. In exchange for the extension of the maturity date, on November 8, 2016, our board of directors granted the lender a warrant to purchase 120,000 shares of our common stock for \$0.01 per share. The warrant is exercisable at any time on or before July 28, 2022, the expiration date of the warrant.

The amendment and related warrant issuance resulted in our treating the debt as having been extinguished and replaced with new debt for accounting purposes. We calculated a loss on the extinguishment of debt of \$108,000 which is included in other expense in the statements of operations and comprehensive loss.

The \$150,000 note is included in notes payable in the balance sheet. We accrued interest of \$33,929, which is included in accrued liabilities in the balance sheet, and incurred \$18,049 and \$15,880 in interest expense in the years ended December 31, 2016 and 2015, respectively.

On December 28, 2016, we entered into an amendment to further extend the maturity date of the note from January 1, 2017 to January 31, 2017. On January 31, 2017, the Company entered into an amendment to further extend the due date of the \$150,000 convertible note payable from January 31, 2017 to January 1, 2018.

In March 2015, we entered into a non-binding letter of intent with an investor. In connection therewith, the investor paid the Company \$1.0 million. At March 31, 2015, we had recorded this amount as a loan advance on the balance sheet. In April 2015, the investor purchased \$1.0 million of convertible promissory notes from us, the terms of which provided that such notes were to be converted into shares of our common stock upon the closing of an IPO at a conversion price of \$5.60 per share. In connection with the purchase of the notes, we issued the investor a warrant to purchase 89,285 shares at \$5.60 per share, which expires December 31, 2017. The notes accrued simple interest of 12% per annum and, upon consummation of our IPO in May 2015, converted into 178,571 shares of our common stock. We analyzed the beneficial nature of the conversion terms and determined that a BCF existed because the effective conversion price was less than the fair value at the time of the issuance. We calculated the value of the BCF using the intrinsic method. A BCF of for the full face value was recorded as a discount to the notes payable and to additional paid-in capital. For the year ended December 31, 2015, we amortized \$1,000,000 of the BCF as interest expense in the statements of operations and comprehensive income. We accrued interest of \$17,753, which is included in accrued liabilities in the balance sheet, and has incurred \$17,753 and \$15,880 in interest expense in the years ended December 31, 2016 and 2015, respectively.

As of December 31, 2016 and 2015, the convertible notes payable obligations were as follows:

	<b>December 31, 2016</b>	<b>December 31, 2015</b>
Notes payable	\$ 150,000	\$ 150,000
Unamortized note discount		
<b>Net debt obligation</b>	<b>\$ 150,000</b>	<b>\$ 150,000</b>

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Interest expense on the convertible notes for the years ended December 31, 2016 and 2015 was as follows:

	Years Ended December 31,	
	2016	2015
Nominal Interest	\$ 18,049	\$ 70,619
Amortization of debt discount		1,925,326
	\$ 18,049	\$ 1,995,945

Interest payable on the convertible notes at December 31, 2016 and 2015 was as follows:

	December 31, 2016	December 31, 2015
Interest Payable:	\$ 94,048	\$ 75,999

### *Notes Payable Bridge Loans*

On October 30, 2014, we entered into a standby bridge financing agreement with two lenders, which was amended and restated on December 3, 2014, which provided a loan commitment in the aggregate principal amount of \$1.0 million (the "Bridge"). Proceeds to us were net of a \$100,000 debt discount under the terms of the Bridge and net of \$104,000 of debt issuance costs. This debt discount and debt issuance costs were recorded as interest expense using the effective interest method, over the six month term of the Bridge. The Bridge became payable upon the IPO. The Bridge was repaid in May 2015, including interest thereon in an amount of \$1,321,600. In connection with the Bridge, the lenders were granted warrants to purchase 178,569 shares of our common stock determined by dividing \$1.0 million by the exercise price of 80% of the IPO price, amended to \$5.60 in March 2015. The fair value of the warrants, \$505,348, was originally recorded as a debt discount and liability at December 3, 2014. The warrants were originally valued using the Black-Scholes model with the following assumptions: stock price of \$5.01, exercise price of \$5.23, term of five years expiring December 2019, volatility of 63%, dividend yield of 0%, and risk-free interest rate of 1.61%. Based on the circumstances, the value derived using the Black-Scholes model approximated that which would be obtained using a lattice model. The debt discount was recorded as interest expense over the six month term of the Bridge. Of the aggregate debt discount of \$605,348 (warrants and original \$100,000 discount), \$521,291 was recorded as interest expense during the year ended December 31, 2015. Additional financing costs of \$104,000 were incurred related to the Bridge and deferred on closing. These were recognized as interest expense over the six-month term of the Bridge using the effective interest method. The Company amortized the remaining \$86,667 of these deferred financing charges by the end of May 2015 was recorded the amortized amounts as interest expense. We fully extinguished the debt and accrued interest in May 2015.

Interest expense on the notes payable-bridge loans for the years ended December 31, 2016 and 2015 was as follows:

	Years Ended December 31,	
	2016	2015
Nominal Interest	\$	\$ 100,000
Amortization of debt discount		521,291
Repayment premium		201,600
Debt issuance costs		86,667
	\$	\$ 909,558

Table of Contents**Standby Line of Credit**

In August 2014, we entered into a standby line of credit with an accredited investor for up to \$1.0 million pursuant to a Line of Credit and Loan Agreement dated August 26, 2014. In connection with the entry into the standby line of credit, we issued the lender a fully vested warrant to purchase 33,333 shares of common stock at an exercise price equal to 80% of the IPO price, amended to \$5.60 in March 2015, which expires in August 2016. The fair value of the warrants, \$114,300, was recorded as interest expense and additional paid-in capital in August 2014. The warrants were originally valued using the Black-Scholes model with the following assumptions: stock price of \$8.00, exercise price of \$6.40, term of two years, volatility of 52%, dividend yield of 0%, and risk-free interest rate of 0.52%. The line of credit expired on March 31, 2015 and there were no drawdowns under the facility.

**Long-term Debt**

In August 2015, we entered into a loan and security agreement with a lender for up to \$8.0 million, which provided for an initial loan commitment of \$6.0 million. The loan agreement requires us to maintain \$4.5 million of the proceeds in cash, which may be reduced or eliminated on the achievement of certain milestones. An additional \$2.0 million is available contingent on the achievement of certain further milestones. The agreement has a term of three years, with interest only payments through February 29, 2016. Thereafter, principal and interest payments will be made with an interest rate of 9.9%. Additionally, there will be a balloon payment of \$560,000 on August 1, 2018. This amount is being recognized over the term of the loan agreement and the effective interest rate, considering the balloon payment, is 15.0%. Proceeds to us were net of a \$134,433 debt discount under the terms of the loan agreement. This debt discount is being recorded as interest expense, using the interest method, over the term of the loan agreement. Under the agreement, we are entitled to prepay principal and accrued interest upon five days prior notice to the lender. In the event of prepayment, we are obligated to pay a prepayment charge. If such prepayment is made during any of the first twelve months of the loan agreement, the prepayment charge will be (a) during such time as we are required to maintain a minimum cash balance, 2% of the minimum cash balance amount plus 3% of the difference between the amount being prepaid and the minimum cash balance, and (b) after such time as we are no longer required to maintain a minimum cash balance, 3% of the amount being prepaid. If such prepayment is made during any time after the first twelve months of the loan agreement, 1% of the amount being prepaid.

On April 21, 2016, the loan and security was amended upon which we repaid \$1.5 million of the debt out of restricted cash. The amendment modified the repayment amortization schedule providing a four-month period of interest only payments for the period from May through August 2016.

As of December 31, 2016 and 2015, the net long-term debt obligation was as follows:

	December 31, 2016	December 31, 2015
Debt and unpaid accrued end-of-term payment	\$ 3,894,320	\$ 6,115,797
Unamortized note discount	(42,493)	(106,635)
Unamortized debt issuance costs	(114,626)	(206,235)
Net debt obligation	\$ 3,737,201	\$ 5,802,927
Current portion of long-term debt	\$ 1,919,675	\$ 1,707,899
Long-term debt, net of discount	1,817,526	\$ 4,095,028
<b>Total</b>	<b>\$ 3,737,201</b>	<b>\$ 5,802,927</b>



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Future principal payments under the long-term debt are as follows:

Years ending December 31	Amount
2017	\$ 2,032,048
2018	1,479,246
<b>Total future principal payments</b>	<b>3,511,294</b>
2018 end-of-term payment	560,000
	4,071,294
Less: unaccreted end-of-term payment at December 31, 2016	(176,974)
<b>Debt and unpaid accrued end-of-term payment</b>	<b>\$ 3,894,320</b>

The obligation at December 31, 2015 includes an end-of-term payment of \$560,000, which accretes over the life of the loan as interest expense. As a result of the debt discount and the end-of-term payment, the effective interest rate for the loan differs from the contractual rate.

Interest expense on the long-term debt for the years ended December 31, 2016 and 2015 was as follows:

	December 31, 2016	December 31, 2015
Nominal Interest	\$ 457,448	\$ 224,400
Amortization of debt discount	64,142	27,798
Accretion of end-of-term payment	267,230	115,797
Debt issuance costs	178,713	43,789
	<b>\$ 967,533</b>	<b>\$ 411,784</b>

At the IPO, our outstanding warrants to purchase convertible preferred stock were all converted to warrants to purchase common stock.

### **Warrants**

On November 22, 2016, we entered into a Securities Purchase Agreement, or the 2016 Purchase Agreement, with certain institutional investors, pursuant to which we sold securities to such investors in a private placement transaction, which we refer to herein as the 2016 Private Placement. In the 2016 Private Placement, we sold an aggregate of 1,666,668 shares of our common stock at a price of \$0.60 per share for net proceeds of \$677,224 or gross proceeds of approximately \$1.0 million less \$322,777 in issuance costs. The investors in the 2016 Private Placement also received (i) warrants to purchase up to an aggregate of 1,666,668 shares of our common stock, at an exercise price of \$0.75 per share, or the Series A Warrants, (ii) warrants to purchase up to an aggregate 1,666,668 shares of our common stock, at an exercise price of \$0.90 per share, or the Series B Warrants, and (iii) warrants to purchase up to an aggregate 1,666,668 shares of our common stock, at an exercise price of \$1.00 per share, or the Series C Warrants and, together with the Series A Warrants and the Series B Warrants, the 2016 Warrants. The issuance costs were

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allocated to common stock, series A warrants, and Series B and C warrants based on the relative fair value of each:

Instruments	Fair Value	% Allocation	Issuance Costs (allocated)
Common Stock	\$ 156,522	16%	\$ 50,522
Warrants (Series A)	700,001	70%	225,944
Warrants (Series B and C)	143,478	14%	46,311
<b>Total</b>	<b>\$ 1,000,001</b>	<b>100%</b>	<b>\$ 322,777</b>

Common stock of a net \$106,000 (fair value less issuance costs) was included in equity in the company's balance sheet. Series A warrants of \$756,001, consisting of the series A warrants of \$700,001 and the series A placement agent warrants of \$56,000, are included in current liabilities in the balance sheet and the \$225,944 of issuance cost was expensed and is in general and administrative expense on the statement of operations and comprehensive loss. Series B and C warrants of a net \$97,167 (fair value less issuance costs) are included in equity in the company's balance sheet.

Our warrant share activity is summarized as follows:

	December 31, 2016	December 31, 2015
Beginning balance at January 1	748,872	494,267
Warrants granted	5,253,337	254,605
Warrants cancelled	(33,333)	
Ending balance at December 31	5,968,876	748,872

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

Since inception, we have not engaged in the use of any off-balance sheet arrangements, such as structured finance entities, special purpose entities or variable interest entities.

### **Critical Accounting Policies and Significant Judgments and Estimates**

The preparation of financial statements in conformity with U.S. generally accepted accounting principles, or U.S. GAAP, requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosures in the financial statements. Critical accounting policies are those accounting policies that may be material due to the levels of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change, and that have a material impact on financial condition or operating performance. While we base our estimates and judgments on our experience and on various other factors that we believe to be reasonable under the circumstances, actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies used in the preparation of our financial statements require significant judgments and estimates. For additional information relating to these and other accounting policies, see Note 2 to our audited financial statements, appearing elsewhere in this report.

### **Accrued Research and Development Expenses**

As part of the process of preparing our financial statements, we are required to estimate accrued research and development expenses. Estimated accrued expenses include fees paid to vendors and clinical sites in connection with our clinical trials and studies. We review new and open contracts and communicate with applicable internal and vendor personnel to identify services that have been performed on our behalf

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and estimate the level of service performed and the associated costs incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost for accrued expenses. The majority of our service providers invoice us monthly in arrears for services performed or as milestones are achieved in relation to our contract manufacturers. We make estimates of our accrued expenses as of each reporting date.

We base our accrued expenses related to clinical trials and studies on our estimates of the services received and efforts expended pursuant to contracts with vendors, our internal resources, and payments to clinical sites based on enrollment projections. The financial terms of the vendor agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of animals and the completion of development milestones. We estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the related expense accrual accordingly on a prospective basis. If we do not identify costs that have been incurred or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. To date, we have not made any material adjustments to our estimates of accrued research and development expenses or the level of services performed in any reporting period presented.

The Company expenses the total cost of a certain long-term manufacturing development contract ratably over the estimated life of the contract, or the total amount paid if greater.

**Accounting for Stock-Based Compensation**

Beginning in the second quarter of 2014, we awarded options and restricted stock units. We measure stock-based awards granted to employees and directors at fair value on the date of grant and recognize the corresponding compensation expense of the awards, net of estimated forfeitures, over the requisite service periods, which correspond to the vesting periods of the awards. The Company revalues non-employee options each reporting period using the fair market value of the Company's common stock as of the last day of each reporting period.

**Key Assumptions.** Our Black-Scholes-Merton option-pricing model requires the input of highly subjective assumptions, including the fair value of the underlying common stock, the expected volatility of the price of our common stock, the expected term of the option, risk-free interest rates and the expected dividend yield of our common stock. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future. These assumptions are estimated as follows:

Fair value of our common stock Our common stock is valued by reference to the publicly-traded price of our common stock.

Expected volatility As we do not have any trading history for our common stock, the expected stock price volatility for our common stock was estimated by taking the average historic price volatility for industry peers based on daily price observations for common stock values over a period equivalent to the expected term of our stock option grants. We did not rely on implied volatilities of traded options in our industry peers' common stock because the volume of activity was relatively low. We intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own common stock share price becomes available.

Expected term The expected term represents the period that our stock-based awards are expected to be outstanding. It is based on the "simplified method" for developing the estimate of the expected life of a "plain vanilla" stock option. Under this approach, the expected term is presumed

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to be the midpoint between the average vesting date and the end of the contractual term for each vesting tranche. We intend to continue to apply this process until a sufficient amount of historical exercise activity is available to be able to reliably estimate the expected term.

**Risk-free interest rate** The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected term of the options for each option group.

**Dividend yield** We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

**Forfeitures** We estimate forfeitures at the time of grant and revise those estimates periodically in subsequent periods. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest.

**Common Stock Valuations.** Prior to our IPO, the fair value of the common stock underlying our stock options was determined by our board of directors, which intended all options granted to be exercisable at a price per share not less than the per share fair value of our common stock underlying those options on the date of grant. The valuations of our common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. The assumptions we used in the valuation model are highly complex and subjective. We base our assumptions on future expectations combined with management judgment. In the absence of a public trading market, our board of directors, with input from management, exercised significant judgment and considered numerous objective and subjective factors to determine the fair value of our common stock as of the date of each option grant and stock award. These judgments and factors will not be necessary to determine the fair value of new awards once the underlying shares begin trading. For now we included the following factors:

the prices, rights, preferences and privileges of our Series A preferred stock relative to those of our common stock;

lack of marketability of our common stock;

our actual operating and financial performance;

current business conditions and projections;

hiring of key personnel and the experience of our management;

our stage of development;

illiquidity of share-based awards involving securities in a private company;

the U.S. capital market conditions; and

the likelihood of achieving a liquidity event, such as an offering or a merger or acquisition of our company given prevailing market conditions.

The fair market value per share of our common stock for purposes of determining stock-based compensation is now the closing price of our common stock as reported on The NASDAQ Stock Market on the applicable grant date.

**Classification of Securities**

We apply the principles of ASC 480-10 "Distinguishing Liabilities From Equity" and ASC 815-40 "Derivatives and Hedging Contracts in Entity's Own Equity" to determine whether financial instruments such as warrants, contingently issuable shares and shares subject to repurchase should be classified as liabilities or equity and whether beneficial conversion features exist. Financial instruments such as warrants

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that are evaluated to be classified as liabilities are fair valued upon issuance and are remeasured at fair value at subsequent reporting periods with the resulting change in fair value recorded in other income/(expense). The fair value of warrants is estimated using the Black Scholes Merton model and requires the input of subjective assumptions including expected stock price volatility and expected life.

**Income Taxes**

As of December 31, 2016, we had net operating loss carryforwards for federal and state income tax purposes of \$24.5 million and \$17.1 million, respectively, which will begin to expire in 2033, subject to limitations. Our management has evaluated the factors bearing upon the realizability of our deferred tax assets, which are comprised principally of net operating loss carryforwards. Our management concluded that, due to the uncertainty of realizing any tax benefits as of December 31, 2016, a valuation allowance was necessary to fully offset our deferred tax assets. We have evaluated our uncertain tax positions and determined that we have no liabilities from unrecognized tax benefits and therefore we have not incurred any penalties or interest. The Tax Reform Act of 1986, as amended, limits the use of net operating loss and tax credit carryforward in certain situations where changes occur in the stock ownership of a company. Utilization of the domestic NOL and tax credit forwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by the Internal Revenue Code Section 382, as well as similar state provisions.

**Recent Accounting Pronouncements**

In November 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2016-18, Statement of Cash Flows: Restricted Cash, or ASU 2016-18, that will require entities to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. As a result, entities will no longer present transfers between cash and cash equivalents and restricted cash and restricted cash equivalents in the statement of cash flows. When cash, cash equivalents, restricted cash and restricted cash equivalents are presented in more than one line item on the balance sheet, the new guidance requires a reconciliation of the totals in the statement of cash flows to the related captions in the balance sheet. This reconciliation can be presented either on the face of the statement of cash flows or in the notes to the financial statements. Entities will also have to disclose the nature of their restricted cash and restricted cash equivalent balances. ASU 2016-18 becomes effective for fiscal years beginning after December 15, 2017, and interim periods within those years, with early adoption permitted. Any adjustments must be reflected as of the beginning of the fiscal year that includes that interim period. The adoption of this standard is not expected to have an impact on our financial position or results of operations.

In August 2016, the FASB issued Accounting Standards Update, or ASU, No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, which addresses the following cash flow issues: (1) debt prepayment or debt extinguishment costs; (2) settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing; (3) contingent consideration payments made after a business combination; (4) proceeds from the settlement of insurance claims; (5) proceeds from the settlement of corporate-owned life insurance policies, including bank-owned life insurance policies; (6) distributions received from equity method investees; (7) beneficial interests in securitization transactions; and (8) separately identifiable cash flows and application of the predominance principle. The amendments in this ASU are effective for public business entities for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years and are effective for all other entities for fiscal years beginning after December 15, 2018 and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted, including adoption in an interim period. We are currently evaluating the impact of the adoption of ASU No. 2016-15 on our consolidated financial statements.

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In March 2016, the FASB issued ASU No. 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, which simplifies several aspects of the accounting for employee stock-based payment transactions. The areas for simplification in ASU No. 2016-09 include the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The amendments in this ASU will be effective for annual periods beginning after December 15, 2016 and interim periods within those annual periods. Early adoption is permitted. We are currently evaluating the impact of the adoption of ASU No. 2016-09 on our consolidated financial statements.

In March 2016 the FASB issued ASU No. 2016-07, Investments – Equity Method and Joint Ventures (Topic 323): Simplifying the Transition to the Equity Method of Accounting. This new standard eliminates the requirement that when an investment qualifies for use of the equity method as a result of an increase in the level of ownership interest or degree of influence, an adjustment must be made to the investment, results of operations and retained earnings retroactively on a step-by-step basis as if the equity method had been in effect during all previous periods that the investment has been held. T ASU 2016-07 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. We are currently evaluating the potential effects of the adoption of this update on its financial statements.

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, Leases (Topic 842), which provides guidance for accounting for leases. Under ASU 2016-02, the Company will be required to recognize the assets and liabilities for the rights and obligations created by leased assets. ASU 2016-02 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. We are currently evaluating the impact of the adoption of ASU 2016-02 on our consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, Balance Sheet Classification of Deferred Taxes (Topic 740), which simplifies the presentation of deferred income taxes. Under ASU 2015-17, deferred tax assets and liabilities are required to be classified as noncurrent, eliminating the prior requirement to separate deferred tax assets and liabilities into current and noncurrent. The new guidance is effective beginning on January 1, 2017, with early adoption permitted. The standard may be adopted prospectively or retrospectively to all periods presented. We elected to early adopt the standard on a retrospective basis effective December 31, 2015, and all deferred tax assets and liabilities are classified as non-current on our balance sheet. Adoption had no effect on our balance sheet for 2016 and 2015 as presented.

In April 2015, the FASB issued ASU No. 2015-03, Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs, to simplify the presentation of debt issuance costs by requiring debt issuance costs to be presented as a deduction from the corresponding debt liability. ASU 2015-03 will be effective beginning in its first quarter of 2016, however early adoption is permitted for financial statements that have not been previously issued. The guidance is to be applied retrospectively to all periods presented. We adopted ASU 2015-03 on December 31, 2015. The adoption of this guidance did not have an impact on our financial condition, results of operations or cash flows.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements – Going Concern (Subtopic 205-40) Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern", which provides guidance regarding management's responsibility to assess whether substantial doubt exists regarding the ability to continue as a going concern and to provide related footnote disclosures. In connection with preparing financial statements for each annual and interim reporting period, management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). This ASU is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. We implemented this

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guidance for the annual period beginning after December 15, 2016. The adoption of this guidance did not have an impact on our statements of financial condition, results of operations or cash flows.

In June 2014, the FASB issued ASU No. 2014-12, "Compensation Stock Compensation (Topic 718)", which requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. The performance target should not be reflected in estimating the grant-date fair value of the award. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. If the performance target becomes probable of being achieved before the end of the requisite service period, the remaining unrecognized compensation cost should be recognized prospectively over the remaining requisite service period. The total amount of compensation cost recognized during and after the requisite service period should reflect the number of awards that are expected to vest and should be adjusted to reflect those awards that ultimately vest. The requisite service period ends when the employee can cease rendering service and still be eligible to vest in the award if the performance target is achieved. This guidance is effective for annual periods (and interim periods within those annual periods) beginning after December 15, 2015. We implemented this guidance for all interim and annual periods beginning after December 15, 2015. The adoption of this guidance did not have an impact on our statements of financial condition, results of operations or cash flows.

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers." The objective of ASU 2014-19 is to establish a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most of the existing revenue recognition guidance, including industry-specific guidance. The core principle of the new standard is that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard is effective for annual reporting periods beginning after December 15, 2018 and allows for prospective or retrospective application. We currently anticipate utilizing the full retrospective method of adoption allowed by the standard, in order to provide for comparative results in all periods presented, and plan to adopt the standard as of January 1, 2018. We are currently evaluating the new guidance, however we do not believe the impact will be significant.

**JOBS Act**

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.



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**For the quarter ended September 30, 2017**

**Overview**

Jaguar Health, Inc. is a natural-products pharmaceuticals company focused on the development and commercialization of novel, sustainably derived gastrointestinal products for both human prescription use and animals on a global basis. Our wholly-owned subsidiary, Napo Pharmaceuticals, Inc., focuses on the development and commercialization of proprietary human gastrointestinal pharmaceuticals for the global marketplace from plants used traditionally in rainforest areas. Our lead prescription drug product, Mytesi (crofelemer), is approved by the FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy (ART). In the field of animal health, we are focused on developing and commercializing first-in-class gastrointestinal products for companion and production animals, foals, and high value horses.

Jaguar was founded in San Francisco, California as a Delaware corporation on June 6, 2013. Napo formed Jaguar to develop and commercialize animal health products. Effective December 31, 2013, Jaguar was a wholly-owned subsidiary of Napo, and until May 13, 2015, Jaguar was a majority-owned subsidiary of Napo. On July 31, 2017, the merger of Jaguar Animal Health, Inc. and Napo became effective, at which point Jaguar Animal Health's name changed to Jaguar Health, Inc. and Napo began operating as a wholly-owned subsidiary of Jaguar focused on human health and the ongoing commercialization of, and development of follow-on indications for, Mytesi.

From our formation in June 2013 until the effective date of the merger, our operations were primarily limited to the research and development of our lead animal prescription drug product candidate, Canalevia intended for the treatment of various forms of diarrhea in dogs; our non-prescription product, Neonorm Calf, to help dairies and calf farms proactively retain fluid in calves; the ongoing commercialization of Neonorm Foal, our antidiarrheal for newborn horses; and Equilevia, our planned product for total gut health in high-performance equine athletes. Since the effective date of the merger, our operations have been primarily focused on research, development and the ongoing commercialization of Mytesi. A portion of our activities has also been focused on other efforts associated with being a recently formed company, including securing necessary intellectual property, recruiting management and key employees, and financing activities.

Our management team has significant experience in gastrointestinal product development. This experience includes the development of crofelemer for human use, from discovery and preclinical and toxicity studies, including the existing animal studies to be used by us for Canalevia regulatory approvals, through human clinical development and commercial manufacturing and supply.

With the merger effective, we believe that our newly combined company is poised to realize a number of synergistic, value adding benefits and an expanded pipeline of potential blockbuster human follow-on indications, a second-generation anti secretory agent, as well as a pipeline of important animal indications for crofelemer, upon which to build global partnerships.

Jaguar, through Napo, controls commercial rights for Mytesi for all indications, territories and patient populations globally. Napo launched Mytesi in early 2017 with one full-time-equivalent Mytesi sales representative for the first half of 2017 focused on targeting high-decile prescribing HIV doctors. Napo recently significantly expanded its internal national salesforce for Mytesi through the hire in key U.S. markets of six sales representatives experienced in the sale of drugs to HIV physicians and gastroenterologists. Napo's new sales representative team covers New York, Miami, Atlanta, Los Angeles, Houston, San Francisco, Chicago, St. Louis, Dallas, and the surrounding regions. All of these regions are key markets for HIV-related drug sales. Three of our new territory managers have been calling on HIV physicians for 18 to 19 years, and others possess extensive experience in drug sales to both gastroenterologists and HIV healthcare providers.

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The goal of Napo's internal sales team is to deliver a frequent and consistent selling message to targeted, high-volume prescribers of antiretroviral therapies and to gastroenterologists who see large numbers of HIV patients. The results of a recent Napo-sponsored survey of 271 U.S. board certified gastroenterologists indicate that the number one GI complaint for people living with HIV/AIDS is diarrhea, and 93 percent of U.S. gastroenterologists see patients with HIV/AIDS in their practice. With seven sales representatives reporting to our newly hired national sales manager, supported by concomitant marketing, promotional activities, and medical education initiatives described below, we expect a proportional response in the number of patients treated with Mytesi. Jaguar estimates the potential U.S. market for Mytesi to be approximately \$100 million in gross annual sales, and anticipates that Mytesi will generate approximately \$7.0 million in revenue by April 2018 (including revenue for January 2017 through March 31, 2018) for its current, FDA-approved specialty indication.

New crofelemer (Mytesi) data from a supplemental analysis of the ADVENT trial was featured in a poster presentation at the 9th International Aids Society (IAS) Conference on HIV Science held from July 23 to 26, 2017 in Paris, France. The presentation was titled Long-Term Crofelemer Use Gives Clinically Relevant Reductions in HIV-Related Diarrhea. IAS features the latest HIV science, including basic, clinical and prevention research, and brings together a broad cross section of HIV professionals from around the world with a focus on implementation moving scientific advances into practice. The results indicate that over 50% of the patients treated had complete resolution of their diarrhea; and 83% had at least a 50% reduction in diarrhea. Entry criteria required at least 7 watery stools in a week, and the average was 20 (with some patients having as high as 67 stools in a week).

In October 2017, Napo launched a national campaign called "Keep your pants on... Unless you don't want to" to highlight the need to recognize and treat diarrhea in people living with HIV/AIDS (PLWHA). The campaign (keep-your-pants-on.com), which launched initially to the 10,000 participants in the AIDS Walk Los Angeles event on October 15, 2017, is designed to raise awareness and to engage PLWHA in a fun and light way to discuss a topic that can be embarrassing. The campaign integrates live third-party events, including the Greater Palm Springs Pride event taking place November 3rd to 5th, 2017, with social media on the web, Twitter, and Facebook. Campaign participants are encouraged to use the hashtag #KeepYourPantsOn when posting photos and videos to social media. Napo is also running "Keep Your Pants On" digital ads on more than 25 HIV and LGBT media outlets around the U.S.

Additionally in Q4 2017, Napo launched a print and digital advertising campaign titled "Enough is Enough" to target PLWHA who are tired of planning their lives around diarrhea as well as HIV physicians and gastroenterologists. The campaign is centered around national HIV magazines, local HIV publications, and publications targeting physicians.

In October 2017, Napo established a scientific advisory board for each potential follow-on indication currently planned for Mytesi. Napo has developed relationships with more than 30 physicians, pharmacists and patient advocates around the world who are recognized specialists and key opinion leaders in the planned Mytesi follow-on indications, and is conducting outreach efforts to discuss the possibility of membership in Napo's new scientific advisory boards with these individuals. As announced on October 19, 2017, Dr. Lee Schwartzberg, MD, FACP, a nationally-recognized medical oncologist and hematologist, has joined Napo's scientific advisory board for cancer therapy-related diarrhea (CTD).

Napo has also established a scientific advisory board for HIV, which Dr. Roscoe Moore Jr., DVM, MPH, Ph.D., DSc, recently joined. Dr. Moore is a former Assistant United States Surgeon General and a Rear Admiral (Retired) in the U.S. Public Health Service. This board will focus primarily on physician education and community awareness regarding the importance and availability of solutions for neglected comorbidities, such as the first-in-class anti-secretory mechanism of action of Mytesi for its currently approved indication.

We are confident that our scientific advisory boards will provide expert, actionable input regarding all aspects of development, including trial design, for Mytesi for our follow-on indications each of which

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addresses a significant, global, unmet medical need. We also expect that our scientific advisory board members will serve as speakers for our medical education programs, authors on Napo abstracts and publications, as a resource for media inquiries.

Napo's HIV Scientific Advisory Board will focus primarily on physician education, and community and global awareness regarding the importance and availability of solutions for neglected comorbidities, such as the first-in-class anti-secretory mechanism of action of Mytesi® for its currently approved indication.

Other key marketing initiatives include the implementation of healthcare provider (HCP) and patient educational programs, including speaker events and the creation of a medical education slide kit for HCPs, as well as a non-branded "My Story with Diarrhea" patient programs delivered by HIV advocates designed to encourage PLWHA who have HIV-related diarrhea to ask their doctor for Mytesi.

Napo is pursuing AIDS Drug Assistance Program (ADAP) status in the following key states: New York, Florida, California, Georgia. ADAP status, if obtained, can provide copay support for Mytesi. Other Napo government affairs initiatives include efforts to convince The U.S. Department of Health and Human Services (HHS) to address HIV-related diarrhea in its HIV treatment guidelines, and to recommend Mytesi as the first line treatment for chronic diarrhea in HIV, as well as efforts to convince other HIV influencer groups (e.g. HIV Medicine Association, Infectious Diseases Society of America) to write a guideline for treatment of chronic diarrhea in people living with HIV.

Mytesi is currently covered by Medicaid in all 50 states. It is also currently covered on 100% of the top 10 commercial insurance plans, representing more than 245 million U.S. lives. Additionally, Napo operates a co-pay coupon to ensure that no participating patients have a Mytesi co-pay greater than \$25. Information about the NapoCares Patient Assistance Program, which assists patients with benefit verification, prior authorization, and claims appeals, can be found at [mytesi.com/mytesi-savings.html](http://mytesi.com/mytesi-savings.html).

According to the World Health Organization, there are nearly 1.7 billion cases of diarrheal disease globally every year. Although not all types of diarrhea are secretory in nature, we view the current, initial approval of Mytesi as the opening of the door to an important pipeline demonstrated by the approval by the FDA of the Chemistry, Manufacturing and Controls ("CMC") for this natural product, as well as acknowledgement by the FDA of the safety of the product for chronic use for the approved indication. Jaguar is pursuing a follow-on indication for Mytesi in cancer therapy-related diarrhea (CTD), an important supportive care indication for patients undergoing primary or adjuvant therapy for cancer treatment. Mytesi is also in development for rare disease indications for infants and children with congenital diarrheal disorders (CDD) and short bowel syndrome (SBS); for irritable bowel syndrome (IBS); as supportive care for post-surgical inflammatory bowel disease patients (IBD); and as a second-generation anti-secretory agent for use in cholera patients. Mytesi has received orphan-drug designation for SBS.

A request for an investigator-initiated trial of Mytesi for CDD and SBS in conjunction with Sheikh Khalifa Medical City in Abu Dhabi has been agreed to with the Company. CDD and SBS lifelong diseases for which there is currently no available treatment except parenteral nutrition cause devastating diarrhea and dehydration.

Two investigator-initiated trials of Mytesi are underway in breast cancer patients suffering from CTD, one funded by Genentech Roche with Herceptin (enrolling patients), and one funded by Puma with neratinib (planning for patient enrollment).

According to data appearing in "Treatment Guidelines for CID" (chemotherapy-induced diarrhea) in the April 2004 issue of *Gastroenterology and Endoscopy News*, diarrhea is the most common adverse event reported in chemotherapy patients. Approved third-party supportive care products for chemotherapy-induced nausea and vomiting (CINV) include Sustol, Aloxi, Akynzeo and Sancuso.

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According to Transparency Market Research, sales of therapeutics for the prevention of CINV approximated \$620 million in 2013, and sales of such therapeutics are expected to reach \$1 billion in 2020.

In this era of novel targeted agents, epidermal growth factor receptor tyrosine kinase inhibitors (TKIs), in particular, may block natural chloride secretion regulation pathways in the normal gastrointestinal mucosa, thereby leading to secretory diarrhea. Diarrhea has been reported as the most common side effect of the recently approved CDK 4/6 inhibitor abemaciclib and the pan-HER TKI neratinib, with occurrence ranging from 86% to >95% in published studies. Diarrhea in this patient population has the potential to cause dehydration, potential infections, and non-adherence to treatment. A novel anti-diarrheal like Mytesi may hold promise for treating secretory diarrhea and therefore also support long-term cancer treatment adherence in this population.

Jaguar's and Napo's portfolio development strategy involves meeting with Key Opinion Leaders (KOLs) to identify indications that are potentially high-value because they address important medical needs that are significantly or globally unmet, obtain input on protocol practicality and protocol generation, and then strategically sequencing indication development priorities, second-generation product pipeline development, and partnering goals on a global basis, as well as identifying possible opportunities for a Special Protocol Assessment (SPA) from the FDA. When granted, SPA provides that, upon request, FDA will evaluate within 45 days certain protocols to assess whether they are adequate to meet scientific and regulatory requirements identified by the sponsor. In 2007, under the SPA process, Napo obtained agreement with the FDA for the design of the pivotal study protocol for the currently approved indication of crofelemer (Mytesi) for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. The 2007 SPA agreement was an important milestone for Napo, allowing Napo to address and mitigate regulatory uncertainty prior to the completion of its final Phase 3 trial of crofelemer for its currently approved indication.

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**Napo Prescription Drug Product Candidates**

<b>Product Candidates</b>	<b>Indication</b>	<b>Completed Milestones</b>	<b>Current Phase of Development</b>	<b>Anticipated Near-Term Milestones</b>
Formulation of crofelemer	Cancer therapy-induced diarrhea (CTD)	Two investigator-initiated clinical trials funded by Genentech, Roche & Puma	Phase 2	Protocol development with KOLs for discussions with FDA  Start pivotal trial in 2018*
Formulation of crofelemer	Supportive care for IBD	Safety  Multiple Phase 2 studies completed in various secretory diarrheas (not IBD)	Phase 2	Protocol development for discussions with FDA
Formulation of crofelemer	Rare disease indications (SBS & CDD)	Phase I study  Orphan designation for SBS	Phase 2	Formulation/proof-of-concept 2018, Abu Dhabi  Pivotal Trial 2018*  Pursue orphan-drug status for CDD
Formulation of crofelemer	Irritable Bowel Syndrome diarrhea predominant (IBS-D)	Phase I study  Two significant Phase 2 studies completed	Phase 2	Protocol development with KOLs for discussions with FDA  Publication of additional analysis of Phase 2 data
SB-300	Second-generation anti-secretory agent for multiple indications including cholera	Animal and human studies in secretory	Pre IND	CMC development for SB-300

diarrheas; successful  
cholera trial design for  
anti-secretory mechanism  
of action with crofelemer

Pre-clinical and Phase 1 in  
2018\*

\*

Clinical trials are funding-dependent

**Estimated Size of Mytesi Target Markets**

We believe the medical need for Mytesi is significant, compelling, and unmet, and that doctors are looking for a drug product with a mechanism of action that is distinct from the options currently available to resolve diarrhea. A growing percentage of HIV patients have lived with the virus in their gut for 10+ years, often causing gut enteropathy and chronic or chronic-episodic diarrhea. According to data from the

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U.S. Centers for Disease Control and Prevention, by 2020 more than 70% of Americans with HIV are expected to be 50 and older.

Market	Number of Competitors for Mytesi's Approved/Anticipated Labelled Indication	Market Size/Potential
HIV-D	0	We estimate the U.S. market revenue potential for Mytesi to be approximately \$100 million in gross annual sales
CTD	0	An estimated 650,000 U.S. cancer patients receive chemotherapy in an outpatient oncology clinic.(1) Comparable supportive care (i.e. CINV) product sales of ~\$620 million in 2013, which is projected to reach \$1.0 billion by 2020(2)
IBD	0	Estimated 1,171,000 Americans have IBD(3)
IBS-D	3	Most IBS products have estimated revenue potential of greater than \$1.0 billion(4)
CDD/SBS-Orphan	0	Financial benefits of Orphan Designation
Cholera (hydration maintenance) PRV (SB-300)	0	Priority review vouchers have recently sold for \$125 million to \$350 million(5)

(1) Centers for Disease Control and Prevention. Preventing Infections in Cancer Patients: Information for Health Care Providers ([cdc.gov/cancer/preventinfections/providers.htm](http://cdc.gov/cancer/preventinfections/providers.htm))

(2) Heron Therapeutics, Inc. Form 10-K for the fiscal year ended December 31, 2016

(3) Kappelman, M. et al. Recent Trends in the Prevalence of Crohn's Disease and Ulcerative Colitis in a Commercially Insured US Population. *Dig Dis Sci*. 2013 Feb; 58(2): 519-525

(4) Merrill Lynch forecasts peak US sales of roughly \$1.5 bn for Ironwood's Linzess (<http://247wallst.com/healthcare-business/2015/04/27/key-analyst-sees-nearly-30-upside-in-ironwood/>); Rodman & Renshaw estimate peak annual sales of Synergy Pharmaceuticals' Trulance at \$2.3 bn in 2021 (Source: <https://www.benzinga.com/analyst-ratings/analyst-color/17/03/9224181/analyst-synergy-pharma-could-achieve-sustainable-profit/>)

(5) In Aug. 2015, AbbVie Inc. bought a priority review voucher from United Therapeutics Corp for \$350 million (<http://www.reuters.com/article/us-abbvie-priorityreview/abbvie-buys-special-review-voucher-for-350-million-idUSKCN0QO1LQ20150819>). In Feb. 2017 Sarpeta Therapeutics sold a priority review voucher to Gilead Sciences, Inc. for \$125 million (<http://fortune.com/2017/02/21/sarepta-gilead-review-voucher/>).

In the animal health space, we focus on developing and commercializing first-in-class gastrointestinal products for companion and production animals, foals, and high value horses.

Our technology for proprietary gastrointestinal disease products is central to the product pipelines of both veterinary and human indications. Crofelemer, the active pharmaceutical ingredient (API) in Mytesi, is





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also the API in Canalevia, and as such the CMC development of Canalevia has benefited from the regulatory approval of Mytesi and the supply chain and quality system that supports the commercial distribution of Mytesi. We achieved statistically significant results in a multicenter canine proof-of-concept study completed in February 2015, supporting the conclusion that Canalevia treatment is superior to placebo. We have received Minor Use in a Minor Species (MUMS) designation for Canalevia for chemotherapy-induced diarrhea (CID) in dogs. The FDA has indicated that the use of Canalevia for the treatment of exercise-induced diarrhea (EID) in dogs qualifies as a "minor use", which means Canalevia is eligible for conditional approval for the indication of EID in dogs. We expect to conduct the commercial launch of Canalevia for CID and EID in dogs in the first half of 2018. This is expected to be the first prescription product approval for Jaguar's animal health product development program.

The clinically-proven performance of Neonorm Foal, in combination with our heightened understanding of market needs within the global equine space, is driving our increased focus on equine product development. The demand, particularly in the Middle East, for a total gut health product for high performance equine athletes appears to be quite strong, and we believe this is indicative of an unmet medical need. Based on this demand, and with support from studies we conducted in horses with gastric ulcers a prevalent problem in competing horses and also horses with diarrhea, we have transitioned development of Equilevia to a create a non-prescription, personalized, premium proprietary product for total gut health in equine athletes. Equilevia is a formulation of a standardized botanical extract. Gut health is of critical importance in horses, as conditions such as ulcers can meaningfully impair equine athlete performance and colic can lead to the death of an otherwise healthy horse in a matter of hours. Although we are still assessing the size of the opportunity represented by this self-funded program, we expect to launch Equilevia in the fourth quarter of 2017.

The reception among users of our two commercialized non-prescription products Neonorm Calf and Neonorm Foal, an anti-diarrheal product we launched for newborn horses in early 2016 has been quite positive, and in June 2017 we launched neonorm.com, a commercial website for both Neonorm products. As we announced this past June, the Organic Materials Review Institute (OMRI) has reviewed Neonorm Calf and determined that it is allowed for use in compliance with the U.S. Department of Agriculture (USDA) National Organic Program. OMRI is an international nonprofit organization that determines which input products are allowed for use in organic production and processing. Organic livestock production plays a vital role in support of a sustainable and safe farm and food system, both in the U.S. and internationally. According to a report published by Allied Market Research, the global market for organic dairy food and drinks organic milk, yogurt, cheese, and others is expected to grow at a compound annual growth rate of 14.25% from 2016 to reach \$36.7 billion by 2022 from \$14.5 billion in 2015. According to the Organic Trade Association's (OTA) 2016 Organic Industry Survey, the U.S. organic industry posted new records in 2015, with total organic product sales hitting a new benchmark of \$43.3 billion, up 11% from the previous year's record level and outpacing the overall food market's growth rate of 3%.

In July 2016 we released data from two China-based studies sponsored by Fresno, California-based Integrated Animal Nutrition and Health Inc. showing remarkable resolution of diarrhea and cure of piglets afflicted with diarrhea following treatment with a *Croton lechleri* botanical extract administered in water. As we announced in September 2016, we signed an exclusive supply and distribution agreement for this botanical extract with Integrated Animal Nutrition and Health Inc. for dairy cattle and pigs in the Chinese marketplace. According to Index Muni, swine production is projected to reach 672.5 million head in 2017 in China, where pork is still the main protein source for many consumers. According to New Zealand-based NZX Agri, in 2017 there will be seven million cows "in milk" (lactating cows) in China. With the world's largest population, China has been experiencing an increase in demand for dairy products as a result of sharply increasing income levels, fast-changing food habits, the desire of parents to feed their babies high-protein formula, and the loosening in 2015 of China's longstanding one-child policy, among other factors. Integrated Animal Nutrition and Health, Inc. has minimum purchase requirements of the botanical extract to maintain their exclusivity.

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Canalevia, Equilevia and Neonorm are distinct products formulated to address specific species and market channels. We have filed nine investigational new animal drug applications, or INADs, with the FDA and intend to develop species-specific formulations of Neonorm in six additional target species, and Canalevia for both cats and dogs.

**Merger with Napo Pharmaceuticals, Inc.**

On July 31, 2017, we completed a merger with Napo Pharmaceuticals, Inc. ("Napo") pursuant to the Agreement and Plan of Merger dated March 31, 2017 by and among Jaguar, Napo, Napo Acquisition Corporation ("Merger Sub"), and Napo's representative (the "Merger Agreement"). In accordance with the terms of the Merger Agreement, upon the completion of the merger, Merger Sub merged with and into Napo, with Napo surviving as our wholly-owned subsidiary. Immediately following the Napo Merger, we changed our name from "Jaguar Animal Health, Inc." to "Jaguar Health, Inc." Napo now operates as a wholly-owned subsidiary of Jaguar focused on human health and the ongoing commercialization of Mytesi, a Napo drug product approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy.

In connection with the merger, (i) each issued and outstanding share of Napo common stock (other than dissenting shares and shares held by us or Napo) was converted into a contingent right to receive (x) up to a whole number of shares of our common stock comprising in the aggregate up to approximately 20.2% of the fully diluted shares of our common stock immediately following the consummation of the merger, which contingent right will vest only if the resale of certain shares of our common stock (the "Tranche A Shares") issued by us to Nantucket Investments Limited ("Nantucket") pursuant to the Napo debt settlement provides Nantucket with specified cash returns over a specified period of time (the "Hurdle Amounts"), and (y) if the applicable Hurdle Amount is achieved before all of the Tranche A Shares are sold, additional shares of our common stock (equal to 50% of the unsold Tranche A Shares), which will be distributed pro rata among holders of contingent rights and holders of Napo restricted stock units, (ii) existing creditors of Napo (inclusive of Nantucket) were issued in the aggregate approximately 42,903,018 shares of our non-voting common stock and 2,282,445 shares of our voting common stock in full satisfaction of all existing indebtedness then owed by Napo to such creditors, and (iii) an existing Napo stockholder ("Invesco") was issued an aggregate of approximately 3,243,243 shares of our common stock in return for \$3 million of new funds invested in us by such investor, which were immediately loaned to Napo to partially facilitate the extinguishment of the debt that Napo owed to Nantucket. The minimum Hurdle Amount needed for the vesting of the contingent rights will vary depending on a number of factors (including, among other things, the time period over which Nantucket receives specified cash returns in connection with the resale of the Tranche A Shares), and Napo stockholders may not receive any shares of Jaguar common stock in certain circumstances (including if the minimum Hurdle Amount is not satisfied).

We expect to incur significant expenses in connection with the merger of Jaguar Animal Health and Napo. While we have assumed that a certain level of expenses will be incurred, there are many factors that could affect the total amount or the timing of the merger expenses, and many of the expenses that will be incurred are, by their nature, difficult to estimate. These expenses could result in the combined company taking significant charges against earnings following the completion of the merger. The ultimate amount and timing of such charges are uncertain at the present time. We incurred approximately \$3.6 million in professional and other fees associated with the proposed merger through July 31, 2017.

**Financial Operations Overview**

We were incorporated in June 2013 in Delaware. Napo formed our company to develop and commercialize animal health products. Prior to our incorporation, the only activities of Napo related to animal health were limited to the retention of consultants to evaluate potential strategic alternatives. We were previously a majority-owned subsidiary of Napo. However, following the closing of our May 2015 initial public offering, we are no longer majority-owned by Napo. On July 31, 2017, Jaguar Animal

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Health, Inc., or Jaguar, completed a merger with Napo pursuant to the Agreement and Plan of Merger dated March 31, 2017 by and among Jaguar, Napo, Napo Acquisition Corporation ("Merger Sub"), and Napo's representative (the "Merger Agreement"). In accordance with the terms of the Merger Agreement, upon the completion of the merger, Merger Sub merged with and into Napo, with Napo surviving as our wholly-owned subsidiary. Immediately following the Napo Merger, Jaguar changed its name from "Jaguar Animal Health, Inc." to "Jaguar Health, Inc." Napo now operates as a wholly-owned subsidiary of Jaguar focused on human health and the ongoing commercialization of Mytesi, a Napo drug product approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy.

On a consolidated basis, we have not yet generated enough revenue to date to achieve break even or positive cash flow, and we expect to continue to incur significant research and development and other expenses. Our net loss and comprehensive loss was \$1.8 million and \$11.1 million for the nine months ended September 30, 2017 and 2016, respectively. As of September 30, 2017, we had total stockholders' equity of \$31.8 million and cash and cash equivalents of \$220,590. We expect to continue to incur losses for the foreseeable future as we expand our product development activities, seek necessary approvals for our product candidates, conduct species-specific formulation studies for our non-prescription products, establish API manufacturing capabilities and begin commercialization activities. As a result, we expect to experience increased expenditures for 2017.

**Revenue Recognition**

We recognize revenue in accordance with ASC 605 "Revenue Recognition", subtopic ASC 605-25 "*Revenue with Multiple Element Arrangements*" and subtopic ASC 605-28 "*Revenue Recognition-Milestone Method*", which provides accounting guidance for revenue recognition for arrangements with multiple deliverables and guidance on defining the milestone and determining when the use of the milestone method of revenue recognition for research and development transactions is appropriate, respectively. For multiple-element arrangements, each deliverable within a multiple deliverable revenue arrangement is accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. If a deliverable in a multiple element arrangement is not deemed to have a stand-alone value, consideration received for such a deliverable is recognized ratably over the term of the arrangement or the estimated performance period, and it will be periodically reviewed based on the progress of the related product development plan. The effect of a change made to an estimated performance period and therefore revenue recognized ratably would occur on a prospective basis in the period that the change was made.

We recognize revenue under its licensing, development, co-promotion and commercialization agreement from milestone payments when: (i) the milestone event is substantive and its achievability has substantive uncertainty at the inception of the agreement, and (ii) it does not have ongoing performance obligations related to the achievement of the milestone earned. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment (a) is commensurate with either our performance subsequent to the inception of the arrangement to achieve the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from our performance subsequent to the inception of the arrangement to achieve the milestone, (b) relates solely to past performance, and (c) is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

Our records revenue related to the reimbursement of costs incurred under the collaboration agreement where the company acts as principal, controls the research and development activities and bears credit risk. Under the agreement, we are reimbursed for associated out-of-pocket costs and for certain employee costs. The gross amount of these pass-through costs is reported in revenue in the accompanying

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statements of operations and comprehensive loss, while the actual expense for which we are reimbursed are reflected as research and development costs.

Determining whether and when some of these revenue recognition criteria have been satisfied often involves assumptions and judgments that can have a significant impact on the timing and amount of revenue we will report. Changes in assumptions or judgments or changes to the elements in an arrangement could cause a material increase or decrease in the amount of revenue that we report in a particular period.

**Product Revenue**

Sales of Neonorm Calf and Foal to distributors are made under agreements that may provide distributor price adjustments and rights of return under certain circumstances. Until we develop sufficient sales history and pipeline visibility, revenue and costs of distributor sales will be deferred until products are sold by the distributor to the distributor's customers. Revenue recognition depends on notification either directly from the distributor that product has been sold to the distributor's customer, when we have access to the data. Deferred revenue on shipments to distributors reflect the estimated effects of distributor price adjustments, if any, and the estimated amount of gross margin expected to be realized when the distributor sells through product purchased from us. Our sales to distributors are invoiced and included in accounts receivable and deferred revenue upon shipment. Inventory is relieved and revenue recognized upon shipment by the distributor to their customer. We had Neonorm revenues of \$33,611 and \$26,357 for the three months ended September 30, 2017 and 2016, and \$139,600 and \$88,646 for the nine months ended September 30, 2017 and 2016.

Sales of Botanical Extract are recognized as revenue when delivered to the customer. We had Botanical Extract revenues of \$48,000 and \$24,000 in the three months ended September 30, 2017 and 2016, and \$78,000 and \$24,000 in the nine months ended September 30, 2017 and 2016.

Sales of Mytesi are recognized as revenue when the products are delivered to the wholesalers. We had Mytesi revenues of \$364,054 and \$0 for the three and nine months months ended September 2017 and 2016, respectively. We record a reserve for estimated product returns under terms of agreements with wholesalers based on its historical returns experience. Reserves for returns at September 30, 2017 were immaterial. If actual returns differed from our historical experience, changes to the reserved could be required in future periods.

**Collaboration Revenue**

On January 27, 2017, we entered into a licensing, development, co-promotion and commercialization agreement with Elanco US Inc. ("Elanco") to license, develop and commercialize Canalevia ("Licensed Product"), our drug product candidate under investigation for treatment of acute and chemotherapy-induced diarrhea in dogs, and other drug product formulations of crofelemer for treatment of gastrointestinal diseases, conditions and symptoms in cats and other companion animals. We granted Elanco exclusive global rights to Canalevia, a product whose active pharmaceutical ingredient is sustainably isolated and purified from the Croton lechleri tree, for use in companion animals. Pursuant to the Elanco Agreement, Elanco will have exclusive rights globally outside the U.S. and co-exclusive rights with us in the U.S. to direct all marketing, advertising, promotion, launch and sales activities related to the Licensed Products.

Under the terms of the Elanco Agreement, we received an initial upfront payment of \$2,548,689, inclusive of reimbursement of past product and development expenses of \$1,048,689, and will receive additional payments upon achievement of certain development, regulatory and sales milestones in an aggregate amount of up to \$61.0 million payable throughout the term of the Elanco Agreement, as well as product development expense reimbursement for any additional product development expenses incurred, and royalty payments on global sales. The \$61.0 million development and commercial milestones consist of

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\$1.0 million for successful completion of a dose ranging study; \$2.0 million for the first commercial sale of license product for acute indications of diarrhea; \$3.0 million for the first commercial sale of a license product for chronic indications of diarrhea; \$25.0 million for aggregate worldwide net sales of licensed products exceeding \$100.0 million in a calendar year during the term of the agreement; and \$30.0 million for aggregate worldwide net sales of licensed products exceeding \$250.0 million in a calendar year during the terms of the agreement. Each of the development and commercial milestones are considered substantive. No revenues associated with the achievement of the milestones has been recognized to date. The Elanco Agreement specifies that we will supply the Licensed Products to Elanco, and that the parties will agree to set a minimum sales requirement that Elanco must meet to maintain exclusivity. The \$2,548,689 upfront payment, inclusive of reimbursement of past product and development expenses of \$1,048,689 is recognized as revenue ratably over the estimated development period of one year resulting in \$637,200 and \$1,734,100 in collaboration revenue in the three and nine months ended September 30, 2017 which are included in our statements of operations and comprehensive loss. The difference of \$814,589 is included in deferred collaboration revenue in our balance sheet.

In addition to the upfront payments, Elanco reimburses us for certain development and regulatory expenses related to our planned target animal safety study and the completion of the Canalevia field study for acute diarrhea in dogs. These are recognized as revenue in the month in which the related expenses are incurred. We have \$17,349 of unreimbursed expenses as of September 30, 2017, which is included in Other Receivables on our balance sheet. We included the \$17,349 and \$503,391 in collaboration revenue in the three and nine months ended September 30, 2017 which are included in the statements of operations and comprehensive loss. On November 1, 2017, the Company received a letter (the "Notice") from Elanco serving as formal notice of Elanco's decision to terminate the Elanco Agreement by giving the Company 90 days written notice. Pursuant to the terms of the Elanco Agreement, termination of the Agreement will become effective on January 30, 2018, which is 90 days after the date of the Notice. On the effective date of termination of the Elanco Agreement, all licenses granted to Elanco by the Company under the Elanco Agreement will be revoked and the rights granted thereunder revert back to the Company.

**Cost of Product Revenue**

Cost of product revenue expenses consist of costs to manufacture, package and distribute Neonorm that distributors have sold through to their customers.

**Research and Development Expense**

Research and development expenses consist primarily of clinical and contract manufacturing expense, personnel and related benefit expense, stock-based compensation expense, employee travel expense, reforestation expenses. Clinical and contract manufacturing expense consists primarily of costs to conduct stability, safety and efficacy studies, and manufacturing startup expenses at an outsourced API provider in Italy.

We typically use our employee and infrastructure resources across multiple development programs. We track outsourced development costs by prescription drug product candidate and non-prescription product but do not allocate personnel or other internal costs related to development to specific programs or development compounds.

The timing and amount of our research and development expenses will depend largely upon the outcomes of current and future trials for our prescription drug product candidates as well as the related regulatory requirements, the outcomes of current and future species-specific formulation studies for our non-prescription products, manufacturing costs and any costs associated with the advancement of our line extension programs. We cannot determine with certainty the duration and completion costs of the current or future development activities.

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The duration, costs and timing of trials, formulation studies and development of our prescription drug and non-prescription products will depend on a variety of factors, including:

the scope, rate of progress, and expense of our ongoing, as well as any additional clinical trials, formulation studies and other research and development activities;

future clinical trial and formulation study results;

potential changes in government regulations; and

the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a prescription drug product candidate or non-prescription product could mean a significant change in the costs and timing associated with our development activities.

We expect research and development expense to increase significantly as we add personnel, commence additional clinical studies and other activities to develop our prescription drug product candidates and non-prescription products.

**Sales and Marketing Expense**

Sales and marketing expenses consist of personnel and related benefit expense, stock-based compensation expense, direct sales and marketing expense, employee travel expense, and management consulting expense. We currently incur sales and marketing expenses to promote Neonorm calf and foal sales.

We expect sales and marketing expense to increase significantly as we develop and commercialize new products and grow our existing Neonorm market. We will need to add sales and marketing headcount to promote the sales of existing and new products.

**General and Administrative Expense**

General and administrative expenses consist of personnel and related benefit expense, stock-based compensation expense, employee travel expense, legal and accounting fees, rent and facilities expense, and management consulting expense.

We expect general and administrative expense to increase in order to enable us to effectively manage the overall growth of the business. This will include adding headcount, enhancing information systems and potentially expanding corporate facilities.

**Interest Expense**

Interest expense consists primarily of interest on convertible promissory notes, the standby bridge financing commitment and the loan and security agreement (long-term debt arrangement). We also include accretion of debt issuance costs, debt discount amortization and the accretion of an end-of-term long-term debt payment in interest expense in our statements of operations and comprehensive loss.

Table of Contents**Results of Operations*****Comparison of the nine months ended September 30, 2017 and 2016***

The following table summarizes the Company's results of operations with respect to the items set forth in such table for the nine months ended September 30, 2017 and 2016 together with the change in such items in dollars and as a percentage:

	<b>Nine Months Ended September 30,</b>			
	<b>2017</b>	<b>2016</b>	<b>Variance</b>	<b>Variance %</b>
Product revenue	\$ 581,654	\$ 112,646	\$ 469,008	416.4%
Collaboration revenue	2,237,491		2,237,491	N/A
<b>Total revenue</b>	<b>2,819,145</b>	<b>112,646</b>	<b>2,706,499</b>	<b>2402.7%</b>
<b>Operating Expenses</b>				
Cost of revenue	247,135	36,867	210,268	570.3%
Research and development expense	3,033,851	5,672,516	(2,638,665)	(46.5)%
Sales and marketing expense	943,908	355,345	588,563	165.6%
General and administrative expense	8,512,195	4,319,856	4,192,339	97.0%
Impairment of goodwill	3,648,000		3,648,000	N/A
<b>Total operating expenses</b>	<b>16,385,089</b>	<b>10,384,584</b>	<b>6,000,505</b>	<b>57.8%</b>
Loss from operations	(13,565,944)	(10,271,938)	(3,294,006)	(32.1)%
Interest expense, net	(800,885)	(774,185)	(26,700)	(3.4)%
Other expense	(13,428)	(11,046)	(2,382)	(21.6)%
Change in fair value of warrants	636,121		636,121	N/A
Loss on extinguishment of debt	(207,713)		(207,713)	N/A
Net loss before tax	(13,951,849)	(11,057,169)	(2,894,680)	(26.2)%
Income tax benefit	12,190,693		12,190,693	N/A
Net loss and comprehensive loss	\$ (1,761,156)	\$ (11,057,169)	\$ 9,296,013	84.1%

***Revenue and Cost of Revenue*****Neonorm Calf and Foal**

Our product revenue of \$139,600 and \$88,646 and related cost of revenue of \$56,366 and \$36,867 for the nine months ended September 30, 2017 and 2016 reflects sell-through of our Neonorm Calf and Neonorm Foal products to our distributors. We defer recognizing revenue and cost of revenue until products are sold by the distributor to the distributor's end customers and recognition depends on notification from the distributor that product has been sold to the distributor's end customer. Revenue increased due to an increase in units sold-through from distributors to their customers in the nine months ended September 30, 2017 compared to the same period in 2016. The increase in cost of revenue was consistent with the increase in sales. We continue to increase our efforts to promote sales growth.

**Botanical extract**

We began selling botanical extract to a distributor for use exclusively in China beginning in September 2016. The revenue from these sales, which totaled \$78,000 and \$24,000 in the nine months ended September 30, 2017 and 2016, is recognized upon shipment to the distributor as no return rights are provided to this distributor. Revenue increased due to an increase in kilograms of botanical extract sold directly to customers in the nine months ended September 30, 2017 compared to the same period in 2016. We had no cost of product revenue associated with the botanical extract as we wrote off the full value of the botanical extract to expense in 2014 due to uncertainty of future use and ability to sell to a customer.





Table of Contents**Collaboration revenue**

On January 27, 2017, we entered into a licensing, development, co-promotion and commercialization agreement with Elanco to license, develop and commercialize Canalevia ("Licensed Product"), our drug product candidate under investigation for treatment of acute and chemotherapy-induced diarrhea in dogs, and other drug product formulations of crofelemer for treatment of gastrointestinal diseases, conditions and symptoms in cats and other companion animals. We granted to Elanco exclusive global rights to Canalevia, a product whose active pharmaceutical ingredient is sustainably isolated and purified from the Croton lechleri tree, for use in companion animals. Pursuant to the Elanco Agreement, Elanco has exclusive rights globally outside the U.S. and co-exclusive rights with us in the U.S. to direct all marketing, advertising, promotion, launch and sales activities related to the Licensed Products. Under the terms of the Elanco Agreement, we received an initial upfront payment of \$2,548,689 and will receive additional payments upon achievement of certain development, regulatory and sales milestones in an aggregate amount of up to \$61.0 million payable throughout the term of the Elanco Agreement, as well as product development expense reimbursement, and royalty payments on global sales. The Elanco Agreement specifies that we will supply the Licensed Products to Elanco, and that the parties will agree to set a minimum sales requirement that Elanco must meet to maintain exclusivity. Elanco will reimburse us for certain development and regulatory expenses related to our planned target animal safety study and the completion of our field study of Canalevia for acute diarrhea in dogs. The \$2,548,689 total of the upfront payment and expense reimbursement is recognized as collaboration revenue ratably over the estimated development period of one year resulting in \$1,734,100 in collaboration revenue in the nine months ended September 30, 2017. The Company included the \$503,391 in collaboration revenue in the nine months ended September 30, 2017 which are included in the Company's statements of operations and comprehensive loss.

**Mytesi revenue**

Napo's product revenue of \$364,054 and related cost of revenue of \$190,768 from the date of acquisition are included in the consolidated results for the nine months ended September 30, 2017 reflecting the delivery of Mytesi product by our distributors to the wholesalers. We record a reserve for estimated product returns under terms of agreements with wholesalers based on its historical returns experience. Reserves for returns at September 30, 2017 were immaterial. If actual returns differed from our historical experience, changes to the reserved could be required in future periods.

***Research and Development Expense***

The following table presents the components of research and development expense for the nine months ended September 30, 2017 and 2016 together with the change in such components in dollars and as a percentage:

	Nine Months Ended September 30,			
	2017	2016	Variance	Variance %
<i>R&amp;D:</i>				
Personnel and related benefits	\$ 1,490,293	\$ 1,993,917	\$ (503,624)	(25.3)%
Materials expense and tree planting	99,409	78,936	20,473	25.9%
Travel, other expenses	168,441	348,135	(179,694)	(51.6)%
Clinical and contract manufacturing	422,449	1,836,816	(1,414,367)	(77.0)%
Stock-based compensation	168,981	116,552	52,429	45.0%
Other	684,278	1,298,160	(613,882)	(47.3)%
Total	\$ 3,033,851	\$ 5,672,516	\$ (2,638,665)	(46.5)%

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Our research and development expense decreased \$2,638,665 from \$5,672,516 in the nine months ended September 30, 2016 to \$3,033,851 for the same period in 2017. Personnel and related benefits decreased \$503,624 from \$1,993,917 in the nine months ended September 30, 2016 to \$1,490,293 in the same period in 2017 due to an increase of \$408,604 employee leasing chargebacks to Napo for services rendered in the seven months ended July 31, 2017 over the nine months ended September 30, 2016 with the remainder of the decrease due to changes in headcount personnel and related salaries and benefits year over year. Travel expenses decreased \$179,694 from \$348,135 in the nine months ended September 30, 2016 to \$168,441 in the same period in 2017 due primarily to a decrease in clinical activity. Significant clinical trial work has decreased and contract manufacturing work was completed in Q1 2016 resulting in a reduction of expense of \$1,414,367 from \$1,836,816 in the nine months ended September 30, 2016 to \$422,449 in the same period in 2017. Clinical expenses decreased \$990,207 from \$1,505,367 in the nine months ended September 30, 2016 to \$515,160 in the same period in 2017, and contract manufacturing expense decreased \$424,161 due to the completion of the manufacturing setup in Italy in the first quarter of 2016 and due to some contract adjustments that arose in the second quarter of 2017. Stock-based compensation increased \$52,429 from \$116,552 in the nine months ended September 30, 2016 to \$168,981 in the same period in 2017 primarily due to an increase in the number of outstanding option grants year over year. Other expenses, consisting primarily of consulting and formulation expenses, decreased \$613,882 from \$1,298,160 in the nine months ended September 30, 2016 to \$684,278 in the same period in 2017. Consulting expenses decreased \$419,182 from \$810,821 in the nine months ended September 30, 2016 to \$391,639 in the same period in 2017 consistent with the decrease in contractor utilization to assist in our clinical trials and in chemistry, manufacturing and controls ("CMC") activities. Formulation expenses decreased \$184,946 from \$331,153 in the nine months ended September 30, 2016 to \$146,207 for the same period in 2017 due to an decrease in work needed for clinical operations. We plan to increase our research and development expense as we continue developing our drug candidates. Our research and development expenses for the nine months ended September 30, 2017 include Napo's research and development expenses for the two months from the acquisition of \$96,017.

We increased support for the reforestation of croton lechleri trees in South America, which is reflected in an increase in our spend by \$20,473 from \$78,936 in the nine months ended September 30, 2016 to \$99,409 in the same period in 2017. We value and take to heart the responsibility to replenish trees consumed in order to extract the raw material to manufacture our primary commercial product and the drug product for use in clinical trials.

**Sales and Marketing Expense**

The following table presents the components of sales and marketing expense for the nine months ended September 30, 2017 and 2016 together with the change in such components in dollars and as a percentage:

	Nine Months Ended September 30,		Variance	Variance %
	2017	2016		
<b>S&amp;M:</b>				
Personnel and related benefits	\$ 191,238	\$ 145,619	\$ 45,619	31.3%
Stock-based compensation	23,307	58,733	(35,426)	(60.3)%
Direct Marketing Fees	76,648	70,171	6,477	9.2%
Other	652,715	80,822	571,893	707.6%
<b>Total</b>	<b>\$ 943,908</b>	<b>\$ 355,345</b>	<b>\$ 588,563</b>	<b>165.6%</b>

Our sales and marketing expense increased \$588,563 from \$355,345 in the nine months ended September 30, 2016 to \$943,908 in the same period in 2017. Personnel and related benefits increased \$45,619 from \$145,619 in the nine months ended September 30, 2016 to \$191,238 in the same period in

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2017 due to an increase in headcount year over year, net of \$50,039 in employee leasing chargebacks to Napo for services rendered in the seven months ended July 31, 2017 over the nine months ended September 30, 2016. Stock based compensation expense decreased \$35,426 from \$58,733 in the nine months ended September 30, 2016 to \$23,307 in the same period in 2017 due to new options granted at a much lower fair value due to a lower strike price and a lower fair market value. Direct marketing and sales expense increased \$6,477 from \$70,171 in the nine months ended September 30, 2016 to \$76,648 for the same period in 2017 due to an increase in marketing programs to promote our Neonom products. Other expenses, consisted primarily of travel expense, consulting expense and royalty expense, which collectively increased \$571,893 from \$80,822 in the nine months ended September 30, 2016 to \$652,715 in the same period in 2017. We plan to expand sales and marketing spend to promote our Neonom products. Other sales and marketing expenses for the nine months ended September 30, 2017 include sales and marketing expenses of \$513,102 for Napo for the two months from the date of acquisition.

### *General and Administrative Expense*

The following table presents the components of general and administrative expense for the nine months ended September 30, 2017 and 2016 together with the change in such components in dollars and as a percentage:

	Nine Months Ended September 30,			
	2017	2016	Variance	Variance %
<i>G&amp;A:</i>				
Personnel and related benefits	\$ 1,331,077	\$ 1,703,951	\$ (372,874)	(21.9)%
Accounting fees	547,977	225,393	322,584	143.1%
Third-party consulting fees and Napo service fees	1,111,473	173,870	937,603	539.3%
Legal fees	2,922,763	456,243	2,466,520	540.6%
Travel	230,736	242,013	(11,277)	(4.7)%
Stock-based compensation	438,636	303,157	135,479	44.7%
Rent and lease expense	226,306	301,677	(75,371)	(25.0)%
Public company expenses	611,746	227,551	384,195	168.8%
Other	1,091,482	686,001	405,481	59.1%
<b>Total</b>	<b>\$ 8,512,195</b>	<b>\$ 4,319,856</b>	<b>\$ 4,192,339</b>	<b>97.0%</b>

Our general and administrative expenses increased \$4,192,339 from \$4,319,856 in the nine months ended September 30, 2016 to \$8,512,195 for the same period in 2017 due primarily to \$3,521,751 in merger related expenses incurred in the nine months ended September 30, 2017, including \$858,103 in consulting services for a fairness opinion, \$101,119 in other consulting services, \$2,202,799 in estimated legal fees and \$136,529 in estimated audit fees, and \$223,201 in estimated printer and filing fees. General and administrative expenses for the nine months ended September 30, 2017 include \$862,250 for Napo's general and administrative expenses for the two months from the date of acquisition. Personnel and related benefits decreased \$372,874 from \$1,703,951 in the nine months ended September 30, 2016 to \$1,331,077 in the same period in 2017 due to an increase of \$92,704 in employee leasing chargebacks for services rendered in the seven months ended July 31, 2017 versus the nine months ended September 30, 2016, a decrease in severance expense of \$105,425 from \$105,425 in the nine months ended September 30, 2016 to \$0 in the same period in 2017, with the remainder of the decrease due to changes in headcount personnel and related salaries year over year, primarily at high paying executive levels. Personnel and related benefits for the nine months ended September 30, 2017 include \$187,505 for Napo's personnel and related benefits for the two months from the date of acquisition. Stock-based compensation increased \$135,479 from \$303,157 in the nine months ended September 30, 2016 to \$438,636 in the same period in 2017 due primarily to expense associated with new grants to existing employees. Our public company

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expenses increased \$384,195 from \$227,551 in the nine months ended September 30, 2016 to \$611,746 in the same period in 2017 due primarily to the \$223,201 in merger related printer expenses. In addition to the \$136,529 of audit related merger fees discussed above, our annual, quarterly and other audit fees increased by another \$186,055 resulting in an aggregate \$322,584 increase in accounting fees from \$225,393 in the nine months ended September 30, 2016 to \$547,977 in the same period in 2017. In addition to the \$2,202,799 of legal related merger fees, our general corporate and public securities legal fees increased an additional \$146,973 resulting in an aggregate increase of \$2,466,520 in legal fees from \$456,243 in the nine months ended September 30, 2016 to \$2,922,763 in the same period in 2017. In addition to the \$858,103 fairness opinion consulting and \$101,119 in other consulting merger related fees, our non-merger related consulting expenses actually decreased by \$21,619 resulting in aggregate increase of \$937,603 from \$173,870 in the nine months ended September 30, 2016 to \$1,111,473 in the same period in 2017. Rent and lease expense decreased \$75,371 from \$301,677 in the nine months ended September 30, 2016 to \$226,306 in the same period in 2017 due primarily to an increase of \$82,506 in employee leasing chargebacks to Napo for space used in connection with our employees providing services to Napo during the seven months ended July 31, 2017, offset by additional parking and apartment rent year over year. Other expenses, including warrant expense, insurance costs, office and facilities expenses increased \$405,481 from \$686,001 in the nine months ended September 30, 2016 to \$1,091,482 in the same period in 2017 primarily due to \$23,000 of warrant expense related to warrants issued in connection with warrant exercises, \$26,470 increase in conferences and meetings, \$9,670 increase in bank and credit card fees, net of a reduction of \$96,266 in recruiting fees. Other general and administrative expenses for the nine months ended September 30, 2017 include \$445,946 for Napo's other general and administrative expenses for the two months from the date of acquisition. We expect to incur additional general and administrative expense as a result of operating as a public company and as we grow our business, including expenses related to compliance with the rules and regulations of the SEC, additional insurance expenses, investor relations activities and other administrative and professional services.

**Impairment of goodwill**

The Company recorded an impairment charge of \$3,648,000 during the three and nine months ended September 30, 2017.

Table of Contents**Comparison of the three months ended September 30, 2017 and 2016**

The following table summarizes the Company's results of operations with respect to the items set forth in such table for the three months ended September 30, 2017 and 2016 together with the change in such items in dollars and as a percentage:

	Three Months Ended September 30,		Variance	Variance %
	2017	2016		
Product revenue	\$ 445,665	\$ 50,357	\$ 395,308	785.0%
Collaboration revenue	654,549		654,549	N/A
<b>Total revenue</b>	<b>1,100,214</b>	<b>50,357</b>	<b>1,049,857</b>	<b>2084.8%</b>
<b>Operating Expenses</b>				
Cost of revenue	206,228	9,858	196,370	1992.0%
Research and development expense	851,608	1,967,128	(1,115,520)	(56.7)%
Sales and marketing expense	663,765	136,882	526,883	384.9%
General and administrative expense	3,070,702	1,115,312	1,955,390	175.3%
Impairment of goodwill	3,648,000		3,648,000	N/A
<b>Total operating expenses</b>	<b>8,440,303</b>	<b>3,229,180</b>	<b>5,211,123</b>	<b>161.4%</b>
Loss from operations	(7,340,089)	(3,178,823)	(4,161,266)	(130.9)%
Interest expense, net	(464,684)	(235,191)	(229,493)	(97.6)%
Other expense	(14,876)	(1,476)	(13,400)	(907.9)%
Change in fair value of warrants	388,800		388,800	N/A
Net loss before tax	(7,430,849)	(3,415,490)	(4,015,359)	(117.6)%
Income tax benefit	12,190,693		12,190,693	N/A
<b>Net income (loss) and comprehensive income (loss)</b>	<b>\$ 4,759,844</b>	<b>\$ (3,415,490)</b>	<b>\$ 8,175,334</b>	<b>239.4%</b>

**Revenue and Cost of Revenue****Neonorm Calf and Foal**

Our product revenue of \$33,611 and \$26,537 and related cost of revenue of \$15,459 and \$9,858 for the three months ended September 30, 2017 and 2016 reflects sell-through of our Neonorm Calf and Neonorm Foal products to our distributors. We defer recognizing revenue and cost of revenue until products are sold by the distributor to the distributor's end customers and recognition depends on notification from the distributor that product has been sold to the distributor's end customer. Revenue increased due to an increase in units sold-through from distributors to their customers in the three months ended September 30, 2017 compared to the same period in 2016. The increase in cost of revenue was consistent with the increase in sales. We continue to increase our efforts to promote sales growth.

**Botanical extract**

We began selling botanical extract to a distributor for use exclusively in China beginning in September 2016. The revenue from these sales, which totaled \$48,000 and \$24,000 in the three months ended September 30, 2017 and 2016, is recognized upon shipment to the distributor as no return rights are provided to this distributor. Revenue increased due to an increase in kilograms of botanical extract sold directly to customers in the three months ended September 30, 2017 compared to the same period in 2016. We do not have cost of product revenue associated with the botanical extract sales as we wrote off the full value of the botanical extract to expense in 2014 due to uncertainty of future use and ability to sell to a customer.

Table of Contents**Collaboration revenue**

On January 27, 2017, we entered into a licensing, development, co-promotion and commercialization agreement with Elanco to license, develop and commercialize Canalevia ("Licensed Product"), our drug product candidate under investigation for treatment of acute and chemotherapy-induced diarrhea in dogs, and other drug product formulations of crofelemer for treatment of gastrointestinal diseases, conditions and symptoms in cats and other companion animals. We are granting to Elanco exclusive global rights to Canalevia, a product whose active pharmaceutical ingredient is sustainably isolated and purified from the Croton lechleri tree, for use in companion animals. Pursuant to the Elanco Agreement, Elanco will have exclusive rights globally outside the U.S. and co-exclusive rights with us in the U.S. to direct all marketing, advertising, promotion, launch and sales activities related to the Licensed Products. Under the terms of the Elanco Agreement, we received an initial upfront payment of \$2,548,689 and will receive additional payments upon achievement of certain development, regulatory and sales milestones in an aggregate amount of up to \$61.0 million payable throughout the term of the Elanco Agreement, as well as product development expense reimbursement, and royalty payments on global sales. The Elanco Agreement specifies that we will supply the Licensed Products to Elanco, and that the parties will agree to set a minimum sales requirement that Elanco must meet to maintain exclusivity. Elanco will reimburse us for certain development and regulatory expenses related to our planned target animal safety study and the completion of our field study of Canalevia for acute diarrhea in dogs. The \$2,548,689 total of the upfront payment and expense reimbursement is recognized as collaboration revenue ratably over the estimated development period of one year resulting in \$637,200 in collaboration revenue in the three months ended September 30, 2017. We included \$17,349 of the additional expense reimbursements in the three months ended September 30, 2017 as collaboration revenue.

**Mytesi revenue**

Napo's product revenue of \$364,054 and related cost of revenue of \$190,768 from the date of acquisition are included in the consolidated results for three months ended September 30, 2017 reflecting the delivery of Mytesi product by our distributors to the wholesalers.

**Research and Development Expense**

The following table presents the components of research and development expense for the three months ended September 30, 2017 and 2016 together with the change in such components in dollars and as a percentage:

	<b>Three Months Ended September 30,</b>			
	<b>2017</b>	<b>2016</b>	<b>Variance</b>	<b>Variance %</b>
<i>R&amp;D:</i>				
Personnel and related benefits	\$ 602,216	\$ 567,896	\$ 34,320	6.0%
Materials expense and tree planting	35,878	32,959	2,919	8.9%
Travel, other expenses	45,431	124,807	(79,376)	(63.6)%
Clinical and contract manufacturing	(13,761)	513,478	(527,239)	(102.7)%
Stock-based compensation	45,009	53,935	(8,926)	(16.5)%
Other	136,835	674,053	(537,218)	(79.7)%
<b>Total</b>	<b>\$ 851,608</b>	<b>\$ 1,967,128</b>	<b>\$ (1,115,520)</b>	<b>(56.7)%</b>

Our research and development expense decreased \$1,115,520 from \$1,967,128 in the three months ended September 30, 2016 to \$851,608 for the same period in 2017. Personnel and related benefits increased \$34,320 from \$567,896 in the three months ended September 30, 2016 to \$602,216 in the same period in 2017 due to a decrease of \$101,016 in employee leasing chargebacks to Napo for services

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rendered in the July 2017 over the three month ended September 30, 2016, more than offset with increases in headcount personnel and related salaries and benefits year over year. Travel expenses decreased \$79,376 from \$124,807 in the three months ended September 30, 2016 to \$45,431 in the same period in 2017 consistent with the decrease in clinical activity. Significant clinical trial work has decreased and contract manufacturing work was completed in Q1 2016 resulting in a reduction of expense of \$527,239 from \$513,478 in the three months ended September 30, 2016 to \$(13,761) in the same period in 2017. Clinical expenses decreased \$527,168 from \$511,353 in the three months ended September 30, 2016 to \$(15,815) in the same period in 2017, and contract manufacturing expense was constant at \$2,125 and \$2,055 in the three months ending September 30, 2016 and 2017 due to the completion of the manufacturing setup in Italy in the first quarter of 2016. Stock-based compensation decreased \$8,926 from \$53,935 in the three months ended September 30, 2016 to \$45,009 in the same period in 2017 primarily due to a decrease in the number of outstanding option grants year over year. Other expenses, consisting primarily of consulting and formulation expenses, decreased \$537,218 from \$674,053 in the three months ended September 30, 2016 to \$136,835 in the same period in 2017. Consulting expenses decreased \$365,844 from \$423,636 in the three months ended September 30, 2016 to \$57,792 in the same period in 2017 consistent with the decrease in contractor utilization to assist in our clinical trials and in chemistry, manufacturing and controls ("CMC") activities. Formulation expenses decreased \$167,576 from \$197,653 in the three months ended September 30, 2016 to \$30,077 for the same period in 2017 due to an decrease in work needed for clinical operations. We plan to increase our research and development expense as we continue developing our drug candidates. Our research and development expenses for the three months ended September 30, 2017 include Napo's research and development expenses for the two months from the acquisition of \$96,017.

We increased support for the reforestation of croton lechleri trees in South America, which is reflected in an increase in our spend by \$2,919 from \$32,959 in the three months ended September 30, 2016 to \$35,878 in the same period in 2017. We value and take to heart the responsibility to replenish trees consumed in order to extract the raw material to manufacture our primary commercial product and the drug product for use in clinical trials.

**Sales and Marketing Expense**

The following table presents the components of sales and marketing expense for the three months ended September 30, 2017 and 2016 together with the change in such components in dollars and as a percentage:

	<b>Three Months Ended September 30,</b>			
	<b>2017</b>	<b>2016</b>	<b>Variance</b>	<b>Variance %</b>
<i>S&amp;M:</i>				
Personnel and related benefits	\$ 60,802	\$ 56,040	\$ 4,762	8.5%
Stock-based compensation	7,938	50,052	(42,114)	(84.1)%
Direct Marketing Fees	17,440	13,245	4,195	31.7%
Other	577,585	17,545	560,040	3192.0%
<b>Total</b>	<b>\$ 663,765</b>	<b>\$ 136,882</b>	<b>\$ 526,883</b>	<b>384.9%</b>

Our sales and marketing expense increased \$526,883 from \$136,882 in the three months ended September 30, 2016 to \$663,765 in the same period in 2017. Personnel and related benefits increased \$4,762 from \$56,040 in the three months ended September 30, 2016 to \$60,802 in the same period in 2017 due to an increase in headcount year over year, net of an increase of \$7,684 in employee leasing chargebacks to Napo for services rendered in the seven months ended July 31, 2017 over the nine months ended September 30, 2016. Stock based compensation expense decreased \$42,114 from \$50,052 in the three months ended September 30, 2016 to \$7,938 in the same period in 2017 due to new options granted at a much lower fair value due to a lower strike price and a lower fair market value. Direct marketing and

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sales expense increased \$4,195 from \$13,245 in the three months ended September 30, 2016 to \$17,440 for the same period in 2017 due to an increase in marketing programs to promote our Neonorm products. Other expenses, consisted primarily of travel expense, consulting expense and royalty expense, which collectively increased \$560,040 from \$17,545 in the three months ended September 30, 2016 to \$577,585 in the same period in 2017. We plan to expand sales and marketing spend to promote our Neonorm products. Other sales and marketing expenses for the three months ended September 30, 2017 include sales and marketing expenses of \$513,102 for Napo for the two months from the date of acquisition.

**General and Administrative Expense**

The following table presents the components of general and administrative expense for the three months ended September 30, 2017 and 2016 together with the change in such components in dollars and as a percentage:

	Three Months Ended September 30,		Variance	Variance %
	2017	2016		
<b>G&amp;A:</b>				
Personnel and related benefits	\$ 544,914	\$ 435,271	\$ 109,643	25.2%
Accounting fees	211,326	56,780	154,546	272.2%
Third-party consulting fees and Napo service fees	103,694	20,084	83,610	416.3%
Legal fees	918,271	72,720	845,551	1162.7%
Travel	125,067	61,009	64,058	105.0%
Stock-based compensation	133,807	145,391	(11,584)	(8.0)%
Rent and lease expense	69,307	88,704	(19,397)	(21.9)%
Public company expenses	276,200	41,234	234,966	569.8%
Other	688,116	194,119	493,997	254.5%
<b>Total</b>	<b>\$ 3,070,702</b>	<b>\$ 1,115,312</b>	<b>\$ 1,955,390</b>	<b>175.3%</b>

Our general and administrative expenses increased \$1,955,390 from \$1,115,312 in the three months ended September 30, 2016 to \$3,070,702 for the same period in 2017 due primarily to \$145,000 in warrant expense in connection with warrant exercises, and \$978,332 in merger related expenses incurred in the three months ended September 30, 2017, including \$789,012 in estimated legal fees, \$101,119 in consulting fees, and \$88,201 in printer and filing fees. General and administrative expenses for the three months ended September 30, 2017 include \$862,250 for Napo's general and administrative expenses for the two months from the date of acquisition. Personnel and related benefits increased \$109,643 from \$435,271 in the three months ended September 30, 2016 to \$544,914 primarily due to a decrease of \$13,156 in employee leasing chargebacks for services rendered in the month of July 2017 over the three months ended September 30, 2016, offset by changes in headcount personnel and related salaries quarter over quarter, primarily at high paying executive levels, including \$187,505 for Napo's personnel and related benefits for the two months from the date of acquisition. Stock-based compensation decreased \$11,584 from \$145,391 in the three months ended September 30, 2016 to \$133,807 in the same period in 2017 due primarily to a reduction of expense associated with outstanding options. Our public company expenses increased \$234,966 from \$41,234 in the three months ended September 30, 2016 to \$276,200 in the same period in 2017 due primarily to the \$88,201 merger related expenses in the three months ended September 30, 2017, to another \$62,109 in additional printer expenses associated with other filings with the Securities and Exchange Commission, and to an increase of \$35,708 in investor relations fees and an increase of \$24,191 in investor services expenses. Audit fees increased by \$81,861 from \$56,780 in the three months ended September 30, 2016 to \$138,641 in the same period in 2017. Our general corporate and public securities legal fees increased \$845,551 from \$72,720 in the three months ended September 30, 2016 to \$918,271 in the same period in 2017, due primarily to the \$789,012 in merger related expenses. Our consulting



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expenses increased by \$83,610 from \$20,084 in the three months ended September 30, 2016 to \$103,694 in the same period in 2017 due primarily to the \$88,201 in merger related consulting services. Rent and lease expense decreased \$19,397 from \$88,704 in the three months ended September 30, 2016 to \$69,307 in the same period in 2017 due primarily to an increase of \$18,524 in employee leasing chargebacks to Napo for space used in connection with our employees providing services to Napo in the month of July 2017 versus three months ended September 30, 2016. Other expenses, including warrant expense, insurance costs, office and facilities expenses increased \$493,997 from \$194,119 in the three months ended September 30, 2016 to \$688,116 in the same period in 2017 due primarily to \$235,000 warrant expenses, as well as increases of \$7,513 in office and computer equipment and \$8,005 in conferences and meetings expenses, and \$6,653 in bank and credit card fees. Other general and administrative expenses for the three months ended September 30, 2017 include \$445,946 for Napo's other general and administrative expenses for the two months from the date of acquisition. We expect to incur additional general and administrative expense as a result of operating as a public company and as we grow our business, including expenses related to compliance with the rules and regulations of the SEC, additional insurance expenses, investor relations activities and other administrative and professional services.

**Impairment of goodwill**

The Company recorded an impairment charge of \$3,648,000 during the three and nine months ended September 30, 2017.

**Liquidity and Capital Resources**

*Sources of Liquidity*

We had an accumulated deficit of \$42.2 million as a result of incurring net losses since our inception as we have not generated enough revenue to cover costs and expenses through the current fiscal year. Our net loss and comprehensive loss was \$14.7 million for the year ended December 31, 2016, and \$1.8 million for the nine months ended September 30, 2017. We expect to continue to incur additional losses through the end of fiscal year 2017 and into future years due to expected significant expenses for toxicology, safety and efficacy clinical trials of our products and product candidates, for establishing contract manufacturing capabilities, and for the commercialization of one or more of our product candidates, if approved.

We had cash and cash equivalents of \$220,590 as of September 30, 2017. We do not believe our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements for the next 12 months. Our independent registered public accounting firm has included an explanatory paragraph in its audit report included in our Form 10-K for the years ended December 31, 2016 and 2015 regarding our assessment of substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty.

To date, we have funded our operations primarily through the issuance of equity securities, short-term convertible promissory notes, and long-term debt, in addition to sales of Neonorm, our commercial product:

In 2013, we received \$400 from the issuance of 2,666,666 shares of common stock to our parent Napo Pharmaceuticals, Inc. We also received \$519,000 of net cash from the issuance of convertible promissory notes in an aggregate principal amount of \$525,000. These notes were all converted to common stock in 2014.

In 2014, we received \$6.7 million in proceeds from the issuance of convertible preferred stock. Effective as of the closing of our initial public offering, the 3,015,902 shares of outstanding convertible preferred stock were automatically converted into 2,010,596 shares of common stock. Following our initial public offering, there were no shares of preferred stock outstanding.

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In 2014, we received \$1.1 million from the issuance of convertible promissory notes in an aggregate principal amount of \$1.1 million. These notes were converted to common stock upon the effectiveness of the initial public offering in May of 2015. In August 2014, we entered into a standby line of credit with an individual, who is an accredited investor, for up to \$1.0 million. To date, we had not made any drawdowns under this facility. Also, in October of 2014, as amended and restated in December 2014, we entered into a \$1.0 million standby bridge loan which was repaid in 2015.

In 2015, we received \$1.25 million in exchange for \$1.25 million of convertible promissory notes, of which \$1.0 million was converted to common stock in 2015, and \$100,000 was repaid in 2015. The remaining \$150,000 remains outstanding.

In May 2015, we received net proceeds of \$15.9 million upon the closing of our initial public offering, gross proceeds of \$20.0 million (2,860,000 shares at \$7.00 per share) net of \$1.2 million of underwriting discounts and commissions and \$3.3 million of offering expenses, including \$0.4 million of non-cash expense. These shares began trading on The NASDAQ Capital Market on May 13, 2015.

In 2015, we received net proceeds of \$5.9 million from the issuance of long-term debt. We entered into a loan and security agreement with a lender for up to \$8.0 million, which provided for an initial loan commitment of \$6.0 million. Under the loan agreement we are required to maintain \$4.5 million of the proceeds in cash, which amount may be reduced or eliminated on the achievement of certain milestones. An additional \$2.0 million is available contingent on the achievement of certain further milestones. The agreement has a term of three years, with interest only payments through February 29, 2016. Thereafter, principal and interest payments will be made with an interest rate of 9.9%. Additionally, there will be a balloon interest payment of \$560,000 on August 1, 2018. This amount is being recognized over the term of the loan agreement and the effective interest rate, considering the balloon payment, is 15.0%. Our proceeds are net of a \$134,433 debt discount under the terms of the agreement.

In 2014 and 2015, we received \$24,000 and \$531,000, respectively, in cash from sales of Neonorm to distributors.

In 2015, we received approximately \$13,000 in proceeds from the exercise of stock options.

In 2016, we received net proceeds of \$4.1 million upon the closing of our follow-on public offering, reflecting gross proceeds of \$5.0 million (2.0 million shares at \$2.50 per share) net of \$373,011 of underwriting discounts and commissions and \$496,887 of offering expenses.

In June 2016, we entered into the CSPA with a private investor. Under the terms of the agreement, we may sell up to \$15.0 million in common stock to the investor during the approximately 30-month term of the agreement. Upon execution of the CSPA, we sold 222,222 shares of our common stock to the investor at \$2.25 per share for net proceeds of \$448,732, reflecting gross proceeds of \$500,000 and offering expenses of \$51,268. In consideration for entering into the CSPA, we issued 456,667 shares of our common stock to the investor. We issued 1,348,601 shares in exchange for net proceeds of \$2,122,570, reflecting gross proceeds of \$2,176,700 net of \$54,130 offering expenses under the CSPA in the year ended December 31, 2016. And in the nine months ended September 30, 2017, we sold another 3,972,510 shares of the Company's common stock in exchange for \$2,387,085 of gross cash proceeds. Of the \$15.0 million available under the CSPA, we have received \$5,063,785 from the sale of 6,000,000 shares of our common stock as of September 30, 2017.

In October 2016, we entered into a Common Stock Purchase Agreement with an existing private investor. Upon execution of the agreement we sold 170,455 shares of our common stock in exchange for \$150,000 in cash proceeds.

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On November 22, 2016, we entered into a Securities Purchase Agreement, or the 2016 Purchase Agreement, with certain institutional investors, pursuant to which we sold securities to such investors in a private placement transaction, which we refer to herein as the 2016 Private Placement. In the 2016 Private Placement, we sold an aggregate of 1,666,668 shares of our common stock at a price of \$0.60 per share for gross proceeds of approximately \$1.0 million. The investors in the 2016 Private Placement also received (i) warrants to purchase up to an aggregate of 1,666,668 shares of our common stock, at an exercise price of \$0.75 per share, or the Series A Warrants, (ii) warrants to purchase up to an aggregate 1,666,668 shares of our common stock, at an exercise price of \$0.90 per share, or the Series B Warrants, and (iii) warrants to purchase up to an aggregate 1,666,668 shares of our common stock, at an exercise price of \$1.00 per share, or the Series C Warrants and, together with the Series A Warrants and the Series B Warrants, the 2016 Warrants.

On January 27, 2017, we entered into a licensing, development, co-promotion and commercialization agreement with Elanco to license, develop and commercialize Canalevia, our drug product candidate under investigation for treatment of acute and chemotherapy-induced diarrhea in dogs, and other drug product formulations of crofelemer for treatment of gastrointestinal diseases, conditions and symptoms in cats and other companion animals. The Elanco Agreement grants Elanco exclusive global rights to Canalevia, a product whose active pharmaceutical ingredient is sustainably isolated and purified from the Croton lechleri tree, for use in companion animals. Pursuant to the Elanco Agreement, Elanco will have exclusive rights globally outside the U.S. and co-exclusive rights with us in the U.S. to direct all marketing, advertising, promotion, launch and sales activities related to the Licensed Products.

Under the terms of the Elanco Agreement, we received an initial upfront payment of \$2,548,689 inclusive of reimbursement of past product and development expenses of \$1,048,689 and we will receive additional payments upon achievement of certain development, regulatory and sales milestones in an aggregate amount of up to \$61.0 million payable throughout the term of the Elanco Agreement, as well as product development expense reimbursement, and royalty payments on global sales. The Elanco Agreement specifies that we will supply the Licensed Products to Elanco, and that the parties will agree to set a minimum sales requirement that Elanco must meet to maintain exclusivity. Elanco will also reimburse us for Canalevia-related expenses, including reimbursement for Canalevia-related expenses in Q4 2016, certain development and regulatory expenses related to our planned target animal safety study and the completion of our field study of Canalevia for acute diarrhea in dogs. On November 1, 2017, Elanco notified the Company of its intention to terminate the Elanco Agreement, effective January 30, 2018.

On March 31, 2017, we entered into a merger agreement with Napo, pursuant to which we are required, among other things, to issue approximately 69,299,346 shares of our common stock and non-voting common stock to Napo creditors, noteholders, holders of Napo warrants, options or restricted stock units, and Invesco upon consummation of the merger.

On June 28, 2017, we closed a private investment in public entities with a member of our board of directors. We received gross proceeds of \$50,000 in exchange for 100,000 shares of our common stock.

On June 29, 2017, we issued a secured convertible promissory note to a lender in the aggregate principal amount of \$2,155,000 less an original issue discount of \$425,000 and less \$30,000 to cover the lender's legal fees for net cash proceeds of \$1,700,000. Interest on the outstanding balance will be paid 8% per annum from the purchase price date until the balance is paid in full. All interest calculations are computed on the basis of a 360-day year comprised of twelve (12) thirty (30) day months compounded daily and payable in accordance with the terms of the Note. All principal and interest on the debt is due in full on August 2, 2018.

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On July 13, 2017, we closed a private investment in public entities with an investor. We received gross proceeds of \$50,000 in exchange for 100,000 shares of our common stock.

On July 31, 2017, as part of the merger with Napo, we sold 3,243,243 shares of our common stock to an investor in exchange for \$1,000,000 in cash and \$2,000,000 in a direct payoff of Napo debt.

On July 31, 2017, the Company entered into Warrant Exercise Agreements, or Exercise Agreements, with certain holders of Series C Warrants, or the Exercising Holders, which Exercising Holders own, in the aggregate, Series C Warrants exercisable for 908,334 shares of the Company's common stock. Pursuant to the Exercise Agreements, the Exercising Holders and the Company agreed that the Exercising Holders would exercise their Series C Warrants with respect to 908,334 shares of common stock underlying such Series C Warrants for a reduced exercise price equal to \$0.40 per share. The Company received aggregate gross proceeds of approximately \$363,334 from the exercise of the Series C Warrants by the Exercising Holders.

We expect our expenditures will continue to increase as we continue our efforts to develop animal health products, expand our commercially available Neonorm product and continue development of our pipeline in the near term. We do not believe our current capital is sufficient to fund our operating plan through June 2018. We will need to seek additional funds through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. We may also not be successful in entering into partnerships that include payment of upfront licensing fees for our products and product candidates for markets outside the United States, where appropriate. If we do not generate upfront fees from any anticipated arrangements, it would have a negative effect on our operating plan. We plan to finance our operations and capital funding needs through equity and/or debt financing as well as revenue from future product sales. However, there can be no assurance that additional funding will be available to us on acceptable terms on a timely basis, if at all, or that we will generate sufficient cash from operations to adequately fund operating needs or ultimately achieve profitability. If we are unable to obtain an adequate level of financing needed for the long-term development and commercialization of our products, we will need to curtail planned activities and reduce costs. Doing so will likely have an adverse effect on our ability to execute on our business plan. These matters raise substantial doubt about the ability of the Company to continue in existence as a going concern within one year after issuance date of the financial statements.

### *Cash Flows for the Nine Months Ended September 30, 2017 Compared to the Nine Months Ended September 30, 2016*

The following table shows a summary of cash flows for the nine months ended September 30, 2017 and 2016:

	<b>Nine Months Ended September 30, 2017</b>	<b>Nine Months Ended September 30, 2016</b>
Total cash used in operating activities	\$ (4,494,788)	\$ (11,686,507)
Total cash (used in)/ provided by investing activities	(1,546,047)	1,907,213
Total Cash Provided by Financing Activities	5,310,446	3,895,174
	\$ (730,389)	\$ (5,884,120)

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***Cash Used in Operating Activities***

During the nine months ended September 30, 2017, cash used in operating activities of \$4,494,788 resulted from our net loss of \$1.8 million, adjusted by non-cash accretion of end of term payment, debt discounts and debt issuance costs of \$368,000, stock-based compensation of \$631,000, change in fair value of modified warrants of \$23,000, reduction in the fair value of warrant liability of \$636,000, loss on extinguishment of debt of \$208,000, stock issued in the merger in exchange for services \$151,000, depreciation and amortization expenses of \$326,000, impairment of goodwill of \$3,648,000, deferred income benefit of 12,190,693 and gain on revaluation of derivative liability of \$1,000, net of changes in operating assets and liabilities of \$4.8 million.

During the nine months ended September 30, 2016, cash used in operating activities of \$11,686,507 resulted from our net loss of \$11.1 million, offset by non-cash accretion of end of term payment, debt discounts and debt issuance costs of \$396,000, stock-based compensation of \$478,000, depreciation expense of \$32,000, net of changes in operating assets and liabilities of \$1.5 million.

***Cash (Used in) Provided by Investing Activities***

During the nine months ended September 30, 2017, cash used in investing activities of \$1,546,047 consisted of cash used in acquisition, net of cash acquired of \$1,557,340 offset by \$11,000 of a release of restricted cash that resulted from principal payments of our long-term debt.

During the nine months ended September 30, 2016, cash provided by investing activities of \$1,907,213 primarily consisted of \$2.0 million of a release of restricted cash that resulted from principal payments on our long-term debt, net of \$104,000 in purchases of property and equipment.

***Cash Provided by Financing Activities***

During the nine months ended September 30, 2017, cash provided by financing activities of \$5,310,446 primarily consisted of \$2.3 million in net proceeds received in the CSPA, \$94,000 in net proceeds received in a PIPE financing, \$1.7 million received in the issuance of convertible debt, \$3.0 million received from the sale of common stock in the merger, and \$363,000 received in the exercise of certain warrants, offset by \$2.2 million in principal payments of our long-term debt.

During the nine months ended September 30, 2016, cash provided by financing activities of \$3,895,174 primarily consisted of \$4.1 million in net cash received in our secondary public offering, net of commissions and certain offering expenses, and \$395,000 in net cash received in the initial sale under the CSPA, net of fees and certain offering expenses, and \$1.4 million received from the issuance of common stock under the aforementioned CSPA, offset by \$2.0 million in principal payments on our long-term debt.

Table of Contents**Standby Lines of Credit, Convertible Notes and Warrant Issuances****Convertible Notes and Warrants**

Convertible notes at September 30, 2017 and December 31, 2016 consist of the following:

	Notes Payable	
	September 30, 2017	December 31, 2016
February 2015 convertible notes payable	150,000	150,000
June 2017 convertible note payable	2,135,000	
Napo convertible notes	12,473,501	
	\$ 14,758,501	\$ 150,000
Less: unamortized debt discount and debt issuance costs	(384,292)	
Net convertible notes payable obligation	\$ 14,374,209	\$ 150,000
Convertible notes payable non-current	11,161,000	
Convertible notes payable current	\$ 3,213,209	\$ 150,000

Interest expense on the convertible notes for the three and nine months ended September 30, 2017 and 2016 follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
February 2015 convertible note nominal interest	\$ 4,537	\$ 4,537	\$ 13,463	\$ 13,512
June 2017 convertible note nominal interest	43,900		44,372	
June 2017 convertible note accretion of debt discount	123,362		124,708	
Napo convertible note nominal interest	175,798		175,798	
Total interest expense on convertible debt	\$ 347,597	\$ 4,537	\$ 358,341	\$ 13,512

Interest expense is classified as such in the statements of operations and comprehensive income.

**February 2015 Convertible Note**

In February 2015, we issued convertible promissory notes to two accredited investors in the aggregate principal amount of \$250,000. These notes were issued pursuant to the convertible note purchase agreement dated December 23, 2014. In connection with the issuance of the notes, we issued the lenders warrants to purchase 22,320 shares at \$5.60 per share, which expire December 31, 2017. Principal and interest of \$103,912 was paid in May 2015 for \$100,000 of these notes. We analyzed the beneficial nature of the conversion terms and determined that a BCF existed because the effective conversion price was less than the fair value at the time of the issuance. We calculated the value of the BCF using the intrinsic method. A BCF for the full face value was recorded as a discount to the notes payable and to additional paid-in capital. The full amount of the BCF was amortized to interest expense by the end of June 2015.

The remaining outstanding note of \$150,000 is payable to an investor at an effective simple interest rate of 12% per annum, and was due in full on July 31, 2016. On July 28, 2016, we entered into an amendment to delay the repayment of the principal and related interest under the terms of the remaining note from July 31, 2016 to October 31, 2016.

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On November 8, 2016, we entered into an amendment to extend the maturity date of the remaining note from October 31, 2016 to January 1, 2017. In exchange for the extension of the maturity date, on November 8, 2016, our board of directors granted the lender a warrant to purchase 120,000 shares of the

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Company's common stock for \$0.01 per share. The warrant is exercisable at any time on or before July 28, 2022, the expiration date of the warrant. The amendment and related warrant issuance resulted in our treating the debt as having been extinguished and replaced with new debt for accounting purposes due to meeting the 10% cash flow test.

***Extinguishment of debt***

On January 31, 2017, we entered into another amendment to extend the maturity date of the remaining note from January 1, 2017 to January 1, 2018. In exchange for the extension of the maturity date, on January 31, 2017, our board of directors granted the lender a warrant to purchase 370,916 shares of our common stock for \$0.51 per share. The warrant is exercisable at any time on or before January 31, 2019, the expiration date of the warrant. The amendment and related warrant issuance resulted in our treating the debt as having been extinguished and replaced with new debt for accounting purposes due to meeting the 10% cash flow test. We calculated a loss on the extinguishment of debt of \$207,713, or the equivalent to the fair value of the warrants granted, which is included in loss on extinguishment of debt in our statements of operations and comprehensive loss in the nine months ended September 30, 2017.

The \$150,000 note is included in notes payable in current liabilities on our balance sheet. We have unpaid accrued interest of \$47,392 and \$33,929, which is included in accrued expenses on our balance sheet as of September 30, 2017 and December 31, 2016, respectively, and incurred interest expense of \$4,537 in the three months ended September 30, 2017 and 2016, respectively, and \$13,463 and \$13,512 in the nine months ended September 30, 2017 and 2016 which are included in interest expense in the statement of operations and comprehensive loss.

***June 2017 Convertible Note***

On June 29, 2017, we issued a secured convertible promissory note, or Note, to a lender in the aggregate principal amount of \$2,155,000 less an original issue discount of \$425,000 and less \$30,000 to cover the lender's legal fees for net cash proceeds of \$1,700,000. Interest on the outstanding balance will be paid 8% per annum from the purchase price date until the balance is paid in full. All interest calculations are computed on the basis of a 360-day year comprised of twelve (12) thirty (30) day months compounded daily and payable in accordance with the terms of the Note. All principal and interest on the debt is due in full on August 2, 2018. We accrued interest of \$44,372 at September 30, 2017 which is included in accrued expenses on our balance sheet, and incurred interest expense of \$43,900 and \$44,372 in interest expense in the three and nine months ended September 30, 2017 which are included in interest expense in our statement of operations and comprehensive loss. We also recorded \$123,362 and \$124,708 in interest expense in the three and nine months ended September 30, 2017 which are included in our statement of operations and comprehensive loss for the accretion of the debt discount. The lender has the right to convert all or any portion of the outstanding balance into our common stock at \$1.00 per share.

The Note provides the lender with an optional monthly redemption that allows for the monthly payment of up to \$350,000 at the creditor's option commencing on the earlier of six months after the purchase price date, June 29, 2017, or the effective date of the registration statement which is expected to be before December 2017. ASC 470-10-45-9 and 45-10 provide that debt that is due on demand or will be due on demand within one year from the balance sheet date should be classified as a current liability, even though the liability may not be expected to be paid within that period or the liability has scheduled repayment dates that extend beyond one year but nevertheless is callable by the creditor within one year. As such, despite the fact that the Note is due in full on August 2, 2018, the full amount of the Note balance has been classified as a current liability in the balance sheet.



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The Note provides for two separate features that result in a derivative liability:

1. Repayment of mandatory default amount upon an event of default upon the occurrence of any event of default, the lender may accelerate the Note resulting in the outstanding balance becoming immediately due and payable in cash; and
2. Automatic increase in the interest rate on and during an event of default during an event of default, the interest rate will increase to the lesser of 17% per annum or the maximum rate permitted under applicable law.

The Company computed fair values at June 30, 2017 of \$15,000 and \$5,000 for the repayment and the interest rate increase feature, respectively, using the Binomial Lattice Model, which was based on the generalized binomial option pricing formula. The \$20,000 combined fair value was carved out and is included as a derivative liability on the balance sheet. The derivatives were revalued at September 30, 2017 using the same Model resulting in a combined fair value of \$19,000. The \$1,000 gain is included in other income and expense in the statement of income and comprehensive income.

The balance of the note payable of \$1,750,708, consisting of the \$2,155,000 face value of the note less note discounts and debt issuance costs of \$509,000, less the \$20,000 derivative liability, plus the accretion of the debt discount and debt issuance costs of \$124,708 in the nine months ended September 30, 2017, is included in notes payable in current liabilities on the balance sheet.

***Napo convertible notes***

In December 2016, Napo entered into a note purchase agreement which provides for the sale of up to \$12,500,000 face amount of notes and issued convertible promissory notes (the Napo December Notes) in the aggregate face amount of \$2,500,000 to three lenders and received proceeds of \$2,000,000 which resulted in \$500,000 of original issue discount. In July 2017, Napo issued convertible promissory notes (the Napo July Notes) in the aggregate face amount of \$7,500,000 to four lenders and received proceeds of \$6,000,000 which resulted in \$1,500,000 of original issue discount. The Napo December Notes and the Napo July Notes mature on December 30, 2019 and bear interest at 10% with interest due each six-month period after December 30, 2016. On June 30, 2017, the accrued interest of \$125,338 was added to principal of the Napo December Notes, and the new principal balance became \$2,625,338. Interest may be paid in cash or in the stock of Jaguar per terms of the note purchase agreement. In each one year period beginning December 30, 2016, up to one-third of the principal and accrued interest on the notes may be converted into the common stock of the merged entity at a conversion price of \$0.925 per share. The Company assumed these convertible notes at fair value of \$11,161,000 as part of the Napo Merger. At September 30, 2017, the balance of the note payable is \$11,161,000 and the accrued interest on these notes is \$193,565.

In March 2017, Napo entered into an exchangeable note purchase agreement with two lenders for the funding of face amount of \$1,312,500 in two \$525,000 tranches of face amount \$656,250. The notes bear interest at 3% and mature on December 1, 2017. Interest may be paid at maturity in either cash or shares of Jaguar per terms of the exchangeable note purchase agreement. The notes may be exchanged for up to 2,343,752 shares of Jaguar common stock, prior to maturity date. The Company assumed the notes at fair value of \$1,312,500 as part of the Napo Merger. At September 30, 2017, the accrued interest on these notes is \$19,957.

***Long term Debt***

In August 2015, we entered into a loan and security agreement with a lender for up to \$8.0 million, which provided for an initial loan commitment of \$6.0 million. The loan agreement requires us to maintain \$4.5 million of the proceeds in cash, which may be reduced or eliminated on the achievement of certain milestones. An additional \$2.0 million is available contingent on the achievement of certain further

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milestones. The agreement has a term of three years, with interest only payments through February 29, 2016. Thereafter, principal and interest payments will be made with an interest rate of 9.9%. Additionally, there will be a balloon payment of \$560,000 on August 1, 2018. This amount is being recognized over the term of the loan agreement and the effective interest rate, considering the balloon payment, is 15.0%. Proceeds were net of a \$134,433 debt discount under the terms of the loan agreement. This debt discount is being recorded as interest expense, using the interest method, over the term of the loan agreement. Under the agreement, we are entitled to prepay principal and accrued interest upon five days prior notice to the lender. In the event of prepayment, we are obligated to pay a prepayment charge. If such prepayment is made during any of the first twelve months of the loan agreement, the prepayment charge will be (a) during such time as we are required to maintain a minimum cash balance, 2% of the minimum cash balance amount plus 3% of the difference between the amount being prepaid and the minimum cash balance, and (b) after such time as we are no longer required to maintain a minimum cash balance, 3% of the amount being prepaid. If such prepayment is made during any time after the first twelve months of the loan agreement, 1% of the amount being prepaid.

On April 21, 2016, the loan and security was amended upon which we repaid \$1.5 million of the debt out of restricted cash. The amendment modified the repayment amortization schedule providing a four-month period of interest only payments for the period from May through August 2016.

On July 7, 2017, we entered into the third amendment to the Loan Agreement upon which we paid \$1.0 million of the outstanding loan balance, and the Lender waived the Prepayment Charge associated with such prepayment. The Third Amendment modified the repayment schedule providing a three-month period of interest only payments for the period from August 2017 through October 2017, and reduced the required cash amount that we must keep on hand to \$500,000, which will be reduced following the Lender's receipt of each principal repayment subsequent to the \$1.0 million.

As of September 30, 2017 and December 31, 2016, the net long-term debt obligation was as follows:

	September 30, 2017	December 31, 2016
Debt and unpaid accrued end-of-term payment	\$ 1,855,328	\$ 3,894,320
Unamortized note discount	(13,141)	(42,493)
Unamortized debt issuance costs	(40,960)	(114,626)
Net debt obligation	\$ 1,801,227	\$ 3,737,201
Current portion of long-term debt	\$ 1,801,227	\$ 1,919,675
Long-term debt, net of discount		1,817,526
Total	\$ 1,801,227	\$ 3,737,201

Future principal payments under the long-term debt are as follows:

Years ending December 31	Amount
2017 September through December	\$ 260,832
2018	1,089,199
Total future principal payments	1,350,031
2018 end-of-term payment	560,000
	1,910,031
Less: unaccreted end-of-term payment at September 30, 2017	(54,703)
Debt and unpaid accrued end-of-term payment	\$ 1,855,328

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The debt obligation includes an end-of-term payment of \$560,000, which accretes over the life of the loan as interest expense. As a result of the debt discount and the end-of-term payment, the effective interest rate for the loan differs from the contractual rate.

Interest expense on the long-term debt for the three and nine months ended September 30, 2017 and 2016 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Nominal interest	\$ 36,906	\$ 103,566	\$ 183,040	\$ 364,566
Accretion of debt discount	7,712	15,337	29,351	50,388
Accretion of end-of-term payment	32,109	63,897	122,269	209,924
Accretion of debt issuance costs	24,038	47,855	91,562	135,795
	<b>\$ 100,765</b>	<b>\$ 230,655</b>	<b>\$ 426,222</b>	<b>\$ 760,673</b>

### **Warrants**

On November 22, 2016, we entered into a Securities Purchase Agreement, or the 2016 Purchase Agreement, with certain institutional investors, pursuant to which we sold securities to such investors in a private placement transaction, which we refer to herein as the 2016 Private Placement. In the 2016 Private Placement, we sold an aggregate of 1,666,668 shares of our common stock at a price of \$0.60 per share for gross proceeds of approximately \$1.0 million. The investors in the 2016 Private Placement also received (i) warrants to purchase up to an aggregate of 1,666,668 shares of our common stock, at an exercise price of \$0.75 per share, or the Series A Warrants, and the Placement Agent received warrants to purchase 133,333 shares of our common stock in lieu of cash for service fees with the same terms as the investors; (ii) warrants to purchase up to an aggregate 1,666,668 shares of our common stock, at an exercise price of \$0.90 per share, or the Series B Warrants, and (iii) warrants to purchase up to an aggregate 1,666,668 shares of our common stock, at an exercise price of \$1.00 per share, or the Series C Warrants and, together with the Series A Warrants and the Series B Warrants, the 2016 Warrants. The warrants were granted in three series with different terms. The warrants were valued using the Black-Scholes-Merton warrant pricing model as follows:

Series A Warrants and Placement Agent Warrants: 1,666,668 warrant shares with a strike price of \$0.75 per share and an expiration date of May 29, 2022; and 133,333 warrant shares to the placement agent with a strike price of \$0.75 and an expiration date of May 29, 2022; the expected life is 5.5 years, the volatility is 71.92% and the risk free rate is 1.87% in valuing these warrants.

Series B Warrants: 1,666,668 warrant shares with a strike price of \$0.90 per share and an expiration date of November 29, 2017; the expected life is one year, the volatility is 116.65% and the risk free rate is 0.78% in valuing these warrants.

Series C Warrants: 1,666,668 warrant shares with a strike price of \$1.00 per share and an expiration date of May 29, 2018; the expected life is 1.5 years, the volatility is 116.92% and the risk free rate is 0.94%.

The warrant valuation date was November 29, 2016 and the closing price of \$0.69 per share was used in determining the fair value of the warrants. The series A warrants and placement agent warrants were valued at \$756,001 and were classified as a warrant liability in the balance sheet. The series A warrants and placement agent warrants were revalued on December 31, 2016 at \$799,201 which is included in the balance sheet, and the \$43,200 increase is included in the statements of operations and comprehensive loss. The stock price was \$0.716, the strike price was \$0.75 per share, the expected life was 5.41 years, the volatility was 73.62% and the risk free rate was 2.0%. The series B and C warrants were classified as equity, and as such were not subject to revaluation at year end. Costs incurred in connection with the issuance

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were allocated based on the relative fair values of the Series A and the Series B and C warrants. The series A warrants and placement agent warrants were revalued on September 30, 2017 at \$163,080 and is included in the balance sheet. The valuation reflects a reduction of \$388,800 from the June 30, 2017 valuation of \$551,880, and a decrease of \$636,121 decrease from the \$799,201 December 31, 2016 valuation. The changes are included in the statements of operations and comprehensive loss. The \$163,080 valuation at September 30, 2017 was computed using the Black-Scholes-Merton pricing model using a stock price of \$0.20, the strike price was \$0.75 per share, the expected life was 4.67 years, the volatility was 90.77% and the risk free rate was 1.87%.

On July 31, 2017, the Company entered into Warrant Exercise Agreements, or the Exercise Agreements, with certain holders of Series C Warrants, the Exercising Holders, which Exercising Holders own, in the aggregate, Series C Warrants exercisable for 908,334 shares of our common stock. Pursuant to the Exercise Agreements, the Exercising Holders and us agreed that the Exercising Holders would exercise their Series C Warrants with respect to 908,334 shares of common stock underlying such Series C Warrants for a reduced exercise price equal to \$0.40 per share. We received aggregate gross proceeds of approximately \$363,334 from the exercise of the Series C Warrants by the Exercising Holders. The difference between the pre-modification and post-modification fair value of \$23,000 was expensed in general and administrative expense in the statements of operations and comprehensive income. The pre-modification fair value was computed using the Black-Scholes-Merton model using a stock price of \$0.56 (fair market value on modification date), original strike price of \$1.00, expected life of 0.83 years, volatility of 115.28%, risk-free rate of 1.20% to arrive at a fair value of \$0.1347 per share. The post-modification fair value was computed using the intrinsic value on the date of modification or \$0.16 per share.

We granted 1,224,875 warrants at a strike price of \$0.08 per share to replace Napo warrants upon the consummation of the merger.

Our warrant activity is summarized as follows:

	Nine Months Ended September 30, 2017	Year Ended December 31, 2016
Beginning balance	5,968,876	748,872
Warrants granted	1,595,791	5,253,337
Warrants exercised	(908,334)	
Warrants cancelled		(33,333)
Ending balance	6,656,333	5,968,876

**Off-Balance Sheet Arrangements**

Since inception, we have not engaged in the use of any off-balance sheet arrangements, such as structured finance entities, special purpose entities or variable interest entities.

**Critical Accounting Policies and Significant Judgments and Estimates**

The preparation of financial statements in conformity with U.S. generally accepted accounting principles, or U.S. GAAP, requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosures in the financial statements. Critical accounting policies are those accounting policies that may be material due to the levels of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change, and that have a material impact on financial condition or operating performance. While we base our estimates and judgments on our experience and on various other factors that we believe to be reasonable under the circumstances, actual results may differ from these estimates under different assumptions or

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conditions. We believe the following critical accounting policies used in the preparation of our financial statements require significant judgments and estimates. For additional information relating to these and other accounting policies, see Note 2 to our financial statements, appearing elsewhere in this report.

**Revenue Recognition**

We recognize revenue in accordance with ASC 605 "Revenue Recognition", subtopic ASC 605-25 "*Revenue with Multiple Element Arrangements*" and subtopic ASC 605-28 "*Revenue Recognition-Milestone Method*", which provides accounting guidance for revenue recognition for arrangements with multiple deliverables and guidance on defining the milestone and determining when the use of the milestone method of revenue recognition for research and development transactions is appropriate, respectively. For multiple-element arrangements, each deliverable within a multiple deliverable revenue arrangement is accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. If a deliverable in a multiple element arrangement is not deemed to have a stand-alone value, consideration received for such a deliverable is recognized ratably over the term of the arrangement or the estimated performance period, and it will be periodically reviewed based on the progress of the related product development plan. The effect of a change made to an estimated performance period and therefore revenue recognized ratably would occur on a prospective basis in the period that the change was made.

We recognize revenue under its licensing, development, co-promotion and commercialization agreement from milestone payments when: (i) the milestone event is substantive and its achievability has substantive uncertainty at the inception of the agreement, and (ii) it does not have ongoing performance obligations related to the achievement of the milestone earned. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment (a) is commensurate with either our performance subsequent to the inception of the arrangement to achieve the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from our performance subsequent to the inception of the arrangement to achieve the milestone, (b) relates solely to past performance, and (c) is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

Our revenue related to the reimbursement of costs incurred under the collaboration agreement where the company acts as principal, controls the research and development activities and bears credit risk. Under the agreement, the Company is reimbursed for associated out-of-pocket costs and for certain employee costs. The gross amount of these pass-through costs is reported in revenue in the accompanying statements of operations and comprehensive loss, while the actual expense for which the Company is reimbursed are reflected as research and development costs.

Determining whether and when some of these revenue recognition criteria have been satisfied often involves assumptions and judgments that can have a significant impact on the timing and amount of revenue the Company will report. Changes in assumptions or judgments or changes to the elements in an arrangement could cause a material increase or decrease in the amount of revenue that the Company reports in a particular period.

**Product Revenue**

Sales of Neonorm Calf and Foal to distributors are made under agreements that may provide distributor price adjustments and rights of return under certain circumstances. Until we develop sufficient sales history and pipeline visibility, revenue and costs of distributor sales will be deferred until products are sold by the distributor to the distributor's customers. Revenue recognition depends on notification either directly from the distributor that product has been sold to the distributor's customer, when we have access

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to the data. Deferred revenue on shipments to distributors reflect the estimated effects of distributor price adjustments, if any, and the estimated amount of gross margin expected to be realized when the distributor sells through product purchased from us. Our sales to distributors are invoiced and included in accounts receivable and deferred revenue upon shipment. Inventory is relieved and revenue recognized upon shipment by the distributor to their customer. We had Neonorm revenues of \$33,611 and \$26,357 for the three months ended September 30, 2017 and 2016, and \$139,600 and \$88,646 for the nine months ended September 30, 2017 and 2016.

Sales of Botanical Extract are recognized as revenue when delivered to the customer. We had Botanical Extract revenues of \$48,000 and \$24,000 in the three months ended September 30, 2017 and 2016, and \$78,000 and \$24,000 in the nine months ended September 30, 2017 and 2016.

The Company's subsidiary Napo sells its drug product, Mytesi through one distributor that in turn sells to various wholesalers in the United States. Sales to the wholesalers are made under agreements that may provide price adjustments and rights of return prior to sell through sales are recognized as revenue when delivered to the wholesalers. Mytesi revenue included in the Company's revenue for the nine months ended September 2017 and 2016 is \$363,868 and \$0, respectively. Mytesi revenue included in the Company's revenue for the three months ended September 2017 and 2016 is \$364,054 and \$0, respectively.

**Collaboration Revenue**

On January 27, 2017, we entered into a licensing, development, co-promotion and commercialization agreement with Elanco US Inc. ("Elanco") to license, develop and commercialize Canalevia ("Licensed Product"), our drug product candidate under investigation for treatment of acute and chemotherapy-induced diarrhea in dogs, and other drug product formulations of crofelemer for treatment of gastrointestinal diseases, conditions and symptoms in cats and other companion animals. We granted Elanco exclusive global rights to Canalevia, a product whose active pharmaceutical ingredient is sustainably isolated and purified from the Croton lechleri tree, for use in companion animals. Pursuant to the Elanco Agreement, Elanco will have exclusive rights globally outside the U.S. and co-exclusive rights with us in the U.S. to direct all marketing, advertising, promotion, launch and sales activities related to the Licensed Products.

Under the terms of the Elanco Agreement, we received an initial upfront payment of \$2,548,689, inclusive of reimbursement of past product and development expenses of \$1,048,689, and will receive additional payments upon achievement of certain development, regulatory and sales milestones in an aggregate amount of up to \$61.0 million payable throughout the term of the Elanco Agreement, as well as product development expense reimbursement for any additional product development expenses incurred, and royalty payments on global sales. The \$61.0 million development and commercial milestones consist of \$1.0 million for successful completion of a dose ranging study; \$2.0 million for the first commercial sale of license product for acute indications of diarrhea; \$3.0 million for the first commercial sale of a license product for chronic indications of diarrhea; \$25.0 million for aggregate worldwide net sales of licensed products exceeding \$100.0 million in a calendar year during the term of the agreement; and \$30.0 million for aggregate worldwide net sales of licensed products exceeding \$250.0 million in a calendar year during the terms of the agreement. Each of the development and commercial milestones are considered substantive. No revenues associated with the achievement of the milestones has been recognized to date. The Elanco Agreement specifies that we will supply the Licensed Products to Elanco, and that the parties will agree to set a minimum sales requirement that Elanco must meet to maintain exclusivity. The \$2,548,689 upfront payment, inclusive of reimbursement of past product and development expenses of \$1,048,689 is recognized as revenue ratably over the estimated development period of one year resulting in \$637,200 and \$1,734,100 in collaboration revenue in the three and nine months ended September 30, 2017 which are included in our statements of operations and comprehensive loss. The difference of \$814,589 is included in deferred collaboration revenue in our balance sheet.

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In addition to the upfront payments, Elanco reimburses us for certain development and regulatory expenses related to our planned target animal safety study and the completion of the Canalevia field study for acute diarrhea in dogs. These are recognized as revenue in the month in which the related expenses are incurred. We have \$17,349 of unreimbursed expenses as of September 30, 2017, which is included in Other Receivables on our balance sheet. We included the \$17,349 and \$503,391 in collaboration revenue in the three and nine months ended September 30, 2017 which are included in the statements of operations and comprehensive loss. On November 1, 2017, Elanco notified us of its intention to terminate the Elanco Agreement, effective January 30, 2018. On the effective date of termination of the Elanco Agreement, all licenses that we granted to Elanco under the Elanco Agreement will be revoked and the rights granted thereunder revert back to us.

**Goodwill and Indefinite-lived Intangible Assets**

Goodwill is tested for impairment on an annual basis and in between annual tests if events or circumstances indicate that an impairment loss may have occurred. The test is based on a comparison of the reporting unit's book value to its estimated fair market value. We perform annual impairment test during the fourth quarter of each fiscal year using the opening consolidated balance sheet as of the first day of the fourth quarter, with any resulting impairment recorded in the fourth quarter of the fiscal year.

If the carrying value of a reporting unit's net assets exceeds its fair value, the goodwill would be considered impaired and would be reduced to its fair value. The goodwill was entirely allocated to the human health reporting unit as the goodwill relates to the Napo Merger. The decline in market capitalization during the three months ended September 30, 2017 was determined to be a triggering event for potential goodwill impairment. Accordingly, we performed the goodwill impairment analysis. We utilized the market capitalization plus a reasonable control premium in the performance of its impairment test. The market capitalization was based on the outstanding shares and the average market share price for the 30 days prior to September 30, 2017. Based on the results of our impairment test, we recorded an impairment charge of \$3,648,000 during the three and nine months ended September 30, 2017. If the market capitalization decreases in the future, a reasonable possibility exists that goodwill could be further impaired in the near term and that such impairment may be material to the financial statements.

Fair value determinations require considerable judgment and are sensitive to changes in underlying assumptions, estimates and market factors. Estimating the fair value of individual reporting units and indefinite-lived intangible assets requires us to make assumptions and estimates regarding our future plans, as well as industry and economic conditions. These assumptions and estimates include projected revenues and income growth rates, terminal growth rates, competitive and consumer trends, market-based discount rates, and other market factors. If current expectations of future growth rates are not met or market factors outside of our control, such as discount rates, change significantly, this may lead to a further goodwill impairment in the future.

Additionally, as goodwill and intangible assets associated with recently acquired businesses are recorded on the balance sheet at their estimated acquisition date fair values, those amounts are more susceptible to an impairment risk if business operating results or macroeconomic conditions deteriorate. Acquired in-process research and development (IPR&D) are intangible assets initially recognized at fair value and classified as indefinite-lived assets until the successful completion or abandonment of the associated research and development efforts. During the development period, these assets will not be amortized as charges to earnings; instead these assets will be tested for impairment on an annual basis or more frequently if impairment indicators are identified.

**Accrued Research and Development Expenses**

As part of the process of preparing our financial statements, we are required to estimate accrued research and development expenses. Estimated accrued expenses include fees paid to vendors and clinical

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sites in connection with our clinical trials and studies. We review new and open contracts and communicate with applicable internal and vendor personnel to identify services that have been performed on our behalf and estimate the level of service performed and the associated costs incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost for accrued expenses. The majority of our service providers invoice us monthly in arrears for services performed or as milestones are achieved in relation to our contract manufacturers. We make estimates of our accrued expenses as of each reporting date.

We base our accrued expenses related to clinical trials and studies on our estimates of the services received and efforts expended pursuant to contracts with vendors, our internal resources, and payments to clinical sites based on enrollment projections. The financial terms of the vendor agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of animals and the completion of development milestones. We estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the related expense accrual accordingly on a prospective basis. If we do not identify costs that have been incurred or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. To date, we have not made any material adjustments to our estimates of accrued research and development expenses or the level of services performed in any reporting period presented.

We expense the total cost of a certain long-term manufacturing development contract ratably over the estimated life of the contract, or the total amount paid if greater.

**Accounting for Stock-Based Compensation**

Beginning in the second quarter of 2014, we awarded options and restricted stock units. We measure stock-based awards granted to employees and directors at fair value on the date of grant and recognize the corresponding compensation expense of the awards, net of estimated forfeitures, over the requisite service periods, which correspond to the vesting periods of the awards. The Company revalues non-employee options each reporting period using the fair market value of the Company's common stock as of the last day of each reporting period.

**Key Assumptions.** Our Black-Scholes-Merton option-pricing model requires the input of highly subjective assumptions, including the fair value of the underlying common stock, the expected volatility of the price of our common stock, the expected term of the option, risk-free interest rates and the expected dividend yield of our common stock. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future. These assumptions are estimated as follows:

Fair value of our common stock Our common stock is valued by reference to the publicly-traded price of our common stock.

Expected volatility As we do not have any trading history for our common stock, the expected stock price volatility for our common stock was estimated by taking the average historic price volatility for industry peers based on daily price observations for common stock values over a period equivalent to the expected term of our stock option grants. We did not rely on implied volatilities of traded options in our industry peers' common stock because the volume of activity was relatively low. We intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own common stock share price becomes available.



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**Expected term** The expected term represents the period that our stock-based awards are expected to be outstanding. It is based on the "simplified method" for developing the estimate of the expected life of a "plain vanilla" stock option. Under this approach, the expected term is presumed to be the midpoint between the average vesting date and the end of the contractual term for each vesting tranche. We intend to continue to apply this process until a sufficient amount of historical exercise activity is available to be able to reliably estimate the expected term.

**Risk-free interest rate** The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected term of the options for each option group.

**Dividend yield** We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

**Forfeitures** We estimate forfeitures at the time of grant and revise those estimates periodically in subsequent periods. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest.

***Common Stock Valuations.*** Prior to our IPO, the fair value of the common stock underlying our stock options was determined by our board of directors, which intended all options granted to be exercisable at a price per share not less than the per share fair value of our common stock underlying those options on the date of grant. The valuations of our common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. The assumptions we used in the valuation model are highly complex and subjective. We base our assumptions on future expectations combined with management judgment. In the absence of a public trading market, our board of directors, with input from management, exercised significant judgment and considered numerous objective and subjective factors to determine the fair value of our common stock as of the date of each option grant and stock award. These judgments and factors will not be necessary to determine the fair value of new awards once the underlying shares begin trading. For now we included the following factors:

the prices, rights, preferences and privileges of our Series A preferred stock relative to those of our common stock;

lack of marketability of our common stock;

our actual operating and financial performance;

current business conditions and projections;

hiring of key personnel and the experience of our management;

our stage of development;

illiquidity of share-based awards involving securities in a private company;

the U.S. capital market conditions; and

the likelihood of achieving a liquidity event, such as an offering or a merger or acquisition of our company given prevailing market conditions.

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The fair market value per share of our common stock for purposes of determining stock-based compensation is now the closing price of our common stock as reported on The NASDAQ Stock Market on the applicable grant date.

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**Classification of Securities**

We apply the principles of ASC 480-10 "Distinguishing Liabilities From Equity" and ASC 815-40 "Derivatives and Hedging Contracts in Entity's Own Equity" to determine whether financial instruments such as warrants, contingently issuable shares and shares subject to repurchase should be classified as liabilities or equity and whether beneficial conversion features exist. Financial instruments such as warrants that are evaluated to be classified as liabilities are fair valued upon issuance and are remeasured at fair value at subsequent reporting periods with the resulting change in fair value recorded in other income/(expense). The fair value of warrants is estimated using the Black-Scholes-Merton model and requires the input of subjective assumptions including expected stock price volatility and expected life.

**Income Taxes**

As of December 31, 2016, we had net operating loss carryforwards for federal and state income tax purposes of \$24.5 million and \$17.1 million, respectively, which will begin to expire in 2033, subject to limitations. Our management has evaluated the factors bearing upon the realizability of our deferred tax assets, which are comprised principally of net operating loss carryforwards. Our management concluded that, due to the uncertainty of realizing any tax benefits as of December 31, 2016, a valuation allowance was necessary to fully offset our deferred tax assets. We have evaluated our uncertain tax positions and determined that we have no liabilities from unrecognized tax benefits and therefore we have not incurred any penalties or interest. The Tax Reform Act of 1986, as amended, limits the use of net operating loss and tax credit carryforward in certain situations where changes occur in the stock ownership of a company. Utilization of the domestic NOL and tax credit forwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by the Internal Revenue Code Section 382, as well as similar state provisions.

**Recent Accounting Pronouncements**

In July 2017, the Financial Accounting Standards Board ("FASB") issued 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, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Non-controlling Interests with a Scope Exception" ("ASU 2017-11"), which addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. The amendments in Part I of this ASU are effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. We are currently evaluating the impact of the adoption of ASU 2017-11 on its consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, "Compensation Stock Compensation (Topic 718): Scope of Modification Accounting" ("ASU 2017-09"), which provides guidance on determining which changes to the terms and conditions of share-based payment awards require an entity to apply modification accounting under Topic 718. The amendments in this ASU are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period, for (1) public business entities for reporting periods for which financial statements have not yet been issued and (2) all other entities for reporting periods for which financial statements have not yet been made available for issuance. The amendments in this ASU should be applied prospectively to an award modified on or after the adoption date. We do not expect the adoption of ASU 2017-09 to have a material impact on our consolidated financial statements.

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In February 2017, the FASB issued ASU No. 2017-05, "Other Income Gains and Losses from the Derecognition of Nonfinancial Assets (Subtopic 610-20): Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets" ("ASU 2017-05"), which clarifies the scope of the nonfinancial asset guidance in Subtopic 610-20. This ASU also clarifies that the derecognition of all businesses and nonprofit activities (except those related to conveyances of oil and gas mineral rights or contracts with customers) should be accounted for in accordance with the derecognition and deconsolidation guidance in Subtopic 810-10. The amendments in this ASU also provide guidance on the accounting for what often are referred to as partial sales of nonfinancial assets within the scope of Subtopic 610-20 and contributions of nonfinancial assets to a joint venture or other noncontrolled investee. The amendments in this ASU are effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Public entities may apply the guidance earlier but only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. We do not expect the adoption of ASU 2017-05 to have a material impact on our consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04 related to goodwill impairment testing. This ASU eliminates Step 2 from the goodwill impairment test. Under the new guidance, if a reporting unit's carrying amount exceeds its fair value, the entity will record an impairment charge based on that difference. The impairment charge will be limited to the amount of goodwill allocated to that reporting unit. Previously, if the fair value of a reporting unit was lower than its carrying amount (Step 1), an entity was required to calculate any impairment charge by comparing the implied fair value of goodwill with its carrying amount (Step 2). Additionally, under the new standard, entities that have reporting units with zero or negative carrying amounts will no longer be required to perform the qualitative assessment to determine whether to perform Step 2 of the goodwill impairment test. As a result, reporting units with zero or negative carrying amounts will generally be expected to pass the simplified impairment test; however, additional disclosure will be required of those entities. This ASU will be effective beginning in the first quarter of our fiscal year 2020. Early adoption is permitted for annual and interim goodwill impairment testing dates after January 1, 2017. The new guidance must be adopted on a prospective basis. We early adopted this ASU in 2017. For impact of the adoption of this standard, refer to Note 6 "Goodwill" to the Condensed Consolidated Financial Statements.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows: Restricted Cash, or ASU 2016-18, that will require entities to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. As a result, entities will no longer present transfers between cash and cash equivalents and restricted cash and restricted cash equivalents in the statement of cash flows. When cash, cash equivalents, restricted cash and restricted cash equivalents are presented in more than one line item on the balance sheet, the new guidance requires a reconciliation of the totals in the statement of cash flows to the related captions in the balance sheet. This reconciliation can be presented either on the face of the statement of cash flows or in the notes to the financial statements. Entities will also have to disclose the nature of their restricted cash and restricted cash equivalent balances. ASU 2016-18 becomes effective for fiscal years beginning after December 15, 2017, and interim periods within those years, with early adoption permitted. Any adjustments must be reflected as of the beginning of the fiscal year that includes that interim period. The adoption of this standard is not expected to have an impact on our financial position or results of operations.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, which addresses the following cash flow issues: (1) debt prepayment or debt extinguishment costs; (2) settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing; (3) contingent consideration payments made after a business combination; (4) proceeds from the settlement of insurance claims; (5) proceeds from the settlement of corporate-owned life insurance policies, including bank-owned life insurance policies; (6) distributions received from equity

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method investees; (7) beneficial interests in securitization transactions; and (8) separately identifiable cash flows and application of the predominance principle. The amendments in this ASU are effective for public business entities for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years and are effective for all other entities for fiscal years beginning after December 15, 2018 and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted, including adoption in an interim period. We are currently evaluating the impact of the adoption of ASU No. 2016-15 on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, which simplifies several aspects of the accounting for employee stock-based payment transactions. The areas for simplification in ASU No. 2016-09 include the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Effective January 1, 2017, we adopted ASU No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. Among other requirements, the new guidance requires all tax effects related to share-based payments at settlement (or expiration) to be recorded through the income statement. Previously, tax benefits in excess of compensation cost ("windfalls") were recorded in equity, and tax deficiencies ("shortfalls") were recorded in equity to the extent of previous windfalls, and then to the income statement. Under the new guidance, the windfall tax benefit is to be recorded when it arises, subject to normal valuation allowance considerations. The adoption of this standard did not have any impact to the Statement of Operations or the Statement of Cash Flows. As of December 31, 2016, we had no unrecognized deferred tax assets related to excess tax benefits, and as such, there was no cumulative-effect adjustment to the beginning accumulated deficit. Additionally, the treatment of forfeitures has not changed as we elected to continue our current process of estimating the number of forfeitures. As such, this has no cumulative effect on accumulated deficit.

In March 2016, the FASB issued ASU No. 2016-06, Derivatives and Hedging (Topic 815): Contingent Put and Call Options in Debt Instruments. ASU 2016-06 clarifies that an entity will only need to consider the four-step decision sequence, as provided by the amended ASC 815-15-25-42, to assess whether the economic characteristics and risks of embedded put or call options are clearly related to those of their hosts. ASU 2016-16 is effective for public business entities for financial statements issued for fiscal years beginning after December 15, 2016; accordingly, we adopted this guidance during 2017.

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, Leases (Topic 842), which provides guidance for accounting for leases. Under ASU 2016-02, the Company will be required to recognize the assets and liabilities for the rights and obligations created by leased assets. ASU 2016-02 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. We are currently evaluating the impact of the adoption of ASU 2016-02 on our consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers." The objective of ASU 2014-09 is to establish a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most of the existing revenue recognition guidance, including industry-specific guidance. The core principle of the new standard is that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard is effective for annual reporting periods beginning after December 15, 2017 and allows for prospective or retrospective application. We currently anticipate utilizing the full retrospective method of adoption allowed by the standard, in order to provide for comparative results in all periods presented, and plan to adopt the standard as of January 1, 2018. The Company is in the process of evaluating the impact of the new standard and related guidance on our consolidated financial statements and related disclosures including the impact of the new standard on its accounting policies, processes, and system requirements. While we continue to assess all potential impacts under the new standard, there is the potential for

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significant impacts to our revenue recognition policy relating to royalty revenues and certain other revenues that are currently recognized on a cash basis or sell through method. Upon adoption of these standards, these revenues will be recognized in the periods in which the sales occur, subject to the constraint on variable consideration. We currently do not expect that adopting these standards will have a material impact on our Condensed Consolidated Financial Statements.

**JOBS Act**

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

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**Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

**Principal Accountants**

Representatives of the principal accountants for the current year and most recently completed fiscal year are not expected to be present at the Special Meeting, but will have the opportunity to make a statement if they desire to do so and will be available to respond to questions.

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**STOCKHOLDER PROPOSALS FOR 2018 ANNUAL MEETING**

In accordance with SEC Rule 14a-8, in order for stockholder proposals intended to be presented at the 2018 Annual Meeting of Stockholders to be eligible for inclusion in our proxy statement and the form of proxy for such meeting, they must have been received by us at our executive offices in San Francisco, California, before December 15, 2017. The Board of Directors has not determined the date of the 2018 Annual Meeting of the Company's Stockholders, but does not currently anticipate that the date will be changed by more than 30 calendar days from the date of this year's annual meeting.

**AVAILABILITY OF ANNUAL REPORT TO STOCKHOLDERS AND REPORT ON FORM 10-K**

Copies of our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 as filed with the Securities and Exchange Commission (exclusive of exhibits and documents incorporated by reference), may be obtained for free by directing written requests to: Jaguar Health, Inc., Attention: Karen S. Wright, 201 Mission Street, Suite 2375, San Francisco, CA 94105 (415.371.8300 phone). Copies of exhibits and basic documents filed with the Annual Report on Form 10-K or referenced therein will be furnished to stockholders upon written request and payment of a nominal fee in connection with the furnishing of such documents. You may also obtain the Annual Report on Form 10-K over the Internet at the SEC's website, [www.sec.gov](http://www.sec.gov), or on our corporate website at <https://jaguar.health/>.

**LIST OF THE COMPANY'S STOCKHOLDERS**

A list of our stockholders as of January 17, 2018, the record date for the Special Meeting, will be available for inspection at our corporate headquarters during normal business hours during the 10-day period prior to the Special Meeting. The list of stockholders will also be available for such examination at the Special Meeting.

**DELIVERY OF PROXY MATERIALS TO HOUSEHOLDS**

Unless contrary instructions are received, we may send a single copy of the Proxy Statement and Notice of Special Meeting to any household at which two or more stockholders reside if we believe the stockholders are members of the same family. Each stockholder in the household will continue to receive a separate proxy card. This process is known as "householding" and helps reduce the volume of duplicate information received at a single household, which reduces costs and expenses borne by us.

If you would like to receive a separate set of our annual disclosure documents this year or in future years, follow the instructions described below and we will deliver promptly a separate set. Similarly, if you share an address with another stockholder and the two of you would like to receive only a single set of our annual disclosure documents, follow the instructions below:

1. If your shares are registered in your own name, please contact our transfer agent by writing to them at Computershare Investor Services, PO Box 30170, College Station, Texas 77842-3170 (Attn: Jaguar Health, Inc. Representative) or calling 1-800-962-4284.
2. If a bank, broker or other nominee holds your shares, please contact your bank, broker or other nominee directly.



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**OTHER MATTERS THAT MAY COME BEFORE THE SPECIAL MEETING**

Our Board of Directors knows of no matters other than those referred to in the accompanying Notice of Special Meeting of Stockholders which may properly come before the Special Meeting. However, if any other matter should be properly presented for consideration and voting at the Special Meeting or any adjournments or postponements thereof, it is the intention of the persons named as proxies on the enclosed form of proxy card to vote the shares represented by all valid proxy cards in accordance with their judgment of what is in the best interest of the Company.

By Order of the Board of Directors.

Lisa A. Conte  
*Chief Executive Officer & President*  
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**CERTIFICATE OF AMENDMENT TO THE  
THIRD AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF  
JAGUAR HEALTH, INC.**

Jaguar Health, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), hereby certifies that:

1. The name of the Corporation is Jaguar Health, Inc.. The date of filing of the Corporation's original Certificate of Incorporation with the Secretary of State of the State of Delaware was June 6, 2013, under the name Jaguar Animal Health, Inc.
2. This Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation was duly authorized and adopted by the Corporation's Board of Directors and stockholders in accordance with Section 242 of the General Corporation Law of the State of Delaware and amends the provisions of the Company's Third Amended and Restated Certificate of Incorporation.
3. The amendments to the existing Third Amended and Restated Certificate of Incorporation being effected hereby are as follows:

- [a. Delete the first paragraph of Article IV in its entirety and to substitute in its place the following:

"The total number of shares of stock that the Corporation shall have authority to issue is Five Hundred Sixty Million (560,000,000) shares, consisting of (i) Five Hundred Million (500,000,000) shares of common stock, \$0.0001 par value per share ("*Common Stock*"), (ii) Fifty Million (50,000,000) shares of convertible non-voting common stock, \$0.0001 par value per share ("*Non-Voting Common Stock*"), and (iii) Ten Million (10,000,000) shares of Preferred Stock, \$0.0001 par value per share ("*Preferred Stock*")."(1)

- [b. Add the following paragraph at the end of Section IV.A. as a new Section IV.A.6:

*"6. Reverse Stock Split.* Upon the effectiveness (the "Effective Time") pursuant to the DGCL of this amendment to the Third Restated Certificate, each \* shares of Common Stock issued and outstanding immediately prior to the Effective Time shall be combined into one (1) validly issued, fully paid and non-assessable share of Common Stock without any further action by the Corporation or the holder thereof; *provided* that no fractional shares shall be issued to any holder and that instead of issuing such fractional shares, the Corporation shall round shares up to the nearest whole number. Each certificate that immediately prior to the Effective Time represented shares of Common Stock ("*Old Certificates*"), shall thereafter represent that number of shares of Common Stock into which the shares of Common Stock represented by the Old Certificate shall have been combined, subject to the treatment of fractional shares as described above."

\*

Number between one and two-tenths (1.2) and ten (10) as determined by the Board of Directors in its sole discretion.](2)

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(1) To be included if the stockholders approve Proposal 1.

(2) To be included if the stockholders approve Proposal 2 and the Board elects, in its sole discretion, to proceed with the reverse stock split.

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4. This Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation was approved by written consent of the board of directors and by the stockholders of this Corporation at a meeting thereof duly called and held on March 12, 2018.

5. This Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation shall be effective immediately upon filing by the Delaware Secretary of State.

\*\*\*\*

IN WITNESS WHEREOF, Jaguar Health, Inc. has caused this Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation to be signed by [ ], its [ ], this [ • ] day of [ • ], 2018.

**JAGUAR HEALTH, INC.**

A Delaware corporation

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

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