Jaguar Health, Inc.
Form 10-Q
November 20, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2017

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number 001-36714

JAGUAR HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**46-2956775**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

201 Mission Street, Suite 2375

San Francisco, California 94105

(Address of principal executive offices, zip code)

(415) 371-8300

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

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

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o (Do not check if a	Smaller reporting company x

smaller reporting company) Emerging growth company x

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

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

As of November 20, 2017, there were 90,836,710 shares of common stock, par value $0.0001 per share, outstanding, of which 48,218,817 are voting shares and 42,617,893 are non-voting shares.

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

JAGUAR HEALTH, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2017 (Unaudited)	December 31, 2016 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 220,590	$ 950,979
Restricted cash	500,000	511,293
Accounts receivable	759,177	4,963
Other receivable	17,349	
Due from former parent		299,648
Inventory	1,831,662	412,754
Deferred offering costs	303,963	72,710
Prepaid expenses and other current assets	609,506	302,694
Total current assets	4,242,247	2,555,041
Property and equipment, net	840,852	885,945
Goodwill	18,389,821	
Intangible assets, net	36,118,889	
Other assets	396,246	122,163
Total assets	$ 59,988,055	$ 3,563,149
Liabilities and Stockholders Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 7,857,404	$ 517,000
Deferred collaboration revenue	814,589	
Deferred product revenue	224,448	224,454
Deferred rent	5,928	
Convertible notes payable	3,213,209	150,000
Accrued expenses	1,927,301	582,522
Warrant liability	163,080	799,201
Derivative liability	19,000	
Current portion of long-term debt	1,801,227	1,919,675
Total current liabilities	16,026,186	4,192,852
Long-term debt, net of discount		1,817,526
Convertible notes payable	11,161,000	
Deferred tax liability	990,549	
Deferred rent		6,956
Total liabilities	$ 28,177,735	$ 6,017,334

Commitments and Contingencies (See Note 7)

Stockholders Equity (Deficit):				
Preferred stock: $0.0001 par value, 10,000,000 shares authorized at September 30, 2017 and December 31, 2016; no shares issued and outstanding at September 30, 2017 and December 31, 2016.				
Common stock: $0.0001 par value, 250,000,000 and 50,000,000 shares authorized at September 30, 2017 and December 31, 2016, respectively; 24,627,367 and 14,007,132 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively.		2,463		1,401
Common stock - non-voting: $0.0001 par value, 50,000,000 and 0 shares authorized at September 30, 2017 and December 31, 2016; 43,173,288 and 0 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively.		4,317		
Additional paid-in capital		74,000,804		37,980,522
Accumulated deficit		(42,197,264)		(40,436,108)
Total stockholders equity (deficit)		31,810,320		(2,454,185)
Total liabilities and stockholders equity (deficit)	$	59,988,055	$	3,563,149

(1) The condensed balance sheet at December 31, 2016 is derived from the audited financial statements at that date included in the Company s Form 10-K filed with the Securities and Exchange Commission on February 15, 2017.

The accompanying notes are an integral part of these condensed consolidated financial statements.

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JAGUAR HEALTH, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Product revenue	$ 445,665	$ 50,357	$ 581,654	$ 112,646
Collaboration revenue	654,549		$ 2,237,491	
Total revenue	1,100,214	50,357	2,819,145	112,646
Operating Expenses				
Cost of product revenue	206,228	9,858	247,135	36,867
Research and development expense	851,608	1,967,128	3,033,851	5,672,516
Sales and marketing expense	663,765	136,882	943,908	355,345
General and administrative expense	3,070,702	1,115,312	8,512,195	4,319,856
Impairment of goodwill	3,648,000		3,648,000	
Total operating expenses	8,440,303	3,229,180	16,385,089	10,384,584
Loss from operations	(7,340,089)	(3,178,823)	(13,565,944)	(10,271,938)
Interest expense	(464,684)	(235,191)	(800,885)	(774,185)
Other expense	(14,876)	(1,476)	(13,428)	(11,046)
Change in fair value of warrants	388,800		636,121	
Loss on extinguishment of debt			(207,713)	
Net loss before income tax	(7,430,849)	(3,415,490)	(13,951,849)	(11,057,169)
Income tax benefit	12,190,693		12,190,693	
Net income (loss) and comprehensive income (loss)	$ 4,759,844	$ (3,415,490)	$ (1,761,156)	$ (11,057,169)
Net income (loss) per share - basic	$ 0.09	$ (0.30)	$ (0.06)	$ (1.07)
Net income (loss) per share - diluted	$ 0.07	$ (0.30)	$ (0.06)	$ (1.07)
Weighted average shares outstanding:				
Basic	55,434,898	11,264,886	28,246,721	10,298,987
Diluted	67,203,530	11,264,886	28,246,721	10,298,987

The accompanying notes are an integral part of these condensed consolidated financial statements.

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JAGUAR HEALTH, INC.

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN COMMON STOCK, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)

(Unaudited)

	Series A Convertible Preferred Stock		Common Stock - voting		Common stock - non-voting				
	Shares	Amount	Shares	Amount	Shares	Amount	Additional paid-in capital	Accumulated deficit	Total stockholders equity (deficit)
Balances - December 31, 2016		$	14,007,132	$ 1,401		$	$ 37,980,522	$ (40,436,108)	$ (2,454,185)
Issuance of common stock associated with private investment in public entities offering, net of offering costs of $72,710 June 2016			3,972,510	397			2,313,977		2,314,374
Issuance of common stock in a private investment in public entities offering, net of offering costs of $6,000 June 2017			200,000	20			93,980		94,000
Issuance of common stock -voting in the Napo merger			2,282,445	228			1,277,941		1,278,169
Issuance of common stock in a July 2017 CSPA			3,243,243	325			2,999,675		3,000,000
Issuance of common stock - non-voting in the Napo merger					43,173,288	4,317	24,172,725		24,177,042
Issuance of warrants in the Napo merger							630,859		630,859
Issuance of stock options in the Napo merger							5,691		5,691
Issuance of RSUs in the Napo merger							3,300,555		3,300,555
Issuance of common stock -voting on exercise of warrants			908,334	91			386,243		386,334
Stock-based compensation							630,924		630,924

Warrants, issued in conjunction with debt extinguishment					207,713			207,713
Issuance of common stock -voting in exchange for vested restricted stock units		13,703		1		(1)		
Net and comprehensive loss							(1,761,156)	(1,761,156)
Balances - September 30, 2017	$	24,627,367	$	2,463	43,173,288	$ 4,317	$ 74,000,804	$ (42,197,264)	$ 31,810,320

The accompanying notes are an integral part of these condensed consolidated financial statements.

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JAGUAR HEALTH, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30,	
	2017	**2016**
Cash Flows from Operating Activities		
Net loss	$ (1,761,156)	$ (11,057,169)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	326,204	32,463
Impairment of goodwill	3,648,000	
Deferred income tax benefit	(12,190,693)	
Loss on extinguishment of debt	207,713	
Stock issued in Napo merger for services	151,351	
Charge in relation to modification of warrants	23,000	
Stock-based compensation	630,924	478,442
Amortization of debt issuance costs and debt discount	367,891	396,107
Change in fair value of warrants	(636,121)	
Change in fair value of derivative liability	(1,000)	
Changes in assets and liabilities		
Accounts receivable - trade	(457,576)	50,904
Other receivable	(17,349)	
Inventory	369,155	(46,356)
Prepaid expenses and other current assets	(256,057)	(331,124)
Deferred offering costs	(231,253)	
Other non-current assets	122,163	
Due from former parent	(164,647)	(269,863)
Deferred collaboration revenue	814,589	
Deferred product revenue	(6)	(5,701)
Deferred rent	(1,028)	3,478
License fee payable		(425,000)
Accounts payable	4,691,363	(151,912)
Accrued expenses	(130,255)	(360,776)
Total cash used in operations	(4,494,788)	(11,686,507)
Cash Flows from Investing Activities		
Purchase of equipment		(104,207)
Cash paid in Napo merger, net of cash acquired	(1,557,340)	
Change in restricted cash	11,293	2,011,420
Total cash (used in)/ provided by investing activities	(1,546,047)	1,907,213
Cash Flows from Financing Activities		
Repayment of long-term debt	(2,161,262)	(2,011,420)
Proceeds from issuance of convertible debt	1,700,000	
Proceeds from issuance of common stock in follow-on secondary public offering, net of commissions, discounts		5,000,000
Commissions, discounts and issuance costs associated with the follow-on secondary public offering		(869,898)
Proceeds from issuance of common stock in a private investment in public entities June 2016	2,376,155	1,881,890
Issuance costs associated with the proceeds from the issuance of common stock in a private investment in public entities June 2016	(61,781)	(105,398)

Proceeds from issuance of common stock in a private investment in public entities June 2017		100,000		
Issuance costs associated with the proceeds from the issuance of common stock in a private investment in public entities June 2017		(6,000)		
Proceeds from issuance of common stock in a July 2017 CSPA		3,000,000		
Proceeds from the issuance of common stock through the exercise of common stock warrants		363,334		
Total Cash Provided by Financing Activities		5,310,446		3,895,174
Net decrease in cash and cash equivalents		(730,389)		(5,884,120)
Cash and cash equivalents, beginning of period		950,979		7,697,531
Cash and cash equivalents, end of period	$	220,590	$	1,813,411
Supplemental Schedule of Non-Cash Financing and Investing Activities				
Interest paid on long-term debt	$	201,835	$	382,810
Fair value of common stock issued in a merger	$	25,303,859	$	
Fair value of replacement of common stock warrants issued in a merger	$	630,859	$	
Fair value of replacement restricted stock units issued in a merger	$	3,300,555	$	
Fair value of replacement stock options issued in a merger	$	5,691	$	

The accompanying notes are an integral part of these condensed consolidated financial statements.

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JAGUAR HEALTH, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Business

Jaguar Health, Inc. (Jaguar or the Company), formerly known as Jaguar Animal Health, Inc., was incorporated on June 6, 2013 (inception) in Delaware. The Company was a majority-owned subsidiary of Napo Pharmaceuticals, Inc. (Napo or the Former Parent) until the close of the Company s initial public offering on May 18, 2015. The Company was formed to develop and commercialize first-in-class gastrointestinal products for companion and production animals and horses. The Company s first commercial product, Neonorm Calf, was launched in 2014 and Neonorm Foal was launched in the first quarter of 2016. In September of 2016, the Company began selling the *Croton lechleri* botanical extract (the botanical extract) to an exclusive distributor for use in pigs in China. The Company s activities are subject to significant risks and uncertainties, including failing to secure additional funding in order to timely compete the development and commercialization of products. The Company manages its operations through two segments human health and animal health and is headquartered in San Francisco, California.

On June 11, 2013, Jaguar issued 2,666,666 shares of common stock to Napo in exchange for cash and services. On July 1, 2013, Jaguar entered into an employee leasing and overhead agreement (the Service Agreement) with Napo, under which Napo agreed to provide the Company with the services of certain Napo employees for research and development and the general administrative functions of the Company. On January 27, 2014, Jaguar executed an intellectual property license agreement with Napo pursuant to which Napo transferred fixed assets and development materials, and licensed intellectual property and technology to Jaguar. On February 28, 2014, the Service Agreement terminated and the associated employees became employees of Jaguar effective March 1, 2014. See Note 10 for additional information regarding the capital contributions and Note 5 for the Service Agreement and license agreement details. Effective July 1, 2016, Napo agreed to reimburse the Company for the use of the Company s employee s time and related expenses, including rent and a fixed overhead amount to cover office supplies and copier use (Note 5).

On July 31, 2017, 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 (the Merger or Napo Merger). Immediately following the 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.

Liquidity

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company has incurred recurring operating losses since inception and has an accumulated deficit of $42,197,264 as of September 30, 2017. The Company expects to incur substantial losses in future periods. Further, the Company s future operations are dependent on the success of the Company s ongoing development and commercialization efforts, as well as the securing of additional financing. There is no assurance that profitable operations, if ever achieved, could be sustained on a continuing basis.

The Company plans to finance its operations and capital funding needs through equity and/or debt financing, collaboration arrangements with other entities, 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. 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. The accompanying financial statements do not include any adjustments that might result from the outcome of these uncertainties.

In June 2016, the Company entered into a common stock purchase agreement with a private investor (the CSPA), which provides that, upon the terms and subject to the conditions and limitations set forth therein, the investor is committed to purchase up to an aggregate of $15.0 million of the Company s common stock over the approximately 30-month term of the agreement. Through September 30, 2017 the Company sold 6,000,000 shares for gross cash proceeds of $5,063,785. The CSPA limited the number of shares that the Company can sell thereunder to 2,027,490 shares, which equals 19.99% of the Company s outstanding shares as of the date of the CSPA (such limit, the 19.99% exchange cap), unless either (i) the Company obtains stockholder approval to issue more than such 19.99% exchange cap or (ii) the average price paid for all shares of the Company s common stock issued under the CSPA is equal to or greater than $1.32 per share (the closing price on the date the CSPA was signed), in either case in compliance with Nasdaq Listing Rule 5635(d). At the 2017 Annual Stockholders Meeting on May 8, 2017, the Company s stockholders voted on the approval, pursuant to Nasdaq Listing Rule 5635(d), of the issuance of an additional 3,555,514 shares of the Company s common stock under the

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CSPA, which when combined with the 2,444,486 shares that the Company has already sold pursuant to the CSPA, equals an aggregate of 6,000,000 shares.

2. Summary of Significant Accounting Policies

Basis of Presentation

The financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) and applicable rules and regulations of the Securities and Exchange Commission (SEC). Our unaudited condensed financial statements reflect all adjustments, which are, in the opinion of management, necessary for a fair presentation of our financial position and results of operations. Such adjustments are of a normal recurring nature, unless otherwise noted. The balance sheet as of September 30, 2017 and the results of operations for the three and nine months ended September 30, 2017 are not necessarily indicative of the results to be expected for the entire year.

Principles of Consolidation

The consolidated financial statements have been prepared in accordance with US GAAP and applicable rules and regulations of the Securities and Exchange Commission (SEC) and include the accounts of the Company and its wholly owned subsidiaries. All inter-company transactions and balances have been eliminated in consolidation.

Use of E stimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company s management to make judgments, assumptions and estimates that affect the amounts reported in its financial statements and the accompanying notes. The accounting policies that reflect the Company s more significant estimates and judgments and that the Company believes are the most critical to aid in fully understanding and evaluating its reported financial results are valuation of stock options; valuation of warrant liabilities; valuation of derivative liability, impairment testing of goodwill, IPR&D, and long lived assets; useful lives for depreciation and amortization; valuation adjustments for excess and obsolete inventory; allowance for doubtful accounts; deferred taxes and valuation allowances on deferred tax assets; evaluation and measurement of contingencies; and recognition of revenue. Those estimates could change, and as a result, actual results could differ materially from those estimates.

Deferred Offering Costs

Deferred offering costs are costs incurred in filings of registration statements with the Securities and Exchange Commission. These deferred offering costs are offset against proceeds received upon the closing of the offerings. Deferred costs of $303,963 as of September 30, 2017 include legal, accounting, printer, and filing fees associated with follow-on public offering in October 2017. Deferred costs of $72,710 as of December 31, 2016, include legal, accounting, printer and filing fees associated with the Company s registration of unissued shares in the CSPA.

Concentration of Credit Risk and Cash and Cash Equivalents

Cash is the financial instrument that potentially subjects the Company to a concentration of credit risk as cash is deposited with a bank and cash balances are generally in excess of Federal Deposit Insurance Corporation (FDIC) insurance limits. The carrying value of cash approximates fair value at September 30, 2017 and December 31, 2016.

Fair Values

The Company s financial instruments include, cash and cash equivalents, accounts receivable, accounts payable, accrued expenses, warrant liabilities, derivative liability, and debt. Cash is reported at fair value. The recorded carrying amount of accounts receivable, accounts payable and accrued expenses reflect their fair value due to their short-term nature. The carrying value of the interest-bearing debt approximates fair value based upon the borrowing rates currently available to the Company for bank loans with similar terms and maturities. See Note 4 for the fair value measurements, and Note 8 for the fair value of the Company s warrant liabilities and derivative liability.

Restricted Cash

On August 18, 2015, the Company entered into a long-term 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 required the Company to maintain a base

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minimum cash balance of $4.5 million until the Company met certain milestones and/or when the Company begins making principal payments. On December 22, 2015, the Company achieved certain milestones and the base minimum cash balance was reduced to $3.0 million. Aggregate principal payments of $3.0 million further reduced the restricted cash balance to $0 as of September 30, 2017. Restrictions were fully released on April 1, 2017. On July 7, 2017, the Company entered into the third amendment to the Loan Agreement upon which the Company 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 the Company 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 payment.

Inventories

Inventories are stated at the lower of cost or market. The Company calculates inventory valuation adjustments when conditions indicate that market is less than cost due to physical deterioration, usage, obsolescence, reductions in estimated future demand or reduction in selling price. Inventory write-downs are measured as the difference between the cost of inventory and market. There have been no write-downs to date.

Property and Equipment

Equipment is stated at cost, less accumulated depreciation. Equipment begins to be depreciated when it is placed into service. Depreciation is calculated using the straight-line method over the estimated useful lives of 3 to 10 years.

Expenditures for repairs and maintenance of assets are charged to expense as incurred. Costs of major additions and betterments are capitalized and depreciated on a straight-line basis over their estimated useful lives. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in the statements of operations and comprehensive loss.

Long-Lived Assets

The Company regularly reviews the carrying value and estimated lives of all of its long-lived assets, including property and equipment to determine whether indicators of impairment may exist that warrant adjustments to carrying values or estimated useful lives. The determinants used for this evaluation include management s estimate of the asset s ability to generate positive income from operations and positive cash flow in future periods as well as the strategic significance of the assets to the Company s business objectives.

Definite-lived intangible assets are amortized on a straight-line basis over the estimated periods benefited, and are reviewed when appropriate for possible impairment.

Should an impairment exist, the impairment loss would be measured based on the excess of the carrying amount over the asset s fair value. The Company has not recognized any impairment losses through September 30, 2017.

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. The Company performs 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 the Company performed the goodwill impairment analysis. The Company 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 the Company s impairment test, the Company 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.

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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.

Research and Development Expense

Research and development expense consists of expenses incurred in performing research and development activities including related salaries, clinical trial and related drug and non-drug product costs, contract services and other outside service expenses. Research and development expense is charged to operating expense in the period incurred.

Revenue Recognition

The Company recognizes 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.

The Company recognizes 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 the Company s 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 the Company s 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.

The Company 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, 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 the Company develops sufficient sales history and pipeline visibility, revenue and

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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 the Company has 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 the Company. Company 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. The Company 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. The Company 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 are recognized as revenue when delivered to the wholesalers. Mytesi revenue included in the Company s revenue for the nine months months ended September 2017 and 2016 is $364,054 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. The Company records 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 the Company s historical experience, changes to the reserved could be required in future periods.

Collaboration Revenue

On January 27, 2017, the Company entered into a licensing, development, co-promotion and commercialization agreement (the Elanco 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. The Company 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 the Company 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, the Company 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 the Company 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 the Company s statements of operations and comprehensive loss. The difference of $814,589 is included in deferred collaboration revenue in the Company s balance sheet.

In addition to the upfront payments, Elanco reimburses the Company 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. The Company has $17,349 of unreimbursed expenses as of September 30, 2017, which is included in Other Receivables on the Company s balance sheet. The Company 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 Company s statements of operations and comprehensive loss.

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Stock-Based Compensation

The Company s 2013 Equity Incentive Plan and 2014 Stock Incentive Plan (see Note 11) provides for the grant of stock options, restricted stock and restricted stock unit awards.

The Company measures stock awards granted to employees and directors at fair value on the date of grant and recognizes 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 issues stock awards with only service-based vesting conditions, and records compensation expense for these awards using the straight-line method.

The Company uses the grant date fair market value of its common stock to value both employee and non-employee options when granted. 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.

Classification of Securities

The Company applies 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 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

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company s tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then

assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate, as well as the related net interest and penalties.

Comprehensive Loss

Comprehensive loss is defined as changes in stockholders equity (deficit) exclusive of transactions with owners (such as capital contributions and distributions). For the three and nine months ended September 30, 2017 and 2016 there was no difference between net loss and comprehensive loss.

Segment Data

Prior to the merger with Napo, the Company managed its operation as a single segment for the purposes of assessing performance and making operating decisions. The Company reorganized their segments to reflect the change in the organizational structure resulting from the merger with Napo. Post-merger with Napo, the Company manages its operations through two segments. The Company has two reportable segments human health and animal health. The animal health segment is focused on developing and commercializing prescription and non-prescription products for companion and production animals. The human health segment is

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focused on developing and commercializing of human products and the ongoing commercialization of Mytesi , which is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy.

The Company s reportable segments net sales and net income consisted of:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue from external customers				
Human Health	$ 364,054	$	$ 364,054	$
Animal Health	736,160	50,357	2,455,091	112,646
Consolidated Totals	$ 1,100,214	$ 50,357	$ 2,819,145	$ 112,646
Interest expense				
Human Health	$ (192,120)	$	$ (192,120)	$
Animal Health	(272,564)	(235,191)	(608,765)	(774,185)
Consolidated Totals	$ 464,684	$ (235,191)	$ (800,885)	$ (774,185)
Depreciation and amortization				
Human Health	$ 281,111	$	$ 281,111	$
Animal Health	15,031	15,031	45,093	32,463
Consolidated Totals	$ 296,142	$ 15,031	$ 326,204	$ 32,463
Segment profit				
Human Health	$ 996,493	$	$ 996,493	$
Animal Health	3,763,351	(3,415,490)	(2,757,649)	(11,057,169)
Total	$ 4,759,844	$ (3,415,490)	$ (1,761,156)	$ (11,057,169)

The Company s reportable segments assets consisted of the following:

	September 30, 2017	December 31, 2016
Segment assets		
Human Health	$ 57,568,731	$
Animal Health	34,754,604	3,563,149
Total	$ 92,323,335	$ 3,563,149

The reconciliation of segments assets to the consolidated assets is as follows:

	September 30, 2017	December 31, 2016
Total assets for reportable segments	$ 92,323,335	$ 3,563,149
Less: investment in subsidiary	(29,240,965)	
Less: Intercompany loan	(2,000,000)	
Less: Intercompany receivable	(1,094,315)	
Consolidated Totals	$ 59,988,055	$ 3,563,149

Basic and Diluted Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders for the period by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders for the period by the weighted-average number of common shares, including potential dilutive shares of common stock assuming the dilutive effect of potential dilutive securities. For periods in which the Company reports a net loss, diluted net loss per common share is the same as basic net loss per common share, because their impact would be anti-

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dilutive to the calculation of net loss per common share. Diluted net loss per common share is the same as basic net loss per common share for the three and nine months ended September 30, 2017 and 2016.

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. The Company is 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. The Company does not expect the adoption of ASU 2017-09 to have a material impact on our consolidated financial statements.

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 reports 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. The Company does not expect the adoption of ASU 2017-05 to have a material impact on our consolidated financial statements.

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In January 2017, the FASB issued ASU No. 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. The Company early adopted this ASU in 2017. For impact of the adoption of this standard, refer to Note 6 Goodwill .

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 the Company s 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 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. The Company is 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, the Company 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, the Company 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 the Company is electing to continue its current process of estimating the number of forfeitures. As such, this has no cumulative effect on accumulated deficit.

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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, the Company adopted this guidance during 2017.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which replaces the current lease accounting standard. ASU 2016-02 establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the statements of operations. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact of the new standard on its 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. The Company currently anticipates utilizing the full retrospective method of adoption allowed by the standard, in order to provide for comparative results in all periods presented, and plans 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 the Company s consolidated financial statements and related disclosures including the impact of the new standard on its accounting policies, processes, and system requirements. While the Company continues to assess all potential impacts under the new standard, there is the potential for 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.

3. Business Combination

As discussed in Note 1 Organization and Business, the Company completed a merger with Napo on July 31, 2017 . 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.

The merger was accounted for under the acquisition method of accounting for business combinations and Jaguar was considered to be the acquiring company. Under the acquisition method of accounting, total consideration exchanged was:

		(Unaudited)
Fair value of Jaguar common stock	$	25,303,859
Fair value of Jaguar common stock warrants		630,859
Fair value of replacement restricted stock units		3,300,555
Fair value of replacement stock options		5,691
Cash		2,000,000
Effective settlement of receivable from Napo		464,295
Total consideration exchanged	$	31,705,259

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The purchase price allocation to assets and liabilities assumed in the transaction was:

Current assets	$	2,578,114
Non-current assets		396,247
Identifiable intangible assets		36,400,000
Current liabilities		(4,052,180)
Convertible notes payable		(12,473,501)
Deferred tax liability		(13,181,242)
Net assets acquired		9,667,438
Goodwill on acquisition		22,037,821
Total consideration	$	31,705,259

Under the acquisition method of accounting, certain identifiable assets and liabilities of Napo including identifiable intangible assets, inventory, debt and deferred revenue were recorded based on their estimated fair values as of the effective time of the Napo Merger. Tangible and other assets and liabilities were valued at their respective carrying amounts, which management believes approximate their fair values.

The Developed Technology (DT) is for the development and commercial processing of Mytesi (crofelemer 125mg delayed-release tablets), which is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy. The DT is a definite lived asset and is being amortized over a 15-year estimated useful life.

The acquired trademarks include Mytesi product trademark, domain names, and other brand related intellectual property. Trademark is a definite lived asset and is being amortized over a 15-year estimated useful life.

The acquired IPR&D projects relate to developing the incomplete technology into a commercially viable product for the several indications related to Mytesi. Mytesi is in development for follow-on indications in cancer therapy-related diarrhea (CTD), an important supportive care indication for patients undergoing primary or adjuvant therapy for cancer treatment. Mytesi is a 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. IPR&D is not amortized during the development period.

The fair value of IPR&D, trademark, and DT was determined using the income approach, which was based on forecasts prepared by management.

The Napo Merger resulted in $22,037,821 of goodwill relating principally to synergies expected to be achieved from the combined operations and planned growth in new markets. Goodwill has been allocated to the human health segment.

As none of the goodwill, IPR&D, and developed technology acquired are expected to be deductible for income tax purposes, it was determined that a deferred income tax liability of $14,498,120 was required to reflect the book to tax differences of the merger. A deferred tax asset of

$1,316,878 was accounted as an element of consideration for the replacement share-based payment awards as the replacement awards are expected to result in a future tax deduction.

The Company valued finished goods using a net realizable value approach, which resulted in a step-up of $84,806. Raw material was valued using the replacement cost approach.

The Company valued convertible debt assumed in the Napo Merger based on the value of the debt and the conversion option at $12,473,501 (see note 8). The Company incurred acquisition related costs of $1,103,331 and $3,554,250 during the three months ended September 30, 2017 and nine months ended September 30, 2017, respectively. The acquisition related costs for the three and nine months ended September 30, 2017 includes the fair value of $151,351 for 270,270 shares of Company s common stock issued to a former creditor of Napo towards reimbursement of acquisition related costs. Acquisition related costs are expensed as incurred to general and administrative expenses in the condensed consolidated statements of operations and comprehensive loss.

The following table provides unaudited proforma results, prepared in accordance with ASC 805, for the three and nine months ended September 30, 2017 and September 30, 2016, as if Napo was acquired on January 1, 2016.

	For the three months ended September 30,		For the nine months ended September 30,	
	2017	**2016**	**2017**	**2016**
Net sales	1,253,447	496,476	3,894,222	677,310
Net income (loss)	5,281,573	(3,698,298)	(2,905,689)	(16,092,681)
Net income (loss) per share, basic	0.10	(0.33)	(0.10)	(1.56)

The unaudited proforma results include adjustments to eliminate the interest on Napo s historical convertible debt not assumed by Jaguar and debt exchanged for Jaguar common stock, record interest on convertible debt assumed by Jaguar, eliminate Napo impairment of investment in related party, and eliminate Napo s loss from investment in related party. The Company made

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proforma adjustments to exclude the acquisition related costs for the three and nine months ended September 30, 2017 and to exclude the acquisition related costs in the results for the three and nine months ended September 30, 2016, because such costs are nonrecurring and are directly related to the Napo Merger.

The unaudited pro forma condensed results do not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the Napo Merger.The unaudited proforma results do not include any anticipated cost savings or other effects of future integration efforts. Unaudited pro forma amounts are not necessarily indicative of results had the Napo Merger occurred on January 1, 2016 or of future results.

4. Fair Value Measurements

ASC 820 Fair Value Measurements, defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under ASC 820 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under ASC 820 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- Level 1 Quoted prices in active markets for identical assets or liabilities;

- Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data; and

- Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The following table presents information about the Company s derivative and warrant liabilities that were measured at fair value on a recurring basis as of September 30, 2017 and December 31, 2016 and indicates the fair value hierarchy of the valuation:

	September 30, 2017			
	Level 1	Level 2	Level 3	Total
Warrant liability	$	$	$ 163,080	$ 163,080

Derivative liability			19,000	19,000
Total fair value	$	$	$ 182,080	$ 182,080

	December 31, 2016			
	Level 1	Level 2	Level 3	Total
Warrant liability	$	$	$ 799,201	$ 799,201
Derivative liability				
Total fair value	$	$	$ 799,201	$ 799,201

The change in the estimated fair value of level 3 liabilities is summarized below:

	For the three months ended			
	September 30, 2017		September 30, 2016	
	Warrant liability	Derivative liability	Warrant liability	Derivative liability
Beginning value of level 3 liability	$ 551,880	$ 20,000	$	$
Issuance				
Change in fair value of level 3 liability	(388,800)	(1,000)		
Ending fair value of level 3 liability	$ 163,080	$ 19,000	$	$

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	For the nine months ended			
	September 30, 2017		September 30, 2016	
	Warrant liability	Derivative liability	Warrant liability	Derivative liability
Beginning value of level 3 liability	$ 799,201	$	$	$
Issuance		20,000		
Change in fair value of level 3 liability	(636,121)	(1,000)		
Ending fair value of level 3 liability	$ 163,080	$ 19,000	$	$

The warrants associated with the level 3 liability were issued in 2016 and were originally valued on November 29, 2016 using the Black-Scholes-Merton model with the following assumptions: stock price of $0.69, exercise price of $0.75, term of 5.5 years expiring May 2022, volatility of 71.92%, dividend yield of 0%, and risk-free interest rate of 1.87%. The warrants were revalued at December 31, 2016 using the Black-Scholes-Merton model with the following assumptions: stock price of $0.72, exercise price of $0.75, term of 5.41 years expiring May 2022, volatility of 73.62%, dividend yield of 0%, and risk-free interest rate of 2.0%. The warrants were again revalued at September 30, 2017 using the Black-Scholes-Merton model with the following assumptions: stock price of $0.20, exercise price of $0.75, term of 4.67 years expiring May 2022, volatility of 90.77%, dividend yield of 0%, and risk-free interest rate of 1.87%.

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, for the June 2017 Convertible Note, 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 derviatives 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 Company s statement of income and comprehensive income.

The change in the fair value of the level 3 derivative and warrant liabilities is reflected in the statement of operations and comprehensive loss for the nine months ended September 30, 2017.

5. Related Party Transactions

The Company was a majority-owned subsidiary of Napo until May 18, 2015, the date of the Company s IPO. Additionally, Lisa A. Conte, Chief Executive Officer of the Company, was also the Interim Chief Executive Officer of Napo Pharmaceuticals, Inc. The Company completed a merger with Napo on July 31, 2017, from which date Napo operates as a wholly-owned subsidiary of the Company see Note 3 Business Combination.

The Company has total outstanding receivables (payables) from Napo at December 31, 2016 as follows:

	December 31, 2016
Due from former parent	$ 299,819
Royalty payable to former parent	(171)
Net receivable (payable) to former parent	$ 299,648

Due from Napo

Employee leasing and overhead allocation

Effective July 1, 2016, Napo agreed to reimburse the Company for the use of the Company s employee s time and related expenses, including rent and a fixed overhead amount to cover office supplies and copier use. The balance of unpaid employee leasing charges due from Napo was $277,529 at December 31, 2016. The total amount of such services was $913,068 and Napo remitted $838,723 for the seven months ended July 31, 2017. The remaining unpaid balance of $351,870 was included in the receivable from Napo at July 31, 2017. Receivable from Napo was effectively settled on merger and is included in the purchase consideration for the acquisition of Napo.

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Loan to Napo

The Company loaned $2.0 million from proceeds of shares issued to an investor in connection with the merger to Napo, to partially extinguish Napo s debt. The Company accounted for this amount as purchase consideration for the acquisition of Napo.

Other transactions

The Company periodically made purchases on behalf of Napo, primarily including travel expenses and investor relations expenses. The balance of unpaid non-employee leasing charges due from Napo was $22,290 at December 31, 2016. The total amount of such purchases was $157,877 and Napo remitted $67,262 for the seven month ended July 31, 2017. The remaining unpaid balance of $112,905 was included in receivable from Napo at July 31, 2017. Receivable from Napo was effectively settled on merger and is included in the purchase consideration for the acquisition of Napo.

Royalty payable to former parent and license fee payable to former parent and related agreement

On July 11, 2013, Jaguar entered into an option to license Napo s intellectual property and technology (the Option Agreement). Under the Option Agreement, upon the payment of $100,000 in July 2013, the Company obtained an option for a period of two years to execute an exclusive worldwide license to Napo s intellectual property and technology to use for the Company s animal health business. The option price was creditable against future license fees to be paid to Napo under the License Agreement (as defined below).

In January 2014, the Company exercised its option and entered into a license agreement (the License Agreement) with Napo for an exclusive worldwide license to Napo s intellectual property and technology to permit the Company to develop, formulate, manufacture, market, use, offer for sale, sell, import, export, commercialize and distribute products for veterinary treatment uses and indications for all species of animals. The Company was originally obligated to pay a one-time non-refundable license fee of $2,000,000, less the option fee of $100,000. At the Company s option, the license fee could have been paid in common stock. In January 2015, the License Agreement was amended to decrease the one-time non-refundable license fee payable from $2,000,000 to $1,750,000 in exchange for acceleration of the payment of the fee. Given that Napo was a significant shareholder of the Company, the abatement of the license fee amount was recorded as a capital contribution in the accompanying condensed financial statements. The Company paid the final $425,000 in the three months ended March 31, 2016.

Milestone payments aggregating $3,150,000 were also potentially due to Napo based on regulatory approvals of various veterinary products. In addition to the milestone payments, the Company wouldowe Napo an 8% royalty on annual net sales of products derived from the *Croton lechleri* tree, up to $30,000,000 and then, a royalty of 10% on annual net sales of $30,000,000 or more. Additionally, if any other products are developed, the Company would owe Napo a 2% royalty on annual net sales of pharmaceutical prescription products that are not derived from *Croton lechleri* and a 1% royalty on annual net sales of non-prescription products that are not derived from *Croton lechleri*. The royalty term expires at the longer of 10 years from the first sale of each individual product or when there is no longer a valid patent claim covering any of the products and a competitive product has entered the market. However, because an IPO of at least $10,000,000 was consummated prior to December 31, 2015, the royalty was reduced to 2% of annual net sales of its prescription products derived from *Croton lechleri* and 1% of net sales of its non-prescription products derived from *Croton lechleri* and no milestone payment will be due and no royalties will be owed on any additional products developed.

The Company had unpaid royalties of $171 at December 31, 2016, which are netted with other receivables due from former parent in current assets in the Company s balance sheet. The Company incurred $765 in royalties during the seven months ended July 31, 2017, which are included in sales and marketing expense in the Company s statement of operations and comprehensive loss, and paid $455 to Napo in the seven months ended July 31, 2017. The remaining balance of unpaid royalties of $481 are netted with receivables due from Napo. The net receivable balance at July 31, 2017 of $464,295 was effectively settled on merger and is included in the purchase consideration for the acquisition of Napo.

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6. Balance Sheet Components

Property and Equipment

Property and equipment at September 30, 2017 and December 31, 2016 consisted of the following:

	September 30, 2017	December 31, 2016
Lab equipment	$ 811,087	$ 811,087
Clinical equipment	64,870	64,870
Software	62,637	62,637
Total property and equipment at cost	938,594	938,594
Accumulated depreciation	(97,742)	(52,649)
Property and equipment, net	$ 840,852	$ 885,945

Depreciation and amortization expense was $15,031 and $15,031 in the three months ended September 30, 2017 and 2016, and $45,093 and $32,463 in the nine months ended September 30, 2017 and 2016, which 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
Depreciation - lab equipment - research and development expense	$ 6,568	$ 6,568	$ 19,704	$ 19,704
Depreciation - clinical equipment - research and development expense	3,243	3,243	9,730	6,959
Depreciation - software - general and administrative expense	5,220	5,220	15,659	5,800
Total depreciation expense	$ 15,031	$ 15,031	$ 45,093	$ 32,463

Intangible assets

Intangible assets at September 30, 2017 and December 31, 2016 consisted of the following:

	September 30, 2017	December 31, 2016
Developed technology	$ 25,000,000	$
IPR&D	11,100,000	
Trademarks	300,000	
Total intangible assets	36,400,000	

Less: Accumulated amortization			(281,111)	
Total intangible assets, net	$		36,118,889	$

Amortization expense was $281,111 and $0 in the three months ended September 30, 2017 and 2016 and was $281,111 and $0 in the nine months ended September 30, 2017 and 2016.

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Goodwill

The change in the carrying amount of goodwill for the nine months ended September 2017 was as follows:

Balance at December 31, 2016	$	
Goodwill acquired in conjunction with Napo Merger		22,037,821
Impairment		(3,648,000)
Balance at September 30, 2017	$	18,389,821

Accrued Expenses

Accrued expenses at September 30, 2017 and December 31, 2016 consist of the following:

		September 30, 2017		December 31, 2016
Accrued compensation and related:				
Accrued vacation	$	264,223	$	223,769
Accrued payroll		150		2,692
Accrued payroll tax		20,312		20,140
		284,685		246,601
Accrued interest		422,179		123,982
Accrued clinical		17,045		36,725
Accrued research and development costs		668,850		
Accrued legal costs				92,500
Accrued audit				37,000
Marketing advance		168,525		
Accrued other		366,017		45,714
Total	$	1,927,301	$	582,522

7. Commitments and Contingencies

Operating Leases

Effective July 1, 2015, the Company leases its San Francisco, California headquarters under a non-cancelable sub-lease agreement that expires August 31, 2018. The Company provided cash deposits of $122,163, consisting of a security deposit of $29,539 and prepayment of the last three months of the lease of $92,623, which are included in prepaid expenses and other current assets on the Company s balance sheet.

Future minimum lease payments under non-cancelable operating leases as of September 30, 2017 are as follows:

Years ending December 31,		Amount
2017 - October through December	$	91,622
2018		245,327
Total minimum lease payments	$	336,949

The Company recognizes rent expense on a straight-line basis over the non-cancelable lease period. Rent expense under the non-cancelable operating lease was $90,278 for the three months ended September 30, 2017 and 2016, and $270,835 for the nine months ended September 30, 2017 and 2016. Rent expense is included in general and administrative expense in the Company s statements of operations and comprehensive loss.

Asset transfer and transition commitment

On September 25, 2017, Napo entered into the Termination, Asset Transfer and Transition Agreement dated September 22, 2017 with Glenmark Pharmaceuticals Ltd. (Glenmark). As a result of the agreement, Napo now controls commercial rights for Mytesi® for all indications, territories and patient populations globally, and also holds commercial rights to the existing regulatory approvals for crofelemer in Brazil, Ecuador, Zimbabwe and Botswana. In exchange, Napo agrees to pay Glenmark 25% of any payment it receives from a third party to whom Napo grants a license or sublicense or with whom Napo partners in respect of, or sells or otherwise transfers any of the transferred assets, subject to certain exclusions, until Glenmark has received a total of $7 million.

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Purchase Commitment

As of September 30, 2017, the Company had issued non-cancelable purchase orders to a vendor for $1.3 million.

Debt Obligations

See Note 8 Debt and Warrants.

Contingencies

Legal Proceedings.

On July 20, 2017, a putative class action complaint was filed in the United States District Court, Northern District of California, Civil Action No. 3:17-cv-04102, by Tony Plant on behalf of pre-Merger shareholders of Jaguar who held shares on June 30, 2017 and were entitled to vote at the 2017 Special Shareholders Meeting, against us and certain individuals who were directors as of the date of the vote, in a matter captioned Tony Plant v. Jaguar Animal Health, Inc., et al. The plaintiff attempts to assert claims arising under Section 14(a) and Section 20(a) of the Exchange Act and Rule 14a-9, 17 C.F.R. § 240.14a-9, promulgated thereunder by the SEC. The plaintiff alleges that material omissions and misstatements were contained in the Joint Proxy Statement/Prospectus on Form S-4 (File No. 333-217364) declared effective by the SEC on July 6, 2017 related to the solicitation of votes from shareholders to approve the Merger and certain transaction related thereto. We believe the claims are without merit. While no monetary damages have been quantified, we intend to vigorously contest this complaint.

The plaintiff has not yet served the complaint and summons on any of the defendants. If the plaintiff elected to proceed with the litigation and made service on the defendants, the defendants would move to dismiss the complaint for failure to state a claim on which relief may be granted.

8. Debt and Warrants

Convertible Notes and Warrants

Convertible notes and related interest payable 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

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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, the Company 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, the Company 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. The Company 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, the Company 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.

On November 8, 2016, the Company 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, the Company s board of directors granted the lender a warrant to purchase 120,000 shares of the 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 the Company 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, the Company 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, the Company s board of directors granted the lender a

warrant to purchase 370,916 shares of the Company s 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 the Company treating the debt as having been extinguished and replaced with new debt for accounting purposes due to meeting the 10% cash flow test. The Company 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 the Company s 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 the Company s balance sheet. The Company has unpaid accrued interest of $47,392 and $33,929, which is included in accrued expenses on the Company s 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.

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June 2017 Convertible Note

On June 29, 2017, the Company issued a secured convertible promisorry note (Note) to a lendor 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. The Company accrued interest of $44,372 at September 30, 2017 which is included in accrued expenses on the Company s 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 the Company s statement of operations and comprehensive loss. The Company also recorded $123,362 and $124,708 in interest expense in the three and nine months ended September 30, 2017 which are included in the Company s 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 the Company s 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.

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 lendor 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 derviatives 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 Company s 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 provided for the sale of up to $12,500,000 face amount of notes and issued convertible promissory notes (the Napo December 2016 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 2017 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 2016 Notes and the Napo July 2017 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.

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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, the Company 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 the Company 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 the Company 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, the Company is entitled to prepay principal and accrued interest upon five days prior notice to the lender. In the event of prepayment, the Company is 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 the Company is 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 the Company is 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 the Company 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, the Company entered into the third amendment to the Loan Agreement upon which the Company 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 the Company 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 the present value of the cash flows under the terms of the third amendment is less than 10% different from the remaining cash flows under the terms of the loan agreement prior to the amendment, the third amendment was accounted as a debt modification.

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

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

Years ending December 31	Amount
2017 - October 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

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
	$ 100,765	$ 230,655	$ 426,222	$ 760,673

Warrants

On November 22, 2016, the Company entered into a Securities Purchase Agreement, or the 2016 Purchase Agreement, with certain institutional investors, pursuant to which the Company 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, the Company sold an aggregate of 1,666,668 shares of the Company s 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 the Company s 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 the Company s 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.

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- 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 Company s balance sheet. The series A warrants and placement agent warrants were revalued on December 31, 2016 at $799,201 which is included in the Company s balance sheet, and the $43,200 increase is included in the Company s 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 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 Company s 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 Company s 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 (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 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. 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.

The Company granted warrants to purchase the 1,224,875 shares of common stock of the Company at an exercise price price of $0.08 per share to replace Napo warrants upon the consummation of the Merger. Of the 1,224,875 warrants, 145,457 warrants expire on December 31, 2018 and 1,079,418 warrants expire on December 31, 2025. The warrants were valued at $630,859, using the Black-Scholes-Merton warrant pricing model as follows: exercise price of $0.08 per share, stock price of $0.56 per share, expected life ranging from 1.42 years to 8.42 years, volatility ranging from 75.07% to 110.03%, and risk free rate ranging from 1.28% to 2.14%. The warrants were accounted in equity.

The Company s 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

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9. Stockholders Equity

Common Stock

On July 31, 2017, the Company filed a third amended and restated certificate of incorporation authorizing the Company to issue 250,000,000 shares of common stock $0.0001 par value and 50,000,000 of convertible non-voting common stock, $0.0001 par value per share. The holders of common stock are entitled to one vote for each share of common stock held at all meetings of stockholders. The holders of non-voting common stock are not entitled to vote, except on an as converted basis with respect to any change of control of the Company that is submitted to the stockholders of the Company for approval.The number of authorized shares of common stock may be increased or decreased by the affirmative vote of the holders of shares of capital stock of the Company representing a majority of the votes represented by all shares (including Preferred Stock) entitled to vote. 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 (former creditor of Napo), upon the release from escrow of certain non-voting shares held by the 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.

On May 18, 2015, the Company completed an initial public offering (IPO) of its common stock. In connection with its IPO, the Company issued and sold 2,860,000 shares of common stock at a price to the public of $7.00 per share. As a result of the IPO, the Company received $15.9 million in net proceeds, after deducting underwriting discounts and commissions of $1.2 million and offering expenses of $2.9 million ($3.3 million including non-cash offering expenses) payable by the Company. In connection with the IPO, the Company s outstanding shares of convertible preferred stock were automatically converted into 2,010,596 shares of common stock and the Company s outstanding warrants to purchase convertible preferred stock were all converted to warrants to purchase common stock.

In February 2016, the Company completed a secondary public offering of its common stock. In connection with its secondary public offering, the Company issued and sold 2,000,000 shares of common stock at a price to the public of $2.50 per share. As a result of the secondary public offering, the Company received $4.1 million in net proceeds, after deducting underwriting discounts and commissions of $373,011 and offering expenses of $496,887.

In June 2016, the Company entered into a common stock purchase agreement with a private investor (the CSPA), which provides that, upon the terms and subject to the conditions and limitations set forth therein, the investor is committed to purchase up to an aggregate of $15.0 million of the Company s common stock over the approximately 30-month term of the agreement. Upon execution of the CSPA, the Company sold 222,222 shares of its common stock to the investor at $2.25 per share for net proceeds of $394,534, reflecting gross proceeds of $500,000 and offering expenses of $105,398. In consideration for entering into the CSPA, the Company issued 456,667 shares of its common stock to the investor. Concurrently with entering into the CSPA, the Company also entered into a registration rights agreement with the investor (the Registration Agreement), in which the Company agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act of 1933, as amended, the sale of the shares of the Company s common stock that have been and may be issued to the investor under the CSPA. On June 22, 2016 and September 22, 2016, the Company filed registration statements on Form S-1 (File Nos. 333-212173 and 333-213751) pursuant to the terms of the Registration Agreement, which registration statements were declared effective on July 8, 2016 and October 5, 2016, respectively. In the year ended December 31, 2016, pursuant to the CSPA, the Company sold an additional 1,348,601 shares of the Company s common stock in exchange for $2,176,700 of cash proceeds. And in the nine months ended September 30, 2017, the Company sold another 3,972,510 shares of the Company s common stock in exchange for $2,387,085 of cash proceeds. Of the $15.0 million available under the CSPA, the Company has received $4,748,017 as of March 31, 2017. The CSPA limits the number of shares that the Company can sell thereunder to 2,027,490 shares, which equals 19.99% of the Company s outstanding shares as of the date of the CSPA (such limit, the 19.99% exchange cap), unless either (i) the Company obtains stockholder approval to issue more than such 19.99% exchange cap or (ii) the average price paid for all shares of the Company s common stock issued under the CSPA is equal to or greater than $1.32 per share (the closing price on

the date the CSPA was signed), in either case in compliance with Nasdaq Listing Rule 5635(d). The Company held its 2017 Annual Meeting on May 8, 2017. At the 2017 Annual Meeting, the Company s stockholders voted on the approval, pursuant to Nasdaq Listing Rule 5635(d), of the issuance of an additional 3,555,514 shares of the Company s common stock under the CSPA, which when combined with the 2,444,486 shares that the Company has already sold pursuant to the CSPA, equals an aggregate of 6,000,000 shares.

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

On November 22, 2016, the Company entered into a Securities Purchase Agreement, or the 2016 Purchase Agreement, with certain institutional investors, pursuant to which the Company sold securities to such investors in a private placement transaction,

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which is referred to herein as the 2016 Private Placement. In the 2016 Private Placement, the Company sold an aggregate of 1,666,668 shares of its 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 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
Total	$	1,000,001	100%	$	322,777

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 company s balance sheet and the $225,944 of issuance cost was expensed and is in general and administrative expense on the company s statement of operations and comprehensive loss. Series B and C warrants of a net $97,167 (fair value less issuance costs) were classified in equity in the company s balance sheet.

In exchange for the extension of the maturity date of the outstanding 2015 Convertible Note, on, November 8, 2016, the Company s board of directors granted the lender a warrant to purchase 120,000 shares of the 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 the Company treating the debt as having been extinguished and replaced with new debt for accounting purposes due to meeting the 10% cash flow test. The Company calculated a loss on the extinguishment of debt of $108,000, or the equivalent to the fair value of the warrants granted, which is included in other expense in the Company s statements of operations and comprehensive loss. The warrants were valued on November 8, 2016 using the Black-Scholes-Merton model with the following assumptions: stock price of $0.91, exercise price of $0.01, term of 5.72 years expiring July 2022, volatility of 70.35%, dividend yield of 0%, and risk-free interest rate of 1.45%.

On June 28, 2017, the Company entered into a Common Stock Purchase Agreement with an existing private investor. Upon execution of the agreement the Company sold 100,000 shares of its common stock in exchange for $50,000 in cash proceeds.

On July 31, 2017, the Company entered into a Common Stock Purchase Agreement with an existing investor. Upon execution of the agreement the Company sold 3,243,243 shares of voting common stock in exchange for $3.0 million in cash proceeds.

On July 31, 2017, the Company completed the merger with Napo and changed it s name to Jaguar Health, Inc. The Company issued 2,282,445 shares of voting common stock and 43,173,288 shares of non-voting stock at the time the merger was consummated.

As of September 30, 2017 and 2016, the Company had reserved shares of common stock for issuance as follows:

	September 30, 2017	September 30, 2016
Options issued and outstanding	2,984,304	2,444,375
Options available for grant	513,385	166,833
RSUs issued and outstanding	5,893,849	20,789
Warrants issued and outstanding	6,656,333	715,539
Convertible notes	15,550,753	26,785
Total	31,598,624	3,374,321

Preferred Stock

The Company s third amended and restated certificate of incorporation authorizes the Company to issue 10,000,000 shares of preferred stock $0.0001 par value. No shares of preferred stock were issued or outstanding at September 30, 2017 or December 31, 2016.

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10. Stock Incentive Plans

2013 Equity Incentive Plan

Effective November 1, 2013, the Company s board of directors and sole stockholder adopted the Jaguar Health, Inc. 2013 Equity Incentive Plan (the 2013 Plan). The 2013 Plan allows the Company s board of directors to grant stock options, restricted stock awards and restricted stock unit awards to employees, officers, directors and consultants of the Company. As of December 31, 2013, the Company had reserved 300,000 shares of its common stock for issuance under the 2013 Plan. In April 2014, the board of directors amended the 2013 Plan to increase the shares reserved for issuance to 847,533 shares. Following the effective date of the IPO and after effectiveness of any grants under the 2013 Plan that were contingent on the IPO, no additional stock awards will be granted under the 2013 Plan. Outstanding grants continue to be exercisable, however any unissued shares under the plan and any forfeitures of outstanding options do not rollover to the 2014 Stock Incentive Plan. There were 565,377 option shares outstanding at September 30, 2017.

2014 Stock Incentive Plan

Effective May 12, 2015, the Company adopted the Jaguar Health, Inc. 2014 Stock Incentive Plan (2014 Plan). The 2014 Plan provides for the grant of options, restricted stock and restricted stock units to eligible employees, directors and consultants to purchase the Company s common stock. The Company reserved 333,333 shares of common stock for issuance pursuant to the 2014 Plan. On January 1, 2017 and 2016, the Company added 280,142 and 162,498 shares to the option pool in accordance with the 2014 Plan that provides for automatic share increases on the first day of each fiscal year in the amount of 2% of the outstanding number of shares of the Company s common stock on last day of the preceding calendar year. The 2014 Plan replaces the 2013 Plan except that all outstanding options under the 2013 Plan remain outstanding until exercised, cancelled or until they expire.

In July 2015, the Company amended the 2014 Plan reserving an additional 550,000 shares under the plan contingent upon approval by the Company s stockholders at the June 2016 annual stockholders meeting. In June 2016, the Company amended the 2014 Plan once again, modifying the increase from 550,000 shares to 1,550,000 shares, which was approved at the 2016 annual stockholders meeting. In July 2017, the Company amended the 2014 Plan reserving an additional 6,500,188 shares under the plan, which was approved at the special stockholders meeting on July 27, 2017.

Stock Options and Restricted Stock Units (RSUs)

The following table summarizes incentive plan activity for the nine months ended September 30, 2017:

	Shares Available for Grant	Stock Options Outstanding	RSUs Outstanding	Weighted Average Stock Option Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value

Combined Incentive Plan Balance December 31, 2016	39,988	2,571,220	20,789	$ 2.52	8.77	$
Additional shares authorized	6,780,330					
Options granted	(78,000)	78,000		0.70		
Options granted in the Napo Merger	(543,301)	543,301		2.07		
RSUs granted in the Napo Merger	(5,893,849)		5,893,849			
Options cancelled	208,217	(208,217)		1.54		
RSUs vested and released			(20,789)			
Combined Incentive Plan Balance September 30, 2017	513,385	2,984,304	5,893,849	$ 2.46	6.76	$
Options vested and exercisable September 30, 2017		1,957,629		$ 2.86	5.67	$
Options vested and expected to vest September 30, 2017		2,707,075		$ 2.47	6.56	$

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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.

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				

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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)
Net loss per share attributable to common stock - diluted	$ 0.07	$ (0.30)	$ (0.06)	$ (1.07)

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

Termination of Elanco Agreement

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.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of financial condition and results of operations should be read together with the condensed consolidated financial statements and the related notes included in Item 1 of Part I of this Quarterly Report on Form 10-Q, and with our audited financial statements and the related notes included in our Annual Report on Form 10-K for the year ended December 31, 2016.

The discussion and analysis below includes certain forward-looking statements related to our research and development and commercialization of our products in the U.S., our future financial condition and results of operations and potential for profitability, the sufficiency of our cash resources, our ability to obtain additional equity or debt financing, if needed, possible partnering or other strategic opportunities for the development of our products, as well as other statements related to the progress and timing of product development, present or future licensing, collaborative or financing arrangements or that otherwise relate to future periods, which are all forward-looking statements as defined by the Private Securities Litigation Reform Act of 1995. These statements represent, among other things, the expectations, beliefs, plans and objectives of management and/or assumptions underlying or judgments concerning the future financial performance and other matters discussed in this document. The words may, will, should, plan, believe, estimate, intend, anticipate, project, and expect and similar expressions are intended to connote forward-looking statements. All forward-looking statements involve certain risks, uncertainties and other factors described in our Annual Report on Form 10-K, that could cause our actual commercialization efforts, financial condition and results of operations, and business prospects and opportunities to differ materially from these expressed in, or implied by, those forward-looking statements. We caution investors not to place significant reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless another date is indicated), and we undertake no obligation to update or revise forward-looking statements.

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.

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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.

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 January2017 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 at 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 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.

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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.

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 Genetech 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. 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

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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.

Napo Prescription Drug Product Candidates

Product Candidates	Indication	Completed Milestones	Current Phase of Development	Anticipated Near-Term Milestones
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	• Animal and human studies in secretory	Pre IND	• CMC development for SB-300

including cholera	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

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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 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)

(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-pro

(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-idUSKCN0QO 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 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

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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.

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.

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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 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

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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 statements of operations and comprehensive loss, while the actual expense for which we arereimbursed 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 repors 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.

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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 ourbalance 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.

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.

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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.

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:

	Nine Months Ended September 30,			
	2017	**2016**	**Variance**	**Variance %**
Product revenue	$ 581,654	$ 112,646	$ 469,008	416.4%
Collaboration revenue	2,237,491		2,237,491	N/A
Total revenue	2,819,145	112,646	2,706,499	2402.7%
Operating Expenses				
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
Total operating expenses	16,385,089	10,384,584	6,000,505	57.8%
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%

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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.

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.

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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 %
R&D:				
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)%

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.

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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,			
	2017	**2016**	**Variance**	**Variance %**
S&M:				
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%
Total	$ 943,908	$ 355,345	$ 588,563	165.6%

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 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 Neonorm 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 Neonorm 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 %**
G&A:				
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%
Total	$ 8,512,195	$ 4,319,856	$ 4,192,339	97.0%

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,

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$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 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.

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,			
	2017	2016	Variance	Variance %
Product revenue	$ 445,665	$ 50,357	$ 395,308	785.0%
Collaboration revenue	654,549		654,549	N/A

Total revenue	1,100,214	50,357	1,049,857	2084.8%
Operating Expenses				
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
Total operating expenses	8,440,303	3,229,180	5,211,123	161.4%
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
Net income (loss) and comprehensive income (loss)	$ 4,759,844	$ (3,415,490)	$ 8,175,334	239.4%

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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.

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.

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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:

	Three Months Ended September 30,			
	2017	2016	Variance	Variance %
R&D:				
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)%
Total	$ 851,608	$ 1,967,128	$ (1,115,520)	(56.7)%

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 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.

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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:

	Three Months Ended September 30,			
	2017	2016	Variance	Variance %
S&M:				
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%
Total	$ 663,765	$ 136,882	$ 526,883	384.9%

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 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,			
	2017	2016	Variance	Variance %
G&A:				
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%
Total	$ 3,070,702	$ 1,115,312	$ 1,955,390	175.3%

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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 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

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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 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.

- 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

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(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 promisorry note to a lendor 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.

- 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

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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:

	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
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)

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

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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.

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.

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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.

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 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 an 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 promisorry note, or Note, to a lendor 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.

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 lendor 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.

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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 derviatives 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 temes 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 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

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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

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
	$ 100,765	$ 230,655	$ 426,222	$ 760,673

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,

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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 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.

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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 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

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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 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

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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 ourbalance 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, 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 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.

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 that are evaluated to be classified as liabilities are fair valued upon issuance and are

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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.

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 reports 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.

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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 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. 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 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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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures

We maintain disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Exchange Act that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal control over financial reporting.

There was no change in our internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

On July 20, 2017, a putative class action complaint was filed in the United States District Court, Northern District of California, Civil Action No. 3:17-cv-04102, by Tony Plant on behalf of pre-Merger shareholders of Jaguar who held shares on June 30, 2017 and were entitled to vote at the 2017 Special Shareholders Meeting, against us and certain individuals who were directors as of the date of the vote, in a matter captioned Tony Plant v. Jaguar Animal Health, Inc., et al. The plaintiff attempts to assert claims arising under Section 14(a) and Section 20(a) of the Exchange Act and Rule 14a-9, 17 C.F.R. § 240.14a-9, promulgated thereunder by the SEC. The plaintiff alleges that material omissions and misstatements were contained in the Joint Proxy Statement/Prospectus on Form S-4 (File No. 333-217364) declared effective by the SEC on July 6, 2017 related to the solicitation of votes from shareholders to approve the Merger and certain transaction related thereto. We believe the claims are without merit. While no monetary damages have been quantified, we intend to vigorously contest this complaint.

The plaintiff has not yet served the complaint and summons on any of the defendants. If plaintiff elected to proceed with the litigation and made service on the defendants, the defendants would move to dismiss the complaint for failure to state a claim on which relief may be granted.

Item 1A. Risk Factors

We wish to caution you that there are risks and uncertainties that could affect our business. A description of the risk factors associated with our business that you should consider when evaluating our business is included under Risk Factors contained in Item 1A. of our Annual Report on Form 10-K/A for the year ended December 31, 2016. In addition to those factors and to other information in this Form 10-Q, the following updates to the risk factors should be considered carefully when evaluating the Company or our business.

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Risks Related to Our Business

We have a limited operating history, expect to incur further losses as we grow and may be unable to achieve or sustain profitability. Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

Since formation in June 2013, our operations have been primarily limited to the research and development of our animal prescription drug product candidate, Canalevia, to treat 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 consummation of the Merger on July 31, 2017, our operations have also been heavily focused on research, development and the ongoing commercialization of our lead prescription drug product candidate, Mytesi, which is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. As a result, we have limited meaningful historical operations upon which to evaluate our business and prospects and have not yet demonstrated an ability to broadly commercialize any of our animal health products, obtain any required marketing approval for any of our animal prescription drug product candidates or successfully overcome the risks and uncertainties frequently encountered by companies in emerging fields such as the animal health industry or the gastrointestinal health industry in general. We also have not generated any material revenue to date, and expect to continue to incur significant research and development and other expenses. Our net loss and comprehensive loss for the year ended December 31, 2016 was $14.7 million. As of December 31, 2016, we had total stockholders deficit of $2.5 million. We expect to continue to incur losses for the foreseeable future, which will increase significantly from historical levels as we expand our product development activities, seek necessary approvals for our human and veterinary drug product candidates, conduct species-specific formulation studies for our non-prescription products and begin commercialization activities. Even if we succeed in developing and broadly commercializing one or more of our products or product candidates, we expect to continue to incur losses for the foreseeable future, and we may never become profitable. If we fail to achieve or maintain profitability, then we may be unable to continue our operations at planned levels and be forced to reduce or cease operations.

As more fully discussed in Note 1 to our financial statements, we believe there is substantial doubt about our ability to continue as a going concern as we do not currently have sufficient cash resources to fund our operations through February 15, 2018, or one year from the filing date of our Form 10-K. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we are unable to continue as a viable entity, our stockholders may lose their entire investment.

We have never generated any material revenue from operations and may not generate any material revenue from our operations in the foreseeable future.

We are 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. Since inception in June 2013, we have not generated any material revenue from operations. There is no guarantee that our recent commercial launch of Mytesi for symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS or our ongoing commercialization efforts for Neonorm Calf for preweaned dairy calves in the United States and Neonorm Foal for newborn horses in the United States will be successful or that we will be able to sell any products in the future. Further, in order to commercialize our prescription drug product candidates, we must receive regulatory approval from the FDA in the United States and other regulatory agencies in various jurisdictions. Other than Mytesi, we have not yet received any regulatory approvals for our prescription drug product candidates. In addition, certain of our non-prescription products, such as Neonorm Calf, may be subject to regulatory approval outside the United States prior to commercialization in other countries. Accordingly, until and unless we receive any necessary regulatory approvals, we cannot market or sell our products in many regions. Moreover, even if we receive the necessary approvals, we may not be successful in generating revenue from sales of our products as we do not have any meaningful experience marketing or distributing our products. Accordingly, we may never generate any material revenue from our operations.

We expect to incur significant additional costs as we continue commercialization efforts for current prescription drug candidates, Neonorm, or other product candidates, and undertake the clinical trials necessary to obtain any necessary regulatory approvals, which will increase our losses.

We commenced sales of Neonorm for preweaned dairy calves in the United States under the brand name Neonorm Calf at the end of 2014, and Napo commenced sales of Mytesi for adults with HIV/AIDS on antiretroviral therapy in February 2017. We will need to continue to invest in developing our internal and third-party sales and distribution network and outreach efforts to key opinion leaders in the gastrointestinal health industry, including physicians and veterinarians, as applicable. We will also need to conduct clinical trials for Canalevia in order to obtain necessary initial regulatory approvals and to subsequently broaden Mytesi to additional

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indications and Canalevia to additional indications and additional species. We will also need to conduct species-specific testing with Neonorm to expand to additional animal populations.

We are actively identifying additional products for development and commercialization, and will continue to expend substantial resources for the foreseeable future to develop Mytesi, Equilevia, Canalevia and Neonorm and develop products from Napo s library of over 2,300 medicinal plants. These expenditures will include costs associated with:

- identifying additional potential prescription drug product candidates and non-prescription products;
- formulation studies;
- conducting pilot, pivotal and toxicology studies;
- completing other research and development activities;
- payments to technology licensors;
- maintaining our intellectual property;
- obtaining necessary regulatory approvals;
- establishing commercial supply capabilities; and
- sales, marketing and distribution of our commercialized products.

We also may incur unanticipated costs in connection with developing and commercializing our products. Because the outcome of our development activities and commercialization efforts is inherently uncertain, the actual amounts necessary to successfully complete the development and commercialization of our current or future products and product candidates may be greater than we anticipate.

Because we anticipate incurring significant costs for the foreseeable future, if we are not successful in broadly commercializing any of our current or future products or product candidates or raising additional funding to pursue our research and development efforts, we may never realize the benefit of our development efforts and our business may be harmed.

We will need to raise substantial additional capital in the future in the event that we conduct clinical trials for new indications and we may be unable to raise such funds when needed and on acceptable terms, which would force us to delay, limit, reduce or terminate one or more of our product development programs.

We are forecasting continued losses and negative cash flows as we continue to fund our operating and marketing activities and research and development programs, and we will not have sufficient cash on hand to fund our operating plan through February 2018 and to complete the development of all the current products in our pipeline, or any additional products we may identify. 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. Other than the loan and security agreement with Hercules (which provided for an initial loan commitment of $6.0 million), the common stock purchase agreement (the CSPA), with Aspire Capital Fund, LLC (Aspire Capital) (which committed Aspire Capital to purchase up to an aggregate of $15.0 million of our shares of common stock over the term of the CSPA), Napo s Amended and Restated Note Purchase Agreement (the Kingdon NPA) with Kingdon Associates, M. Kingdon Offshore Master Fund L.P., Kingdon Family Partnership, L.P., and Kingdon Credit Master Fund L.P. (pursuant to which we issued $10.0 million aggregate principal amount of convertible notes in exchange for a cash payment of $8.0 million), and convertible note purchase agreements with three purchasers (pursuant to which we issued approximately $3.5 million aggregate principal amount of convertible notes in exchange for a cash payment of $2.75 million), we have no current agreements or arrangements with respect to any such financings or collaborations, and any such financings or collaborations may result in dilution to our stockholders, the imposition of debt covenants and repayment obligations or other restrictions that may harm our business or the value of our common stock. We may also seek from time to time to raise additional capital based upon favorable market conditions or strategic considerations such as potential acquisitions or potential license arrangements.

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Our future capital requirements depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching and developing our current and future prescription drug product candidates and non-prescription products;

- the timing of, and the costs involved in, obtaining any regulatory approvals for our current and any future products;

- the number and characteristics of the products we pursue;

- the cost of manufacturing our current and future products and any products we successfully commercialize;

- the cost of commercialization activities for Mytesi, Neonorm, Equilevia and Canalevia, if approved, including sales, marketing and distribution costs;

- the expenses needed to attract and retain skilled personnel;

- the costs associated with being a public company;

- our ability to establish and maintain strategic collaborations, distribution or other arrangements and the financial terms of such agreements; and

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing possible patent claims, including litigation costs and the outcome of any such litigation.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate one or more of our product development programs or future commercialization efforts.

We are substantially dependent on the success of our current lead prescription drug product candidates, Mytesi and Canalevia, and our non-prescription products, Equilevia and Neonorm, and cannot be certain that necessary approvals will be received for planned Mytesi follow-on indications or Canalevia or that these product candidates will be successfully commercialized, either by us or any of our partners.

Other than Mytesi, we currently do not have regulatory approval for any of our prescription drug product candidates, including Canalevia. Our current efforts are primarily focused on the ongoing commercialization of Mytesi, Neonorm Calf and Neonorm Foal in the United States, and development efforts related to Mytesi, Equilevia, and Canalevia, and on the development of formulations of Neonorm for additional species. With regard to Mytesi, we are focused on the commercial launch of the product in the United States as well as on development efforts related to a follow-on indication for Mytesi in CID, an important supportive care indication for patients undergoing primary or adjuvant chemotherapy for cancer treatment. Mytesi is also in development for rare disease indications for infants and children with congenital diarrheal disorders and short bowel syndrome; for IBS (Mytesi has demonstrated benefit to IBS-D patients in published Phase 2 studies); for supportive care for IBD; and as a second-generation anti-secretory agent for use in cholera patients. Mytesi has received orphan-drug designation for SBS. Accordingly, our near term prospects, including our ability to generate material product revenue, obtain any new financing if needed to fund our business and operations or enter into potential strategic transactions, will depend heavily on the success of Mytesi, Equilevia and Neonorm, as well as on Canalevia, if Canalevia is approved.

Substantial time and capital resources have been previously devoted by third parties in the development of crofelemer, the active pharmaceutical ingredient, or API, in Mytesi and Canalevia, and the development of the botanical extract used in Equilevia and Neonorm. Both crofelemer and the botanical extract used in Equilevia and Neonorm were originally developed at Shaman Pharmaceuticals, Inc. (Shaman), by certain members of our management team, including Lisa A. Conte, our chief executive officer and president, and Steven R. King, Ph.D., our executive vice president of sustainable supply, ethnobotanical research and intellectual property and secretary. Shaman spent significant development resources before voluntarily filing for bankruptcy in 2001 pursuant to Chapter 11 of the U.S. Bankruptcy Code. The rights to crofelemer and the botanical extract used in Equilevia and Neonorm, as well as other intellectual property rights, were subsequently acquired by Napo from Shaman in 2001 pursuant to a court approved sale of assets. Ms. Conte founded Napo in 2001 and was the current interim chief executive officer of Napo and a member of Napo s board of directors prior to the Merger. While at Napo, certain members of our management team, including Ms. Conte and Dr. King, continued the development of crofelemer. In 2005, Napo entered into license agreements with Glenmark and Luye Pharma Group Limited for

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rights to various human indications of crofelemer in certain territories as defined in the respective license agreements with these licensees. Subsequently, after expending significant sums developing crofelemer, including trial design and on-going patient enrollment in the final pivotal Phase 3 trial for crofelemer for non-infectious diarrhea in adults with HIV/AIDS on antiretroviral therapy, in late 2008, Napo entered into a collaboration agreement with Salix Pharmaceuticals, Inc., or Salix, for development and commercialization rights to certain indications worldwide and certain rights in North America, Europe, and Japan, to crofelemer for human use. In January 2014, Jaguar entered into the Napo License Agreement pursuant to which Jaguar acquired an exclusive worldwide license to Napo s intellectual property rights and technology, including crofelemer and the botanical extract used in Equilevia and Neonorm, for all veterinary treatment uses and indications for all species of animals. In February 2014, most of the executive officers of Napo, and substantially all Napo s employees, became Jaguar s employees. Following the Merger in July 2017, Napo became Jaguar s wholly-owned subsidiary. If we are not successful in the development and commercialization of Mytesi, Neonorm, Equilevia and Canalevia, our business and our prospects will be harmed.

The successful development and commercialization of Mytesi, Equilevia and Neonorm, and, if approved, Canalevia will depend on a number of factors, including the following:

- the successful completion of the pivotal trials and toxicology studies for Canalevia, which may take significantly longer than we currently anticipate and will depend, in part, upon the satisfactory performance of third-party contractors;

- our ability to demonstrate to the satisfaction of the FDA and any other regulatory bodies, the safety and efficacy of Canalevia;

- our ability and that of our contract manufacturers to manufacture supplies of Mytesi, Neonorm, Equilevia and Canalevia and to develop, validate and maintain viable commercial manufacturing processes that are compliant with current good manufacturing practices, or cGMP, if required;

- the success of Neonorm field studies and acceptance of their results by dairy producers;

- our ability to successfully launch Mytesi and Neonorm, whether alone or in collaboration with others;

- our ability to successfully launch Canalevia, assuming approval is obtained, and Equilevia, whether alone or in collaboration with others;

- the availability, perceived advantages, relative cost, relative safety and relative efficacy of our prescription drug product candidates and non-prescription products compared to alternative and competing treatments;

- the acceptance of our prescription drug product candidates and non-prescription products as safe and effective by physicians, veterinarians, patients, animal owners and the human and animal health community, as applicable;

- our ability to achieve and maintain compliance with all regulatory requirements applicable to our business; and

- our ability to obtain and enforce our intellectual property rights and obtain marketing exclusivity for our prescription drug product candidates and non-prescription products, and avoid or prevail in any third-party patent interference, patent infringement claims or administrative patent proceedings initiated by third parties or the U.S. Patent and Trademark Office (USPTO).

Many of these factors are beyond our control. Accordingly, we may not be successful in developing or commercializing Mytesi, Neonorm, Equilevia, Canalevia or any of our other potential products. If we are unsuccessful or are significantly delayed in developing and commercializing Mytesi, Neonorm, Equilevia, Canalevia or any of our other potential products, our business and prospects will be harmed and you may lose all or a portion of the value of your investment in our common stock.

If we are not successful in identifying, licensing, developing and commercializing additional product candidates and products, our ability to expand our business and achieve our strategic objectives could be impaired.

Although a substantial amount of our efforts is focused on the commercial performance of Mytesi, Equilevia and Neonorm and the continued development and potential approval of Canalevia, a key element of our strategy is to identify, develop and commercialize a portfolio of products to serve the gastrointestinal health market. Most of our potential products are based on our knowledge of medicinal plants. Our current focus is primarily on product candidates whose active pharmaceutical ingredient or

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botanical extract has been successfully commercialized or demonstrated to be safe and effective in human or animal trials. In some instances, we may be unable to further develop these potential products because of perceived regulatory and commercial risks. Even if we successfully identify potential products, we may still fail to yield products for development and commercialization for many reasons, including the following:

- competitors may develop alternatives that render our potential products obsolete;

- an outside party may develop a cure for any disease state that is the target indication for any of our planned or approved drug products;

- potential products we seek to develop may be covered by third-party patents or other exclusive rights;

- a potential product may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;

- a potential product may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and

- a potential product may not be accepted as safe and effective by physicians, veterinarians, patients, animal owners, key opinion leaders and other decision-makers in the gastrointestinal health market, as applicable.

While we are developing specific formulations, including flavors, methods of administration, new patents and other strategies with respect to our current potential products, we may be unable to prevent competitors from developing substantially similar products and bringing those products to market earlier than we can. If such competing products achieve regulatory approval and commercialization prior to our potential products, our competitive position may be impaired. If we fail to develop and successfully commercialize other potential products, our business and future prospects may be harmed and we will be more vulnerable to any problems that we encounter in developing and commercializing our current potential products.

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Mytesi faces significant competition from other pharmaceutical companies, both for its currently approved indication and for planned follow-on indications, and our operating results will suffer if we fail to compete effectively.

The development and commercialization of products for human gastrointestinal health is highly competitive and our success depends on our ability to compete effectively with other products in the market. During the ongoing commercialization of Mytesi for its currently approved indication, and during the future commercialization of Mytesi for any planned follow-on indications, if such follow-on indications receive regulatory approval, we expect to compete with major pharmaceutical and biotechnology companies that operate in the gastrointestinal space, such as Sucampo AG, Takeda Pharmaceuticals, Allergan, Inc., Ironwood Pharmaceuticals, Inc., Synergy Pharmaceuticals Inc., Heron Therapeutics, Inc., Sebela Pharmaceuticals, Inc. and Salix Pharmaceuticals.

Many of our competitors and potential competitors in the human gastrointestinal space have substantially more financial, technical and human resources than we do. Many also have more experience in the development, manufacture, regulation and worldwide commercialization of human gastrointestinal health products.

For these reasons, we cannot be certain that we and Mytesi can compete effectively.

Our animal health products face significant competition from other pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The development and commercialization of animal health products is highly competitive and our success depends on our ability to compete effectively with other products in the market. We expect to compete with the animal health divisions of major pharmaceutical and biotechnology companies such as Merck Animal Health, Merial Inc., Elanco Animal Health, Bayer Animal Health GmbH, Novartis Animal Health Inc. and Boehringer Ingelheim Animal Health, as well as specialty animal health medicines companies such as Zoetis Inc., Phibro Animal Health Corporation and, in Europe, Virbac S.A., Vétoquinol S.A., Ceva Animal Health S.A. and Dechra Pharmaceuticals PLC. We are also aware of several early-stage companies that are developing products for use in the animal health market, including Aratana Therapeutics, Inc., Kindred Biosciences, Inc., Parnell Pharmaceuticals Holdings Ltd, Nexvet Biopharma and ImmuCell Corporation. We also compete with academic institutions, governmental agencies and private organizations that are conducting research in the field of animal health products.

Although there are currently no FDA-approved anti-secretory products to treat chemotherapy-induced diarrhea (CID) in dogs, we anticipate that Canalevia, if approved, may face competition from various products, including products approved for use in humans that are used extra-label in animals. Extra-label use is the use of an approved drug outside of its cleared or approved indications in the animal context. All of our potential products could also face competition from new products in development. These and other potential competing products may benefit from greater brand recognition and brand loyalty than our products and product candidates may achieve.

Many of our competitors and potential competitors have substantially more financial, technical and human resources than we do. Many also have more experience in the development, manufacture, regulation and worldwide commercialization of animal health products, including animal prescription drugs and non-prescription products.

For these reasons, we cannot be certain that we and our products can compete effectively.

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We may be unable to obtain, or obtain on a timely basis, regulatory approval for our existing or future human or animal prescription drug product candidates under applicable regulatory requirements, which would harm our operating results.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of human and animal health products are subject to extensive regulation. We are typically not permitted to market our prescription drug product candidates in the United States until we receive approval of the product from the FDA through the filing of an NDA or NADA, as applicable. To gain approval to market a prescription drug, we must provide the FDA with safety and efficacy data from pivotal trials that adequately demonstrate that our prescription drug product candidates are safe and effective for the intended indications. Likewise, to gain approval to market an animal prescription drug for a particular species, we must provide the FDA with safety and efficacy data from pivotal trials that adequately demonstrate that our prescription drug product candidates are safe and effective in the target species (*e.g.* dogs, cats or horses) for the intended indications. In addition, we must provide manufacturing data evidencing that we can produce our product candidates in accordance with cGMP. For the FDA, we must also provide data from toxicology studies, also called target animal safety studies, and in some cases environmental impact data. In addition to our internal activities, we will partially rely on contract research organizations (CROs), and other third parties to conduct our toxicology studies and for certain other product development activities. The results of toxicology studies, other initial development activities, and/or any previous studies in humans or animals conducted by us or third parties may not be predictive of future results of pivotal trials or other future studies, and failure can occur at any time during the conduct of pivotal trials and other development activities by us or our CROs. Our pivotal trials may fail to show the desired safety or efficacy of our prescription drug product candidates despite promising initial data or the results in previous human or animal studies conducted by others. Success of a prescription drug product candidate in prior animal studies, or in the treatment of humans, does not ensure success in subsequent studies. Clinical trials in humans and pivotal trials in animals sometimes fail to show a benefit even for drugs that are effective because of statistical limitations in the design of the trials or other statistical anomalies. Therefore, even if our studies and other development activities are completed as planned, the results may not be sufficient to obtain a required regulatory approval for a product candidate.

Regulatory authorities can delay, limit or deny approval of any of our prescription drug product candidates for many reasons, including:

- if they disagree with our interpretation of data from our pivotal studies or other development efforts;
- if we are unable to demonstrate to their satisfaction that our product candidate is safe and effective for the target indication and, if applicable, in the target species;
- if they require additional studies or change their approval policies or regulations;
- if they do not approve of the formulation, labeling or the specifications of our current and future product candidates; and
- if they fail to approve the manufacturing processes of our third-party contract manufacturers.

Further, even if we receive a required approval, such approval may be for a more limited indication than we originally requested, and the regulatory authority may not approve the labeling that we believe is necessary or desirable for successful commercialization.

Any delay or failure in obtaining any necessary regulatory approval for the intended indications of our human or animal product candidates would delay or prevent commercialization of such product candidates and would harm our business and our operating results.

The results of our earlier studies of Mytesi and Neonorm may not be predictive of the results in any future clinical trials and species-specific formulation studies, respectively, and we may not be successful in our efforts to develop or commercialize line extensions of Mytesi and Neonorm.

Our human and animal product pipeline includes a number of potential indications of Mytesi, our lead prescription product, and a number of species-specific formulations of Neonorm, our commercially available non-prescription product. The results of our studies and other development activities and of any previous studies in humans or animals conducted by us or third parties may not be predictive of future results of these clinical studies and formulation studies, respectively. Failure can occur at any time during the conduct of these trials and other development activities. Even if our formulation/clinical studies and other development activities are completed as planned, the results may not be sufficient to pursue a particular line extension for Mytesi or Neonorm, respectively. Further, even if we obtain promising results from our clinical trials or species-specific formulation studies, as applicable, we may not

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successfully commercialize any line extension. Because line extensions are developed for a particular market, we may not be able to leverage our experience from the commercial launch of Mytesi, Neonorm Calf and Neonorm Foal in new markets. If we are not successful in developing and successfully commercializing these line extension products, we may not be able to grow our revenue and our business may be harmed.

Development of prescription drug products is inherently expensive, time-consuming and uncertain, and any delay or discontinuance of our current or future pivotal trials would harm our business and prospects.

Development of prescription drug products for human and animal gastrointestinal health remains an inherently lengthy, expensive and uncertain process, and our development activities may not be successful. We do not know whether our current or planned pivotal trials for any of our product candidates will begin or conclude on time, and they may be delayed or discontinued for a variety of reasons, including if we are unable to:

- address any safety concerns that arise during the course of the studies;
- complete the studies due to deviations from the study protocols or the occurrence of adverse events;
- add new study sites;
- address any conflicts with new or existing laws or regulations; or
- reach agreement on acceptable terms with study sites, which can be subject to extensive negotiation and may vary significantly among different sites.

Further, we may not be successful in developing new indications for Mytesi and/or species-specific formulations for Neonorm, and Neonorm may be subject to the same regulatory regime as prescription drug products in jurisdictions outside the United States. Any delays in completing our development efforts will increase our costs, delay our development efforts and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition and prospects. In addition, factors that may cause a delay in the commencement or completion of our development efforts may also ultimately lead to the denial of regulatory approval of our product candidates which, as described above, would harm our business and prospects.

We will partially rely on third parties to conduct our development activities. If these third parties do not successfully carry out their contractual duties, we may be unable to obtain regulatory approvals or commercialize our current or future human or animal product candidates on a timely basis, or at all.

We will partially rely upon CROs to conduct our toxicology studies and for other development activities. We intend to rely on CROs to conduct one or more of our planned pivotal trials. These CROs are not our employees, and except for contractual duties and obligations, we have limited ability to control the amount or timing of resources that they devote to our programs or manage the risks associated with their activities on our behalf. We are responsible for ensuring that each of our studies is conducted in accordance with the development plans and trial protocols presented to regulatory authorities. Any deviations by our CROs may adversely affect our ability to obtain regulatory approvals, subject us to penalties or harm our credibility with regulators. The FDA and foreign regulatory authorities also require us and our CROs to comply with regulations and standards, commonly referred to as good clinical practices (GCPs), or good laboratory practices (GLPs), for conducting, monitoring, recording and reporting the results of our studies to ensure that the data and results are scientifically valid and accurate.

Agreements with CROs generally allow the CROs to terminate in certain circumstances with little or no advance notice. These agreements generally will require our CROs to reasonably cooperate with us at our expense for an orderly winding down of the CROs services under the agreements. If the CROs conducting our studies do not comply with their contractual duties or obligations, or if they experience work stoppages, do not meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised, we may need to secure new arrangements with alternative CROs, which could be difficult and costly. In such event, our studies also may need to be extended, delayed or terminated as a result, or may need to be repeated. If any of the foregoing were to occur, regulatory approval, if required, and commercialization of our product candidates may be delayed and we may be required to expend substantial additional resources.

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Even if we obtain regulatory approval for planned follow-on indications of Mytesi, or for Canalevia or our other product candidates, they may never achieve market acceptance. Further, even if we are successful in the ongoing commercialization of Mytesi and Neonorm, we may not achieve commercial success.

If we obtain necessary regulatory approvals for planned follow-on indications of Mytesi or for Canalevia or our other product candidates, such products may still not achieve market acceptance and may not be commercially successful. Market acceptance of Mytesi, Canalevia, Neonorm and any of our other products depends on a number of factors, including:

- the safety of our products as demonstrated in our target animal studies;
- the indications for which our products are approved or marketed;
- the potential and perceived advantages over alternative treatments or products, including generic medicines and competing products currently prescribed by physicians or veterinarians, as applicable, and, in the case of animal products, products approved for use in humans that are used extra-label in animals;
- the acceptance by physicians, veterinarians, companion animal owners and production animal owners, including in the dairy industry, as applicable, of our products as safe and effective;
- the cost in relation to alternative treatments and willingness on the part of physicians, veterinarians, patients and animal owners, as applicable, to pay for our products;
- the prevalence and severity of any adverse side effects of our products;
- the relative convenience and ease of administration of our products; and
- the effectiveness of our sales, marketing and distribution efforts.

Any failure by Mytesi, Canalevia, Equilevia, Neonorm or any of our other products to achieve market acceptance or commercial success would harm our financial condition and results of operations.

The dairy industry is subject to conditions beyond our control and the occurrence of any such conditions may harm our business and impact the demand for our products.

The demand for production animal health products, such as Neonorm Calf, is heavily dependent on factors that affect the dairy market that are beyond our control, including the following, any of which may harm our business:

- cost containment measures within the dairy industry, in response to international, national and local general economic conditions, which may affect the market adoption of our products;

- state and federal government policies, including government-funded programs or subsidies whose discontinuance or modification could erode the demand for our products;

- a decline in demand for dairy products due to changes in consumer diets away from dairy products, which could adversely affect the demand for production animal health products;

- adverse weather conditions and natural disasters, such as floods, droughts, and pestilence, which can lower dairy yields; and

- disease or other conditions beyond our control.

Human and animal gastrointestinal health products are subject to unanticipated post-approval safety or efficacy concerns, which may harm our business and reputation.

The success of our commercialization efforts will depend upon the perceived safety and effectiveness of human and animal gastrointestinal health products, in general, and of our products, in particular. Unanticipated safety or efficacy concerns can

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subsequently arise with respect to approved prescription drug products, such as Mytesi, or non-prescription products, such as Neonorm, which may result in product recalls or withdrawals or suspension of sales, as well as product liability and other claims. Any safety or efficacy concerns, or recalls, withdrawals or suspensions of sales of our products could harm our reputation and business, regardless of whether such concerns or actions are justified.

Future federal and state legislation may result in increased exposure to product liability claims, which could result in substantial losses.

Under current federal and state laws, companion and production animals are generally considered to be the personal property of their owners and, as such, the owners recovery for product liability claims involving their companion and production animals may be limited to the replacement value of the animal. Companion animal owners and their advocates, however, have filed lawsuits from time to time seeking non-economic damages such as pain and suffering and emotional distress for harm to their companion animals based on theories applicable to personal injuries to humans. If new legislation is passed to allow recovery for such non-economic damages, or if precedents are set allowing for such recovery, we could be exposed to increased product liability claims that could result in substantial losses to us if successful. In addition, some horses can be worth millions of dollars or more, and product liability for horses may be very high. While we currently have product liability insurance, such insurance may not be sufficient to cover any future product liability claims against us.

If we fail to retain current members of our senior management, or to identify, attract, integrate and retain additional key personnel, our business will be harmed.

Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We are highly dependent upon our senior management, particularly Lisa A. Conte, our president and Chief Executive Officer. The loss of services of any of our key personnel would cause a disruption in our ability to develop our current or future product pipeline and commercialize our products and product candidates. Although we have offer letters with these key members of senior management, such agreements do not prohibit them from resigning at any time. For example, the resignation of our former Chief Financial Officer, Charles O. Thompson, in September 2014, and the mutually agreed departure of our former Chief Veterinary Officer, Serge Martinod, D.V.M., Ph.D. in February 2015, caused us to incur additional expenses and expend resources to ensure a smooth transition with their respective successors, which diverted management attention away from executing our operational plan during this period. We currently do not maintain key man life insurance on any of our senior management team. The loss of Ms. Conte or other members of our current senior management could adversely affect the timing or outcomes of our current and planned studies, as well as the prospects for commercializing our products.

In addition, competition for qualified personnel in the human and animal gastrointestinal health fields is intense, because there are a limited number of individuals who are trained or experienced in the field. Further, our headquarters are located in San Francisco, California, and the dairy and agriculture industries are not prevalent in urban areas such as San Francisco. We will need to hire additional personnel as we expand our product development and commercialization activities. Even if we are successful in hiring qualified individuals, as we are a growing organization, we do not have a track record for integrating and retaining individuals. If we are not successful in identifying, attracting, integrating or retaining qualified personnel on acceptable terms, or at all, our business will be harmed.

We are dependent on two suppliers for the raw material used to produce the active pharmaceutical ingredient in Mytesi and Canalevia and the botanical extract in Neonorm and Equilevia. The termination of either of these contracts would result in a disruption to product development and our business will be harmed.

The raw material used to manufacture Mytesi, Canalevia, Neonorm and Equilevia is crude plant latex (CPL), derived from the *Croton lechleri* tree, which is found in countries in South America, principally Peru. The ability of our contract suppliers to harvest CPL is governed by the terms of their respective agreements with local government authorities. Although CPL is available from multiple suppliers, we only have contracts with two suppliers to obtain CPL and arrange the shipment to our contract manufacturer. Accordingly, if our contract suppliers do not or are unable to comply with the terms of our respective agreements, and we are not able to negotiate new agreements with alternate suppliers on terms that we deem commercially reasonable, it may harm our business and prospects. The countries from which we obtain CPL could change their laws and regulations regarding the export of the natural products or impose or increase taxes or duties payable by exporters of such products. Restrictions could be imposed on the harvesting of the natural products or additional requirements could be implemented for the replanting and regeneration of the raw material. Such events could have a significant impact on our cost and ability to produce Mytesi, Canalevia, Neonorm, Equilevia and anticipated line extensions.

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We are dependent upon third-party contract manufacturers, both for the supply of the active pharmaceutical ingredient in Mytesi and Canalevia and the botanical extract in Neonorm and Equilevia, as well as for the supply of finished products for commercialization.

We have contracted with third parties for the formulation of API and botanical extract into finished products for our studies. We have also entered into memorandums of understanding with Indena S.p.A. for the manufacture of CPL received from our suppliers into the API in Canalevia to support our regulatory filings, as well as the botanical extract in Neonorm and agreed to negotiate a commercial supply agreement. Indena S.p.A. has never manufactured either such ingredient to commercial scale. As a second supplier situation, we have entered into a four-year manufacturing and supply agreement with Glenmark for the supply of the API in Canalevia. Glenmark is the current manufacturer of crofelemer, the active API in Canalevia, for Mytesi, and the manufacturer on file for the NADA to which we have a right of reference. As announced in October of 2015, we have entered an agreement with Patheon, a provider of drug development and delivery solutions, under which Patheon provides enteric-coated tablets to us for use in animals. We also may contract with additional third parties for the formulation and supply of finished products, which we will use in our planned studies and commercialization efforts.

We will be dependent upon our contract manufacturers for the supply of the API in Mytesi and Canalevia. We currently have sufficient quantities of the botanical extract used in Neonorm and Equilevia to support initial commercialization of Neonorm and Equilevia. However, we will require additional quantities of the botanical extract if our ongoing commercial launch of Neonorm or our commercial launch of and Equilevia is successful. If we are not successful in reaching agreements with third parties on terms that we consider commercially reasonable for manufacturing and formulation, or if our contract manufacturer and formulator are not able to produce sufficient quantities or quality of API, botanical extract or finished product under their agreements, it could delay our plans and harm our business prospects.

The facilities used by our third-party contractors are subject to inspections, including by the FDA, and other regulators, as applicable. We also depend on our third-party contractors to comply with cGMP. If our third-party contractors do not maintain compliance with these strict regulatory requirements, we and they will not be able to secure or maintain regulatory approval for their facilities, which would have an adverse effect on our operations. In addition, in some cases, we also are dependent on our third-party contractors to produce supplies in conformity to our specifications and maintain quality control and quality assurance practices and not to employ disqualified personnel. If the FDA or a comparable foreign regulatory authority does not approve the facilities of our third-party contractors if so required, or if it withdraws any such approval in the future, we may need to find alternative manufacturing or formulation facilities, which could result in delays in our ability to develop or commercialize our human and animal products, if at all. We and our third-party contractors also may be subject to penalties and sanctions from the FDA and other regulatory authorities for any violations of applicable regulatory requirements. The USDA and the European Medicines Agency (the EMA), employ different regulatory standards than the FDA, so we may require multiple manufacturing processes and facilities for the same human or animal product candidate or any approved product. We are also exposed to risk if our third-party contractors do not comply with the negotiated terms of our agreements, or if they suffer damage or destruction to their facilities or equipment.

If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell our current or future human or animal products and product candidates, if approved, and generate product or other revenue.

We currently have limited sales, marketing or distribution capabilities, and prior to Napo s launch of Mytesi for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy, and our launch of Neonorm for preweaned dairy calves, we had no experience in the sale, marketing and distribution of human or animal health products. There are significant risks involved in building and managing a sales organization, including our potential inability to attract, hire, retain and motivate qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively oversee a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities and entry into adequate arrangements with distributors or other partners would adversely impact the commercialization of Mytesi, Neonorm, Equilevia and, if approved, Canalevia. If we are not successful in commercializing Mytesi, Neonorm, Equilevia, Canalevia or any of our other line extension products, either on our own or

through one or more distributors, or in generating upfront licensing or other fees, we may never generate significant revenue and may continue to incur significant losses, which would harm our financial condition and results of operations.

Changes in distribution channels for animal health prescription drugs may make it more difficult or expensive to distribute our animal health prescription drug products.

In the United States, animal owners typically purchase their animal health prescription drugs from their local veterinarians who also prescribe such drugs. There is a trend, however, toward increased purchases of animal health prescription drugs from

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Internet-based retailers, big-box retail stores and other over-the-counter distribution channels, which follows an emerging shift in recent years away from the traditional veterinarian distribution channel. It is also possible that animal owners may come to rely increasingly on Internet-based animal health information rather than on their veterinarians. We currently expect to market our animal health prescription drugs directly to veterinarians, so any reduced reliance on veterinarians by animal owners could harm our business and prospects by making it more difficult or expensive for us to distribute our animal health prescription drug products.

Legislation has been or may be proposed in various states that would require veterinarians to provide animal owners with written prescriptions and disclosures that the animal owner has the right to fill the prescriptions through other means. If enacted, such legislation could lead to a reduction in the number of animal owners who purchase their animal health pharmaceuticals directly from veterinarians, which also could harm our business.

Consolidation of our customers could negatively affect the pricing of our animal health products.

Veterinarians will be our primary customers for our prescription animal health drug products, as well as, to some extent, our non-prescription animal health products, such as Neonorm and Equilevia. In recent years, there has been a trend towards the consolidation of veterinary clinics and animal hospitals. If this trend continues, these large clinics and hospitals could attempt to leverage their buying power to obtain favorable pricing from us and other animal health product companies. Any downward pressure on the prices of any of our animal health products could harm our operating results and financial condition.

We will need to increase the size of our organization and may not successfully manage such growth.

As of August 31, 2017, we had 25 full-time equivalent (FTE) employees. Our ability to manage our growth effectively will require us to hire, train, retain, manage and motivate additional employees and to implement and improve our operational, financial and management systems. These demands also may require the hiring of additional senior management personnel or the development of additional expertise by our senior management personnel. If we fail to expand and enhance our operational, financial and management systems in conjunction with our potential future growth, it could harm our business and operating results.

Research and development with respect to our animal health products and product candidates relies on evaluations in animals, which is controversial and may become subject to bans or additional regulations.

The evaluation of our animal health products and product candidates in target animals is required to develop, formulate and commercialize our animal health products and product candidates. Although our animal testing will be subject to GLPs and GCPs, as applicable, animal testing in the human pharmaceutical industry and in other industries continues to be the subject of controversy and adverse publicity. Some organizations and individuals have sought to ban animal testing or encourage the adoption of additional regulations applicable to animal testing. To the extent that such bans or regulations are imposed, our research and development activities with respect to animal health products, and by extension our operating results and financial condition, could be harmed. In addition, negative publicity about animal practices by us or in our industry could harm our reputation among potential customers.

If approved, our animal health prescription drug product candidates may be marketed in the United States only in the target animals and for the indications for which they are approved, and if we want to expand the approved animals or indications, it will need to obtain additional approvals, which may not be granted.

If our animal health prescription drug product candidates are approved by regulatory authorities, we may market or advertise them only in the specific species and for treatment of the specific indications for which they were approved, which could limit use of the products by veterinarians and animal owners. We intend to develop, promote and commercialize approved products for other animals and new treatment indications in the future, but we cannot be certain whether or at what additional time and expense we will be able to do so. If we do not obtain marketing approvals for other species or for new indications, our ability to expand our animal health business may be harmed.

Under the Animal Medicinal Drug Use Clarification Act of 1994, veterinarians are permitted to prescribe extra-label uses of certain approved animal drugs and approved human drugs for animals under certain conditions. While veterinarians may in the future prescribe and use human-approved products or use our products for extra-label uses, we may not promote our animal health products for extra-label uses. We note that extra-label uses are uses for which the product has not received approval. If the FDA determines that any of our marketing activities constitute promotion of an extra-label use, we could be subject to regulatory enforcement, including seizure of any misbranded or mislabeled drugs, and civil or criminal penalties, any of which could have an adverse impact on our reputation and expose us to potential liability. We will continue to spend resources ensuring that our promotional claims for our animal health products and product candidates remain compliant with applicable FDA laws and regulations, including materials we

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post or link to on our website. For example, in 2012, our Chief Executive Officer received an untitled letter from the FDA while at Napo regarding preapproval promotion statements constituting misbranding of crofelemer, which was then an investigational drug. These statements were included in archived press releases included on Napo s website. Napo was required to expend time and resources to revise its website to remove the links in order to address the concerns raised in the FDA s letter.

If our human or animal prescription drug product candidates are approved by regulatory authorities, the misuse or extra-label use of such products may harm our reputation or result in financial or other damages.

If our human or animal prescription drug product candidates are approved by regulatory authorities, there may be increased risk of product liability if physicians, veterinarians, patients, animal owners or others, as applicable, attempt to use such products extra-label, including the use of our products for indications or in species for which they have not been approved. Furthermore, the use of an approved human or animal drug for indications other than those indications for which such products have been approved may not be effective, which could harm our reputation and lead to an increased risk of litigation. If we are deemed by a governmental or regulatory agency to have engaged in the promotion of any approved human or animal product for extra-label use, such agency could request that we modify our training or promotional materials and practices and we could be subject to significant fines and penalties, and the imposition of these sanctions could also affect our reputation and position within the gastrointestinal health industry. Any of these events could harm our reputation and our operating results.

We may not maintain the benefits associated with MUMS designation, including market exclusivity.

Although we have received MUMS designation for Canalevia for the treatment of CID in dogs, we may not maintain the benefits associated with MUMS designation. MUMS designation is a status similar to orphan drug status for human drugs. When we were granted MUMS designation for Canalevia for the indication of CID in dogs, we became eligible for incentives to support the approval or conditional approval of the designated use. This designation does not allow us to commercialize a product until such time as we obtain approval or conditional approval of the product.

Because Canalevia has received MUMS designation for the identified particular intended use, we are eligible to obtain seven years of exclusive marketing rights upon approval (or conditional approval) of Canalevia for that intended use and become eligible for grants to defray the cost of our clinical work. Each designation that is granted must be unique, *i.e.*, only one designation can be granted for a particular API in a particular dosage form for a particular intended use. The intended use includes both the target species and the disease or condition to be treated.

At some point, we could lose MUMS designation. The basis for a lost designation can include but is not limited to, our failure to engage with due diligence in moving forward with a non-conditional approval, or a competing product has received conditional approval or approval prior to our product candidate for the same indication or species. In addition, MUMS designation may be withdrawn for a variety of reasons such as where the FDA determines that the request for designation was materially defective, or if the manufacturer is unable to assure sufficient quantity of the prescription drug product to meet the needs of animals with the rare disease or condition. If this designation is lost, it could have a negative impact on the product and us, which includes but is not limited to, market exclusivity related to MUMS designation, or eligibility for grants as a result of MUMS designation.

The market for our human or animal products, and the gastrointestinal health market as a whole, is uncertain and may be smaller than we anticipate, which could lead to lower revenue and harm our operating results.

It is very difficult to estimate the commercial potential of any of our human or animal products because the gastrointestinal health market continues to evolve and it is difficult to predict the market potential for our products. The market will depend on important factors such as safety and efficacy compared to other available treatments, changing standards of care, preferences of physicians and veterinarians, as applicable, the willingness of patients and companion and production animal owners, as applicable, to pay for such products, and the availability of competitive alternatives that may emerge either during the product development process or after commercial introduction. If the market potential for our human or animal products is less than we anticipate due to one or more of these factors, it could negatively impact our business, financial condition and results of operations. Further, the willingness of patients and companion and production animal owners to pay for our products may be less than we anticipate, and may be negatively affected by overall economic conditions. Moreover, with respect to our animal health products, the current penetration of animal insurance in the United States is low, animal owners are likely to have to pay out-of-pocket, and such owners may not be willing or able to pay for our products.

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Insurance coverage for Mytesi for its current approved indication could decrease or end, or Mytesi might not receive insurance coverage for any approved follow-on indications, which could lead to lower revenue and harm our operating results.

For its current approved indication, Mytesi is currently covered by all of the top 10 commercial insurance plans, representing more than 245 million U.S. lives. In 50% of these plans it is currently on Tier 3 with no restrictions, and in 50% it is currently on Tier 3 with a prior authorization required. In the top 10 Managed Medicare plans, which represent 24 million covered lives, Mytesi is currently covered on 10% of plans. Mytesi is currently covered on Medicaid in all 50 states. However, the nature or extent of coverage for Mytesi by any of these plans or programs could change or be terminated, or Mytesi might not receive insurance coverage for any approved follow-on indications. Either outcome could lead to significantly lower revenue and significantly harm our operating results.

If we fail to maintain effective internal control over financial reporting in the future, the accuracy and timing of our financial reporting may be adversely affected.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended (the Exchange Act).

Preparing our consolidated financial statements involves a number of complex manual and automated processes, which are dependent upon individual data input or review and require significant management judgment. One or more of these elements may result in errors that may not be detected and could result in a material misstatement of our consolidated financial statements. If we fail to maintain the adequacy of our internal controls over financial reporting, our business and operating results may be harmed and we may fail to meet our financial reporting obligations. If material weaknesses in our internal control are discovered or occur, our consolidated financial statements may contain material misstatements and we could be required to restate our financial results.

Our internal control over financial reporting may not prevent or detect misstatements because of its inherent limitations, including the possibility of human error, the circumvention or overriding of controls, or fraud. Even effective internal controls can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements. Any failure of our internal controls could adversely affect the results of the periodic management evaluations regarding the effectiveness of our internal control over financial reporting. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information, and the trading price of our stock may decline.

We may engage in future acquisitions that increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may evaluate various strategic transactions, including licensing or acquiring complementary products, technologies or businesses. Any potential acquisitions may entail numerous risks, including increased operating expenses and cash requirements, assimilation of operations and products, retention of key employees, diversion of our management s attention and uncertainties in our ability to maintain key business relationships of the acquired entities. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that

may be important to the development of our business.

Certain of the countries in which we plan to commercialize our products in the future are developing countries, some of which have potentially unstable political and economic climates.

We may commercialize our products in jurisdictions that are developing and emerging countries. This may expose us to the impact of political or economic upheaval, and we could be subject to unforeseen administrative or fiscal burdens. At present, we are not insured against the political and economic risks of operating in these countries. Any significant changes to the political or economic climate in any of the developing countries in which we operate or plan to sell products either now or in the future may have a substantial adverse effect on our business, financial condition, trading performance and prospects.

Fluctuations in the exchange rate of foreign currencies could result in currency transactions losses.

As we expand our operations, we expect to be exposed to risks associated with foreign currency exchange rates. We anticipate that we will commercialize Neonorm for preweaned dairy calves and its line extensions, as well as possibly Canalevia and its line extensions in jurisdictions outside the United States. As a result, we will also be further affected by fluctuations in exchange rates in the future to the extent that sales are denominated in currencies other than U.S. dollars. We do not currently employ any hedging or other strategies to minimize this risk, although we may seek to do so in the future.

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The unaudited pro forma combined condensed financial statements incorporated by reference in this document are preliminary and the actual financial condition and results of operations after the Merger may differ materially.

The unaudited pro forma combined condensed financial statements included in this quarterly report on Form 10-Q are presented for illustrative purposes only and are not necessarily indicative of what our actual financial condition or results of operations would have been had the Merger been completed on the dates indicated. The unaudited pro forma combined condensed financial statements reflect adjustments to illustrate the effect of the Merger had it been completed on the dates indicated, which are based upon preliminary estimates, to record the Napo identifiable assets acquired and liabilities assumed at fair value and the resulting goodwill recognized. The purchase price allocation for the Merger reflected in the pro forma combined financial statements is preliminary, and final allocation of the purchase price will be based upon the actual purchase price and the fair value of the assets and liabilities of Napo as of the date of the completion of the Merger. Accordingly, the final acquisition accounting adjustments may differ materially from the pro forma adjustments reflected in financial statements incorporated by reference in this document.

There are other gastrointestinal-focused human pharmaceutical companies, and we face competition in the marketplaces in which we operate or plan to operate.

Our commercial success in the human drug arena remains dependent on maintaining or establishing a competitive position in the market for the current, approved specialty indication of Mytesi as well as for planned Mytesi follow-on indications. In the IBS-D market in particular, several competitors have commercially available products approved for our planned IBS-D indication. The availability of our competitors products could limit the demand, and the price we are able to charge, for any drug candidate we develop. The inability to compete with existing or subsequently introduced drug candidates would have a material adverse impact on our business, financial condition and prospects.

Our obligations to Hercules, and subject to certain events, to CVP, are secured by a security interest in substantially all of our veterinary related assets, so if we default on those obligations, Hercules or CVP could foreclose on our assets.

Our obligations under the loan and security agreement with Hercules Capital, Inc. (f/k/a Hercules Technology Growth Capital, Inc.) (Hercules) are secured by a security interest in substantially all of our veterinary related assets, including intellectual property. As a result, if we default on our obligations under the loan and security agreement (the Hercules Debt), Hercules could foreclose on its security interests and liquidate some or all of these assets, which would harm our veterinary related business, financial condition and results of operations and could require us to reduce or cease operations. In addition, Chicago Venture Partners, L.P. (CVP) may acquire a security interest in substantially all of our veterinary related assets upon the earlier of CVP purchasing Hercules Debt or the repayment in full of the Hercules Debt, as provided in the Security Agreement, dated June 29, 2017, between us and CVP and the Subordination Agreement and Right to Purchase Debt, dated June 29, 2017, by and among us, CVP and Hercules.

Napo s obligations to the holders of the Kingdon Notes are secured by a security interest in substantially all of Napo s assets, so if we default on those obligations, the convertible note holders could foreclose on Napo s assets.

Napo s obligations under the convertible promissory notes (the Kingdon Notes) issued pursuant to the Amended and Restated Note Purchase Agreement, dated March 31, 2017, by and among Kingdon Associates, M. Kingdon Offshore Master Fund L.P., Kingdon Family

Partnership, L.P. and Kingdon Credit Master Fund L.P. (collectively, the Kingdon Purchasers) and Napo and the related transaction documents are secured by a security interest in substantially all of Napo s assets, including Napo intellectual property. As a result, if we default under our obligations under the Kingdon Notes or the transaction documents, the holders of such Kingdon Notes, acting through their appointed agent, could foreclose on their security interests and liquidate some or all of these assets, which would harm our business, financial condition and results of operations and could require us to reduce or cease operations.

Risks Related to Intellectual Property

We cannot be certain that our patent strategy will be effective to protect against competition

Our commercial success depends in large part on obtaining and maintaining patent, trademark and trade secret protection of our human or animal products, both prescription and non-prescription, our current human or animal product candidates and any future human or animal product candidates, and their respective components, formulations, methods used to manufacture them and methods of treatment, as well as successfully defending our patents and other intellectual property rights against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our products or our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents, trade secrets and other similar

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intellectual property that cover these activities. The patent prosecution process is expensive and time-consuming, and we may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of inventions made in the course of development and commercialization activities in time to obtain patent protection on them.

We have a portfolio of United States and foreign issued patents and pending applications related to our products and product candidates. We have five issued United States patents listed in the FDA s Orange Book for Mytesi. We plan to rely on certain of these issued patents as protection for Canalevia. The strength of patents in the field of pharmaceuticals and animal health involves complex legal and scientific questions and can be uncertain. We cannot be certain that pending applications will issue as patents. For those patents that are already issued and even if other patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents may not adequately protect our intellectual property or prevent others from designing around their claims. If the patents we have are not maintained or their scope is significantly narrowed or if we are not able to obtain issued patents from pending applications, our business and prospects would be harmed.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of any patent applications and the enforcement or defense of any patents that issue. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switch the U.S. patent system from a first-to-invent system to a first-to-file system. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO has developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-to-file provisions, became effective on March 16, 2013. Among some of the other changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and that provide opportunities for third parties to challenge any issued patent in the USPTO. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our patents and any other patents that issue, all of which could harm our business and financial condition.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent and, in certain jurisdictions, pending applications, are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our prescription drug products, prescription drug product candidates and non-prescription products, our competitors might be able to enter the market, which would harm our business.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, which would be costly, time-consuming and, if successfully asserted against us, delay or prevent the development and commercialization of our current or future products and product candidates.

Our research, development and commercialization activities may infringe or otherwise violate or be claimed to infringe or otherwise violate patents owned or controlled by other parties. There may be patents already issued of which we are unaware that might be infringed by a product or one of our current or future prescription drug product candidates or non-prescription products. Moreover, it is also possible that patents may exist that we are aware of, but that we do not believe are relevant to our current or future prescription drug product candidates or non-prescription products, which could nevertheless be found to block our freedom to market these products. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be applications now pending of which we are unaware and which may later result in issued patents that may be infringed by our current or future prescription drug product candidates or non-prescription products. We cannot be certain that our products, current or future prescription drug product candidates or non-prescription products will not infringe these or other existing or future

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third-party patents. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

To the extent we become subject to future third-party claims against us or our collaborators, we could incur substantial expenses and, if any such claims are successful, we could be liable to pay substantial damages, including treble damages and attorney s fees if we or our collaborators are found to be willfully infringing a third party s patents. If a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the human or animal prescription drug or non-prescription product that is the subject of the suit. Even if we are successful in defending such claims, infringement and other intellectual property claims can be expensive and time-consuming to litigate and divert management s attention from our business and operations. As a result of or in order to avoid potential patent infringement claims, we or our collaborators may be compelled to seek a license from a third party for which we would be required to pay license fees or royalties, or both. Moreover, these licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain such a license, the rights may be nonexclusive, which could allow our competitors access to the same intellectual property. Any of these events could harm our business and prospects.

Our proprietary position depends upon patents that are formulation or method-of-use patents, which do not prevent a competitor from using the same human or animal drug for another use.

Composition-of-matter patents on the API in prescription drug products are generally considered to be the strongest form of intellectual property protection because such patents provide protection without regard to any particular method of use or manufacture or formulation of the API used. The composition-of-matter patents for crofelemer, the API in Mytesi and Canalevia, have expired, and the issued patents and applications relevant to our products and product candidates cover formulations and methods of use for crofelemer and the botanical extract in Neonorm and Equilevia.

Method-of-use patents protect the use of a product for the specified method and formulation patents cover formulations of the API or botanical extract. These types of patents do not prevent a competitor from developing or marketing an identical product for an indication that is outside the scope of the patented method or from developing a different formulation that is outside the scope of the patented formulation. Moreover, with respect to method-of-use patents, even if competitors do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend that patients use our products extra-label, and veterinarians may recommend that animal owners use these products extra-label, or animal owners may do so themselves. Although extra-label use may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful, and third parties may challenge the validity or enforceability of our patents and they may be successful.

We intend to rely upon a combination of regulatory exclusivity periods, patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to Mytesi, our current prescription drug product candidates, non-prescription products and our development programs.

If the breadth or strength of protection provided by any patents, patent applications or future patents we may own, license, or pursue with respect to any of our current or future product candidates or products is threatened, it could threaten our ability to commercialize any of our current or

future human or animal product candidates or products. Further, if we encounter delays in our development efforts, the period of time during which we could market any of our current or future product candidates or products under any patent protection we obtain would be reduced.

Given the amount of time required for the development, testing and regulatory review of new product candidates or products, patents protecting such candidates might expire before or shortly after such product candidates or products are commercialized. Patent term extension has been applied for US 7,341,744 to account for regulatory delays in obtaining human marketing approval for crofelemer. The FDA and the USPTO have confirmed that US 7,341,744 is eligible for an extension of 1075 days and we await issuance of the patent term extension certificate. With respect to requests for patent term extensions, the applicable authorities, including the USPTO and the FDA, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to patents, or may grant more limited extensions than requested. If this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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Even where laws provide protection or we are able to obtain patents, costly and time-consuming litigation may be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us, and some of our competitors have substantially greater intellectual property portfolios than we have. To counter infringement or unauthorized use of any patents we may obtain, we may be required to file infringement claims, which can be expensive and time-consuming to litigate. In addition, if we or one of our future collaborators were to initiate legal proceedings against a third party to enforce a patent covering one of our products, current product candidates, or one of our future products, the defendant could counterclaim that the patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace and challenges to validity of patents in certain foreign jurisdictions is common as well. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. In particular, Mytesi has regulatory exclusivity as a new chemical entity until December 31, 2017. Under the Hatch-Waxman Act, a competitor seeking to market a generic form of Mytesi before the expiration of any of the patents listed in the FDA s Orange Book for Mytesi could file (and could have filed after December 31, 2016) an ANDA with a certification under 21 U.S.C. § 3559j)(2)(A)(iv) that each of these patents (except for those which the ANDA filer states it will market only after its expiration) is either invalid, unenforceable or not infringed. We may assert the patents in Hatch-Waxman litigation against the party filing the ANDA to keep the competing product off of the market until the patents expire but there is a risk that we will not succeed. The party filing the ANDA may also counterclaim in the litigation that the our patents are not valid or unenforceable, and the court may find one or more claims of our patents invalid or unenforceable. If this occurs, a competing generic product could be marketed prior to expiration of our patents listed in the Orange Book, which would harm our business.

Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as *ex parte* reexaminations, *inter partes* review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on one or more of our products or our current or future product candidates. Such a loss of patent protection could harm our business. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution or other basis for a finding of invalidity. Litigation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be unsuccessful, it could have an adverse effect on the price of our common stock. Finally, we may not be able to prevent, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

If we are unable to prevent disclosure of our trade secrets or other confidential information to third parties, our competitive position may be impaired.

We also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or for which we have not filed patent applications, processes for which patents are difficult to enforce and other elements of our product development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us, and endeavor to execute confidentiality agreements with all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology, we cannot be certain that we have executed such agreements with all parties who may have helped to develop our intellectual property or had access to our proprietary information, or that our agreements will not be breached. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If we are unable to prevent disclosure of our intellectual property to third parties, we may not be able to maintain a competitive advantage in our market, which would harm our business.

Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, and erode our competitive position in our market.

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Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other human or animal pharmaceutical product companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the human and animal health industries involves both technological and legal complexity. Therefore, obtaining and enforcing patents is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting and defending patents on human and animal drug products, product candidates and non-prescription products throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to animal health products, which could make it difficult for us to stop the infringement of our future patents, if any, or patents we have in licensed, or marketing of competing products in violation of our proprietary rights generally. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Proceedings to enforce our future patent rights, if any, in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Our business could be harmed if we fail to obtain certain registered trademarks in the United States or in other countries.

Our registered and pending U.S. trademarks include NEONORM®, MYTESI®, NAPO®, Napo Logo®, CANALEVIA, EQUILEVIA, JAGUAR ANIMAL HEALTH, the Jaguar Animal Health logo and MY HIV THANK YOU. We also own pending applications for the CANALEVIA mark in a number of foreign countries. We have not yet filed applications for our company name or our logo in the U.S. During trademark registration proceedings, we may receive rejections of our trademark applications. If so, we will have an opportunity to respond, but we may be unable to overcome such rejections. In addition, the USPTO and comparable agencies in many foreign jurisdictions may permit third parties to oppose pending trademark applications and to seek to cancel registered trademarks. If opposition or cancellation proceedings are filed against any of our trademark applications or any registered trademarks, our trademarks may not survive such proceedings. Moreover, any name we propose to use with our prescription drug product candidates in the United States, including CANALEVIA, must be approved by the FDA, regardless of whether we have registered or applied to register as a trademark. The FDA typically conducts a review of proposed prescription drug product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed

proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology, pharmaceutical or animal health companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees former employers. Litigation may be necessary to defend against any such claims. Even if we were successful in defending against any such claims, such litigation could result in substantial cost and be a distraction to our management and employees.

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Risks Related to Government Regulation

Even if we receive any of the required regulatory approvals for our current or future prescription drug product candidates and non-prescription products, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense.

If the FDA or any other regulatory body approves any of our current or future prescription drug product candidates, or if necessary, our non-prescription products, the manufacturing processes, clinical development, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product may be subject to extensive and ongoing regulatory requirements. These requirements could include, but are not limited to, submissions of efficacy and safety and other post-marketing information and reports, establishment registration, and product listing, compliance with new rules promulgated under the FSMA, as well as continued compliance with cGMP, GLP and GCP for any studies that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our contract manufacturers or manufacturing processes, or failure to comply with regulatory requirements, are reportable events to the FDA and may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, revised labeling, or voluntary or involuntary product recalls;

- additional clinical studies, fines, warning letters or holds on target animal studies;

- refusal by the FDA, or other regulators to approve pending applications or supplements to approved applications filed by us or our strategic collaborators related to the unknown problems, or suspension or revocation of the problematic product s license approvals;

- product seizure or detention, or refusal to permit the import or export of products; and

- injunctions and/or the imposition of civil or criminal penalties.

The FDA or other regulatory agency s policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates or require certain changes to the labeling or additional clinical work concerning safety and efficacy of the product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would harm our business. In addition, failure to comply with these regulatory requirements could result in significant penalties.

In addition, from time to time, we may enter into consulting and other financial arrangements with veterinarians, who prescribe or recommend our products, once approved. As a result, we may be subject to state, federal and foreign healthcare and/or veterinary medicine laws.. If our financial relationships with veterinarians are found to be in violation of such laws that apply to us, we may be subject to penalties.

The issuance by the FDA of protocol concurrences for our pivotal studies does not guarantee ultimate approval of our NADA.

We intend to seek protocol concurrences from the FDA for the pivotal trial of Canalevia that we have initiated for acute diarrhea in dogs and for future pivotal trials in other indications. A pivotal study protocol is submitted to the FDA by a drug sponsor for purposes of obtaining FDA review of the protocol. Prior FDA review of the protocol for a pivotal study makes it more likely that the study design will generate information the sponsor needs to demonstrate to the satisfaction of the FDA whether the drug is safe and effective for its intended use. It creates an expectation by the sponsor that the FDA should not later alter its perspectives on these issues unless public or animal health concerns appear that were not recognized at the time of protocol assessment. Even if the FDA issues a protocol concurrence, ultimate approval of an NADA by the FDA is not guaranteed because a final determination that the agreed-upon protocol satisfies a specific objective, such as the demonstration of efficacy, or supports an approval decision, will be based on a complete review of all the data submitted to the FDA including the outcome of the study for which protocol concurrence was received. Even if we were to obtain protocol concurrence such concurrence does not guarantee that the results of the study will support a particular finding or approval of the new drug.

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Any of our current or future prescription drug product candidates or non-prescription products may cause or contribute to adverse medical events that we would be required to report to regulatory authorities and, if we fail to do so, we could be subject to sanctions that would harm our business.

If we are successful in commercializing any of our current or future prescription drug product candidates or non-prescription products, certain regulatory authorities will require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if such event is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the regulatory authorities could take action including, but not limited to, criminal prosecution, seizure of our products, facility inspections, removal of our products from the market, recalls of certain lots or batches, or cause a delay in approval or clearance of future products.

Legislative or regulatory reforms with respect to animal health may make it more difficult and costly for us to obtain regulatory clearance or approval of any of our current or future product candidates and to produce, market, and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in the U.S. Congress or other jurisdictions in which we intend to operate that could significantly change the statutory provisions governing the testing, regulatory clearance or approval, manufacture, and marketing of regulated products. In addition, the FDA s regulations and guidance are often revised or reinterpreted by the FDA and such other regulators in ways that may significantly affect our business and our products and product candidates. Similar changes in laws or regulations can occur in other countries. Any new regulations or revisions or reinterpretations of existing regulations in the United States or in other countries may impose additional costs or lengthen review times of any of our current or future products and product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;
- additional clinical trials or testing;
- new requirements related to approval to enter the market;
- recall, replacement, or discontinuance of certain products; and
- additional record keeping or the development of certain regulatory required hazard identification plans.

Each of these would likely entail substantial time and cost and could harm our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products would harm our business, financial condition, and results of operations.

We believe that our non-prescription products are not subject to regulation by regulatory agencies in the United States, but there is a risk that regulatory bodies may disagree with our interpretation, or may redefine the scope of their regulatory reach in the future, which would result in additional expense and could delay or prevent the commercialization of these products.

The FDA retains jurisdiction over all animal prescription drug products however, in many instances, the Federal Trade Commission will exercise primary or concurrent jurisdiction with FDA on non-prescription products as to post marketing claims made regarding the product. On April 22, 1996, the FDA published a statement in the Federal Register, 61 FR 17706, that it believes that the Dietary Supplement and Health Education Act (DSHEA), does not apply to animal health supplement products, such as our non-prescription products. Accordingly, the FDA s Center for Veterinary Medicine only regulates those animal supplements that fall within the FDA s definition of an animal drug, animal food or animal feed additive. The Federal Food Drug and Cosmetic Act defines food as articles used for food or drink for man or other animals and articles used as components of any such article. Animal foods are not subject to pre-market approval and are designed to provide a nutritive purpose to the animals that receive them. Feed additives are defined as those articles that are added to an animal s feed or water as illustrated by the guidance documents. Our non-prescription products are not added to food, are not ingredients in food nor are they added to any animal s drinking water. Therefore, our non-prescription products do not fall within the definition of a food or feed additive. In light of the pronouncement by the FDA that the DSHEA was not intended to apply to animals, the FDA seeks to regulate such supplements as food or food additives depending on

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the intended use of the product. The intended use is demonstrated by how the article is included in a food, or added to the animals intake (*i.e.,* through its drinking water). If the intended use of the product does not fall within the proscribed use making the product a food, it cannot be regulated as a food. There is no intent to make our non-prescription products a component of an animal food, either directly or indirectly. A feed additive is a product that is added to a feed for any reason including the top dressing of an already prepared feed. Some additives, such as certain forage, are deemed to be Generally Recognized as Safe, or GRAS, and therefore, not subject to a feed Additive Petition approval prior to use. However, the substances deemed GRAS are generally those that are recognized as providing nutrients as a food does. We do not believe that our non-prescription products fit within this framework either. Finally, a new animal drug refers to drugs intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals. Our non-prescription Neonorm Foal and Neonorm Calf products are not intended to diagnose, cure, mitigate, treat or prevent disease and therefore, do not fit within the definition of an animal drug. Additionally, because a previously marketed human formulation of the botanical extract in our non-prescription products was regulated as a human dietary supplement subject to the DSHEA (and not regulated as a drug by the FDA), we do not believe that the FDA would regulate the animal formulation used in our non-prescription products in a different manner. We do not believe that our non-prescription products fit the definition of an animal drug, food or food additive and therefore are not regulated by the FDA at this time.

However, despite many such unregulated animal supplements currently on the market, the FDA may choose in the future to exercise jurisdiction over animal supplement products in which case, we may be subject to unknown regulations thereby inhibiting our ability to launch or to continue marketing our non-prescription products. In the past, the FDA has redefined or attempted to redefine some non-prescription non-feed products as falling within the definition of drug, feed or feed additive and therefore subjected those products to the relevant regulations. We have not discussed with the FDA its belief that the FDA currently does not exercise jurisdiction over our non-prescription products. Should the FDA assert regulatory authority over our non-prescription products, we would take commercially reasonable steps to address the FDA s concerns, potentially including but not limited to, seeking registration for such products, reformulating such products to further distance such products from regulatory control, or ceasing sale of such products. Further, the Animal and Plant Health Inspection Service, an agency of the USDA, may at some point choose to exercise jurisdiction over certain non-prescription products that are not intended for production animals. We do not believe we are currently subject to such regulation, but could be in the future. If the FDA or other regulatory agencies, such as the USDA, try to regulate our non-prescription products, we could be required to seek regulatory approval for our non-prescription products, which would result in additional expense and could delay or prevent the commercialization of these products.

Even if Napo receives the required regulatory approvals for Napo s current or future prescription drug product candidates and non-prescription products, Napo will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense.

If the FDA or any other regulatory body approves any of Napo s current or future prescription drug product candidates, or if necessary, Napo s non-prescription products, the manufacturing processes, clinical development, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product is subject to extensive and ongoing regulatory requirements. These requirements could include, but are not limited to, submissions of efficacy and safety and other post-marketing information and reports, establishment registration, and product listing, compliance with new rules promulgated under the FSMA, as well as continued compliance with cGMP, GLP and GCP for any studies that Napo conducts post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with Napo s contract manufacturers or manufacturing processes, or failure to comply with regulatory requirements, are reportable events to the FDA and may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, revised labeling, or voluntary or involuntary product recalls;

- additional clinical studies fines, warning letters or holds on studies;

- refusal by the FDA, or other regulators to approve pending applications or supplements to approved applications filed by Napo or Napo s strategic collaborators related to the unknown problems, or suspension or revocation of the problematic product s license approvals;

- product seizure or detention, or refusal to permit the import or export of products; and

- injunctions or the imposition of civil or criminal penalties.

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The FDA or other regulatory agency s policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of Napo s product candidates or require certain changes to the labeling or require additional clinical work concerning safety and efficacy of the product candidates. Napo cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If Napo is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if Napo is not able to maintain regulatory compliance, Napo may lose any marketing approval that Napo may have obtained and Napo may not achieve or sustain profitability, which would harm Napo s business. In addition, failure to comply with these regulatory requirements could result in significant penalties.

In addition, from time to time, Napo may enter into consulting and other financial arrangements with physicians, who prescribe or recommend Napo s products, once approved. As a result, Napo may be subject to state, federal and foreign healthcare laws, including but not limited to anti-kickback laws. If Napo s financial relationships with physicians are found to be in violation of such laws that apply to Napo, Napo may be subject to penalties.

The issuance by the FDA of protocol concurrences for Napo s pivotal studies does not guarantee ultimate approval of Napo s NDA.

Napo intends to seek protocol concurrences from the FDA for future pivotal trials that Napo initiates. A pivotal study protocol is submitted to the FDA by a drug sponsor for purposes of obtaining FDA review of the protocol. Prior FDA review of the protocol for a pivotal study makes it more likely that the study will generate information the sponsor needs to demonstrate whether the drug is safe and effective for its intended use. It creates an expectation by the sponsor that the FDA should not later alter its perspectives on these issues unless public concerns appear that were not recognized at the time of protocol assessment. Even if the FDA issues a protocol concurrence, ultimate approval of an NDA by the FDA is not guaranteed because a final determination that the agreed-upon protocol satisfies a specific objective, such as the demonstration of efficacy, or supports an approval decision, will be based on a complete review of all the data submitted to the FDA. Even if Napo were to obtain protocol concurrence such concurrence does not guarantee that the results of the study will support a particular finding or approval of the new drug.

Any of Napo s current or future prescription drug product candidates or non-prescription products may cause or contribute to adverse medical events that Napo would be required to report to regulatory authorities and, if Napo fails to do so, Napo could be subject to sanctions that would harm Napo s business.

If Napo is successful in commercializing any of Napo s current or future prescription drug product candidates or non-prescription products, certain regulatory authorities will require that Napo report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of Napo s obligation to report would be triggered by the date Napo becomes aware of the adverse event as well as the nature of the event. Napo may fail to report adverse events Napo becomes aware of within the prescribed timeframe. Napo may also fail to appreciate that Napo has become aware of a reportable adverse event, especially if it is not reported to Napo as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of Napo s products. If Napo fails to comply with Napo s reporting obligations, the regulatory authorities could take action including, but not limited to, criminal prosecution, seizure of Napo s products, facility inspections, removal of Napo s products from the market, recalls of certain lots or batches, or cause a delay in approval or clearance of future products.

Legislative or regulatory reforms make it more difficult and costly for Napo to obtain regulatory clearance or approval of any of Napo s current or future product candidates and to produce, market, and distribute Napo s products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in the U.S. Congress or other jurisdictions in which Napo intends to operate that could significantly change the statutory provisions governing the testing, regulatory clearance or approval, manufacture, and marketing of regulated products. In addition, the FDA s regulations and guidance are often revised or reinterpreted by the FDA and such other regulators in ways that may significantly affect Napo s business and Napo s products and product candidates. Similar changes in laws or regulations can occur in other countries. Any new regulations or revisions or reinterpretations of existing regulations in the United States or in other countries may impose additional costs or lengthen review times of any of Napo s current or future products and product candidates. Napo cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on Napo s business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;

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- additional clinical trials or testing;
- new requirements related to approval to enter the market;
- recall, replacement, or discontinuance of certain products; and
- additional record keeping or the development of certain regulatory required hazard identification plans.

Each of these would likely entail substantial time and cost and could harm Napo s financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products would harm Napo s business, financial condition, and results of operations.

Risks Related to Our Common Stock

Our failure to meet the continued listing requirements of The NASDAQ Capital Market could result in a delisting of our common stock.

Our common stock is listed on The NASDAQ Capital Market, which imposes, among other requirements a minimum bid requirement. The closing bid price for our common stock must remain at or above $1.00 per share to comply with NASDAQ s minimum bid requirement for continued listing. If the closing bid price for our common stock is less than $1.00 per share for 30 consecutive business days, NASDAQ may send us a notice stating that we will be provided a period of 180 days to regain compliance with the minimum bid requirement or else NASDAQ may make a determination to delist our common stock. our common stock traded for less than $1.00 for 30 consecutive business days, and we received notice of this from The NASDAQ Capital Market on May 16, 2017. We have a 180 calendar day grace period, or until November 13, 2017, to regain compliance with the minimum bid price requirement. The minimum bid price requirement will be met if our common stock has a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days during the 180 calendar day grace period. We are diligently working to evidence compliance with the minimum bid requirement for continued listing on NASDAQ; however, there can be no assurance that we will be able to regain compliance or that NASDAQ will grant us a further extension of time to regain compliance, if necessary.

The delisting of our common stock from NASDAQ may make it more difficult for us to raise capital on favorable terms in the future. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. Further, if we were to be delisted from The NASDAQ Capital Market, our common stock would cease to be recognized as covered securities and we would be subject to regulation in each state in which it offers its securities.

Moreover, there is no assurance that any actions that we take to restore our compliance with the NASDAQ minimum bid requirement would stabilize the market price or improve the liquidity of our common stock, prevent our common stock from falling below the NASDAQ minimum bid price required for continued listing again or prevent future non-compliance with NASDAQ s listing requirements.

If our shares become subject to the penny stock rules, it would become more difficult to trade our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain a listing on The NASDAQ Capital Market and if the price of our common stock is less than $5.00, our common stock will be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser s written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.

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The price of our common stock could be subject to volatility related or unrelated to our operations, and purchasers of our common stock could incur substantial losses.

The trading price of our common stock could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed previously in this Risk Factors section of this report and others, such as:

- delays in the commercialization of Mytesi, Neonorm, Canalevia, Equilevia or our other current or future prescription drug product candidates and non-prescription products;

- any delays in, or suspension or failure of, our current and future studies;

- announcements of regulatory approval or disapproval of any of our current or future product candidates or of regulatory actions affecting our company or our industry;

- manufacturing and supply issues that affect product candidate or product supply for our studies or commercialization efforts;

- quarterly variations in our results of operations or those of our competitors;

- changes in our earnings estimates or recommendations by securities analysts;

- the payment of licensing fees or royalties in shares of our common stock;

- announcements by us or our competitors of new prescription drug products or product candidates or non-prescription products, significant contracts, commercial relationships, acquisitions or capital commitments;

- announcements relating to future development or license agreements including termination of such agreements;

- adverse developments with respect to our intellectual property rights or those of our principal collaborators;

- commencement of litigation involving us or our competitors;

- any major changes in our board of directors or management;

- new legislation in the United States relating to the prescription, sale, distribution or pricing of gastrointestinal health products;

- product liability claims, other litigation or public concern about the safety of our prescription drug product or product candidates and non-prescription products or any such future products;

- market conditions in the human or animal industry, in general, or in the gastrointestinal health sector, in particular, including performance of our competitors; and

- general economic conditions in the United States and abroad.

In addition, the stock market, in general, or the market for stocks in our industry, in particular, may experience broad market fluctuations, which may adversely affect the market price or liquidity of our common stock. Any sudden decline in the market price of our common stock could trigger securities class-action lawsuits against us. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the time and attention of our management would be diverted from our business and operations. We also could be subject to damages claims if we were found to be at fault in connection with a decline in our stock price.

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No active market for our common stock exists or may develop, and you may not be able to resell our common stock when you wish to sell them or at a price that you consider attractive or satisfactory.

Prior to our initial public offering in May 2015, there was no public market for shares of our common stock. The listing of our common stock on The NASDAQ Capital Market does not assure that a meaningful, consistent and liquid trading market exists. Although our common stock is listed on The NASDAQ Capital Market, trading volume in our common stock has been limited and an active trading market for our shares my never develop or be sustained. If an active market for our common stock does not develop, you may be unable to sell your shares when you wish to sell them or at a price that you consider attractive or satisfactory. The lack of an active market may also adversely affect our ability to raise capital by selling securities in the future, or impair our ability to license or acquire other product candidates, businesses or technologies using our shares as consideration.

The sale of our common stock to Aspire Capital may cause substantial dilution to our existing stockholders and the sale of the shares of common stock acquired by Aspire Capital could cause the price of our common stock to decline.

On June 8, 2016, we entered into the CSPA with Aspire Capital, in which Aspire Capital committed to purchase, at our election, up to an aggregate of $15.0 million shares of our common stock over a period of approximately 30 months (i.e., 30 months from July 8, 2016, the effective date of the initial registration statement on Form S-1 that we filed to register the shares that we issued and may issue to Aspire pursuant to the CSPA).

Through September 30, 2017, we have issued 6,000,000 shares of our common stock to Aspire Capital under the CSPA for gross proceeds of approximately $5.1 million. We may ultimately sell all, some or none of the approximately $10.0 million of common stock remaining under the CSPA to Aspire Capital, and Aspire Capital may sell all, some or none of our shares that it holds or comes to hold under the CSPA. Sales by Aspire Capital of shares acquired pursuant to the CSPA may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Aspire Capital, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and the CSPA may be terminated by us at any time at our discretion without any penalty or cost to us.

If securities or industry analysts do not publish research or reports about our company, or if they issue adverse or misleading opinions regarding us or our stock, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that industry or financial analysts publish about us or our business. We do not influence or control the reporting of these analysts. If one or more of the analysts who do cover us downgrade or provide a negative outlook on our company or our industry, or the stock of any of our competitors, the price of our common stock could decline. If one or more of these analysts ceases coverage of our company, we could lose visibility in the market, which in turn could cause the price of our common stock to decline.

You may be diluted by conversions of outstanding non-voting common stock and convertible notes and exercises of outstanding options and warrants.

As of August 31, 2017, we had (i) outstanding options to purchase an aggregate of 2,992,039 shares of our common stock at a weighted average exercise price of $2.46 per share, (ii) warrants to purchase an aggregate of 6,656,333 shares of our common stock at a weighted-average exercise price of $1.15 per share and (iii) outstanding convertible promissory notes in an aggregate principal amount of $13,800,627, which are convertible for up to 15,549,637 shares of our common stock.

The exercise of such options and warrants or conversion of the convertible promissory notes will result in further dilution of your investment. In addition, you may experience additional dilution if we issue common stock in the future. As a result of this dilution, you may receive significantly less in net tangible book value than the full purchase price you paid for the shares in the event of liquidation.

Shares eligible for future sale may adversely affect the market for our common stock.

Of the 89,050,655 shares of our common stock outstanding as of October 4, 2017, approximately 88,445,146 shares are held by non-affiliates and are, or will become, freely tradable without restriction pursuant to Rule 144. In addition, in August 2017 and October 2017, we filed with the SEC registration statements on Form S-3 for purposes of registering the resale of an aggregate of 59,098,882 shares of restricted common stock that were sold to certain Napo creditors and investors in connection with the Merger and related refinancing transactions, including (i) 1,489,741 shares of voting common stock, (ii) 22,917,268 shares of voting common

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stock issuable upon conversion of non-voting common stock, (iii) 1,224,875 shares of voting common stock issuable upon exercise of warrants with an exercise price of $0.08, (iv) 23,315,544 shares of voting common stock issuable upon conversion of Convertible Promissory Notes due December 30, 2019 (plus accrued interest), (v) 2,492,084 shares of voting common stock issuable upon conversion of Exchangeable Promissory Notes due December 1, 2017, and (vi) 4,000,000 shares of voting common stock issuable upon conversion of Secured Convertible Promissory Notes due August 2, 2018. While sales of certain of these shares are subject to contractual resale restrictions, any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our common stock.

If shares of our non-voting common stock are converted into shares of our voting common stock, your voting power will be diluted.

As of October 4, 2017, we had 45,777,367 shares of voting common stock and 43,173,288 shares of non-voting common stock outstanding. Generally, holders of our non-voting common stock have no voting power (other than in connection with a change of control of our company) and have no right to participate in any meeting of stockholders or to have notice thereof. However, shares of our non-voting common stock that are converted into voting common stock will have all the voting rights of the voting common stock. Shares of our non-voting common stock are convertible into shares of our voting common stock on a one-for-one basis (i) at the option of the respective holders thereof, at any time and from time to time on or after April 1, 2018 or (ii) automatically, without any payment of additional consideration by the holder thereof, (x) upon a transfer of such shares to any person or entity that is neither an affiliate of Nantucket nor an investment fund, investment vehicle or other account, that is, directly or indirectly, managed or advised by Nantucket or any of its affiliates pursuant to a sale of such stock to a third-party for cash in accordance with the terms and condition set forth in the Investor Rights Agreement, or (y) upon the subsequent release or transfer of such shares to the registered pre-Merger legacy stockholders of Napo s outstanding shares of common stock as of July 31, 2017 (the Napo Legacy Stockholders). Upon conversion of any non-voting common stock, your voting power will be diluted in proportion to the decrease in your ownership of the total outstanding voting common stock.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our third amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions to include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;

- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;

- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could adversely affect the rights of our common stockholders or be used to deter a possible acquisition of our company;

- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;

- the required approval of the holders of at least 75% of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our third amended and restated certificate of incorporation regarding the election and removal of directors;

- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and

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- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer s own slate of directors or otherwise attempting to obtain control of us.

These provisions could inhibit or prevent possible transactions that some stockholders may consider attractive.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation generally may not engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our amended and restated bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain actions and proceedings that may be initiated by our stockholders, which could limit our stockholders ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, (iv) any action asserting a claim that is governed by the internal affairs doctrine or (v) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws. Any person purchasing or otherwise acquiring any interest in any shares of our capital stock shall be deemed to have notice of and to have consented to this provision of our amended and restated bylaws. This choice-of-forum provision may limit our stockholders ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. Alternatively, if a court were to find this provision of our amended and restated bylaws inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could harm our business and financial condition.

We do not intend to pay dividends on our common stock, and your ability to achieve a return on your investment will depend on appreciation in the market price of our common stock.

We currently intend to invest our future earnings, if any, to fund our growth and not to pay any cash dividends on our common stock. Moreover, so long as Nantucket or any of its affiliates owns any shares of our non-voting common stock, we cannot pay dividends on our common stock or non-voting common stock without obtaining the prior written consent of Nantucket. Because we do not intend to pay dividends and may be required to obtain written consent if we were to do so, your ability to receive a return on your investment will depend on any future appreciation in the market price of our common stock. We cannot be certain that our common stock will appreciate in price.

Our principal stockholders own a significant percentage of our voting stock and will be able to exert significant control over matters subject to stockholder approval.

As of August 31, 2017, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned in the aggregate approximately 62% of the outstanding shares of our voting common stock. As a result of their stock ownership, these stockholders may have the ability to influence our management and policies, and will be able to significantly affect the outcome of matters requiring stockholder approval such as elections of directors, amendments of our organizational documents or approvals of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

The requirements of being a public company, including compliance with the reporting requirements of the Exchange Act and the requirements of the Sarbanes-Oxley Act, may strain our resources, increase our costs and distract management, and we may be unable to comply with these requirements in a timely or cost-effective manner.

Our initial public offering had a significant, transformative effect on us. Prior to our initial public offering, our business operated as a privately-held company, and we were not required to comply with public reporting, corporate governance and financial accounting practices and policies required of a publicly-traded company. As a publicly-traded company, we incur significant

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additional legal, accounting and other expenses compared to historical levels. In addition, new and changing laws, regulations and standards relating to corporate governance and public disclosure, including the Dodd-Frank Wall Street Reform and Consumer Protection Act and the rules and regulations thereunder, as well as under the Sarbanes-Oxley Act, the JOBS Act and the rules and regulations of the SEC and The NASDAQ Capital Market, may result in an increase in our costs and the time that our board of directors and management must devote to our compliance with these rules and regulations. These rules and regulations have substantially increased our legal and financial compliance costs and diverted management time and attention from our product development and other business activities.

The Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of its internal control over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. In particular, Section 404 of the Sarbanes-Oxley Act, or Section 404, requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm potentially to attest to, the effectiveness of our internal control over financial reporting. We have needed to expend time and resources on documenting our internal control over financial reporting so that we are in a position to perform such evaluation when required. As an emerging growth company, we expect to avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail itself of this exemption when we cease to be an emerging growth company. When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 requires that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

We are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not emerging growth companies. In particular, while we are an emerging growth company (i) we will not be required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, (ii) we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iii) we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved. In addition, the JOBS Act provides that an emerging growth company can delay its adoption of any new or revised accounting standards, but we have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. In addition, investors may find our common stock less attractive if we rely on the exemptions and relief granted by the JOBS Act. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline and/or become more volatile.

We may remain an emerging growth company until as late as December 31, 2020 (the fiscal year-end following the fifth anniversary of the closing of our initial public offering, which occurred on May 18, 2015), although we may cease to be an emerging growth company earlier under certain circumstances, including (i) if the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of any June 30, in which case we would cease to be an emerging growth company as of December 31 of such year, (ii) if our gross revenue exceeds $1.0 billion in any fiscal year or (iii) if we issue more than $1.0 billion of non-convertible debt over a three-year period.

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Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

On July 13, 2017, pursuant to a share purchase agreement, we issued 100,000 shares of our common stock to an existing investor for gross proceeds of $50,000.

On July 31, 2017, pursuant to a share purchase agreement, we issued 3,243,243 shares of our common stock to an institutional investor for gross proceeds of approximately $3.0 million.

On July 31, 2017, we issued 64,866 shares of our voting common stock to KCSA Strategic Communications (KCSA) pursuant to the Agreement and Plan of Merger, dated March 31, 2017 (the Merger Agreement), by and among the Company, Napo, Napo Acquisition Corporation (Merger Sub), and Napo s representative (the Merger) and an agreement between Napo and KCSA, as a complete settlement and satisfaction of Napo s outstanding obligations to KCSA.

On March 31, 2017, in order to induce us to enter into the Merger Agreement, Napo entered into a Settlement and Discounted Payoff Agreement with Nantucket Investments Limited (Nantucket) and the lenders named therein (the Settlement Agreement), pursuant to which, among other things, we issued to Nantucket, simultaneously with the consummation of the Merger on July 31, 2017, 2,217,579 shares of our voting common stock and 38,180,451 shares of our non-voting common stock.

On or about March 31, 2017, in order to induce us to enter into the Merger Agreement, Napo entered into debt settlement agreements with Dorsar Investment Company, Alco Investment Company, Two Daughters LLC, Boies Schiller Flexner LLP and Dan Becka (collectively, the Debt Settlement Agreements), pursuant to which we issued in the aggregate 4,167,172 shares of our non-voting common stock and warrants to purchase 1,224,875 shares of our voting common stock, with an exercise price of $0.08 per share (the Warrants), to such creditors and their respective affiliates as a complete settlement and satisfaction of Napo s outstanding obligations to such creditors.

The offers, sales, and issuances of the securities described above were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act, Regulation D or Regulation S promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited or sophisticated person and had adequate access, through employment, business or other relationships, to information about us.

Other than as provided above and the shares of our common stock sold pursuant to the CSPA, as disclosed on our Form 8-K filed with the SEC on June 9, 2016, there were no unregistered sales of equity securities during the period.

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Item 6. Exhibits

Exhibit No.	Description
3.1	Third Amended and Restated Certificate of Incorporation of Jaguar Health, Inc. (f/k/a Jaguar Animal Health, Inc.) (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K (No. 001-36714) filed on August 1, 2017).
4.1	Specimen Non-Voting Common Stock Certificate of Jaguar Health, Inc. (incorporated by reference to Exhibit 4.1 to the Form 8-K of Jaguar Health, Inc. filed August 1, 2017, File No. 001-36714).
10.1	Form of Warrant Exercise Agreement (incorporated by reference to Ex. 10.1 to the Current Report on Form 8-K filed on July 31, 2017).
10.2*	Share Purchase Agreement, dated July 31, 2017, by and between Jaguar Health, Inc. and Invesco Asset Management Limited.
10.3	Letter Agreement, dated September 1, 2017, by and among Napo Pharmaceuticals, Inc., MEF I, L.P. and Riverside Merchant Partners (incorporated by reference to Exhibit 10.33 to the Form 8-K/A of Jaguar Health, Inc. filed September 14, 2017, File No. 001-36714).
10.4	Letter Agreement, dated August 31, 2017, by and among Napo Pharmaceuticals, Inc., M. Kingdon Offshore Master Fund L.P., Kingdon Family Partnership, L.P. and Kingdon Credit Master Fund L.P. (incorporated by reference to Exhibit 10.34 to the Form 8-K/A of Jaguar Health, Inc. filed September 14, 2017, File No. 001-36714).
10.5	Letter Agreement, dated August 28, 2017, by and among Napo Pharmaceuticals, Inc., Dorsar Investment Company, Alco Investment Company and Two Daughters LLC (incorporated by reference to Exhibit 10.35 to the Form 8-K/A of Jaguar Health, Inc. filed September 14, 2017, File No. 001-36714).
10.6	Letter Agreement, dated September 1, 2017, by and between Napo Pharmaceuticals, Inc. and Boies Schiller Flexner LLP (incorporated by reference to Exhibit 10.36 to the Form 8-K/A of Jaguar Health, Inc. filed September 14, 2017, File No. 001-36714).
10.7	Letter Agreement, dated August 30, 2017, by and between Jaguar Health, Inc. and Chicago Venture Partners, L.P. (incorporated by reference to Exhibit 10.37 to the Form 8-K/A of Jaguar Health, Inc. filed September 14, 2017, File No. 001-36714).
10.8*	Termination, Asset Transfer and Transition Agreement, dated September 22, 2017, by and between Napo Pharmaceuticals, Inc. and Glenmark Pharmaceuticals, Ltd.
31.1*	Principal Executive Officer s Certification Pursuant to Section 302 of the Sarbanes- Oxley Act of 2002.
31.2*	Principal Financial Officer s Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
32.2**	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934 (the Exchange Act) or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933 except to the extent that the registrant specifically incorporates it by reference.

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SIGNATURE

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

Date: November 20, 2017

JAGUAR HEALTH, INC.

By: /s/ Karen S. Wright
Karen S. Wright
Chief Financial Officer
Principal Financial and Accounting Officer