
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2017

OR

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
(State or other jurisdiction of
incorporation or organization)

46-2956775
(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 No

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 No

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

Accelerated filer

Non-accelerated filer
(Do not check if a
smaller reporting company)

Smaller reporting company
Emerging growth company

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

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

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.

[Table of Contents](#)

	<u>Page No.</u>
PART I. — FINANCIAL INFORMATION (Unaudited)	1
Item 1. Condensed Consolidated Unaudited Financial Statements	1
Condensed Consolidated Balance Sheets as of September 30, 2017 and December 31, 2016	1
Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Nine Month Periods Ended September 30, 2017 and 2016	2
Condensed Consolidated Statement of Changes in Common Stock, Convertible Preferred Stock and Stockholders' Equity (Deficit) for the period from December 31, 2016 through September 30, 2017	3
Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2017 and 2016	4
Notes to the Condensed Consolidated Financial Statements	5
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	33
Item 3. Quantitative and Qualitative Disclosures About Market Risk	66
Item 4. Controls and Procedures	66
PART II. — OTHER INFORMATION	66
Item 1. Legal Proceedings	66
Item 1A. Risk Factors	66
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	96
Item 6. Exhibits	97
SIGNATURE	98

[Table of Contents](#)

PART I. — FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

JAGUAR HEALTH, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	<u>September 30, 2017 (Unaudited)</u>	<u>December 31, 2016 (⁽¹⁾)</u>
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	<u>4,242,247</u>	<u>2,555,041</u>
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	<u>\$ 59,988,055</u>	<u>\$ 3,563,149</u>
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	<u>16,026,186</u>	<u>4,192,852</u>
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.

1

[Table of Contents](#)

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.

2

[Table of Contents](#)

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		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount	Shares	Amount			
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.

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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 Estimates

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

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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	<u>\$ 1,100,214</u>	<u>\$ 50,357</u>	<u>\$ 2,819,145</u>	<u>\$ 112,646</u>
Interest expense				
Human Health	\$ (192,120)	\$ —	\$ (192,120)	\$ —
Animal Health	(272,564)	(235,191)	(608,765)	(774,185)
Consolidated Totals	<u>\$ 464,684</u>	<u>\$ (235,191)</u>	<u>\$ (800,885)</u>	<u>\$ (774,185)</u>
Depreciation and amortization				
Human Health	\$ 281,111	\$ —	\$ 281,111	\$ —
Animal Health	15,031	15,031	45,093	32,463
Consolidated Totals	<u>\$ 296,142</u>	<u>\$ 15,031</u>	<u>\$ 326,204</u>	<u>\$ 32,463</u>
Segment profit				
Human Health	\$ 996,493	\$ —	\$ 996,493	\$ —
Animal Health	3,763,351	(3,415,490)	(2,757,649)	(11,057,169)
Total	<u>\$ 4,759,844</u>	<u>\$ (3,415,490)</u>	<u>\$ (1,761,156)</u>	<u>\$ (11,057,169)</u>

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	<u>\$ 92,323,335</u>	<u>\$ 3,563,149</u>

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	<u>\$ 59,988,055</u>	<u>\$ 3,563,149</u>

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-

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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	<u>\$ 31,705,259</u>

[Table of Contents](#)

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	<u>9,667,438</u>
Goodwill on acquisition	22,037,821
Total consideration	<u>\$ 31,705,259</u>

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 anti-diarrheal 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 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)
Net income (loss) per share, diluted	0.08	(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

[Table of Contents](#)

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			Total
	Level 1	Level 2	Level 3	

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	\$	—	\$	—

16

[Table of Contents](#)

	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 derivatives were revalued at September 30, 2017 using the same Model resulting in a combined fair value of \$19,000. The \$1,000 gain is included in other income and expense in the 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.

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 would owe 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.

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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.

[Table of Contents](#)

June 2017 Convertible Note

On June 29, 2017, the Company issued a secured convertible promissory note ("Note") to a lender in the aggregate principal amount of \$2,155,000 less an original issue discount of \$425,000 and less \$30,000 to cover the lender's legal fees for net cash proceeds of \$1,700,000. Interest on the outstanding balance will be paid 8% per annum from the purchase price date until the balance is paid in full. All interest calculations are computed on the basis of a 360-day year comprised of twelve (12) thirty (30) day months compounded daily and payable in accordance with the terms of the Note. All principal and interest on the debt is due in full on August 2, 2018. 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 lender may accelerate the Note resulting in the outstanding balance becoming immediately due and payable in cash; and
2. Automatic increase in the interest rate on and during an event of default — during an event of default, the interest rate will increase to the lesser of 17% per annum or the maximum rate permitted under applicable law.

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

[Table of Contents](#)

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	<u>\$ 1,801,227</u>	<u>\$ 3,737,201</u>
Current portion of long-term debt	\$ 1,801,227	\$ 1,919,675
Long-term debt, net of discount	—	1,817,526
Total	<u>\$ 1,801,227</u>	<u>\$ 3,737,201</u>

[Table of Contents](#)

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

Years ending December 31	Amount
2017 - October through December 2018	\$ 260,832
Total future principal payments	1,089,199
2018 end-of-term payment	1,350,031
	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	<u>\$ 1,855,328</u>

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
	<u>\$ 100,765</u>	<u>\$ 230,655</u>	<u>\$ 426,222</u>	<u>\$ 760,673</u>

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.

25

Table of Contents

- 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

[Table of Contents](#)

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,

[Table of Contents](#)

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	\$	<u>1,000,001</u>	<u>100%</u>	\$	<u>322,777</u>

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 its 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	<u>31,598,624</u>	<u>3,374,321</u>

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.

[Table of Contents](#)

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	\$ —

29

[Table of Contents](#)

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%

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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 January 2017 through March 31, 2018) for its current, FDA-approved specialty indication.

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

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

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

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

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

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

[Table of Contents](#)

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 Genentech—Roche with Herceptin (enrolling patients), and one funded by Puma with neratinib (planning for patient enrollment).

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

[Table of Contents](#)

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	Phase 2	· Protocol development with KOLs for discussions with

		· Two significant Phase 2 studies completed	FDA
SB-300	Second-generation anti-secretory agent for multiple indications including cholera	· Animal and human studies in secretory diarrheas; successful cholera trial design for anti-secretory mechanism of action with crofelemer	· Publication of additional analysis of Phase 2 data · CMC development for SB-300 · Pre-clinical and Phase 1 in 2018*

* Clinical trials are funding-dependent

[Table of Contents](#)

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-profit>)

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

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

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

[Table of Contents](#)

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 Mundi, 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.

[Table of Contents](#)

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

[Table of Contents](#)

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 standalone 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 are reimbursed are reflected as research and development costs.

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

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.

40

[Table of Contents](#)

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

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.

41

[Table of Contents](#)

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,		Variance	Variance %
	2017	2016		
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%

[Table of Contents](#)

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.

[Table of Contents](#)

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,		Variance	Variance %
	2017	2016		
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	<u>\$ 3,033,851</u>	<u>\$ 5,672,516</u>	<u>\$ (2,638,665)</u>	<u>(46.5)%</u>

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.

[Table of Contents](#)**Sales and Marketing Expense**

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

	Nine Months Ended September 30,		Variance	Variance %
	2017	2016		
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	<u>\$ 943,908</u>	<u>\$ 355,345</u>	<u>\$ 588,563</u>	<u>165.6%</u>

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,		Variance	Variance %
	2017	2016		
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	<u>\$ 8,512,195</u>	<u>\$ 4,319,856</u>	<u>\$ 4,192,339</u>	<u>97.0%</u>

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,

[Table of Contents](#)

\$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,		Variance	Variance %
	2017	2016		
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%

[Table of Contents](#)

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.

47

[Table of Contents](#)

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,		Variance	Variance %
	2017	2016		
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	<u>\$ 851,608</u>	<u>\$ 1,967,128</u>	<u>\$ (1,115,520)</u>	<u>(56.7)%</u>

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.

48

[Table of Contents](#)

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,		Variance	Variance %
	2017	2016		
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	<u>\$ 663,765</u>	<u>\$ 136,882</u>	<u>\$ 526,883</u>	<u>384.9%</u>

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,		Variance	Variance %
	2017	2016		
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%

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

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

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

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

- On March 31, 2017, we entered into a merger agreement with Napo, pursuant to which we are required, among other things, to issue approximately 69,299,346 shares of our common stock and non-voting common stock to Napo creditors, noteholders, holders of Napo warrants, options or restricted stock units, and Invesco upon consummation of the merger.
- On June 28, 2017, we closed a private investment in public entities with a member of our board of directors. We received gross proceeds of \$50,000 in exchange for 100,000 shares of our common stock.
- On June 29, 2017, we issued a secured convertible promissory note to a lender in the aggregate principal amount of \$2,155,000 less an original issue discount of \$425,000 and less \$30,000 to cover the lender's legal fees for net cash proceeds of \$1,700,000. Interest on the outstanding balance will be paid 8% per annum from the purchase price date until the balance is paid in full. All interest calculations are computed on the basis of a 360-day year comprised of twelve (12) thirty (30) day months compounded daily and payable in accordance with the terms of the Note. All principal and interest on the debt is due in full on August 2, 2018.
- 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

[Table of Contents](#)

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
	<u>\$ (730,389)</u>	<u>\$ (5,884,120)</u>

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

[Table of Contents](#)

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	—
	<u>\$ 14,758,501</u>	<u>\$ 150,000</u>
Less: unamortized debt discount and debt issuance costs	(384,292)	—
Net convertible notes payable obligation	<u>\$ 14,374,209</u>	<u>\$ 150,000</u>
Convertible notes payable - non-current	11,161,000	—
Convertible notes payable - current	<u>\$ 3,213,209</u>	<u>\$ 150,000</u>

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	<u>\$ 347,597</u>	<u>\$ 4,537</u>	<u>\$ 358,341</u>	<u>\$ 13,512</u>

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

[Table of Contents](#)

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 on extinguishment of debt in our statements of operations and comprehensive loss in the nine months ended September 30, 2017.

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

June 2017 Convertible Note

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

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

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

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

[Table of Contents](#)

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

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

Napo convertible notes

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

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

Long term Debt

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

[Table of Contents](#)

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	<u>\$ 1,801,227</u>	<u>\$ 3,737,201</u>
Current portion of long-term debt	\$ 1,801,227	\$ 1,919,675
Long-term debt, net of discount	—	1,817,526
Total	<u>\$ 1,801,227</u>	<u>\$ 3,737,201</u>

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

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

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
	<u>\$ 100,765</u>	<u>\$ 230,655</u>	<u>\$ 426,222</u>	<u>\$ 760,673</u>

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,

Table of Contents

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.

Table of Contents

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	<u>6,656,333</u>	<u>5,968,876</u>

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

[Table of Contents](#)

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

[Table of Contents](#)

months ended September 30, 2017 which are included in our statements of operations and comprehensive loss. The difference of \$814,589 is included in deferred collaboration revenue in our balance sheet.

In addition to the upfront payments, Elanco reimburses us for certain development and regulatory expenses related to our planned target animal safety study and the completion of the Canalevia field study for acute diarrhea in dogs. These are recognized as revenue in the month in which the related expenses are incurred. We have \$17,349 of unreimbursed expenses as of September 30, 2017, which is included in Other Receivables on our balance sheet. We included the \$17,349 and \$503,391 in collaboration revenue in the three and nine months ended September 30, 2017 which are included in the statements of operations and comprehensive loss. On November 1, 2017, 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.

[Table of Contents](#)

- 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.

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

[Table of Contents](#)

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 periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Public entities may apply the guidance earlier but only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. We do not expect the adoption of ASU 2017-05 to have a material impact on our consolidated financial statements.

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

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 Neonom 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.

[Table of Contents](#)

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. § 355(j)(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.

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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.

[Table of Contents](#)

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;

[Table of Contents](#)

- 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.

[Table of Contents](#)

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.

[Table of Contents](#)

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 may 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

[Table of Contents](#)

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

- 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

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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

10.4	(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), 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.

97

[Table of Contents](#)

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

98

THE SECURITIES TO WHICH THIS AGREEMENT RELATES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (“SECURITIES ACT”), OR UNDER ANY STATE SECURITIES LAWS (“BLUE SKY LAWS”), AND MAY NOT BE OFFERED OR SOLD WITHOUT REGISTRATION UNDER THE SECURITIES ACT, AND AS REQUIRED BY BLUE SKY LAWS IN EFFECT AS TO SUCH TRANSFER, UNLESS AN EXEMPTION FROM SUCH REGISTRATION UNDER STATE AND FEDERAL LAW IS AVAILABLE

SHARE PURCHASE AGREEMENT

THIS SHARE PURCHASE AGREEMENT (the “Agreement”) is deemed to be effective as of July 31, 2017 (the “Effective Date”), by and between Jaguar Animal Health, Inc., a Delaware corporation (the “Company”), and Invesco Asset Management Limited, acting as agent for and on behalf of its discretionary managed clients (“Invesco”).

RECITALS

- A. Pursuant to the commitment letter, dated February 21, 2017 (the “Commitment”), Invesco desires to purchase from the Company, and the Company desires to sell to Invesco that number of shares of the Company’s Common Stock, par value \$0.0001 per share, set forth below Invesco’s name on the signature page hereto (the “Shares”) at a purchase price of Ninety-Two and a Half United States Cents (US\$0.925) per share and on the additional terms and conditions hereinafter set forth.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual agreements, covenants, representations and warranties contained in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the parties hereby agree as follows:

1. Purchase and Sale of Stock.

a. Sale and Issuance of Stock. Subject to the terms and conditions of this Agreement, Invesco agrees to purchase at the Closing (as defined below), and the Company agrees to sell and issue to Invesco at the Closing, the Shares at a price of US\$0.925 per share.

b. Closing, Payment and Delivery. Subject to fulfillment of the conditions set forth in Section 5 below, the consummation of the transactions contemplated herein (the “Closing”) shall take place at the offices of Reed Smith LLP, 1510 Page Mill Road, Suite 110, Palo Alto, California, 94304 (or remotely via the exchange of documents and signatures) on the Effective Date. At the Closing, the Company shall deliver to Invesco a letter of direction in the form set forth in Exhibit A hereto (the “Letter of Direction”). Invesco shall purchase the Shares by making payment to the Company and/or the Company’s designee in cash or wire transfer of funds of the purchase price as set forth below Invesco’s name on the signature page hereto (the “Purchase Price”) in accordance with the Letter of Direction.

For the purposes of this Agreement, “Business Day” means a day other than Saturday, Sunday or any day on which banks located in the State of New York or the City of London are authorized or obligated to close.

If the Merger Effective Date (as defined below) does not occur before August 2, 2017, the Company shall return the Purchase Price (if paid) to Invesco, Invesco and the Company shall instruct the Transfer Agent to cancel any instructions given pursuant to Section 1(c) below, and the parties hereto shall terminate this Agreement.

c. Delivery of Share Certificate. At the Closing, the Company shall deliver to Invesco a copy of the irrevocable instructions to Computershare Trust Company, N.A., the current transfer agent of the Company, with a mailing address of 8742 Lucent Blvd., Suite 225 Highlands Ranch, CO 80129 Attn: Brooke Webb (the “Transfer Agent”), instructing the Transfer Agent to deliver, on an expedited basis, a certificate or certificates evidencing the Shares, registered in the names set forth on the signature page hereto, in exchange for the Purchase Price.

2. Company’s Representations and Warranties. The Company hereby represents and warrants to Invesco as of the Effective Date and as of the Closing as follows, subject to the exceptions as are disclosed prior to the Effective Date in the Company’s reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act of 1933, as amended (the “Securities Act”) and the Exchange Act of 1934, as amended (the “Exchange Act”) including pursuant to Section 13(a) or 15(d) thereof (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, being collectively referred to herein as the “SEC Reports”), which SEC Reports as filed prior to the Effective Date shall be deemed a part hereof and shall qualify any representation or warranty otherwise made herein to the extent of the disclosure contained in the SEC Reports as filed prior to the Effective Date:

a. Organization, Good Standing and Qualification. The Company is a corporation duly organized and validly existing under the laws of the State of Delaware. The Company has all requisite corporate power and authority to own and operate its properties and assets, to execute and deliver this Agreement and sell the Shares, and to carry out the provisions of this Agreement and to carry on its business as presently conducted. The Company is duly qualified and is authorized to do business and is in good standing as a foreign corporation in all jurisdictions in which the nature of its activities and of its properties (both owned and leased) makes such qualification necessary, except for those jurisdictions in which failure to do so would not have a material adverse effect on the Company or its business.

b. Authorization; Binding Obligations. All corporate action on the part of the Company, its officers, directors and shareholders necessary for the authorization of this Agreement and the Shares, the performance of all obligations of the Company hereunder at the Closing, and the sale, issuance and delivery of the Shares pursuant hereto has been taken or will be taken prior to the Closing.

c. No Conflict. Neither the execution and delivery of this Agreement, nor the consummation of the transactions contemplated hereby, will (i) violate or result in a breach of or constitute a default under any contract or agreement to which the Company is a party or by

which it is bound, (ii) conflict with or result in a breach of or constitute a default under any provision of the certificate of incorporation or bylaws (or other charter documents) of the Company, or (iii) violate or result in a breach of or constitute a default under any judgment, order, decree, rule or regulation of any court or governmental agency to which the Company is subject.

d. SEC Reports; Financial Statements. The Company has filed all SEC Reports required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two years preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material). The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the U.S. Securities and Exchange Commission (the "Commission") with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

e. Capitalization. Except as set forth on Schedule 2.e., the authorized capital stock of the Company and the issued and outstanding securities of the Company are as disclosed as of the Effective Date in the SEC Reports.

f. Absence of Litigation. Neither the Company nor any of its directors is engaged in any litigation, administrative, mediation or arbitration proceedings or other proceedings or hearings before any statutory or governmental body, department, board or agency and is not the subject of any investigation, inquiry or enforcement proceedings by any governmental, administrative or regulatory body. Except as set forth on Schedule 2.f., no such proceedings, investigation or inquiry are pending or, to the Company's knowledge, threatened against the Company, and, to the Company's knowledge, there are no circumstances likely to give rise to any such proceedings.

g. Intellectual Property. The Company has, or has rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights as described in the SEC Reports as necessary or required for use in connection with its business and which the failure to so have could have a material adverse effect (collectively, the "Intellectual Property Rights"). The Company has not received a notice (written or otherwise) that any of, the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights.

h. Valid Issuance. The Shares issued hereunder will be duly and validly issued, fully paid and non-assessable and will be free of restrictions on transfer other than restrictions on transfer under this Agreement and under applicable state and federal securities laws.

3. Invesco Representations and Warranties. Invesco represents and warrants to the Company that:

a. Requisite Power and Authority. Invesco has all necessary power and authority under all applicable provisions of law to execute and deliver this Agreement and to carry out its provisions. All action on Invesco's part required for the lawful execution and delivery of this Agreement has been or will be taken prior to the Closing.

b. Own Account. Invesco is acquiring the Shares for investment for Invesco's managed clients' accounts, and not with a view to, or for resale in connection with, any distribution thereof in the United States, and Invesco has no present intention of selling or distributing any Shares in the United States. Invesco understands that the Shares have not been registered under the Securities Act by reason of a specific exemption from the registration provisions of the Securities Act which depends upon, among other things, the bona fide nature of the investment as expressed herein. For the avoidance of doubt, this Section 3(b) is not intended to restrict Invesco's ability to transfer the securities outside the United States pursuant to Regulation S promulgated under the Securities Act. It is the parties' understanding that the provisions of the Securities Act will not ordinarily restrict Invesco's ability to transfer the Shares outside the United States pursuant to Regulation S promulgated under the Securities Act.

c. Access to Data. Invesco has had an opportunity to discuss the Company's business, management and financial affairs with the Company's management and to obtain any additional information which Invesco has deemed necessary or appropriate for deciding whether or not to purchase the Shares, including an opportunity to receive, review and understand the information regarding the Company's financial statements, capitalization and other business information contained in the SEC Reports and the Company's Registration Statement on Form S-4 (File No. 333-217364) filed with the Commission on July 3, 2017 as Invesco deems prudent. Invesco acknowledges that no representations or warranties, oral or written, have been made by the Company or any agent thereof except as set forth in this Agreement.

d. No Fairness Determination. Invesco is aware that no federal, state or other agency has made any finding or determination as to the fairness of the investment, nor made any recommendation or endorsement of the Shares.

e. Knowledge And Experience. Invesco has such knowledge and experience in financial and business matters, including investments in other start-up companies, that such entity or individual is capable of evaluating the merits and risks of the investment in the Shares and it is able to bear the economic risk of such investment. Invesco is an "accredited" investor as that term is defined under Regulation D promulgated under the Securities Act, and as set forth on Schedule I attached hereto. Further, Invesco has such knowledge and experience in financial and business matters that such individual is capable of utilizing the information made available in connection with the offering of the Shares, of evaluating the merits and risks of an

investment in the Shares and of making an informed investment decision with respect to the Shares. Neither Invesco, nor any person or entity with whom Invesco will share beneficial ownership of the Shares, is subject to any of the “Bad Actor” disqualifications described in Rule 506(d)(1)(i) to (viii) under the Securities Act.

f. General Solicitation. Invesco is not, to Invesco’s knowledge, purchasing the Shares as a result of any advertisement, article, notice or other communication regarding the Shares published in any newspaper, magazine or similar media or broadcast over television or radio or presented at any seminar or any other general solicitation or general advertisement.

g. Residence. Invesco’s principal place of business or residence is and its investment decisions are made in the jurisdiction identified in the address or other jurisdiction set forth on the signature page.

4. Restrictions on Transfer.

a. Each instrument evidencing the Shares which Invesco may purchase hereunder and any other securities issued upon any stock split, stock dividend, recapitalization, merger, consolidation or similar event (unless no longer required in the opinion of the counsel for the Company) shall be imprinted with a legend substantially in the following form:

THIS SECURITY HAS NOT BEEN REGISTERED WITH THE U.S. SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE “SECURITIES ACT”), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS. THIS SECURITY MAY BE SUBJECT TO ADDITIONAL RESTRICTIONS PURSUANT TO EXEMPTIONS IN THE VARIOUS JURISDICTIONS WHERE THEY ARE BEING SOLD.

b. Certificates evidencing the Shares shall not contain any legend (including the legend set forth in Section 4(a) above), (i) while a registration statement (including the Registration Statement (as defined below)) covering the resale of such security is effective under the Securities Act, (ii) following any sale of such Shares pursuant to Rule 144, (iii) if such Shares are eligible for sale under Rule 144, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such Shares and without volume or manner-of-sale restrictions, or (iv) if such legend is not required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the staff of the Commission). The Company shall cause its counsel to issue a legal opinion to the Transfer Agent promptly after the Registration Statement Effective Date (as defined below) if required by the Transfer Agent to effect the removal of the legend hereunder.

5

5. Conditions to Closing.

a. The obligation of Invesco to consummate the transactions contemplated herein at the Closing is subject to the satisfaction on or before the date of the Closing of the following conditions, all or any of which may be waived in writing by Invesco as to its obligation to consummate the transaction so contemplated:

i. **Performance.** The Company shall have performed all obligations, covenants and agreements herein required to be performed by the Company on or prior to the Closing.

ii. **Proceedings.** All corporate and other proceedings taken or to be taken in connection with the transactions contemplated hereby to be consummated at or prior to the Closing and all documents incidental thereto or required to be delivered prior to or at the Closing will be reasonably satisfactory in form and substance to Invesco.

iii. **Suits/Proceedings.** No action, suit, proceeding or investigation by or before any court, administrative agency or other governmental authority shall have been instituted or threatened to restrain, prohibit or invalidate the transactions contemplated by this Agreement.

iv. **Authorization of Issuance.** The Company’s board of directors will have authorized the issuance and sale by it to Invesco pursuant to this Agreement of the Shares.

v. **Consents and Approvals.** The Company shall have obtained any and all consents (including all governmental or regulatory consents, approvals or authorizations required in connection with the valid execution and delivery of this Agreement), permits and waivers necessary or appropriate for consummation of the transactions contemplated by this Agreement.

vi. **Certificate of the CEO.** The Company shall have delivered to Invesco a written certificate executed by the Chief Executive Officer of the Company certifying that each of the conditions to the consummation of the Merger set forth in Article VIII of the Merger Agreement, other than those conditions that by their nature or the terms of the Merger Agreement are to be satisfied at the consummation thereof, has been satisfied (the “CEO Certificate”).

vii. **Representations and Warranties.** The representations and warranties of the Company contained in this Agreement that are not qualified by materiality or similar qualification shall be true and correct in all material respects on and as of the Closing, except to the extent expressly made as of an earlier date, in which case such representations and warranties shall be true and correct in all material respects as of such earlier date, and the representations and warranties of the Company contained in this Agreement that are qualified by materiality or similar qualification shall be true and correct in all respects on and as of the Closing, except to the extent expressly made as of an earlier date, in which case such representations and warranties shall be true and correct in all respects as of such earlier date.

6

b. The obligation of the Company to consummate the transactions contemplated herein at the Closing is subject to the satisfaction on or before the date of the Closing of the following conditions, all or any of which may be waived in writing by the Company as to its obligation to consummate the transaction so contemplated:

i. **Performance.** Invesco shall have performed all obligations, covenants and agreements herein required to be performed by Invesco on or prior to the Closing.

ii. **Instruments and Documents.** All instruments and documents required to carry out this Agreement or incidental thereto shall be reasonably satisfactory to the Company and its counsel.

iii. **Suits/Proceedings.** No action, suit, proceeding or investigation by or before any court, administrative agency or other governmental authority shall have been instituted or threatened to restrain, prohibit or invalidate the transactions contemplated by this Agreement.

iv. **Representations and Warranties.** The representations and warranties of Invesco contained in this Agreement that are not qualified by materiality or similar qualification shall be true and correct in all material respects on and as of the Closing, except to the extent expressly made as of an earlier date, in which case such representations and warranties shall be true and correct in all material respects as of such earlier date, and the representations and warranties of Invesco contained in this Agreement that are qualified by materiality or similar qualification shall be true and correct in all respects on and as of the Closing, except to the extent expressly made as of an earlier date, in which case such representations and warranties shall be true and correct in all respects as of such earlier date.

6. Reliance. Invesco is aware that the Company is relying on the accuracy of the representations and warranties set forth in Section 3 hereof to establish compliance with Federal and State securities laws. If any such warranties or representations are not true and accurate in any respect as of the Closing, Invesco shall so notify the Company in writing immediately and shall be cause for rescission by the Company at its sole election.

7. Registration Rights.

a. The Company hereby agrees that, within 45 days after the Merger Effective Date as such term is defined below along with any other terms used in this Section 7, the Company shall file a shelf registration statement (or such other form available, the "Registration Statement") with the Commission with respect to the Shares. The Company shall use its commercially reasonable efforts to cause the Registration Statement to be declared effective under the Securities Act as promptly as possible after the filing thereof, but in any event (x) no later than the sixtieth (60th) day following the filing of the Registration Statement in the event of "limited review" by the Commission, or (y) in the event of a "review" by the Commission, the ninetieth (90th) day following the filing of the Registration Statement, and shall use its commercially reasonable efforts to keep such Registration Statement continuously effective under the Securities Act during the entire Effectiveness Period.

7

b. Notwithstanding anything in this Section to the contrary, the Company may, on no more than two occasions during any 12-month period, delay or suspend the effectiveness of the Registration Statement for up to 30 days on each occasion (a "Delay Period") if the board of directors of the Company determines in good faith that (i) effectiveness of the Registration Statement must be suspended in accordance with the rules and regulations under the Securities Act or that (ii) the disclosure of material non-public information ("Pending Developments") at such time would be detrimental to the Company and its subsidiaries, taken as a whole. Notwithstanding the foregoing, the Company shall use its reasonable best efforts to ensure that the Registration Statement is declared effective and its permitted use is resumed following a Delay Period as promptly as practicable.

c. If at any time the Company proposes to file a Registration Statement (other than to file a shelf registration that is not in connection with a particular offering), or the Company proposes to sell Company Common Stock in an underwritten offering for cash (excluding the Excluded Registration Statements and excluding an offering relating solely to an employee benefit plan or an offering relating to a transaction on Form S-4) (a "Piggyback Registration Statement"), the Company shall give prompt written notice (the "Piggyback Notice") to all Holders that hold Registrable Securities (collectively, the "Piggyback Eligible Holders") of the Company's intention to file a Piggyback Registration Statement reasonably in advance of (and in any event at least ten (10) Business Days before) the anticipated filing date of such Piggyback Registration Statement. The Piggyback Notice shall offer the Piggyback Eligible Holders the opportunity to include for registration in such Piggyback Registration Statement the number of Registrable Securities of the same class and series as those proposed to be registered as they may request, subject to pro ration for the maximum number of shares that can be sold in the reasonable judgment of the lead underwriter (a "Piggyback Registration"). The Company shall use its commercially reasonable efforts to include in each such Piggyback Registration such Registrable Securities for which the Company has received written requests (each, a "Piggyback Request") from Piggyback Eligible Holders within five (5) Business Days after giving the Piggyback Notice. The Company shall use its commercially reasonable efforts to effect the registration under the Securities Act of all Registrable Securities which the Company has been so requested to register pursuant to the Piggyback Requests, to the extent required to permit the disposition of the Registrable Securities so requested to be registered.

d. All fees and expenses incident to the performance of or compliance with this Section by the Company shall be borne by the Company whether or not any Registrable Securities are sold pursuant to a Registration Statement.

e. Except for registration rights granted on or prior to the Merger Effective Date, the Company has not entered into and, unless agreed in writing by each Holder on or after the date of this Agreement, will not enter into, any agreement or arrangement that (i) is inconsistent with the rights granted to the Holders with respect to Registrable Securities in this Agreement or otherwise conflicts with the provisions hereof in any material respect or (ii) other than as set forth in this Agreement, would allow any holder of Company Common Stock or other securities of the Company to include such securities in any Registration Statement filed by the Company on a basis that is more favorable in any material respect to the rights granted to the Holders hereunder including granting registration rights that would have priority over the Registrable Securities with respect to the inclusion of such securities in any registration.

f. As used in this Section, the following terms have the respective meanings:

“Effectiveness Period” means, the period commencing on the Registration Statement Effective Date and ending on the earlier of (i) the time as all of the Registrable Securities covered by such Registration Statement have been sold (either pursuant to a Registration Statement or otherwise) by the Holders, or (ii) the time as all of the remaining Registrable Securities are eligible to be sold by the Holders without compliance with the volume limitations or public information requirements of Rule 144.

“Holder” or “Holders” means the holder or holders, as the case may be, from time to time, of Registrable Securities.

“Excluded Registration Statements” means (i) the registration statement relating to the resale of approximately 42,987,436 shares of the Company’s common stock to be filed within four business days after the Merger Effective Date, (ii) the post-effective amendment to the registration statement on Form S-4 (File No. 333-217364) relating to the resale of shares of the Company’s common stock issuable upon vesting of the contingent rights issued to holders of common stock of Napo Pharmaceuticals, Inc., pursuant to the Merger Agreement, and (iii) one or more registration statements relating to the resale of shares of the Company’s common stock issued or issuable pursuant to the Common Stock Purchase Agreement, dated June 8, 2016, by and between the Company and Aspire Capital Fund, LLC.

“Merger” means the merger of Napo into Merger Sub pursuant to the terms of the Merger Agreement.

“Merger Agreement” means an agreement and plan of merger among the Company, Napo and Merger Sub, whereby Napo will merge into the Merger Sub and become a wholly-owned subsidiary of the Company, and as a result of such Merger the equity holders of Napo shall receive Common Stock (except as otherwise provided therein).

“Merger Effective Date” means the date on which the Merger is consummated.

“Merger Sub” means a wholly owned subsidiary of the Company formed for purposes of effectuating the Merger.

“Napo” means Napo Pharmaceuticals, Inc., a Delaware corporation.

“Registrable Securities” means: (i) the Shares and (ii) any securities issued or issuable upon any stock split, dividend or other distribution, recapitalization or similar event, or any price adjustment as a result of such stock splits, reverse stock splits or similar events with respect to any of the securities referenced in (i).

“Registration Statement” means the registration statements required to be filed in accordance with this Section and any additional registration statements required to be filed under this Section, including in each case the prospectus, amendments and supplements to such registration statements or prospectus, including pre and post effective amendments, all exhibits thereto, and all material incorporated by reference or deemed to be incorporated by reference therein.

“Registration Statement Effective Date” means, as to a Registration Statement, the date on which such Registration Statement is first declared effective by the Commission.

“Trading Day” means a day on which the Nasdaq Stock Market is open for trading.

8. Miscellaneous.

a. **Survival.** The representations, warranties, covenants and agreements made herein shall survive the closing of the transactions contemplated hereby for a period of one year.

b. **Successors and Assigns.** Except as otherwise expressly provided herein, the provisions hereof shall inure to the benefit of, and be binding upon, the successors, assigns, heirs, executors and administrators of the parties hereto.

c. **Entire Agreement.** This Agreement and the Schedule attached hereto constitute the entire agreement and understanding between the parties with respect to the subject matters herein, and supersede and replace any prior agreements and understandings, whether oral or written between and among them with respect to such matters. This Agreement supersedes and replaces the Commitment which is hereby terminated. The provisions of this Agreement may be waived, altered, amended or repealed, in whole or in part, only upon the written consent of the Company and Invesco.

d. **Title and Subtitles.** The titles of the Sections and subsections of this Agreement are for convenience of reference only and are not to be considered in construing this Agreement.

e. **Counterparts.** This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument.

f. **Applicable Law.** This Agreement shall be governed by and construed in accordance with laws of the State of California, applicable to contracts between California residents entered into and to be performed entirely within the State of California.

g. **Venue.** Any action, arbitration, or proceeding arising directly or indirectly from this Agreement or any other instrument or security referenced herein shall be litigated or arbitrated, as appropriate, in the County of New York, in the State of New York.

h. **Authority.** The individual executing and delivering this Agreement on behalf of Invesco has been duly authorized and is duly qualified to execute and deliver this Agreement in connection with the purchase of the Shares and the signature of such individual is binding upon Invesco.

i. Notices. All notices and other communications provided for or permitted hereunder shall be made by hand-delivery, telecopier, or overnight air courier guaranteeing next day delivery at the address set forth on the signature page hereof to Invesco and with respect to

the Company at its principal place of business. All such notices and communications shall be deemed to have been duly given at the time delivered by hand, if personally delivered; when receipt acknowledged, if telecopied; and the next business day after timely delivery to the courier, if sent by overnight air courier guaranteeing next day delivery. The parties may change the addresses to which notices are to be given by giving five days prior written notice of such change in accordance herewith.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

(Signature Page to July 31, 2017, Jaguar Share Purchase Agreement)

IN WITNESS WHEREOF, the parties hereto have executed this Agreement effective as of the day and year first set forth above.

INVESCO

COMPANY

INVESCO ASSET MANAGEMENT LIMITED, acting as agent for and on behalf of its discretionary managed clients

JAGUAR ANIMAL HEALTH, INC.

By: /s/ Colin Fitzgerald
(Signature)

By: /s/ Lisa A. Conte
Lisa A. Conte, CEO

Colin Fitzgerald, Director
(Print Name and Title)

Perpetual Park Drive

Henley-on-Thames, RG9 1HH
(Address)

Purchase Price: \$2,999,999.78

Shares: 3,243,243

Shares to be registered in the name of:

Bank of New York

As Nominee For

Invesco Perpetual UK Strategic Income Fund

Schedule 2.e.

- i. Common Stock, par value \$0.0001 per share: 50,000,000 authorized shares and 19,001,679 shares issued and outstanding; and
- ii. 7,840,196 shares of Common Stock reserved for issuance for the exercise or conversion of all issued or granted derivative securities, including:
 - (A) Warrants to purchase 5,431,458 shares of Common Stock;
 - (B) Options to purchase 2,408,738 shares of Common Stock granted under either the Company's 2013 Equity Incentive Plan or the Company's 2014 Stock Plan (collectively, the "Option Plans"); and
 - (C) 0 RSUs granted under the Option Plans.

Schedule 2.f.

Tony Plant, a shareholder of the Company, filed a purported class action complaint in federal district court in the Northern District of California (Tony Plant v. Jaguar Animal Health, Inc., et al., Civil Action No. 3:17-CV-04102 (N.D. Cal.), filed on 7/20/17) alleging that the Company failed to disclose all material information in connection with the Merger. The Company believes the complaint is without merit and plans to defend vigorously against it.

SCHEDULE I

Invesco is an “accredited investor” as that term is defined in Regulation D promulgated by the Securities and Exchange Commission. The term “Accredited Investor” under Regulation D refers to:

- A person or entity who is a director or executive officer of the Company;
 - Any bank as defined in Section 3(a)(2) of the Securities Act, or any savings and loan association or other institution as defined in Section 3(a)(5) (A) of the Securities Act whether acting in its individual or fiduciary capacity; any broker or dealer registered pursuant to Section 15 of the Exchange Act; any insurance company as defined in Section 2(a)(13) of the Securities Act; any investment company registered under the Investment Company Act of 1940 or a business development company as defined in Section 2(a)(48) of that Securities Act; Small Business Investment Company licensed by the U.S. Small Business Administration under Section 301(c) or (d) of the Small Business Investment Act of 1958; any plan established and maintained by a state, its political subdivisions, or any agency or instrumentality of a state or its political subdivisions for the benefit of its employees, if such plan has total assets in excess of \$5,000,000; any employee benefit plan within the meaning of the Employee Retirement Income Security Act of 1974, if the investment decision is made by a plan fiduciary, as defined in Section 3(21) of such Act, which is either a bank, savings and loan association, insurance company, or registered investment adviser, or if the employee benefit plan has total assets in excess of \$5,000,000 or, if a self-directed plan, with investment decision made solely by persons that are accredited investors;
 - Any private business development company as defined in Section 202(a)(22) of the Investment Advisers Act of 1940;
 - Any organization described in Section 501(c)(3) of the Internal Revenue Code, corporation, Massachusetts or similar business trust, or partnership, not formed for the specific purpose of acquiring the securities offered, with total assets in excess of \$5,000,000;
 - Any natural person whose individual net worth, or joint net worth with that person’s spouse, at the time of his purchase exceeds \$1,000,000 (exclusive of his or her principal residence);
 - Any natural person who had an individual income in excess of \$200,000 during each of the two most recent years or joint income with that person’s spouse in excess of \$300,000 in each of those years and has a reasonable expectation of reaching the same income level in the current year;
 - Any trust, with total assets in excess of \$5,000,000, not formed for the specific purpose of acquiring the securities offered, whose purchase is directed by a person who has such knowledge and experience in financial and business matters that he is capable of evaluating the merits and risks of the prospective investment; or
-
- Any entity in which all of the equity owners are accredited investors.

As used in this Schedule I, the term “net worth” means the excess of total assets over total liabilities excluding any primary residence. As used in this Schedule I, “income” means actual economic income, which may differ from adjusted gross income for income tax purposes. Accordingly, the undersigned should consider whether it should add any or all of the following items to its adjusted gross income for income tax purposes in order to reflect more accurately its actual economic income: any amounts attributable to tax-exempt income received, losses claimed as a limited partner in any limited partnership, deductions claimed for depletion, contributions to an IRA or Keogh retirement plan, and alimony payments.

Exhibit A

Form of Letter of Direction

Dated: July 31, 2017

Invesco Asset Management Limited
Perpetual Park, Perpetual Park Drive
Henley-on-Thames, Oxfordshire
RG9 1HH United Kingdom

Ladies and Gentlemen:

Reference is hereby made to (1) that certain Share Purchase Agreement (the “SPA”) dated as of the date hereof by and between Jaguar Animal Health, Inc., a Delaware corporation (“Jaguar”) and Invesco Asset Management Limited, acting as agent for and on behalf of its discretionary managed clients (“Invesco”), (2) that certain Agreement and Plan of Merger (the “Merger Agreement”) by and among Jaguar, Napo Pharmaceuticals, Inc., a Delaware corporation (“Napo”) and Napo Acquisition Corporation, a Delaware corporation and (3) that certain Settlement and Discounted Payoff Agreement (the “Settlement Agreement”) dated as of March 31, 2017 by and among Nantucket Investment Limited, a company organized under the laws of Guernsey (“Nantucket”), certain affiliates of Nantucket (collectively with Nantucket, the “Nantucket Lenders”) and Napo.

Pursuant to the terms of the SPA, Invesco will purchase certain equity interests in Jaguar in exchange for a cash purchase price of \$2,999,999.78 (the “Purchase Price”). In anticipation of the consummation of the transactions being consummated pursuant to the Merger Agreement, the Purchase Price will immediately be loaned by Jaguar to Napo and \$2,000,000 of the Purchase Price (the “Payment Amount”) will be used by Napo to repay certain obligations owing to the Nantucket Lenders in accordance with the terms of the Settlement Agreement.

Each of Jaguar and Napo hereby irrevocably authorizes and directs Invesco to disburse the Payment Amount directly to Nantucket pursuant to the following wire transfer instructions:

Bank: HSBC Bank plc
St Peter Port, Guernsey
SWIFT/BIC:
Sort number:
Account Name: Nantucket Investments Limited
Account Number:
IBAN:

Jaguar hereby irrevocably authorizes and directs Invesco to disburse the remainder of the

Purchase Price (after distribution of the Payment Amount in accordance with the prior paragraph) to Jaguar pursuant to the following wire transfer instructions:

Bank: Bridge Bank, a Division of Western Alliance Bank
55 Almaden Blvd
San Jose, CA 95113, U.S.A.
SWIFT Code:
ABA Routing #:
Account Name: Jaguar Animal Health, Inc.
Account Number:
Beneficiary Address: 201 Mission Street, Suite 2375
San Francisco, CA 94105 USA

This letter agreement and the rights and obligations of the parties hereunder shall be governed by, and shall be construed and enforced in accordance with, the laws of the State of New York without regard to conflict of laws principles (other than sections 5-1401 and 5-1402 of the New York General Obligations Law) thereof.

[Signature Page to Follow]

Very truly yours,

JAGUAR ANIMAL HEALTH, INC.

By: _____
Name:
Title:

NAPO PHARMACEUTICALS, INC.

By: _____
Name:
Title:

TERMINATION, ASSET TRANSFER AND TRANSITION AGREEMENT

BETWEEN

NAPO PHARMACEUTICALS, INC.

AND

GLENMARK PHARMACEUTICALS, LTD.

DATED SEPTEMBER 22, 2017

TERMINATION, ASSET TRANSFER AND TRANSITION AGREEMENT

THIS TERMINATION, ASSET TRANSFER AND TRANSITION AGREEMENT (this "Agreement") dated as of September 22, 2017 ("Transfer Date"), is entered into between Napo Pharmaceuticals, Inc., a wholly-owned subsidiary of Jaguar Health, Inc., a Delaware corporation having its principal place of business at 201 Mission Street, Ste. 2375, San Francisco, California 94105 ("Napo"), and Glenmark Pharmaceuticals, Ltd., a company organized under the laws of the Republic of India having its principal place of business at Glenmark House, B D Sawant Marg, Chakala, Off Western Express Highway Andheri (E), Mumbai - 400099 ("Glenmark").

RECITALS

A. The Parties (as defined below) entered into that certain Collaboration Agreement dated as of July 2, 2005, as amended (the "Original Agreement"), pursuant to which Napo granted to Glenmark certain rights to develop and commercialize "Licensed Products" for certain specified human indications, in certain identified countries only, all in accordance with the terms of the Original Agreement.

B. The Parties are terminating the Original Agreement and all other Prior Agreements, and are providing, among other matters, for the reversion to Napo of all rights with respect to any Licensed Products and to the Licensed IP (as defined in the Original Agreement), on the terms and conditions, and for the consideration, set forth in this Agreement.

NOW, THEREFORE, on the following terms and conditions, and for the consideration described herein, the sufficiency of which is hereby acknowledged, the Parties agree as follows:

ARTICLE I
DEFINITIONS

The following capitalized terms when used in this Agreement will have the meanings set forth below. All capitalized terms used in this Agreement, but not defined in the Recitals above or in this Article I, shall have the meanings ascribed to them in the Original Agreement.

1.1 "Activities" has the meaning assigned to such term in the Original Agreement.

1.2 "Affiliate" means, with respect to a Party, a Person that (directly or indirectly) controls, is controlled by, or is under common control with such Party. For purposes hereof, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to a Person (including a Party), means (a) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person (including a Party), whether through the ownership of voting securities, by contract or otherwise, or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a Person (including a Party).

1.3 "Agreement" means this *Termination, Asset Transfer and Transition Agreement*.

1.4 "Applicable Laws" means the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative

codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, permits of or from any court, arbitrator, Regulatory Authority or governmental agency or authority having jurisdiction over or related to the subject item.

1.5 "Approved Drug Registration" shall mean, with respect to any particular country, all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a Licensed Product in such country, including, where applicable, (a) pricing or reimbursement approval in such country, (b) pre- and post-approval marketing authorizations (including any prerequisite manufacturing approval or authorization related thereto), (c) labeling approval, and (d) technical, medical and scientific licenses.

1.6 "Assignment of Transferred Glenmark Patents" means the form of Assignment of Transferred Glenmark Patents attached hereto as Schedule 1.6 to be executed by Glenmark and/or its relevant Affiliates and by Napo on the Transfer Date for the Transferred Glenmark Patents.

1.7 "Batch Records" means the executed production batch records, the master batch record(s) and the test methods for each production process run prior to the Transfer Date, whether run at a Glenmark facility, or at any Third-Party facility on behalf of Glenmark or its Affiliate.

1.8 "cGMP" means current good manufacturing practices required by the FDA, as set forth in the applicable regulations, guidance and regulatory requirements promulgated under the U.S. Federal Food, Drug and Cosmetic Act, as amended, together with the ICH Guidelines applicable to the

manufacture and testing of products.

1.9 “Claims” shall mean any and all claims, actions, causes of action, demands, costs, grievances, duties, obligations, rights, counterclaims, debts, damages, losses, liabilities, judgments, and charges of whatever nature, whether known or unknown.

1.10 “Confidential Information” has the meaning assigned to such term in Section 6.1.

1.11 “Control” (including any variations such as “Controlled” and “Controlling”), in the context of intellectual property rights of a Party, shall mean that such Party or its Affiliate owns or possesses rights to intellectual property sufficient to effect the transfer or grant the applicable license, as the case may be, under this Agreement, without violating the terms of an agreement with a Third Party or requiring any payment to any Third Party in connection with or as a result of such transfer or license.

1.12 “Crofelemer API” shall mean the active pharmaceutical ingredient described as oligomeric proanthocyanidin (OPC) of varying chain lengths with an average molecular weight of approximately 2000 daltons.

1.13 “Dispute” has the meaning assigned to such term in Section 8.1.

1.14 “Dollars” or “\$” means the legal tender of the United States.

1.15 “Drug Approval Application” means a New Drug Application as defined in the U.S. Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated thereunder, or any corresponding application in a country or jurisdiction other than the United States.

2

1.16 “Drug Master File” means any drug master file filed with the FDA with respect to a Licensed Product, and any equivalent filing in other countries or regulatory jurisdictions.

1.17 “Encumbrance” means any claim, security interest, pledge, hypothecation, mortgage, charge, escrow, option, proxy, right of first refusal, preemptive right, license, joint ownership interest, prior assignment, title retention agreement, indenture, lien, encumbrance or security agreement.

1.18 “Excluded Assets” means, other than the Transferred Assets, all assets, property, rights and interests of Glenmark and its Affiliates.

1.19 “FDA” shall mean the U.S. Food and Drug Administration, or any successor entity thereto performing similar functions.

1.20 “GAAP” means United States generally accepted accounting principles, consistently applied.

1.21 “Glenmark” has the meaning assigned to such term in the Recitals.

1.22 “Glenmark Indemnitees” has the meaning assigned to such term in Section 7.1

1.23 “Glenmark IP” has the meaning assigned to such term in the Original Agreement.

1.24 “Glenmark Territory” means, with respect to both human and veterinary indications, those countries listed in Exhibit A (the AAID Specific Territory) to the Original Agreement, without regard to the field of use designation in that Exhibit.

1.25 “Glenmark Vendors” shall mean all Third Party vendors with which Glenmark or one of its Affiliates has contracts or course-of-trade arrangements that are related to the development, manufacture, marketing or commercialization of Crofelemer API or a Licensed Product, including supply arrangements, all related quality contracts for any raw and pack materials, supplies and packaging materials therefor, market research arrangements, clinical trial agreements, licenses, purchase orders, sale orders, bids, understandings or commitments.

1.26 “Indemnification Claim Notice” has the meaning assigned to such term in Section 7.4(a).

1.27 “Indemnified Party” has the meaning assigned to such term in Section 7.4(a).

1.28 “Indemnifying Party” has the meaning assigned to such term in Section 7.4(a).

1.29 “Information” means techniques and data relating to the development, manufacture, analysis, commercialization and other exploitation of Crofelemer API, Licensed IP and/or any Licensed Product, including inventions, practices, methods (including analytical test methods), knowledge, know-how, test data, including pharmacological, toxicological, biological, chemical and physical and pre-clinical and clinical test data, analytical and quality control data, regulatory submissions, correspondence and communications, patent and legal data related thereto, information (whether or not confidential, proprietary, patented or patentable), and Manufacturing IP, in each case in written, electronic or any other form now known or hereafter developed.

3

1.30 “Inventory” means all assays, reagents, chromatographic resins, excipients, crude plant latex, chromatographic resins, “Stage A” intermediates, Stage B intermediates (also referred to as Crofelemer sublots), and other raw materials required to produce Crofelemer API, and all finished Crofelemer API and packaging materials relating to the foregoing, Controlled by Glenmark or its Affiliates (regardless of where such inventory is held) as of the Transfer Date.

1.31 “Jaguar” means Jaguar Health, Inc., the parent company of Napo, and also a licensee of certain rights from Napo, with respect to Crofelemer API.

- 1.32 “Joint IP” has the meaning assigned to such term in the Original Agreement.
- 1.33 “Liability” or “Liabilities” means, collectively, any indebtedness, guaranty, endorsement, claim, loss, damage, deficiency, cost, expense, obligation or responsibility, fixed or unfixed, known or unknown, choate or inchoate, liquidated or unliquidated, secured or unsecured, direct or indirect, matured or unmatured, determined or determinable, or absolute, contingent or otherwise, including any product liability.
- 1.34 “Licensed Product” has the meaning assigned to such term in the Original Agreement.
- 1.35 “Losses” has the meaning assigned to such term in Section 7.1.
- 1.36 “Manufacturing and Supply Agreement” shall mean that certain manufacturing and supply agreement to be entered into by Napo and Glenmark contemporaneously with the execution of this Agreement or in any event no later than within ninety (90) days after the Transfer Date.
- 1.37 “Manufacturing IP” shall mean (i) all Glenmark IP and Joint IP relating in any way to the manufacturing or analysis of Crofelemer API, and to the scaling up of manufacturing of Crofelemer API (ii) the complete and current technical documentation for the manufacturing and analysis of Crofelemer API (including, specifically, process development and/or optimization documentation for both Ankleshwar and Aurangabad) and for the scaling up of manufacturing of Crofelemer API (including all assays and analytical methods listed in Schedule 1.62), and (iii) the complete, and current contact information for Glenmark Vendors, if any, who have served Glenmark as a supplier, contract manufacturer or vendor of any Crofelemer API-related materials or services for, or related to, the manufacturing or analysis of Crofelemer API, during the term of the Original Agreement.
- 1.38 “Napo” has the meaning assigned to such term in the Recitals.
- 1.39 “Napo Indemnitees” has the meaning assigned to such term in Section 7.1.
- 1.40 “Napo Provided Equipment” means the required dedicated equipment, as set forth on Exhibit A to Schedule 4.5(a)(iii), Resin CM Sepharose and Resin LH-20 provided by Napo, at its sole cost and expense, and used in the manufacture of Crofelemer API and or any Licensed Product and located at Glenmark’s Ankleshwar manufacturing facility.
- 1.41 “Original Agreement” has the meaning set forth in the Recitals.
- 1.42 “Original Term” shall mean the period commencing on July 2, 2005, the effective date of the Original Agreement, and ending on the Transfer Date.

4

-
- 1.43 “Party” shall mean Napo or Glenmark individually, and “Parties” shall mean Napo and Glenmark collectively.
- 1.44 “Patent(s)” shall mean any patents and patent applications, together with all additions, divisions, continuations, continuations-in-part, substitutions, reissues, re-examinations, extensions, registrations, patent term extensions, supplemental protection certificates and renewals of any of the foregoing.
- 1.45 “Person” shall mean any individual, corporation, partnership, firm, association, joint venture, joint stock company, trust or other entity, or any government or regulatory administrative or political subdivision or agency, department or instrumentality thereof.
- 1.46 “Prior Agreements” means all prior agreements between Napo and Glenmark, including without limitation, those agreements listed on Schedule 1.46
- 1.47 “Regulatory Authority” means any supra-national, federal, national, regional, state, provincial or local regulatory agency, department, bureau, commission, council or other government entity, including the FDA, regulating or otherwise exercising authority with respect to the commercialization (including the determination of pricing/reimbursement) of Licensed Products in any country or other jurisdiction.
- 1.48 “Regulatory Documentation” means (a) submissions to any Regulatory Authority, including INDs, Drug Approval Applications, Drug Master Files, correspondence with regulatory agencies (including Approved Drug Registrations and licenses, regulatory drug lists, advertising and promotion documents), period safety update reports, adverse event files, complaint files and manufacturing records and, if applicable, any updates or supplements to any of the foregoing, (b) any minutes or contact logs, with respect to any telephone conferences conducted with any Regulatory Authority relating to the subject matter described in clause (a) of this sentence, and (c) materials in the working regulatory and clinical files of Glenmark pertaining to the conduct of annual reviews and required reports to the FDA that have yet to be filed, in each case ((a), (b), and (c)) to the extent relating to the Licensed IP or Licensed Products, including all items identified on the roster to be created pursuant to Section 3.1(b).
- 1.49 “Taxes” means all taxes of any kind, and all charges, fees, customs, levies, duties, imposts, required deposits or other assessments, including all federal, state, local or foreign net income, capital gains, gross income, gross receipt, property, franchise, sales, use, excise, withholding, payroll, employment, social security, worker’s compensation, unemployment, occupation, capital stock, transfer, gains, windfall profits, net worth, asset, transaction and other taxes, and any interest, penalties or additions to tax with respect thereto, imposed upon any Person by any Taxing Authority or other governmental authority under Applicable Laws.
- 1.50 “Taxing Authority” means any federal, national, supranational, state, provincial, local or foreign government, any subdivision, agency, commission or authority thereof or any quasi-governmental body exercising tax regulatory authority.
- 1.51 “Territory” means the General Territory and AAID-Specific Territory, as those terms are defined in the Original Agreement.
- 1.52 “Third Party” shall mean any Person other than Napo, Glenmark and their respective Affiliates.

5

1.53 “Third Party Claim” has the meaning assigned to such term in Section 7.1

1.54 “Third Party Consideration” means any consideration or Third-Party Payment, in any form, received by Napo from any Third Party to whom Napo grants a license or sublicense, or with whom Napo partners (e.g., via a collaboration, joint venture or distribution or similar arrangement) in respect of, or sells or otherwise transfers any of the Transferred Assets, including the following:

- (a) any upfront payment, development, regulatory, commercialization or other milestone or deferred payment, royalty, profit share, sales proceeds, license maintenance fee, or the like, net of customary trade discounts and all applicable taxes and tariffs;
- (b) all payments for Inventory from such Third Party that are in excess of Napo’s cost for such Inventory;
- (c) all payments for the reimbursement of research and development costs incurred by Napo (or on behalf of Napo) that are in excess of Napo’s costs to perform such research and development, calculated based on an FTE rate of \$280,000 per FTE (the equivalent of a full-time employee or consultant performing such activities, measured on the basis of two thousand (2000) hours per year) plus out-of-pocket expenses for materials and subcontractors to perform any such research and development activities;
- (d) the fair market value (such fair market value to be determined in good faith by Board of Directors of Napo or at the option of Glenmark, by an independent reputable valuation expert chosen by both Parties (and paid for by Glenmark) of any equity securities of a Third Party issued to Napo that exceeds any amount paid by Napo for such securities;
- (e) the amount by which any amount paid by a Third Party to Napo for equity securities in Napo, issued or transferred to such Third Party, exceeds the fair market value (such fair market value to be determined in good faith by Board of Directors of Napo or at the option of Glenmark, by an independent reputable valuation expert chosen by both Parties (and paid for by Glenmark) of such equity securities; and
- (f) amounts payable or paid to Napo in connection with a noncompetition agreement or any employment, consulting, licensing, supply, or other agreement, to the extent that such amounts payable or paid are greater than what would customarily be paid on an arm’s-length basis to an employee, consultant, licensee, or supplier, or the like;

provided, that the following shall be excluded from Third Party Consideration:

- (a) reimbursement for patent prosecution and/or maintenance expenses related directly to the Licensed IP or any Licensed Product to cover Napo’s or its Affiliates’ actual, out-of-pocket expenses for the same;
- (b) any revenue received by Napo and/or its Affiliates from the *bona fide* sale of any Licensed Product by Napo or such Affiliates directly to the wholesale or retail market in

circumstances where Napo or such Affiliates are themselves (including, for clarity, through the use of Third Party contractors) directly commercializing the relevant Licensed Product or Veterinary Product to the wholesale or retail market for their own account in the country in which such sales occur;

- (c) any revenue received by Napo and/or its Affiliates for any license, sublicense or sales of a Licensed Product or Veterinary Product to any not-for-profit organization, any non-governmental organization, or any social enterprise (i) to allow *bona fide* research and development related to a Licensed Product, or (ii) to allow the distribution by such not-for-profit organization, non-governmental organization, or social enterprise of a Licensed Product to under-served populations or populations in resource-constrained areas, unless such revenue is in excess of Napo’s COGS for such Licensed Product; and,
- (d) any amount received by Napo and/or its Affiliates paid by a Third Party to Napo for equity securities in Napo, issued or transferred to such Third Party, at the fair market value of such equity securities (such fair market value to be determined in good faith by the Board of Directors of Napo or, at the option of Glenmark, by an independent reputable valuation expert chosen by both Parties and paid for by Glenmark).

1.55 “Third Party Payments” means all payments, up-front fees or milestones (including any fees or milestones payable in installments), royalties, or other payments of whatever kind or nature payable to a Third Party in consideration for rights necessary or useful for making, having made, using, developing, importing, offering for sale, selling, distributing, marketing, promoting and otherwise exploiting the Licensed IP and/or a Licensed Product.

1.56 “TM” means any registered trademark, service mark, logo or trade name of a Party.

1.57 “Transfer Date” has the meaning assigned to such term in the Recitals.

1.58 “Transfer Taxes” means all recordation, transfer, documentary, excise, sales, value added, use, stamp, conveyance, or other similar Taxes imposed or levied by reason of, in connection with or attributable to, this Agreement or the transactions contemplated hereby.

1.59 “Transferred Assets” means all right, title and interest of Glenmark and its Affiliates in and to the following assets: (a) Transferred Information; (b) Transferred Regulatory Documentation; (c) all Batch Records, (d) the Transferred Glenmark Patents and (e) all Inventory.

1.60 “Transferred Information” means all Information that relates to Crofelemer API, the Licensed IP and/or any Licensed Products, with such Information to be deemed the Confidential Information of Napo, after the Transfer Date.

1.61 “Transferred Regulatory Documentation” means all Regulatory Documentation that relates to Crofelemer API, the Licensed IP and/or any Licensed Product.

1.62 “Transferred Glenmark Patents” means all Patents that claim or cover making, having made, analyzing, using, developing Crofelemer API or any Licensed Product and are Controlled by Glenmark or its Affiliates as of the Transfer Date, including those identified in Schedule 1.62.

7

1.63 “Transition Coordinators” has the meaning assigned to such term in Section 3.3.

1.64 “United States” or “U.S.” shall mean the fifty (50) states of the United States of America and the District of Columbia and the territories of the United States of America.

1.65 “Veterinary Product” means any prescription drug containing pure Crofelemer API formulated for veterinary indications.

ARTICLE II TERMINATION; TRANSFER TO NAPO

2.1 Termination of All Prior Agreements; Reversion of All Licenses and Rights.

(a) As of the Transfer Date, this Agreement supersedes the Original Agreement and all other Prior Agreements, including without limitation, the agreements listed on Schedule 1.46. Except with respect to certain definitions set forth in the Original Agreement, and specifically referred to in this Agreement, this Agreement renders null and void the Original Agreement and all other Prior Agreements; and, the Original Agreement and the other Prior Agreements shall be of no further force and effect.

(b) As of the Transfer Date, all licenses granted by Napo to Glenmark under the Original Agreement to the Licensed IP, the Joint IP (to the extent of Napo’s rights therein) and Licensed Products, shall terminate immediately, and all such licenses shall revert to Napo.

(c) Only certain provisions of the Original Agreement, specifically referenced in this Agreement, as, for example, the definitions of certain defined terms used in this Agreement shall be deemed to survive after the Transfer Date.

2.2 Transfer to Napo; License Back to Glenmark

(a) As of the Transfer Date, Glenmark shall assign and transfer to Napo all of Glenmark’s right, title and interest in and to (i) all Glenmark IP, (ii) all Joint IP (to the extent of Glenmark’s rights therein), and (iii) all Manufacturing IP (that is not Glenmark IP or Joint IP), including all those items listed on Schedule 1.62; *provided that*, except with respect to the Transferred Glenmark Patents, the assignment of all such right, title and interest is intended by the Parties to be self- executing, requiring no further action by Glenmark. Napo hereby licenses back to Glenmark a non-exclusive, royalty-free license to the Manufacturing IP strictly for the limited purpose of manufacturing and supplying Crofelemer API for Napo, and for Jaguar, or any Affiliate of Napo or Jaguar.

(b) At the Transfer Date and thereafter, except as set forth in Section 2.2(a) and as set forth in the Manufacturing and Supply Agreement, Glenmark shall have no rights to the Glenmark IP, the Joint IP, the Manufacturing IP or any of the Licensed IP, including all those items listed on Schedule 1.62; and, Glenmark shall have no rights to any Licensed Product, for commercializing

8

or for any other purpose whatsoever, anywhere in the world (including, specifically, the Glenmark Territory, as that term was defined in the Original Agreement).

(c) On the Transfer Date or promptly thereafter, Glenmark shall assign and transfer to Napo all of Glenmark’s right, title and interest in and to (i) the Approved Drug Registrations granted to Glenmark for, and with respect to a Licensed Product in the countries of Ecuador, Brazil, Zimbabwe and Botswana, and (ii) any applications and/or filings, initiated by Glenmark, that are *in process* in other countries, seeking an Approved Drug Registration for a Licensed Product. A list of such other countries, in which Glenmark has filed applications for an Approved Drug Registration of a Licensed Product is set forth on Schedule 2.2(c).

ARTICLE III TRANSITION OBLIGATIONS

3.1 Transfer of Transferred Information and Transferred Regulatory Documentation.

(a) Within ninety (90) days after the Transfer Date, Glenmark shall provide to Napo all Transferred Information and Transferred Regulatory Documentation to the extent not already provided under Section 3.1(b) below.

(b) Within sixty (60) days after the Transfer Date, Glenmark and Napo will have together generated a written roster of Transferred Information and Transferred Regulatory Documentation. All such Transferred Information and Transferred Regulatory Documentation shall be provided in an electronic format (where electronic format is available) readable by generally available Third-Party software by electronic mail (“Email”) or in a digital storage medium (*e.g.*, optical disc, hard drive, flash drive, etc.), and Glenmark shall provide an electronic export of all such Information, and Regulatory Documentation, including all terminology lists used for encoding such items. To the extent any such Information and Regulatory Documentation is not available in electronic format and, if, it is not practical (in terms of efficiency or costs or time) to convert such Information and Regulatory Documentation from print copies into an electronic format, Glenmark shall further permit Napo (or its designees) to access and reproduce any such Information, and Regulatory Documentation. To the

extent Applicable Laws reasonably require Napo to possess or control original copies of documents reflecting or containing Information, and Regulatory Documentation, in order to initiate, assume and/or continue development, manufacture, registration and commercialization of the Licensed IP and any Licensed Product following the Transfer Date, Glenmark agrees, upon Napo's written request and at Napo's cost and expense, to promptly provide, and cause its Affiliates to promptly provide, such original copies to Napo or its designee (it being understood and agreed that, so long as (and *only* for so long as) Glenmark is manufacturing Crofelemer API for Napo Jaguar and/or its Affiliates, Glenmark may retain copies thereof). For any cost or expense incurred by Glenmark to be reimbursed by Napo, such (i) such cost or expense must have been pre-approved by Napo, (ii) Glenmark must deliver to Napo, within thirty (30) days after incurring the cost or expense, a *bona fide* receipt from a Third-Party vendor setting forth such itemized cost or expense,

and (iii) Napo shall reimburse such cost or expense within thirty (30) days of such delivery to Napo of the such Third-Party vendor receipt. The Parties agree to coordinate and reasonably cooperate to facilitate the transfer of Information and Regulatory Documentation as contemplated in Section 3.1(a) with the goal of providing such Information and Regulatory Documentation in an orderly and expeditious manner, and in a *usable* format, to facilitate Napo's efforts to prepare for, and to continue, the development, manufacture and registration of the Licensed IP and Licensed Products from and after the Transfer Date. Any documented and itemized cost or expense incurred by Glenmark from the Transfer Date, with respect to any such request made by Napo, as described herein, shall be paid for by Napo, or reimbursed, by Napo within thirty (30) days of such cost or expense being incurred subject to submission by Glenmark of supporting documents, on a strictly pass-through basis without any mark-up by Glenmark.

(c) The Parties acknowledge that, for so long as Glenmark is manufacturing Crofelemer API for Napo and/or Jaguar, Glenmark will be generating new and useful information and regulatory documentation relating to Crofelemer API. Glenmark agrees that, after the Transfer Date, it shall diligently hold for Napo, all comparable information and regulatory documentation relating to Crofelemer API generated by, or obtained by, Glenmark. Glenmark shall, at Napo's cost and expense upon written request, provide to Napo true, complete and legible copies of all such new information, regulatory documentation (including all modifications, revisions or updates thereto) to the extent not previously provided to Napo. If Glenmark actually incurs any cost or expense to be reimbursed by Napo, then (i) such cost or expense must have been pre-approved by Napo, (ii) Glenmark must deliver to Napo, within thirty (30) days after incurring the cost or expense, a *bona fide* receipt from a Third Party vendor setting forth such reasonable itemized expenses and (iii) Napo shall reimburse such cost or expense within thirty (30) days of such delivery by Glenmark to Napo of the such Third Party vendor receipt.

(d) From and after the Transfer Date, Napo shall own the Transferred Information and Transferred Regulatory Documentation and may use and disclose such Transferred Information and Transferred Regulatory Documentation in its sole discretion for any purpose.

3.2 Development; Regulatory Matters; Commercialization; Publications.

(a) From and after the Transfer Date, Glenmark shall have no right to have any interactions or communications with Regulatory Authorities related to the Licensed IP and/or any Licensed Product, except as and unless specifically requested by Napo in accordance with Section 3.2(d) below.

(b) Within ninety (90) days after the Transfer Date, Glenmark shall provide Napo a copy of any and all material documents, information and correspondence submitted to a Regulatory Authority, prior to the Transfer Date, relating to Regulatory Documentation or filings for or in respect of the Licensed IP and/or a Licensed Product.

(c) Within ninety (90) days after the Transfer Date, Glenmark shall promptly provide Napo with the originals of all material documents, information and correspondence received from a Regulatory Authority prior to the Transfer Date, related to the Licensed IP and/or a Licensed Product. In the event that, after the Transfer Date, Glenmark receives any material documents, information and correspondence from a Regulatory Authority, related to the Licensed IP and/or a Licensed Product, Glenmark shall promptly (and, in no event later than ten (10) business days after receipt by Glenmark) deliver to Napo all such material documents, information and correspondence.

(d) Promptly after the Transfer Date, Glenmark shall notify in writing each of the Regulatory Authorities in the countries listed on Schedule 2.2(c) of the transfer to Napo of the Transferred Assets. After the Transfer Date, Glenmark agrees to cooperate and to assist Napo in the event that Napo must respond to questions from Regulatory Authorities concerning previous development, manufacturing, registration, and other Activities conducted by, or on behalf of, Glenmark with respect to the Licensed IP or any Licensed Product; and, Glenmark agrees to promptly provide to Napo, or its designee, such information regarding the development, manufacturing, and registration of any Licensed Product by or under authority of Glenmark as is reasonably necessary for Napo to respond to and submit information as required by Regulatory Authorities or as required by Applicable Laws in connection with Napo's development, manufacturing and/or commercialization activities of the Licensed IP and any Licensed Product (including information regarding Glenmark's activities that is required for Napo to complete and submit its annual report to the FDA with respect to any Licensed Product for the year in which the Transfer Date occurs). Except to the extent agreed herein between the Parties, during the first fifteen (15) months following the Transfer Date, Glenmark shall, consistent with its covenant to cooperate and actively assist Napo in the transfer of the Transferred Assets and the transition, promptly respond to any such request by Napo at no additional charge to Napo; and, thereafter, should Napo continue to require assistance from Glenmark, any documented and itemized expense incurred by Glenmark after the first fifteen (15) months from the Transfer Date, with respect to any such request made by Napo, as described herein, shall be paid for or reimbursed by Napo on a strictly pass-through basis (without any mark-up by Glenmark) within thirty (30) days of the delivery by Glenmark to Napo of the relevant invoice together with Third Party vendor receipt.

(e) After the Transfer Date, Glenmark shall not publish, present publicly, or submit for written or oral publication any manuscript, abstract presentation, poster session or the like that includes Information relating to the Licensed IP or any Licensed

3.3 Transition Coordination. Within two (2) days after the Transfer Date, the Parties shall each appoint a representative (the “Transition Coordinators”) to facilitate the complete transition in a timely fashion of all Transferred Assets from Glenmark to Napo pursuant to this Agreement. The Transition Coordinators shall coordinate and facilitate communications between and among personnel of the various operational groups of the Parties involved in the transfer of the Transferred Assets. The Transition Coordinators shall meet, by telephone, internet platform or in person, to discuss the status of the transition and to attempt to amicably resolve any disagreements or miscommunications between the Parties that may arise in connection with

information to be exchanged, timelines for transfer of documents or information, or the like. Such meetings shall be held at such times as is necessary to accomplish the purposes set forth in the foregoing sentence; either Transition Coordinator may by written or Email communication to the other Transition Coordinator request that a meeting be scheduled and the Transition Coordinators shall then cooperate in good faith to schedule the requested meeting. The Transition Coordinators are intended (i) to facilitate the smooth delivery by Glenmark to Napo of all Transferred Assets, (ii) to ensure the timely execution of the Manufacturing and Supply Agreement, in accordance with Section 4.7(c) below, and (iii) to serve as the primary contact and authoritative decision-making point person with respect to any and all matters arising in connection with the performance of this Agreement.

ARTICLE IV TRANSFER OF TRANSFERRED ASSETS

4.1 Title to Transferred Assets. Subject to Section 4.3, as of the Transfer Date, Glenmark hereby assigns, conveys, transfers and delivers to Napo, and Napo hereby acquires and accepts from Glenmark, all of Glenmark’s right, title and interest in, to and under the Transferred Assets, free and clear from all Encumbrances.

4.2 Excluded Assets. Napo has no rights to and shall not acquire any rights to, the Excluded Assets, it being understood that Glenmark shall continue to retain its rights in and to the Excluded Assets.

4.3 Limitations.

(a) To the extent not attributable to gross negligence or willful misconduct of Napo and/or its Affiliates, Glenmark and/or its Affiliates shall retain and shall be responsible for paying, performing and discharging when due, all Glenmark’s Liabilities; *provided, however*, that this Section 4.3(a) shall in no way alter the scope of Napo’s indemnification obligations under ARTICLE VII herein. Napo shall not assume, nor have any responsibility for, any Liabilities of Glenmark and/or its Affiliates, including:

- (i) any Liabilities arising out of, or relating to, any of the Transferred Assets, on or prior to the Transfer Date;
- (ii) Glenmark’s and/or its Affiliates’ obligations under this Agreement; and,
- (iii) any Liabilities of Glenmark and/or its Affiliates arising out of or related, in any way, to any of the Excluded Assets.

(b) Glenmark and/or its Affiliates shall have paid in full, after November 2, 2016 and prior to the Transfer Date, all filing, prosecution, renewal and maintenance fees of all Joint IP and Glenmark IP, currently due and payable. On the Transfer Date, there shall be no balance due for any such fees. Thereafter, within thirty (30) days from the Transfer Date, Napo will reimburse Glenmark for documented payment by Glenmark of all such fees, *if any*, upon receipt from Glenmark of clear documentation reflecting the payments remitted after November 2, 2016.

(c) Upon the terms and subject to the conditions of this Agreement, from and after the Transfer Date, Napo will be responsible for and pay, perform and/or otherwise discharge those Liabilities incurred *after* the Transfer Date (including any Liabilities arising in respect of Taxes imposed after the Transfer Date) directly arising out of or in connection with or directly related to the Transferred Assets or the Licensed IP, the use thereof, or the marketing or sale of the Licensed Products by or on behalf of Napo or its Affiliates; *provided*, that notwithstanding anything to the contrary in this Agreement, the Liabilities of Napo shall, in no event include any existing Liabilities that arose prior to the Transfer Date.

4.4 Closing of Transfer of Transferred Assets. The closing of the transactions contemplated by Sections 4.1 through 4.3(a) will take place via electronic exchange of closing deliverables, and will be effective as of 5:00 p.m. Pacific Time on the Transfer Date.

4.5 Closing Deliverables. On the Transfer Date, or in the case of Section 4.5(a)(vi), as promptly as reasonably practicable after the Transfer Date:

- (a) Glenmark shall deliver or cause to be delivered to Napo:
 - (i) An executed copy of this Agreement;
 - (ii) the Assignment of Transferred Glenmark Patents executed by a duly authorized representative of Glenmark;
 - (iii) the Assignment of Napo Provided Equipment executed by a duly authorized representative of Glenmark
 - (iv) a complete, accurate and exhaustive list, in the form attached as Schedule 2.2(c) of all countries in which Glenmark and/or its Affiliates have applied for regulatory approval and/or market registration, and all countries in which Glenmark and/or its Affiliates have been issued Approved Drug Registrations

(v) a *Certification of Officer*, executed by a duly authorized officer of Glenmark, under penalty of perjury, attesting as follows: (i) that all fees and annuities due on or prior to the Transfer Date have been paid in full by Glenmark in a timely fashion and (ii) that, with respect to any item set forth on Schedule 1.62, to the extent any filings were due to be filed on or prior to the Transfer Date (including any responses to Official Actions, Notices or Requests from patent offices or taking any action necessary to maintain any such item in force), all such filings have been submitted in a timely fashion; and,

(vi) a copy of each letter sent from Glenmark to each Regulatory Authority, from which an approval has been sought and/or obtained, transferring to Napo ownership of each such approval or application for approval, effective as of the Transfer Date.

(b) Napo shall deliver or cause to be delivered to Glenmark:

(i) An executed copy of this Agreement;

(ii) the Assignment of Transferred Glenmark Patents executed by a duly authorized representative of Napo; and

13

(iii) the Assignment of Napo Provided Equipment executed by a duly authorized representative of Napo

4.6 Transfer of TM. As of the Transfer Date, Glenmark hereby transfers and assigns to Napo, any and all TM related to Crofelemer API and/or any Licensed Products.

4.7 Consideration from Napo.

(a) In consideration for the assignment and transfer of the Transferred Assets on the Transfer Date, the licenses granted by Glenmark pursuant to Section 4.6, and the assignment to Napo of Glenmark's ownership of each regulatory approval or application for regulatory approval, Napo agrees that, in the event Napo should (i) sell, out-license, partner (via any collaboration, joint venture or similar arrangement with a Third Party), monetize or should otherwise transfer or dispose of the Transferred Assets to a Third Party, or (ii) receive revenue from the sale of Licensed Products or Veterinary Products within the Glenmark Territory, then Napo shall pay Glenmark, in cash within forty-five (45) days after receipt by Napo, twenty-five percent (25%) of such Third Party Consideration, in whatever form received until Glenmark has received a total of seven million U.S. Dollars (\$7,000,000); *provided, however*, Glenmark understands and agrees:

(i) that the term Third Party Consideration shall not include (A) any upfront payments from Elanco US Inc., a subsidiary of Eli Lilly and Company, (B) any future revenue from capital-raising transactions and/or (C) any future revenue that is expressly dedicated as product development funding.

(ii) that revenue attributable to Section 4.7(a)(i)(A), (B) and/or (C) shall not be taken into account when calculating the twenty-five percent (25%) to be paid to Glenmark.

(iii) that the term Third Party Consideration **shall** include revenue from sales of Licensed Products and/or Veterinary Products in the Glenmark Territory (including, specifically, royalties received from Elanco US Inc.).

(b) As an additional consideration for the assignment and transfer of the Transferred Assets on the Transfer Date and the licenses granted by Glenmark pursuant to Section 4.6, Napo shall enter into with Glenmark a Manufacturing and Supply Agreement, for Crofelemer API, to be manufactured at either or both of Glenmark's Ankleshwar and/or Aurangabad facilities; and

(c) As a further consideration for the assignment and transfer of the Transferred Assets on the Transfer Date and the licenses granted by Glenmark pursuant to Section 4.6, Napo effective on and from the Transfer Date, transfers and assigns to Glenmark all right, title and interest in and to Napo

14

Provided Equipment located at Glenmark's Ankleshwar facility; **provided** (i) that Glenmark accepts all of such equipment "as is" and "where is" and Napo disclaims all warranties, both express and implied with respect to such equipment. Glenmark acknowledges that given the unique utility of the five (5) columns of 45- cm diameter and the associated ultrafiltration units (the "Columns"), Glenmark hereby grants back to Napo a first right-of-access to purchase these Columns for consideration (which will be the book value of the Columns at that time or a reasonable price mutually agreed upon at that time), under any of the following circumstances: (A) in the event that Glenmark contemplates selling the Columns, (B) in the event these columns are to be decommissioned or (C) in the event Glenmark is unable or unwilling to fulfill a purchase order for Crofelemer API within six (6) months (assuming such purchase order would require full use of the Columns for at least three (3) months), in accordance with the fully-executed Manufacturing and Supply Agreement.

(d) Glenmark acknowledges and agrees (i) that Napo is no longer receiving any royalties from the sale of any Licensed Product by any licensee in the Western Countries (as defined in the letter dated December 9, 2008, concerning royalties on certain net sales in Western Countries), (ii) that as of November 2, 2016, all royalties due to Glenmark from Napo have been paid in full and, (iii) that the consideration set forth in this Section 4.7 constitutes the sole consideration due to Glenmark for the Transferred Assets.

4.8 Delivery of Physical Assets. Following the Transfer Date, by such date specified below, unless otherwise agreed to by the Parties, Glenmark and/or its Affiliates shall deliver the physical embodiments of the following Transferred Assets to Napo or its designee at Napo's cost and expense:

(a) the Transferred Regulatory Documentation (which, where applicable, may be delivered in electronic form) shall be delivered ninety (90) after the Transfer Date;

(b) the Batch Records (to the extent that Napo does not already have copies of them) and the Transferred Information (which, where applicable, may be delivered in electronic form), shall be delivered within ninety (90) days after the Transfer Date; and

(c) the Inventory existing as of the Transfer Date shall, at Napo's election, (i) remain at Glenmark, to be held for Napo's account and used in the development and manufacture of Crofelemer API, pursuant to the Manufacturing and Supply Agreement, or (ii) be delivered by Glenmark to such location(s), as directed by Napo, FCA (Incoterms 2010) at Glenmark's facility (at Napo's risk and expense) or FCA at any Third-Party vendor's facility, within ninety (90) business days after the Transfer Date. All documented and itemized expenses for packing and shipping, with respect to any such request made by Napo, as described herein, shall be borne by Napo. For any cost or expense to be incurred by Glenmark for which Glenmark expects to be reimbursed by Napo, then (i) such cost or expense must have been pre-approved by Napo, (ii) Glenmark must deliver to Napo, within thirty (30) days after incurring the cost or expense, a *bona fide* receipt from a Third-Party vendor setting forth such itemized cost or expense and (iii) Napo shall reimburse Glenmark within thirty (30) days of

15

the delivery by Glenmark to Napo of the relevant invoice together with Third Party vendor receipt.

Except as otherwise expressly set forth herein, the cost of delivering Transferred Assets to Napo and/or its designees shall be borne by Glenmark.

4.9 Further Assurances.

(a) Glenmark and Napo shall use commercially reasonable efforts to conduct in an expeditious manner all activities to be conducted under this Agreement. Except as provided herein, for a period of up to fifteen (15) months from the Transfer Date, at Napo's request, Glenmark shall, and shall cause its Affiliates to, except as provided herein, at no additional cost or expense to Napo, execute and deliver such further instruments of conveyance, transfer and assignment, cooperate and assist in providing information for making and completing regulatory filings, and take such other actions as Napo may reasonably require of Glenmark to more effectively assign, convey and transfer to Napo, and perfect Napo's interest in, the Transferred Assets as contemplated by this Agreement, including any such Transferred Assets not listed on any of the Schedules attached hereto. Without in any way limiting the foregoing, Glenmark shall use commercially reasonable efforts to cooperate with Napo and/or Napo's designee to effect a smooth and orderly transition to Napo or Napo's designee of the development, manufacture, and pharmacovigilance for Crofelemer API and any existing Licensed Product. At any time, and from time to time, within a period of up to eighteen (18) months from the Transfer Date, at the reasonable request of Napo, Glenmark shall and shall cause its Affiliates to, execute and deliver such instruments of transfer, conveyance, assignment and confirmation, and assumption, and provide such materials and information and take such other actions as Napo may reasonably request to perfect or evidence the transfer, conveyance, and/or assignment to Napo of the Transferred Assets (including, specifically, all the Approved Drug Registrations and all the Drug Approval Applications and/or filings for market registration), in each case in accordance with this Agreement.

(b) From time to time, at the reasonable request of Glenmark, whether at or after the Transfer Date, Napo shall, and shall cause its Affiliates to, at no additional cost or expense to Glenmark, execute and deliver such further instruments of conveyance, transfer, assignment, and assumption, cooperate and assist in providing information for making and completing regulatory filings, and take such other actions as Glenmark may reasonably require in order to more effectively assign, transfer and convey to Glenmark the Napo Provided Equipment located at Glenmark's Ankleshwar facility and to perfect or evidence the transfer, conveyance, and/or assignment to Glenmark of the Napo Provided Equipment located at Glenmark's Ankleshwar facility, as contemplated by Section 4.7(c) of this Agreement

4.10 Records Retention; Audits.

(a) Napo shall keep (and shall ensure that its sublicensees and partners shall keep) such records as are required to determine, in a manner consistent with GAAP and this Agreement, amounts due from it to Glenmark

16

under Section 4.7(a). All such books, records and accounts shall be retained by Napo until the later of (i) three (3) years after the end of the period to which such books, records and accounts pertain and (ii) the expiration of the applicable Tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Laws.

(b) Glenmark shall have the right to have the books and records of Napo and its Affiliates inspected by an independent certified auditor selected by Glenmark (an auditor selected by Glenmark shall be submitted prior to such audit for approval to Napo, whose acceptance shall not be unreasonably delayed, conditioned, denied or withheld), to confirm payments due to it under Section 4.7(a), for a period covering not more than the preceding three (3) calendar years. Such auditor will execute a reasonable written confidentiality agreement with Napo and will disclose to Glenmark only such information directly regarding any actual discrepancies between the amounts reported or paid and the amounts payable under this Agreement. Such auditor will send a copy of its report to Napo within fifteen (15) calendar days of delivery of such report to Glenmark. Such report will include the methodology and calculations used to determine the results. Prompt adjustments shall be made by the Parties to reflect the results of such audit. Records to be available for an inspection and audit under this Section 4.10(b) shall include all relevant documents (including contracts, invoices, receipts, and all other documents and records of whatever nature) wherever stored pertaining to payments specified above. The appointed auditor shall have the right to interview selected staff and inspect and copy all relevant documents. Such right may be exercised by Glenmark only once per calendar year.

(c) Glenmark shall bear the fees and expenses of such inspection, *provided* that, if an underpayment of more than ten percent (10%) of the payments due for any calendar year is discovered in any inspection, then Napo shall bear all fees and expenses of

that inspection within thirty (30) days after receipt of a copy of the auditor's invoice from Glenmark for same, and shall pay to Glenmark within thirty (30) days after receipt of the auditor's report any deficiency not previously paid, plus accrued interest on the underpayment at the floating rate of 30-day LIBOR +5% (as quoted in The Wall Street Journal or its successor) on the day after the payment is due, calculated from the initial due date to the date paid in full and compounded monthly, or the maximum rate permitted by law, if less.

4.11 Tax Withholding. If Napo is required to make a payment to Glenmark subject to a deduction of tax or withholding tax, then the sum payable by Napo (in respect of which such deduction or withholding is required to be made) shall be decreased to the extent necessary to pay such withholding tax, and the amount required to be deducted or withheld shall be remitted by Napo to the proper governmental authority in accordance with Applicable Laws, and promptly transmit to Glenmark an official tax certificate or other evidence of such withholding sufficient to enable Glenmark to claim such payments of taxes.

4.12 Payment Method. All amounts due by Napo to Glenmark hereunder shall be paid in Dollars by wire transfer in immediately available funds to an account designated by Glenmark. Any undisputed payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement shall accrue interest from the date that is thirty (30)

17

days after the date on which payment was due at a rate equal to the floating rate of 30-day LIBOR +5% (as quoted in The Wall Street Journal or its successor) on the day after the payment is due, calculated from the initial due date to the date paid in full and compounded monthly, or the maximum rate permitted by law, if less.

4.13 Foreign Exchange. For the purpose of computing any Third-Party Consideration in a currency other than Dollars, such Third-Party Consideration amounts thereof shall be converted into Dollars each quarter using an exchange rate that is the arithmetic average of the daily exchange rates (obtained as described below) during such quarter. Each daily exchange rate shall be obtained from The Wall Street Journal, Eastern United States Edition, or, if not so available, then as otherwise agreed by the Parties.

4.14 Cooperation on Further Transfer of Assets and/or Payments.

(a) Assets. For a period of up to twelve (12) months after the Transfer Date, if either Napo or Glenmark becomes aware that any of the Transferred Assets was not transferred to Napo on the Transfer Date (or as otherwise prescribed in this Agreement) or that any of the Excluded Assets was inadvertently transferred to Napo, it shall promptly notify the other in writing, and the Parties shall, as soon as reasonably practicable, ensure that such property is transferred, at the expense of the Party that is seeking the assets to be transferred to it. The Party that has the asset(s) to be transferred to the rightful Party shall ensure that any necessary prior third-party consent or approval has first been obtained.

(b) Payments. If, on or after the Transfer Date, either Party shall receive any payments or other funds due to the other pursuant to the terms of this Agreement, then the Party receiving such funds shall promptly forward such funds to the proper Party.

ARTICLE V REPRESENTATIONS AND WARRANTIES

(a) General Representations. Each Party hereby represents and warrants to the other Party, as of the Transfer Date, as follows:

(b) Such Party is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent such Party from performing its obligations under this Agreement.

(c) This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by such Party have been duly authorized by all necessary corporate action and do not and will not: (i) require any consent or approval of its stockholders; (ii) to such Party's knowledge, violate any Applicable Law, order, writ, judgment, decree, determination or award of any court, governmental body or administrative or other agency having jurisdiction over such Party; nor (iii) conflict with, or constitute a default under, any agreement,

18

instrument or understanding, oral or written, to which such Party is a party or by which it is bound. In particular, and without limiting the generality of the foregoing, each Party represents and warrants to the other Party that it is fully entitled to enter into the covenants, and undertake the obligations set forth herein.

(d) Such Party has not sold, assigned, conveyed, pledged, encumbered, or otherwise in any way transferred to any Person, in the case of Glenmark, any of the Transferred Assets and, in the case of Napo, title to any of the Napo Provided Equipment located at Glenmark's Ankleshwar facility.

(e) Such Party is not aware of any currently filed and pending, legal or administrative proceeding of any kind or nature whatsoever against the other Party (including any pending arbitration) initiated by such Party or by any Third Party, relating to the Original Agreement or this Agreement.

(f) Such Party is not relying in any manner on any statement, promise, representation or omission, whether oral or written, express or implied, made by any Person or entity, not specifically set forth in this Agreement.

(g) Additional Representations and Warranties of Glenmark. In addition, Glenmark represents, warrants and covenants, as of the Transfer Date, as follows:

(h) Title; Rights to Transfer Transferred Assets. Glenmark has good and valid title, and owns all right, title and interest, in and to all of the Transferred Assets, free and clear of any Encumbrances, and has the right to transfer and assign (as applicable) each of the foregoing to Napo or its designee as provided in this Agreement.

(i) Schedules. Schedule 1.6 sets forth the form of assignment for the Transferred Patents; Schedule 1.46 sets forth all Prior Agreements; and Schedule 4.5(a)(iii) sets forth the form of assignment for the Napo Provided Equipment, to Glenmark's best knowledge, true, complete, and correct in all material respects;

(j) Compliance with Applicable Laws. To the extent that Glenmark has conducted the development, manufacture, and registration of the Licensed IP and/or any Licensed Product in the Territory, it has done so in material compliance with all applicable Regulatory Documentation and Applicable Laws. Glenmark has not received any written communication from any Regulatory Authority relating to any violation by Glenmark of any applicable Regulatory Documentation or Applicable Laws in conducting the development, and manufacture of any Licensed Product in the Territory.

(k) Regulatory Matters. Glenmark and/or its Affiliates have completed and filed all material reports required by the Regulatory Authorities in those countries in which they are submitting a Drug Approval Application or have received approval for a Licensed Product. Neither Glenmark nor any of its Affiliates have received written notice from a Regulatory Authority of the proposed or actual revocation, suspension, termination, cancellation or withdrawal of a previously granted approval with respect to any Licensed Product.

19

(l) Inventory. Inventory includes, among other things, finished Crofelemer API. Glenmark and its Affiliates represent and warrant: (i) each unit of Inventory that is finished Crofelemer API, Stage A intermediate or Stage B Intermediate has been manufactured, stored, and handled materially in compliance with the then-current specifications and the information shown on the certificate of analysis provided therefor, the applicable quality agreement, and cGMP and other Applicable Laws (including that each unit has not been adulterated or misbranded); (ii) each unit of Inventory that is not Stage A intermediate, Stage B intermediate, or finished Crofelemer API has been stored and handled materially in compliance with the then-current specifications and the information shown on the certificate of analysis provided therefor, the applicable quality agreement and other Applicable Laws; and (iii) title to all items in Inventory (*other than* the crude plant latex which already belongs to Napo), including all units of Crofelemer API, Stage A intermediate or Stage B Intermediate shall pass to Napo, free and clear of any Encumbrances.

(m) No Sales, Marketing or Commercialization Activities. Glenmark represents, for itself and its Affiliates, that neither Glenmark, nor any of its Affiliates, have directly or indirectly (through any Third Party) (a) engaged in any marketing or promotion of Crofelemer API or any Licensed Product, (b) consummated any sales of Crofelemer API or any Licensed Product, (c) distributed any Crofelemer API or any Licensed Product and/or (d) executed any *other* commercialization plans, programs or activities with respect to Crofelemer API or any Licensed Product, in each case (a) through (d) above for any Person other than Napo or Jaguar.

5.2 Additional Representation and Warranty of Napo.

(a) Title; Rights to Transfer. Napo has good and valid title, and owns all right, title and interest (assuming no Encumbrance attributable to Glenmark's possession thereof), in and to all of the Napo Provided Equipment located at Glenmark's Ankleshwar manufacturing facility free and clear of any Encumbrances, and has the right to transfer and assign (as applicable) the same to Glenmark or its Affiliates provided in this Agreement; and

(b) Compliance with Applicable Laws and Obligations. On and from the Transfer Date, to the extent it relates or affects Transferred Assets, Napo shall conduct its business, in material compliance with all Applicable Laws and comply with its obligations hereunder.

5.3 **DISCLAIMER. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, AND EXPRESSLY DISCLAIMS ANY REPRESENTATION AND WARRANTY, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.**

ARTICLE VI CONFIDENTIALITY; PRESS RELEASE

6.1 Confidential Information. Except as expressly provided in this Agreement, the Parties agree that the receiving Party shall not publish or otherwise disclose and shall not use for

20

any purpose any information furnished to it by the other Party hereto pursuant to the Original Agreement or this Agreement (collectively, "Confidential Information") for a period ending on the fifth anniversary of the Transfer Date. Notwithstanding the foregoing, for purposes of this ARTICLE VI, the Parties agree that from and after the Transfer Date and continuing until the fifth anniversary of the Transfer Date, Glenmark shall treat as Confidential Information of Napo all Transferred Information and Transferred Regulatory Documentation, to the extent the same relates to the Licensed IP and/or Licensed Products, in its possession or Control, without regard to the exceptions under subsections (a) or (e) below, and shall not publish or otherwise disclose such Transferred Information or Transferred Regulatory Documentation to the extent it relates to the Licensed IP and/or Licensed Products other than as provided in Section 6.2. With respect to any information exchanged other than Transferred Information and Transferred Regulatory Documentation, Confidential Information shall not include information that, in each case as demonstrated by written documentation:

(a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure or, as shown by written documentation, was developed by the receiving Party prior to its disclosure by the disclosing Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party, or any receiving Party's Affiliate, in breach of the Original Agreement or this Agreement;

(d) was subsequently lawfully disclosed to the receiving Party by a person other than the disclosing Party, and who did not directly or indirectly receive such information from disclosing Party; or

(e) is developed by the receiving Party without use of or reference to any Confidential Information disclosed by the disclosing Party.

6.2 Permitted Disclosures. Notwithstanding the provisions of Section 6.1, and subject to Section 6.3, each Party may use and disclose the other Party's Confidential Information to its Affiliates, licensees, contractors and any other Third Parties, but only to the extent such use and/or disclosure is: (a) reasonably necessary to perform its obligations under this Agreement; (b) necessary to comply with Applicable Laws, including applicable court orders or other legal process; (c) made to existing or prospective acquirers or merger candidates, existing or prospective pharmaceutical collaborators, investment bankers, existing or prospective investors, venture capital firms or other financial institutions or investors for purposes of obtaining financing, or Affiliates, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this ARTICLE VI; (d) reasonably necessary to enforce this Agreement against the other Party; or, (e) in the case of Napo, is made in connection with the development, manufacture, commercialization or other exploitation of the Licensed IP or Licensed Products anywhere in the world for any purpose. If a Party proposes to make a disclosure of Confidential Information under Section 6.2(b), to the extent it may legally do so, it will give reasonable advance notice to the disclosing Party of such disclosure and will use its good faith efforts to secure confidential treatment of such Confidential Information prior to its disclosure (whether through protective orders or otherwise). For any other disclosures of the

21

other Party's Confidential Information, including to Affiliates, licensees, contractors and other Third Parties, a Party shall ensure that the recipient thereof is bound by appropriate confidentiality provisions consistent with the nature of the information disclosed and shall be ultimately liable for the conduct of all those to whom disclosure of Confidential Information is made.

6.3 Confidentiality Restrictions Regarding This Agreement. Each Party agrees not to disclose to any Third Party the terms of this Agreement, without the prior written consent of the other Party, except each Party may disclose the terms of this Agreement: (a) to Affiliates, licensees, contractors and any other Third Parties on a need-to-know basis, in each case under appropriate confidentiality provisions consistent with the nature of the information disclosed; (b) to the extent necessary to comply with Applicable Laws, including securities laws, regulations or guidances; *provided* that in the case of this clause (b) the disclosing Party shall promptly notify the other Party and (other than in the case where such disclosure is necessary, in the reasonable opinion of the disclosing Party's legal counsel, to comply with securities laws, regulations or guidances), to the extent allowable by Applicable Laws, allow the other Party to seek, solely at its own expense, limitations on the portion of the Agreement that is required to be disclosed; (c) in the case of Napo, if made in connection with the development, manufacture, commercialization or other exploitation of the Licensed IP or Licensed Products, under appropriate confidentiality provisions consistent with the nature of the information disclosed, or (d) in the case of Napo, if made to existing or prospective acquirers or merger candidates, existing or prospective pharmaceutical collaborators, investment bankers, existing or prospective investors, venture capital firms or other financial institutions or investors for purposes of obtaining financing, or Affiliates, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this ARTICLE VI. Notwithstanding the foregoing, if either Party desires to issue a press release to announce the execution of this Agreement, and the transfer of all the rights being transferred back to Napo hereunder, such Party must obtain the approval of the other Party prior to publication; and, thereafter, each Party may disclose to Third Parties the information contained in such press release without the need for further approval by the other Party.

22

ARTICLE VII INDEMNIFICATION

7.1 Indemnification of Glenmark. Napo shall indemnify and hold harmless each of Glenmark, and its directors, officers, employees, and agents and the successors and assigns of any of the foregoing (the "Glenmark Indemnitees"), from and against any and all liabilities, damages, penalties, fines, costs, expenses (including, reasonable attorneys' fees and other expenses of litigation) ("Losses") from any claims, actions, suits or proceedings brought by a Third Party (a "Third Party Claim") incurred by any Glenmark Indemnitee, arising from, or occurring as a result of (a) any material breach by Napo of its obligations under this Agreement, or (b) any breach of any representations, warranties or covenants by Napo under this Agreement, or (c) the gross negligence or willful misconduct of a Napo Indemnitee; except to the extent such Third Party Claims arise from and are attributable, in whole or in part, to causes described in Section 7.2 (a) through (c) or such Third Party Claims arise from and are attributable to, in whole or in part, the gross negligence or willful misconduct of a Glenmark Indemnitee.

7.2 Indemnification of Napo. Glenmark shall indemnify and hold harmless each of Napo, and the directors, officers, employees, and agents of Napo and the successors and assigns of any of the foregoing (the "Napo Indemnitees"), from and against any and all Losses from any Third Party Claim incurred by any Napo Indemnitee, arising from, or occurring as a result of (a) any material breach by Glenmark of its obligations under this Agreement, or (b) any breach of any representations, warranties or covenants by Glenmark under this Agreement, or (c) the gross negligence or willful misconduct of a Glenmark Indemnitee; except to the extent such Third Party Claims arise from and are attributable, in whole or in part, to causes described in Section 7.1(a) through (c) or such Third Party Claims arise from and are attributable to, in whole or in part, the gross negligence or willful misconduct of a Napo Indemnitee.

(a) The provisions for indemnification under Sections 7.1 and 7.2 shall be effective only (i) for any individual claim, or series of related claims arising from the same facts and circumstances, where the Loss exceeds \$50,000, and (ii) when the aggregate amount of all Losses for claims, or series of related claims arising from the same facts and circumstances, in excess of \$50,000 exceeds \$200,000, in which case the Napo Indemnatee or the Glenmark Indemnatee, as the case may be, shall be entitled to indemnification of the Losses in excess thereof.

(b) EXCEPT WITH RESPECT TO A BREACH BY A PARTY OF ITS OBLIGATIONS UNDER ARTICLE VITO TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAWS, NEITHER NAPO NOR GLENMARK SHALL BE LIABLE TO THE OTHER OR THEIR AFFILIATES OR ANY THIRD PARTY, FOR ANY CLAIMS, DEMANDS OR SUITS FOR CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE, INDIRECT OR MULTIPLE DAMAGES, INCLUDING LOSS OF PROFITS, REVENUE OR INCOME, DIMINUTION IN VALUE OR LOSS OF BUSINESS OPPORTUNITY (WHETHER OR NOT FORESEEABLE AT THE TRANSFER DATE), CONNECTED WITH OR

RESULTING FROM ANY BREACH OF THIS AGREEMENT, OR ANY ACTIONS UNDERTAKEN IN CONNECTION WITH, OR RELATED HERETO.

7.4 Indemnification Procedure.

(a) Notice of Claim. A Party believing that it is entitled to indemnification under Section 7.1 or Section 7.2 (an "Indemnified Party") shall give prompt written notification (each, an "Indemnification Claim Notice") to the other Party (the "Indemnifying Party") of the commencement of any Claim for which indemnification may be sought or, if earlier, upon the assertion of any such Claim by a Third Party (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Third Party Claim as provided in this Section 7.4(a) shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give notice). Each Indemnification Claim Notice shall contain a description of the Claim and the nature and amount of the Loss (to the extent that the nature and amount of such Loss are known at such time). The Indemnified Party shall furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any Losses.

(b) Control of Defense. At its option, the Indemnifying Party may assume the defense of any Claim by giving written notice to the Indemnified Party within thirty (30) days after the Indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Claim by the Indemnifying Party shall not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify the Indemnified Party in respect of the Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Claim any legal counsel selected by the Indemnifying Party that is reasonably acceptable to the Indemnified Party. In the event the Indemnifying Party assumes the defense of a Claim, the Indemnified Party shall immediately deliver to the Indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Claim. Should the Indemnifying Party assume the defense of a Claim, the Indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of such Claim. In the event that it is ultimately determined that the Indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Claim, the Indemnified Party shall reimburse the Indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any Losses incurred by the Indemnifying Party in its defense of the Claim with respect to such Indemnified Party.

(c) Right to Participate in Defense. Without limiting Section 7.4(b), the Indemnified Party shall be entitled to (i) participate in, but not control, the defense of such Claim and to engage counsel of its choice for such purpose; *provided, however*, that such engagement shall be at the Indemnified Party's own expense, and (ii) control its defense of such Claim and to engage counsel of its

choice for such purpose, at the expense of the Indemnifying Party to the extent of a single counsel and any necessary local counsel only, if (A) the Indemnifying Party has failed to assume the defense and engage counsel in accordance with Section 7.4(b), or (B) the Indemnifying Party denies or fails to timely admit its obligation to defend the action.

(d) Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Claim and that will not result in the Indemnified Party becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the Indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the Indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Claims, where the Indemnifying Party has assumed the defense of the Claim in accordance with Section 7.4(b), the Indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; *provided* it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned, or delayed). The Indemnifying Party shall not be liable for any settlement or other disposition of a Loss by the Indemnified Party that is reached without the written consent of the Indemnifying Party. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Claim, the Indemnified Party shall not admit any liability with respect to, or settle, compromise or discharge, any Claim without the prior written consent of the Indemnifying Party, not to be unreasonably withheld, conditioned, or delayed.

(e) Cooperation. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Claim, the Indemnified Party shall reasonably cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Claim, and making employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

(f) Expenses. Except as, and subject to the limits, provided above (including in Section 7.4(c)), the reasonable and verifiable costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim shall be reimbursed on a quarterly basis by the Indemnifying Party, without prejudice to the Indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

25

7.5 Mitigation. The Indemnified Party shall take all commercially reasonable steps to mitigate any Losses incurred by such Party upon and after becoming aware of any event or condition that would reasonably be expected to give rise to any indemnification rights hereunder. The amount of Losses recovered by an Indemnified Party shall be reduced by (a) any amounts actually recovered by the Indemnified Party from a Third Party in connection with such claim and (b) the amount of any insurance proceeds paid to the Indemnified Party relating to such claim, in each case ((a) and (b)), in excess of the Indemnified Party's expenses of recovery. Each Party shall use its commercially reasonable efforts to collect insurance proceeds for any Loss that is subject to indemnification under Section 7.1 or Section 7.2. If any amounts referenced in the preceding clauses (a) and (b) are received after payment of the full amount otherwise required to be paid to an Indemnified Party pursuant to this ARTICLE VII, the Indemnified Party shall repay to the Indemnifying Party promptly after such receipt, any amount that the Indemnified Party would not have had to pay pursuant to this ARTICLE VII had such amounts been received prior to such payment.

7.6 No Rescission.

Notwithstanding anything to the contrary contained in this Agreement, no breach of any representation, warranty, covenant or agreement contained herein shall give rise to any right on the part of Napo, on the one hand, or Glenmark, on the other hand, to rescind this Agreement or any of the transactions contemplated hereby.

ARTICLE VIII DISPUTE RESOLUTION

8.1 Dispute Resolution. Except as otherwise provided in this Agreement, any dispute, controversy or claim arising under, out of or in connection with this Agreement, including any subsequent amendments, or the validity, enforceability, interpretation, performance or breach hereof (and including the applicability of this Article VIII to any such dispute, controversy or claim) (each a "Dispute") shall first be presented to the Chief Executive Officer of Napo and the Chief Executive Officer of Glenmark, or their respective designees for resolution. If the Chief Executive Officer of Napo and the Chief Executive Officer of Glenmark, or their respective designees, cannot resolve the Dispute within thirty (30) days of the request to do so, either Party may, upon written notice to the other, refer such Dispute to be resolved by final, binding arbitration in accordance with the provisions of Section 8.2.

8.2 Arbitration.

(a) The Parties agree that any Dispute that is not resolved pursuant to Section 8.1 above shall be finally settled by binding arbitration under this Section 8.2. The arbitration shall be conducted in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA") then in effect, except as modified in this Agreement. The arbitration shall be conducted in the English language by a panel of three (3) arbitrators, one selected by each of the Parties and one jointly agreed to by the Parties. If the Parties are unable to agree on the third arbitrator, such arbitrator shall be selected in accordance with the AAA rules. In the event of a failure, refusal or inability of the arbitrators to act, their successors shall be appointed in accordance with the AAA.

(b) With respect to any dispute to be resolved under this Section 8.2, arbitration shall be conducted on an expedited basis. The Parties

26

and the arbitration panel shall use all reasonable efforts to complete any such arbitration within ninety (90) days from the issuance of notice of a referral of any such dispute to arbitration. The arbitration panel shall determine what discovery will be permitted, consistent with the goal of limiting the cost and time that the Parties must expend for discovery; *provided* that the arbitration panel shall permit such discovery it deems necessary to permit an equitable resolution of the Dispute.

(c) The arbitrators shall have no power to change the provisions of this Agreement nor to make an award of reformation. The Parties agree that the decision of the arbitration panel shall be the binding remedy between them regarding the Dispute presented to the arbitration panel. Any decision of the arbitration panel may be entered in a court of competent jurisdiction for judicial recognition of the decision and an order of enforcement. The arbitration proceedings and the decision of the arbitration panel shall not be made public without the joint consent of the Parties and each Party shall maintain the confidentiality of such proceedings and decision unless each Party otherwise agrees in writing; *provided* that either Party may make such disclosures as are permitted for Confidential Information of the other Party under ARTICLE VI above.

(d) Unless otherwise mutually agreed upon by the Parties, the arbitration proceedings shall be conducted in the Borough of Manhattan, New York, New York. The arbitration panel shall have the right to consult experts and competent authorities with

factual information or knowledge concerning the Dispute and the fees of such authorities shall be an expense of the arbitration. The arbitration panel prepare and deliver a written, reasoned opinion conferring its decision; and, the panel shall be instructed to provide in its decision either, as the arbitration panel determines to be appropriate in the circumstances, for (a) the unsuccessful Party in such arbitration to bear all expenses of such arbitration, including the reasonable attorneys' fees and costs and expenses of the prevailing Party, or (b) all such expenses of such arbitration to be allocated between the Parties in proportion to the extent to which each such Party is deemed to have been unsuccessful, as determined by the arbitration panel.

(e) The Parties hereto acknowledge that money damages are an inadequate remedy for a breach of certain terms of this Agreement, and that a Party shall be entitled to specific performance of this Agreement or injunctive relief against the breach of any such provision. Nothing in this Agreement shall limit the right of either Party to obtain in any court of competent jurisdiction any equitable or interim relief or provisional remedy, including injunctive relief, that may be necessary to protect the rights or property of that Party pending resolution of a Dispute under this Section 8.2. A Party seeking such equitable or interim relief or provisional remedy in a court may do so without posting any bond (unless such bond is required by statute and the statute mandating the bond does not permit such bond to be waived) and without showing actual damages. Such action shall not be deemed a waiver of the agreement to arbitrate. For clarity, any such equitable remedies shall be cumulative and not exclusive and are in addition to any other remedies that either Party may have under this Agreement or Applicable Laws.

27

ARTICLE IX GENERAL PROVISIONS

9.1 Governing Law; Jurisdiction; Venue.

(a) This Agreement and all questions regarding its validity or interpretation, or the breach or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the internal laws of the State of New York, without reference to conflicts of law principles. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

(b) Subject to ARTICLE VIII above, each Party irrevocably and unconditionally consents to the exclusive jurisdiction of the arbitration tribunals and the jurisdiction of the courts of general jurisdiction of the State of New York, and the United States District Court for the Southern District of New York sitting in the Borough of Manhattan for any action, suit or proceeding concerning any matter arising out of or relating to this Agreement, and agrees not to commence any action, suit or proceeding related thereto except in such courts.

(c) Subject to ARTICLE VIII above, the Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding arising out of or relating to this Agreement in such courts and hereby further irrevocably and unconditionally agree not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in any of such courts, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such court does not have any jurisdiction over such Party.

(d) Each Party hereto further agrees that service of any process, summons, notice or document by United States registered mail or by nationally-recognized express courier, to its address and contact person for notices provided for in Section 9.6 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any of such courts.

9.2 Entire Agreement. This Agreement (including the Schedules and exhibits attached hereto), together with the Manufacturing and Supply Agreement when entered into by the Parties pursuant to Section 4.7(b) constitutes the entire agreement between the Parties and, as clarified in Section 2.1(a) supersedes all prior or contemporaneous agreements, understandings or representations, either written or oral between Napo and Glenmark (except as to certain definitions in the Original Agreement specifically noted herein).

9.3 Modification. No amendment or modification of any provision of this Agreement shall be effective unless in writing signed by a duly authorized representative of each Party.

9.4 Waiver of Breach. Except as otherwise expressly provided in this Agreement, any term of this Agreement may be waived only by a written instrument executed by a representative of the Party waiving compliance. The delay or failure of either Party at any time to require performance of any provision of this Agreement shall in no manner affect such Party's rights at a

28

later time to enforce the same. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

9.5 Severability. In the event any provision of this Agreement should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions of this Agreement shall remain in full force and effect in such jurisdiction. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

9.6 Notices. Unless otherwise agreed by the Parties or specified in this Agreement, all communications between the Parties relating to, and all written documentation to be prepared and provided under, this Agreement shall be in the English language. Any notice required or permitted under this Agreement shall be: (a) delivered personally; (b) sent by registered or certified mail (return receipt requested and postage prepaid); (c) sent by nationally-recognized express courier service providing evidence of receipt, postage pre-paid where applicable; or (d) sent by facsimile or Email (marked as of "high

importance” and a copy promptly sent by another permissible method of providing notice described in clauses (a), (b), or (c) above), to the following addresses of the Parties or such other address for a Party as may be specified by like notice:

To Napo:

Napo Pharmaceuticals, Inc.
201 Mission Street, Ste. 2375,
San Francisco, California 94105
Attention: Lisa A. Conte
Facsimile: (415) 371-8311
Email: lconte@jaguar.health

To Glenmark:

Glenmark Pharmaceuticals, Ltd.
Glenmark House, B D Sawant Marg, Chakala,
Off Western Express Highway Andheri (E),
Mumbai - 400099
Attention: Sr. Vice President, Legal & General Counsel
Facsimile: 91 22 4018 9986
Email: meera.vanjari@glenmarkpharma.com

Any such communication shall be deemed to have been received, if sent in accordance with this Section 9.6, (a) when delivered, if personally delivered or sent by facsimile or electronic mail on a business day, (b) on the business day after dispatch, if sent by nationally-recognized express courier, and (c) on the third business day following the date of mailing, if sent by registered or certified mail.

9.7 Assignment. Without the prior written consent of the other Party hereto, which consent shall not be unreasonably withheld, conditioned, or delayed, neither Party shall sell, transfer, assign, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; *provided, however*, that either Party may assign or transfer this Agreement and all of its rights and obligations hereunder, without the consent of the other (i) to any Affiliate of such Party; or (ii) to any Third Party with which it merges or consolidates, or to which it transfers all or substantially all of its assets to which this Agreement relates if in any such event set forth in clause (i) or (ii): (A) the assigning Party (provided that it is not the surviving entity) remains jointly and severally liable with the relevant Affiliate assignee or Third Party assignee under this Agreement, and (B) the relevant

29

Affiliate assignee, Third Party assignee, or surviving entity assumes in writing all of the assigning Party’s obligations under this Agreement.

9.8 No Partnership or Joint Venture. It is expressly agreed that the Parties shall be independent contractors of one another and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

9.9 Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or from other countries that may be imposed upon or related to Napo or Glenmark from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Laws.

9.10 Interpretation. The captions to the several Articles and Sections of this Agreement are not a part of this Agreement, but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word “including” shall be deemed to be followed by the phrase “without limitation” or like expression; (b) the singular shall include the plural and vice versa; (c) masculine, feminine and neuter pronouns and expressions shall be interchangeable and (d) the word “promptly”, unless otherwise specified, means within two (2) business days. All references to a “business day” or “business days” in this Agreement means any day other than a day which is a Saturday, a Sunday or any day banks are authorized or required to be closed in Mumbai, India or New York, New York. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under GAAP.

9.11 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. This Agreement may be executed by scanned and electronically or facsimile transmitted signatures and, if identified, legible and complete, such signatures shall be deemed to bind each Party as if they were original signatures.

9.12 Continued Prosecution of IP. Glenmark and/or its Affiliates acknowledge and agree (a) that, after the Transfer Date, Napo shall hold all rights to the Transferred Glenmark Patents, the Glenmark IP and the Joint IP, and (b) that, the decision to pursue or not to pursue any particular patent application and/or to pursue the prosecution and/or maintenance of any particular Patent shall be Napo’s decision, in its sole discretion.

SIGNATURE PAGE TO FOLLOW

30

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Transfer Date.

NAPO PHARMACEUTICALS, INC., a wholly-owned subsidiary of Jaguar Health, Inc.

BY: /s/ Lisa A. Conte
NAME: Lisa A. Conte
TITLE: President and CEO

GLENMARK PHARMACEUTICALS, LTD.

BY: /s/ Meera Vanjari
NAME: Meera Vanjari
TITLE: Senior Vice President and General Counsel-Legal

Acknowledged and agreed to, only with respect to Section 4.7:

JAGUAR HEALTH, INC.

BY: /s/ Karen S. Wright
NAME: Karen S. Wright
TITLE: Chief Financial Officer

31

SCHEDULE 1.6

ASSIGNMENT OF TRANSFERRED GLENMARK PATENTS

THIS ASSIGNMENT OF TRANSFERRED GLENMARK PATENTS (this "Assignment") is made and entered into as of September 22, 2017, by and between Glenmark Pharmaceuticals, Ltd., a company organized under the laws of the Republic of India ("Assignor"), and Napo Pharmaceuticals, Inc., a wholly-owned subsidiary of Jaguar Health, Inc., a Delaware corporation ("Assignee"). Capitalized terms used but not otherwise defined herein shall have the definition assigned to such terms in the Termination, Asset Transfer and Transition Agreement dated as of September 22, 2017 (the "Transfer Agreement").

WHEREAS, Assignor and Assignee are parties to the Transfer Agreement;

WHEREAS, pursuant to the Transfer Agreement, Assignor has agreed to assign or cause to be assigned to Assignee or its designee the Transferred Glenmark Patents;

WHEREAS, the execution and delivery of this Assignment by the Assignor and Assignee is contemplated by Section 4.1 of the Transfer Agreement; and,

WHEREAS, pursuant to Section 4.3(c) of the Transfer Agreement, Assignee has agreed to pay, perform or otherwise discharge all Liabilities (as defined in the Transfer Agreement) arising, after the Transfer Date, in connection with Assignor's acquisition of the Transferred Assets.

NOW, THEREFORE, in consideration of the mutual promises made in the Transfer Agreement herein and upon the terms and subject to the conditions set forth in the Transfer Agreement and herein, the parties hereto hereby agree as follows:

1. **Assignment of Patents**. On the terms and conditions set forth in the Transfer Agreement, Assignor hereby assigns, conveys, transfers and delivers to Assignee all of Assignor's right, title and interest in, to and under all of the patents and patent applications, together with all additions, divisions, continuations, continuations-in-part, substitutions, reissues, re-examinations, extensions, registrations, patent term extensions, supplemental protection certificates and renewals, and any legal equivalent thereof in a foreign country, of the Transferred Glenmark Patents, set forth on **Exhibit A** attached hereto, and the right to claim priority from any of the foregoing under the patent laws of the United States, the International Convention, or any other international agreement or domestic laws of any and all foreign countries, and Assignee hereby accepts such assignment. The Transferred Glenmark Patents are to be held and enjoyed by Assignee, subject to determination by Assignee, in Assignee's sole discretion, as to future prosecution of each patent in Assignee's patent portfolio.

2. **Authorization**. Assignor, as a registered holder of the Transferred Glenmark Patents listed on **Exhibit A**, hereby authorizes and requests the Commissioner or Director of Patents and Trademarks of the United States, and the official of any foreign patent office with power to do so, to issue and transfer Assignor's right, title and interest in the relevant Transferred Glenmark Patents to Assignee, its successors and assigns, in accordance with the terms of this Assignment,

32

or otherwise as Assignee may direct.

3. **Terms of the Transfer Agreement**. The terms of the Transfer Agreement are incorporated herein by reference. The parties acknowledge and agree that the representations, warranties, covenants, agreements and indemnities contained in the Transfer Agreement shall not be limited or expanded hereby, and shall not be superseded hereby, but shall remain in full force and effect to the full extent provided therein. In the event of any conflict or inconsistency between the terms of the Transfer Agreement and the terms hereof, the terms of the Transfer Agreement shall govern.

4. **Assignor's Warranties**. The only representations and warranties of Assignor with respect to the Patents are set forth in that certain *Certification of Officer*, executed by a duly authorized officer of Assignor as of the Transfer Date, and in the Transfer Agreement. The representations and warranties, set forth in the *Certification of Officer* and the Transfer Agreement are the sole representations and warranties of Assignor.

5. **No Modification of Transfer Agreement**. Nothing contained herein shall release the Assignor or Assignee from any of their respective obligations under the Transfer Agreement or in any way diminish, limit, or modify any of the representations, warranties, indemnities, covenants or agreements of such parties set forth in the Transfer Agreement. To the extent that any provision of this Assignment conflicts or is inconsistent with the terms of the Transfer Agreement, the Transfer Agreement shall govern, including with respect to the enforcement of the rights and obligations of the parties hereto.

6. **Assistance**. Assignor, when called upon to do so by the Assignee, shall execute all documents and instruments, and shall do all lawful acts, in each case as may be reasonably necessary to perfect the title to the Transferred Glenmark Patents, and generally do everything reasonably possible to aid the

Assignee, its successors, legal representatives and assigns, including execution of all necessary documents and instruments and to provide all necessary information and documents to obtain the Transferred Glenmark Patents, in all countries, at the expense of the Assignee, its successors, legal representatives and assigns.

7. No Third-Party Beneficiaries. This Assignment is for the sole and exclusive benefit of the Assignor and Assignee and their respective successors and permitted assigns and nothing herein is intended or shall be construed to confer upon any party other than Assignor and Assignee and their respective successors and permitted assigns any right, remedy, or claim under or by reason of this Assignment or any term, covenant or condition hereof.

8. Successors and Assigns. This Assignment shall be binding upon the parties hereto and their successors and assigns.

9. Amendments. This Assignment and any of the provisions hereof may not be amended or modified except by an instrument in writing and signed by each party hereto.

10. Governing Law. This Assignment shall in all respects be construed in accordance with and governed by the laws of State of New York, without reference to conflict of law principles.

11. Severability. Any term or provision of this Assignment that is invalid or unenforceable in any jurisdiction shall, as to that jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions

33

of this Assignment or affecting the validity or enforceability of any of the terms of provisions of this Assignment in any other jurisdiction.

12. Headings. The descriptive headings used in this Assignment are inserted for convenience of reference only and are not intended to be part of or to affect the meaning or interpretation of this Assignment.

13. Counterparts; Facsimile Signature. This Assignment may be executed in two separate counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument. A facsimile or scanned signature to this Assignment shall have the same legal force and effect as an original signature.

[Signature Page Follows]

34

IN WITNESS WHEREOF, the parties hereto have executed this Assignment of Transferred Glenmark Patents as of the Transfer Date.

GLENMARK PHARMACEUTICALS, LTD.

By: /s/ Meera Vanjari
Name: Meera Vanjari
Title: Senior Vice President and General Counsel-Legal

NAPO PHARMACEUTICALS, INC.

By: /s/ Lisa A. Conte
Name: Lisa A. Conte
Title: President and CEO

35

SCHEDULE 1.46

Superseded Agreements Executed between Napo and Glenmark

Collaboration Agreement dated July 2, 2005

First Amendment dated October 21, 2005

Second Amendment dated October 26, 2005

Third Amendment dated May 3, 2006

Fourth Amendment dated May 30, 2006

Fifth Amendment dated December 9, 2008

Western Countries Royalty letter dated December 9, 2008

Clarification Side letter dated December 9, 2008

SCHEDULE 1.62

Intellectual Property

Transferred Glenmark Patents

Crofelemer Patent Portfolio Overview

	Type of application	Owner/Assignee	PCT Pub No.	Remark
A.	API Process	Glenmark + Napo	WO/2011/024049	Maintained by Glenmark (3 Countries)
		Glenmark Alone	WO/2012/101008	Maintained by Glenmark (6 countries)
B.	IR formulation	Glenmark Alone	WO/2013/093655	Maintained by Glenmark (16 Countries)

A: API/Process

Glenmark and Napo (WO/2011/024049)

Country	Patent/Pub No.	Status
India	IN266932	Granted
Eurasia (maintained only in Russia)	EA201290098	Granted
South Africa	ZA2012/02160	Granted

Glenmark Alone (WO/2012/101008)

Country	Patent/Pub No.	Status
India	281/MUMNP/2012	Under examination
Venezuela	2012-000073	Pending
Argentina	2012 01 00277	Published and pending
Brazil	BR 11 2013 018688 7	Published and pending

Russia	2013134704	Granted
South Africa	ZA2013/05263	Granted

B: IR Formulation

Glenmark Alone (WO 2013/093655)

Country	Patent/Pub No.	Status
South Africa	ZA2012/07398	Granted
India	2384/MUMNP/2012	Application Awaiting Examination
Brazil	BR112014015314-0	Examination requested
Malaysia	PI 2014001798	Pending; preliminary examination cleared
Egypt	1019/2014	Examination requested
Bangladesh	P/2013/60	Pending
UAE	664/2014	Pending
Indonesia	ID201503277	Under examination
Kenya	KE/P/2014/02088	Pending
Mexico	MX/A/2014/007635	Pending
Nigeria	NG/PT/C/2014/302	Pending
Philippines	1-2014-501352	Pending
Russia	2014124981	Examination requested
Thailand	1401003321	Under examination
Venezuela	2013-000416	Published and pending
Vietnam	VN39635	Examination requested

Analytical Methods

Test	Method
Content of Taspine	HPLC (anhydrous basis) (Glenmark STP RMTL.002)
Content of Crofelemer	HPLC (anhydrous basis) (Glenmark STP RMTL.002)
Chromatographic Purity	HPLC (area normalization)

Test	Test Method Number
Identification:HPLC	
Content of Taspine by HPLC (anhydrous basis)	IPTA006A.01 Sr. 05
Content of Crofelemer by HPLC (anhydrous basis)	IPTA006A.01 Sr. 06
Chromatographic Purity by HPLC by area normalization	IPTA006A.01 Sr. 07

Test	Test Method Number
Solubility	Glenmark FPTA006.01 Sr. 02
Identification: Retention Time on Assay	Glenmark FPTA006.01 Sr. 03
Assay (Anhydrous Basis)	Glenmark FPTA006.01 Sr. 04 HPL
Residual Solvents	Glenmark FPTA006.01 Sr. 05 GC
Taspine Related Substance	Glenmark EPTA006.01 Sr. 09 HPLC

39

Related Substances	Glenmark EPTA006.01 Sr. 11 HPLC
Known Related Substances	Glenmark EPTA006.01 Sr. 12 HPLC

40

SCHEDULE 2.2(c) List of Countries in which Glenmark Has Received, or Is Actively Seeking, an Approved Drug Registration for a Licensed Product

Country	Stability Zone	Filing Date	Registration Status
Switzerland	II	Aug 2013 - Complete	Application to withdraw — 09 April 2015
South Africa	II	Oct 2013 - Complete	Ongoing
Ukraine	II	Dec 2013 - Complete	Procedure Cancelled
Tanzania	IV (accepts Z.II + commitment)	Dec 2013 - Complete	Ongoing
Zimbabwe	IV (accepts Z.II + commitment)	Feb 2014 - Complete	Registered - 14 May 2015
India	IV 3m	Feb 2014 - Complete	Ongoing
Botswana	IV (accepts Z.II + commitment)	Mar 2014 - Complete	Registered - 13 Feb 2015
Brazil	IV 6m	Mar 2014 - Complete	Approved — 25 May 2015
Uganda	IV 6m	April 2014 - Complete	Review complete. GMP inspection required

41

Guatemala	IV 6m	May 2014 - Complete	No information received from MOH
Malaysia	IV 12m	May 2014 - Complete	Application rejected
Vietnam	IV 6m	July 2014 - Complete	Ongoing
Venezuela	IV 6m	Aug 2014 - Complete	Not approved (Fast track) *
Ecuador	IV 12m	Aug 2014 - Complete	Registered - 20 Jan 2015
Myanmar	IV 12m	Dec 2014 - Complete	Rejected-Samples with 3/4 shelf life required
Colombia	IV 12m	June 2014 - Complete	Not approved (Jan 2016)
Egypt	IV 6m + 6m Acc	Q3 FY15	Not pursued **

* Didn't approval as medical service product (fast track), and now submit it as a new molecule.

** Salix considered the MAH in USA and a Legalized letter from Salix authorizing GPL to submit this application in Egypt could not be submitted

SCHEDULE 4.5(a)(iii)

ASSIGNMENT OF NAPO PROVIDED EQUIPMENT

THIS ASSIGNMENT OF NAPO PROVIDED EQUIPMENT (this "Assignment") is made and entered into as of September 22, 2017, by and between Napo Pharmaceuticals, Inc., a wholly-owned subsidiary of Jaguar Health, Inc. ("Assignor") and Glenmark Pharmaceuticals, Ltd., a company organized under the laws of the Republic of India ("Assignee"). Capitalized terms used but not otherwise defined herein shall have the definition assigned to such terms in the Termination, Asset Transfer and Transition Agreement dated as of September 22, 2017 (the "Transfer Agreement").

WHEREAS, Assignor and Assignee are parties to the Transfer Agreement;

WHEREAS, pursuant to the Transfer Agreement, Assignor has agreed to assign or cause to be assigned to Assignee or its designee the Napo Provided Equipment;

WHEREAS, the execution and delivery of this Assignment by the Assignor and Assignee is contemplated by Section 4.7(c) of the Transfer Agreement; and,

WHEREAS, pursuant to Section 4.7(c) of the Transfer Agreement, Assignee has agreed to accept the Napo Provided Equipment "as is" and "where is" and Assignor disclaims all warranties, both express and implied with respect to such equipment.

NOW, THEREFORE, in consideration of the mutual promises made in the Transfer Agreement herein and upon the terms and subject to the conditions set forth in the Transfer Agreement and herein, the parties hereto hereby agree as follows:

14. **Assignment of Napo Provided Equipment**. Subject to the terms of Section 4.7(c) of the Transfer Agreement, Assignor hereby transfers and assigns, to Assignee, Assignor's right and title in the Napo Provided Equipment located at Glenmark's Ankleshwar facility, identified on **Exhibit A** attached hereto. Assignee hereby accepts all of such equipment "as is" and "where is" and Assignor disclaims all warranties, both express and implied with respect to such equipment.

15. **Terms of the Transfer Agreement**. The terms of the Transfer Agreement are incorporated herein by reference. The parties acknowledge and agree that the representations, warranties, covenants, agreements and indemnities contained in the Transfer Agreement shall not be limited or expanded hereby, and shall not be superseded hereby, but shall remain in full force and effect to the full extent provided therein. In the event of any conflict or inconsistency between the terms of the Transfer Agreement and the terms hereof, the terms of the Transfer Agreement shall govern.

16. **No Modification of Transfer Agreement**. Nothing contained herein shall release the Assignor or Assignee from any of their respective obligations under the Transfer Agreement or in any way diminish, limit, or modify any of the representations, warranties, indemnities, covenants or agreements of such parties set forth in the Transfer Agreement. To the extent that

any provision of this Assignment conflicts or is inconsistent with the terms of the Transfer Agreement, the Transfer Agreement shall govern, including with respect to the enforcement of the rights and obligations of the parties hereto.

17. **No Third-Party Beneficiaries**. This Assignment is for the sole and exclusive benefit of the Assignor and Assignee and their respective successors and permitted assigns and nothing herein is intended or shall be construed to confer upon any party other than Assignor and Assignee and their respective successors and permitted assigns any right, remedy, or claim under or by reason of this Assignment or any term, covenant or condition hereof.

18. **Successors and Assigns**. This Assignment shall be binding upon the parties hereto and their successors and assigns.

19. **Amendments**. This Assignment and any of the provisions hereof may not be amended or modified except by an instrument in writing, signed by each party hereto.

20. **Governing Law**. This Assignment shall in all respects be construed in accordance with and governed by Article VIII and Section 9.1 of the Transfer Agreement.

21. **Severability**. Any term or provision of this Assignment that is invalid or unenforceable in any jurisdiction shall, as to that jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this Assignment or affecting the validity or enforceability of any of the terms of provisions of this Assignment in any other jurisdiction.

22. **Headings**. The descriptive headings used in this Assignment are inserted for convenience of reference only and are not intended to be part of or to affect the meaning or interpretation of this Assignment.

23. **Counterparts; Facsimile Signature**. This Assignment may be executed in two separate counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument. A facsimile or scanned signature to this Assignment shall have the same legal force and effect as an original signature.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have executed this Assignment of Napo Provided Equipment as of the Transfer Date.

GLENMARK PHARMACEUTICALS, LTD.

By: /s/ Meera Vanjari

Name: Meera Vanjari

Title: Senior Vice President and General Counsel-Legal

NAPO PHARMACEUTICALS, INC.

By: /s/ Lisa A. Conte

Name: Lisa A. Conte

Title: President and CEO

45

Exhibit 4.5(a)(v)

CERTIFICATION OF OFFICER

The undersigned, in his or her capacity as an officer of Glenmark Pharmaceuticals, Ltd. ("Glenmark"), does hereby certify and attest, to the following:

1. that Glenmark and Napo Pharmaceuticals, Inc. ("Napo") have entered into a *Termination, Asset Transfer and Transition Agreement* dated of even date herewith (the "Transfer Agreement"), to effect the assignment and transfer from Glenmark to Napo, of, among other assets, the Transferred Glenmark Patents;
2. that with respect to each of the Transferred Glenmark Patents:
 - A. all fees and annuities due on or prior to the Transfer Date, have been paid in full by Glenmark in a timely fashion; and
 - B. to the extent any filings were due to be filed, on or prior to the Transfer Date (including any responses to Official Actions, Notices or Requests from patent offices or taking any action necessary to maintain any such item in force), all such filings have been submitted in a timely fashion.
3. that all capitalized terms used in this Certification, but not otherwise defined herein, shall have the meanings ascribed to them in the Transfer Agreement.
4. that the undersigned is a duly elected, or appointed, officer of Glenmark and is duly authorized to act on behalf of Glenmark in executing this Certification.

IN WITNESS WHEREOF, I have set my hand hereto as of the 22nd day of September 2017

Signature: /s/ Meera Vanjari

Print Name: Meera Vanjari

Print Officer Title: Senior Vice President and General Counsel-Legal

46

**PRINCIPAL EXECUTIVE OFFICER'S CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Lisa A. Conte, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Jaguar Health, Inc. for the quarter ended September 30, 2017;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 20, 2017

/s/ Lisa A. Conte

Lisa A. Conte

President and Chief Executive Officer
(Principal Executive Officer)

**PRINCIPAL FINANCIAL OFFICER'S CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Karen S. Wright, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Jaguar Health, Inc. for the quarter ended September 30, 2017;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 20, 2017

/s/ Karen S. Wright

Karen S. Wright

Chief Financial Officer

(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Jaguar Health, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 20, 2017

/s/ Lisa A. Conte

Lisa A. Conte
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Jaguar Health, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 20, 2017

/s/ Karen S. Wright

Karen S. Wright

Chief Financial Officer

(Principal Financial and Accounting Officer)
