# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# **FORM 10-Q**

(Mark One)

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

For the quarterly period ended June 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)

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)

46-2956775 (I.R.S. Employer Identification No.)

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

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

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

Large accelerated filer o

Accelerated filer o

Non-accelerated filer o (Do not check if a smaller reporting company) Smaller reporting company x Emerging growth company x

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

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

As of August 9, 2017, there were 67,430,585 shares of common stock, par value \$0.0001 per share, outstanding, of which 24,527,367 are voting shares and 42,903,218 are non-voting shares.

PART I. — FINANCIAL INFORMATION (Unaudited)	2
Item 1. Condensed Unaudited Financial Statements	2
Condensed Balance Sheets as of June 30, 2017 and December 31, 2016	2
Condensed Statements of Operations and Comprehensive Loss for the Three and Six Month Periods Ended June 30, 2017 and 2016	3
Condensed Statement of Changes in Common Stock, Convertible Preferred Stock and Stockholders' Equity (Deficit) for the period from	
December 31, 2015 through June 30, 2017	4
Condensed Statements of Cash Flows for the Six Months Ended June 30, 2017 and 2016	5
Notes to the Condensed Financial Statements	6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	28
Item 3. Quantitative and Qualitative Disclosures About Market Risk	53
Item 4. Controls and Procedures	53
PART II. — OTHER INFORMATION	54
Item 1. Legal Proceedings	54
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	54
Item 6. Exhibits	54
SIGNATURE	55
1	

## Table of Contents

## PART I. — FINANCIAL INFORMATION

## Item 1. Condensed Financial Statements

## JAGUAR HEALTH, INC.

## CONDENSED BALANCE SHEETS

		June 30, 2017	D	ecember 31, 2016
		(Unaudited)		(1)
Assets				
Current assets:	¢	27(0.040	¢	050.070
Cash and cash equivalents	\$	2,760,848	\$	950,979
Restricted cash Accounts receivable		12 101		511,293
Other receivable		12,191		4,963
		197,876		200 (49
Due from former parent		222,024		299,648
Inventory		396,175		412,754
Deferred offering costs		10,930 360,501		72,710 302,694
Prepaid expenses Total current assets				
		3,960,545		2,555,04
Property and equipment, net		855,883		885,94
Other assets	<u></u>	122,163	<u>_</u>	122,16
Total assets	\$	4,938,591	\$	3,563,14
Liabilities and Stockholders' Deficit				
Current liabilities:				
Accounts payable	\$	3,443,924	\$	517,00
Deferred collaboration revenue		1,451,789		
Deferred product revenue		184,674		224,454
Convertible notes payable		1,777,346		150,000
Accrued expenses		860,851		582,522
Warrant liability		551,880		799,20
Derivative liability		20,000		_
Current portion of long-term debt		2,071,646		1,919,67
Total current liabilities		10,362,110		4,192,852
Long-term debt, net of discount		835,976		1,817,52
Deferred rent		7,271		6,95
Total liabilities	\$	11,205,357	\$	6,017,334
	· · · ·	, ,	<u> </u>	, )
Commitments and Contingencies (See Note 6)				
Stockholders' Deficit:				

Stockholders' Deficit:

Preferred stock: \$0.0001 par value, 10,000,000 shares authorized at June 30, 2017 and December 31, 2016; no shares issued and outstanding at June 30, 2017 and December 31, 2016.	_	_
Common stock: \$0.0001 par value, 50,000,000 shares authorized at June 30, 2017 and December 31, 2016;		
17,482,501 and 14,007,132 shares issued and outstanding at June 30, 2017 and December 31, 2016,		
respectively.	1,748	1,401
Additional paid-in capital	40,688,594	37,980,522
Accumulated deficit	(46,957,108)	(40,436,108)
Total stockholders' deficit	(6,266,766)	(2,454,185)
Total liabilities and stockholders' deficit	\$ 4,938,591	\$ 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 financial statements.

## 2

## Table of Contents

## JAGUAR HEALTH, INC.

## CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

## (Unaudited)

	Three Months Ended June 30,				Six Months Ended June 30,			
		2017		2016		2017		2016
Product revenue	\$	61,445	\$	24,143	\$	135,989	\$	62,289
Collaboration revenue		835,076		_		1,582,942		_
Total revenue	_	896,521		24,143		1,718,931		62,289
Operating Expenses								
Cost of product revenue		24,762		8,641		40,907		27,009
Research and development expense		926,791		1,953,647		2,182,243		3,705,388
Sales and marketing expense		157,231		54,050		280,143		218,463
General and administrative expense		2,137,990		1,416,159		5,441,493		3,204,544
Total operating expenses		3,246,774		3,432,497		7,944,786		7,155,404
Loss from operations		(2,350,253)		(3,408,354)		(6,225,855)		(7,093,115)
Interest expense		(156,129)		(254,758)		(336,201)		(538,994)
Other income/(expense)				5,637		1,448		(9,570)
Change in fair value of warrants		700,740		_		247,321		_
Loss on extinguishment of debt		—		—		(207,713)		—
Net loss and comprehensive loss	\$	(1,805,642)	\$	(3,657,475)	\$	(6,521,000)	\$	(7,641,679)
Net loss per share, basic and diluted	\$	(0.12)	\$	(0.35)	\$	(0.45)	\$	(0.78)
Weighted-average common shares outstanding, basic and diluted		14,694,316		10,314,106		14,427,317		9,810,730
			_					

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

## 3

Table of Contents

## JAGUAR HEALTH, INC.

## CONDENSED STATEMENT OF CHANGES IN COMMON STOCK, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

## (Unaudited)

	Series A Conver Stoo		Commo	n Stock			
	Shares	Amount	Shares	Amount	Additional paid-in capital	Accumulated deficit	Total Stockholders' Equity (Deficit)
Balances - December 31, 2015	—	\$ —	8,124,923	\$ 812	\$ 30,100,613	\$ (25,702,328)	\$ 4,399,097
Issuance of common stock in a secondary public offering ,net of discounts and commissions of \$373,011 and offering costs of \$496,887 February 2016	_	_	2,000,000	200	4,129,902	_	4,130,102
Issuance of common stock in a private investment in public entities offering, net of offering costs of \$105,398 June 2016.	_	_	2,027,490	203	2,571,099	_	2,571,302
Issuance of common stock in a private investment in public entities offering October 2016	_	_	170,455	17	149,983	_	150,000
Issuance of common stock and equity warrants in a private investment in public entities offering, net of warrant liability of \$700,001 and net of offering costs of \$96,833 November 2016	_	_	1,666,668	167	203,000	_	203,167
Warrants, issued in conjunction with debt extinguishment	_	_	_	_	108,000	_	108,000
Issuance of common stock in exchange for vested restricted stock units	_	_	17,596	2	(2)	_	_
Stock-based compensation	—	—	_	_	717,927		717,927
Net and comprehensive loss						(14,733,780)	(14,733,780)
Balances - December 31, 2016	—	\$ —	14,007,132	\$ 1,401	\$ 37,980,522	\$ (40,436,108)	\$ (2,454,185)

			l				
Issuance of common stock associated with the June 2016 private investment in public entities offering, net of offering costs of \$61,781	_	_	3,375,369	337	2,009,199	_	2,009,536
Issuance of common stock in a private investment in public entities offering, net of offering costs of \$3,000 June 2017			100,000	10	46,990		47,000
Stock-based compensation	—	_	_	—	444,170	—	444,170
Warrants, issued in conjunction with debt extinguishment	_	_	_	_	207,713	_	207,713
Net and comprehensive loss						(6,521,000)	(6,521,000)
Balances - June 30, 2017	\$		17,482,501	<u>\$ 1,748</u>	\$ 40,688,594	\$ (46,957,108)	<u>\$ (6,266,766</u> )

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

4

Table of Contents

## JAGUAR HEALTH, INC. CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)

	Six Months Ended June 30,				
		2017		2016	
Cash Flows from Operating Activities					
Net loss	\$	(6,521,000)	\$	(7,641,679)	
Adjustments to reconcile net loss to net cash used in operating activities:		(-)- ))	•	(-)/	
Depreciation expense		30,062		17,432	
Loss on extinguishment of debt		207,713		,	
Stock-based compensation		444,170		229,064	
Amortization of debt issuance costs and debt discount		180,670		269,019	
Change in fair value of warrants		(247,321)		_	
Changes in assets and liabilities					
Accounts receivable - trade		(7,228)		36,755	
Other receivable		(197,876)		_	
Inventory		16,579		(46,753)	
Prepaid expenses		(57,807)		(526,147)	
Deferred offering costs		61,780			
Due from parent		77,624		3,199	
Deferred collaboration revenue		1,451,789			
Deferred product revenue		(39,780)		10,730	
Deferred rent		315		3,321	
License fee payable		_		(425,000)	
Accounts payable		2,909,770		(115,306)	
Accrued expenses		224,329		(117,690)	
Total cash used in operations		(1,466,211)		(8,303,055)	
Cash Flows from Investing Activities					
Purchase of equipment				(98,266)	
Change in restricted cash		511,293		1,855,703	
Total cash provided by investing activities		511,293		1,757,437	
Cash Flows from Financing Activities		<u> </u>			
Repayment of long-term debt		(991,749)		(1,855,703)	
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		2,071,317		500,000	
Issuance costs associated with the proceeds from the issuance of common stock in a private investment in					
public entities June 2016		(61,781)		(51,268)	
Proceeds from issuance of common stock in a private investment in public entities June 2017		50,000			
Issuance costs associated with the proceeds from the issuance of common stock in a private investment in					
public entities June 2017		(3,000)		_	
Total Cash Provided by Financing Activities		2,764,787		2,723,131	
Net increase in cash and cash equivalents		1,809,869		(3,822,487)	
Cash and cash equivalents, beginning of period		950,979		7,697,531	
Cash and cash equivalents, end of period	\$	2,760,848	\$	3,875,044	

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

## JAGUAR HEALTH, INC.

#### NOTES TO CONDENSED 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 operates as one segment 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 9 for additional information regarding the capital contributions and Note 4 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 4).

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. 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 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 \$46,957,108 as of June 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 will need 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 June 30, 2017 the Company sold 5,402,859 shares for gross cash proceeds of \$4,748,017. 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

#### Table of Contents

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.

#### 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"). 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 June 30, 2017 and the results of operations for the three and six months ended June 30, 2017 are not necessarily indicative of the results to be expected for the entire year.

#### **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 of long lived assets; useful lives for depreciation; valuation adjustments for excess and obsolete inventory; 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 \$10,930 and \$72,710 as of June 30, 2017 and December 31, 2016, respectively, include legal, accounting 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 June 30, 2017 and December 31, 2016.

#### **Fair Values**

The Company's financial instruments include, cash and cash equivalents, accounts payable, accrued expenses, amounts due to Napo, the former parent, warrant liabilities, derivative liability, and debt. Cash is reported at fair value. The recorded carrying amount of accounts payable, accrued expenses and amounts due to Napo approximates 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 3 for the fair value measurements, and Note 7 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 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 further reduced the restricted cash balance to \$0 as of June 30, 2017. Restrictions were fully released on April 1, 2017.

#### Table of Contents

#### 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 income (loss) from operations.

#### 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.

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 June 30, 2017.

## **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

8

## Table of Contents

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 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 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 \$61,445 and \$24,143 for the three months ended June 30, 2017 and 2016, and \$105,989 and \$62,289 for the six months ended June 30, 2017 and 2016.

Sales of Botanical Extract are recognized as revenue when delivered to the customer. The Company had Botanical Extract revenues of \$0 in the three months ended June 30, 2017 and 2016, and \$30,000 and \$0 in the six months ended June 30, 2017 and 2016.

#### **Collaboration Revenue**

On January 27, 2017, the Company 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. 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 chronic indications of diarrhea; \$25.0 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 \$835,076 and \$1,582,942 in collaboration revenue in the three and six months ended June 30, 2017 which are included in the Company's statements of operations and comprehensive loss. The difference of \$1,451,789 is included in deferred collaboration revenue in the Company's balance sh

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 \$197,876 of unreimbursed expenses as of June 30, 2017, which is included in Other Receivables on the Company's balance sheet. The Company included the \$197,876 and \$486,042 in collaboration revenue in the three and six months ended June 30, 2017 which are included in the Company's statements of operations and comprehensive loss.

9

## Table of Contents

#### **Stock-Based Compensation**

The Company's 2013 Equity Incentive Plan and 2014 Stock Incentive Plan (see Note 10) 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 six months ended June 30, 2017 and 2016 there was no difference between net loss and comprehensive loss.

#### Segment Data

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company is an animal health company focused on developing and commercializing prescription and non-prescription products for companion and production animals.

## 10

#### Table of Contents

#### **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-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 six months ended June 30, 2017 and 2016.

#### **Recent Accounting Pronouncements**

In November 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 equivalents in the statement of cash flows. When cash, cash equivalents, 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, 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 for the three-month periods ended March 31, 2016 or 2017. 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.

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 lesse 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 lesses 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

1	1
	Т
-	-

## Table of Contents

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 currently evaluating the new guidance, however it does not believe the impact will be significant.

#### 3. 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 warrant liabilities that were measured at fair value on a recurring basis as of June 30, 2017 and December 31, 2016 and indicates the fair value hierarchy of the valuation:

	Lev	el 1	Level 2	Level 3	Total
As of June 30, 2017 Warrant Liability	\$	_	\$ 	\$ 551,880	\$ 551,880
	Lev	el 1	 Level 2	 Level 3	 Total
As of December 31, 2016 Warrant Liability	\$		\$ 	\$ 799,201	\$ 799,201

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

	Beginning Value of Level 3 Liability			Change in Fair Value of Level 3 Liability	Ending Fair Value of Level 3 Liability		
For the six months ended June 30, 2017	\$	1,252,620	\$	(700,740)	\$	551,880	
For the six months ended June 30, 2016	\$		\$		\$	_	

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 \$0.716, 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 June 30, 2017 using the Black-Scholes-Merton model with the following assumptions: stock price of \$0.53, exercise price of \$0.75, term of 4.91 years expiring May 2022, volatility of 80.51%, dividend yield of 0%, and risk-free interest rate of 1.87%.

1	1
т	
•	-

#### Table of Contents

The change in the fair value of the level 3 warrant liability is reflected in the statement of operations and comprehensive loss for the six months ended June 30, 2017.

#### 4. 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, is also the Interim Chief Executive Officer of Napo Pharmaceuticals, Inc. The Company has total outstanding receivables (payables) from former parent ("Napo") at June 30, 2017 and December 31, 2016 as follows:

	June 30, 2017	I	December 31, 2016
Due from former parent	\$ 222,403	\$	299,819
Royalty payable to former parent	(379)		(171)
Net receivable (payable) to former parent	\$ 222,024	\$	299,648

#### Due from former parent

#### 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 \$760,222 and Napo remitted \$838,723 for the six months ended June 30, 2017. The remaining unpaid balance of \$199,028 is included in due from former parent in current assets on the Company's balance sheet.

#### **Other transactions**

The Company periodically makes 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 \$68,347 and Napo remitted \$67,262 in the six months ended June 30, 2017. The remaining unpaid balance of \$23,375 is included in due from former parent in current assets on the Company's balance sheet.

## 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 is a significant shareholder of the Company, the abatement of the license fee amount has been recorded as a capital contribution in the accompanying condensed financial statements. The Company paid the final \$425,000 in the six months ended June 30, 2016.

Milestone payments aggregating \$3,150,000 may also be due to Napo based on regulatory approvals of various veterinary products. In addition to the milestone payments, the Company will 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 will owe Napo a 2% royalty on annual net sales of pharmaceutical prescription

## Table of Contents

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 \$663 in royalties in the six months ended June 30, 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 six months ended June 30, 2017. The remaining balance of unpaid royalties of \$379 are netted with other receivables due from the former parent and are included in current assets in the Company's balance sheet. The Company may, at its sole discretion, elect to remit any milestone payments and/or royalties in the form of the Company's common stock.

In addition to receiving a License Agreement to Napo's intellectual property and technology, the License also transferred to the Company certain materials and equipment. Raw materials of \$1.2 million transferred from Napo were included in research and development expense on the statements of operations and comprehensive loss during the year ended December 31, 2014. Equipment of \$811,087 related to the License is included in property and equipment on the Company's balance sheet at June 30, 2017 and December 31, 2016 at the cost paid by Napo, which approximates fair value.

The Company has agreed under the License Agreement to defend, indemnify and hold Napo, its affiliates, and the officers, directors, employees, consultants and contractors of Napo harmless from and against any losses, costs, damages, liabilities, fees and expenses arising out of any third-party claim related to the Company's gross negligence, breach of covenants or the manufacture, sale or use of the product or products.

#### 5. Balance Sheet Components

#### **Property and Equipment**

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

	June 30, 2017	December 31, 2016
Lab equipment	\$ 811,0	87 \$ 811,087
Clinical equipment	64,8	70 64,870
Software	62,6	37 62,637
Total property and equipment at cost	938,5	94 938,594
Accumulated depreciation	(82,7	11) (52,649)
Property and Equipment, net	\$ 855,8	83 \$ 885,945

Depreciation and amortization expense was \$15,031 and \$9,554 in the three months ended June 30, 2017 and 2016, and \$30,062 and \$17,432 in the six months ended June 30, 2017 and 2016, which are included in the statements of operations and comprehensive loss as follows:

	Three Months Ended June 30,			hs Ended e 30,		
		2017	2016	2017		2016
Depreciation - Lab Equipment - research and development						
expense	\$	6,568	\$ 6,568	\$ 13,136	\$	13,136
Depreciation - Clinical Equipment - research and development						
expense		3,244	2,551	6,487		3,716
Depreciation - Software - general and administrative expense		5,219	435	10,439		580
Total Depreciation Expense	\$	15,031	\$ 9,554	\$ 30,062	\$	17,432
		14				

## Table of Contents

#### Accrued Expenses

	June 30, 2017		ecember 31, 2016
Accrued compensation and related:		_	
Accrued vacation	\$ 231,718	\$	223,769
Accrued payroll	265		2,692
Accrued payroll tax	19,769		20,140
	 251,752		246,601
Accrued interest	124,239		123,982
Accrued clinical	78,822		36,725
Accrued legal costs	249,998		92,500
Accrued audit			37,000
Accrued other	156,040		45,714
Total	\$ 860,851	\$	582,522

## 6. 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 other assets on the Company's balance sheet.

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

Years ending December 31,	Amount
2017 - July through December	\$ 183,244
2018	245,327
Total minimum lease payments	\$ 428,571

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 \$90,279 for the three months ended June 30, 2017 and 2016, and \$180,557 for the six months ended June 30, 2017 and 2016. Rent expense is included in general and administrative expense in the Company's statements of operations and comprehensive loss.

## **Contract Manufacturing Commitment**

Effective June 26, 2014 the Company entered into a technology transfer and commercial manufacturing agreement (the "Transfer Agreement") with a contract manufacturer in Italy (the "Manufacturer"), whereby the Company and the Manufacturer will cooperate to develop and refine the manufacturing process for the Company's prescription and non-prescription products. Pursuant to the Transfer Agreement, the Company was to make prepayments to the Manufacturer as follows: (1) a start-up fee of  $\in$ 500,000,  $\notin$ 250,000 of which was to be paid at the earlier to occur of September 15, 2014 or the closing date of an initial public offering and  $\notin$ 250,000 of which was to be paid at the time of installation and qualification of the Company's equipment at their facility, (2) related to the technology transfer,  $\notin$ 620,000,  $\notin$ 310,000 of which was paid subsequent to the signature of the Transfer Agreement and  $\notin$ 310,000 of which was to be paid after the delivery of a final study report, (3) for design of a portion of the Manufacturer's facility,  $\notin$ 100,000 was to be paid within five days of the signature of the Transfer Agreement, and (4) a  $\notin$ 300,000 bonus fee payable in two equal installments, the first of which is due by the end of March 2015, with the remainder paid by the end of December 2015. The first  $\notin$ 150,000 of the bonus fee payable was paid in May 2015. Additionally, the Transfer Agreement stipulated that the Company was to pay the Manufacturer an aggregate of  $\notin$ 500,000 upon the delivery of agreed-upon levels of satisfactory product. Further, the Company issued the Manufacturer warrants to purchase 16,666 shares of common stock with an exercise price of 90% of the initial public offering price, amended to 6.30 in March 2015.

1	5
1	2

#### Table of Contents

Effective February 12, 2015, March 25, 2015 and July 15, 2015 the Company entered into amendments delaying payments to the Manufacturer as follows: (i) the  $\notin$ 500,000 start-up fee was due by the end of April 2015 and has been paid during the year ended December 31, 2015, (ii) related to the technology transfer, of the remaining  $\notin$ 310,000,  $\notin$ 215,000 was due April 2015 and  $\notin$ 95,000 was due June 30, 2015, both of which were paid during the year ended December 31, 2015, (iii) related to the design of a portion of the Manufacturer's facility, the payment has increased to  $\notin$ 170,000,  $\notin$ 150,000 of which was due at the end of April 2015 and  $\notin$ 20,000 was due on June 30, 2015, both of which have been paid during the year ended December 31, 2015 (iv) the fees linked to the deliverables are now due  $\notin$ 250,000 on December 31, 2015 and  $\notin$ 250,000 on March 31, 2015, (v) the bonus fee payable of  $\notin$ 300,000,  $\notin$ 150,000 was due at the end of April 2015 and has been paid during the year ended December 31, 2015. In May 2015, the Company entered into a Memorandum of Understanding ("MOU") with the contract manufacturer and paid the start-up fee of  $\notin$ 500,000 and the technology transfer fee of  $\notin$ 215,000. In accordance with the terms of the Memorandum of Understanding, the Manufacturer will supply 400Kg of the Company's API at no cost in anticipation of the future deduction by December 2015. The final  $\notin$  250,000 was paid on March 29, 2016.

In December 2015, we entered into an amendment to our technology transfer and commercial manufacturing agreement with our contract manufacturer in Italy delaying a  $\in$ 150,000 bonus fee payment which was originally due on December 31, 2015 to March 31, 2016. On April 4, 2016, the Company further amended the payment date to June 30, 2016. The Company paid the final  $\in$ 150,000 bonus fee on July 15, 2016.

The Company expensed the total cost of the contract ratably over the estimated life of the contract, or the total amount paid if greater. As of June 30, 2016, the amortized costs exceeded amounts paid by \$170,850, which were included in accrued manufacturing costs in accrued liabilities in the Company's balance sheet.

#### **Debt Obligations**

#### **Contingencies**

From time to time, the Company may be involved in legal proceedings arising in the ordinary course of business. The Company believes there is no litigation pending that could have, individually or in the aggregate, a material adverse effect on the financial position, results of operations or cash flows.

#### 7. Debt and Warrants

## **Convertible** Notes and Warrants

#### 2013 Convertible Notes

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

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

16

#### Table of Contents

#### 2014 Convertible Notes

On June 2, 2014, pursuant to a convertible note purchase agreement, the Company issued convertible promissory notes in the aggregate principal amount of \$300,000 to two accredited investors, including a convertible promissory note for \$200,000 to a board member to which Series A preferred stock was sold. These notes accrued interest at 3% per annum and automatically were to mature on June 1, 2015. The Company has unpaid accrued interest of \$8,507, which is included in accrued liabilities in the balance sheet. All interest was to be paid in cash upon maturity. No interest was incurred for the three and six months ended June 30, 2017 and 2016. Upon the closing of the IPO, the outstanding principal amount automatically converted into 53,571 shares common stock at \$5.60, as amended in March 2015. Upon issuance, the Company analyzed the beneficial nature of the conversion terms and determined that a beneficial conversion feature ("BCF") existed because the effective conversion price on issuance of the notes was less than the fair value at the time of the issuance. The Company calculated the value of the BCF using the intrinsic method and recorded a BCF of \$75,000 as a discount to notes payable and to additional paid-in capital. The full amount of the BCF was amortized to interest expense by the end of May 2015 when the notes were converted to equity.

On July 16, 2014, pursuant to a convertible note purchase agreement, the Company issued a convertible promissory note in the principal amount of \$150,000 to an accredited investor. This note accrued interest at 3% per annum and automatically was to mature on June 1, 2015. The Company has unpaid accrued interest of \$3,711, which is included in accrued liabilities in the balance sheet. All interest was to be paid in cash upon maturity. No interest was incurred for the three and six months ended June 30, 2017 and 2016. Upon the closing of the IPO, the outstanding principal amount automatically converted into 26,785 shares of common stock at \$5.60, as amended in March 2015. Upon issuance, 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 and recorded a BCF of \$37,500 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 May 2015 when the notes were converted to equity.

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

On December 23, 2014, pursuant to a convertible note purchase agreement, the Company issued convertible promissory notes in the aggregate principal amount of \$650,000 to three accredited investors, including a convertible promissory note for \$250,000 to the same board member to which the June 2, 2014 \$200,000 convertible promissory note was issued and to which Series A preferred stock was sold. These notes accrued interest at 12% per annum and became payable within thirty days following the IPO. The Company has unpaid accrued interest of is \$30,132, which is included in accrued liabilities in the balance sheet. All interest was to be paid in cash upon maturity. No interest expense was accrued for the three and six months ended June 30, 2017 and 2016. Upon consummation of the Company's IPO, the noteholders converted the notes into 116,070 shares of common stock at a conversion price equal to 80% of the IPO price, amended to \$5.60 in March 2015. In connection with these notes, the Company also issued the lenders a fully vested warrant to purchase shares of the Company's common stock at an exercise price equal to 80% of the IPO price, amended to \$5.60 in March 2015. These warrants entitle the noteholders to purchase 58,035 shares of common stock. The fair value of the warrants, \$147,943, was recorded as a debt discount and liability at December 23, 2014. The Company fully amortized the discount by the end of May 2015 when the notes were converted to equity. The warrants were originally valued using the Black-Scholes-Merton model with the following assumptions: stock price of \$4.59, exercise price of \$4.15, term of three years expiring December 2017, volatility of 49%, dividend yield of 0%, and risk-free interest rate of 1.10%. Based on the circumstances, the value derived using the Black-Scholes-Merton model approximated that which would be obtained using a lattice model. The debt discount was amortized as interest expense over the one hundred ninety days from issuance of the notes through their first maturity date of July 31, 2015, beginning in January 2015. 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 of \$502,057 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 May 2015 when the notes were converted to equity.

#### 2015 Convertible Notes

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

#### Table of Contents

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. 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 in the three months ended December 31, 2017.

#### • Extinguishment of debt

On January 31, 2017, the Company entered into an 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 other expense in the Company's statements of operations and comprehensive loss in the six months ended June 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 \$42,855 and \$33,929, which is included in accrued liabilities on the Company's balance sheet as of June 30, 2017 and December 31, 2016, respectively, and incurred interest expense of \$4,488 in the three months ended June 30, 2017 and 2016, respectively, and \$8,926 and \$8,975 in the six months ended June 30, 2017 and 2016 which are included in interest expense in the statement of operations and comprehensive loss.

In March 2015, the Company entered into a non-binding letter of intent with an investor. In connection therewith, the investor paid the Company \$1.0 million. At March 31, 2015, the Company had recorded this amount as a loan advance on the balance sheet. In April 2015, the investor purchased \$1.0 million of convertible promissory notes from the Company, the terms of which provided that such notes were to be converted into shares of the Company's common stock upon the closing of an IPO at a conversion price of \$5.60 per share. In connection with the purchase of the notes, the Company issued the investor a warrant to purchase 89,285 shares at \$5.60 per share, which expires December 31, 2017. The notes accrued simple interest of 12% per annum and, upon consummation of the Company's IPO in May 2015, converted into 178,571 shares of the Company's common stock. 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 of 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. While the note was converted to equity, the Company has not yet remitted the related accrued interest of \$17,753, which is included in accrued liabilities in the Company's balance sheet. No interest expense was accrued in the three months ended June 30, 2017 and 2016.

#### 2017 Convertible Notes

On June 29, 2017, the Company issued a secured convertible promisorry note ("Note") to a lendor in the aggregate principal amount of \$2,155,000 less an original issue discount of \$425,000 and less \$30,000 to cover the lender's legal fees for net cash proceeds of \$1,700,000. Interest on the outstanding balance will be paid 8% per annum from the purchase price date until the balance is paid in full. All interest calculations are computed on the basis of a 360-day year comprised of twelve (12) thirty (30) day months compounded daily and payable in accordance with the terms of the Note. All principal and interest on the debt is due in full on August 2, 2018. The Company accrued interest of \$472 at June 30, 2017 which is included in accrued expenses on the Company's balance sheet and in interest expense in the Company's statement of operations and comprehensive loss. The Company also recorded \$1,346 in interest expense in the Company's common stock at \$1.00 per share.

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

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

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

The Company computed fair values 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 balance of the note payable of \$1,627,346, 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 \$1,346 in June of 2017, is included in notes payable in current liabilities on the balance sheet.

#### 18

#### Table of Contents

As of June 30, 2017 and December 31, 2016, the aggregate convertible notes payable obligations were as follows:

	June 30, 2017	December 31, 2016		
Notes payable	\$ 2,285,000	\$	150,000	
Unamortized note discount and debt issuance costs	(507,654)		_	
Net debt obligation	\$ 1,777,346	\$	150,000	

Interest payable on the convertible notes at June 30, 2017 and December 31, 2016 was \$103,446 and \$94,048, respectively and are included in accrued expenses on the Balance Sheet.

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

	Three Months Ended June 30,			Six Months Ended June 30,			ed	
		2017		2016		2017		2016
Nominal interest	\$	4,960	\$	4,487	\$	9,398	\$	8,975
Amortization of debt discount		1,346				1,346		—
	\$	6,306	\$	4,487	\$	10,744	\$	8,975

#### Notes Payable—Bridge Loans

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

#### Standby Line of Credit

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

#### 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.

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

	June 30, 2017	Γ	ecember 31, 2016
Debt and unpaid accrued end-of-term payment	\$ 2,993,473	\$	3,894,320
Unamortized note discount	(20,854)		(42,493)
Unamortized debt issuance costs	(64,997)		(114,626)
Net debt obligation	\$ 2,907,622	\$	3,737,201
Current portion of long-term debt	\$ 2,071,646	\$	1,919,675
Long-term debt, net of discount	835,976		1,817,526
Total	\$ 2,907,622	\$	3,737,201

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

Years ending December 31	 Amount
2017 - July through December	\$ 1,041,040
2018	1,479,246
Total future principal payments	2,520,286
2018 end-of-term payment	560,000
	 3,080,286
Less: unaccreted end-of-term payment at June 30, 2017	(86,813)
Debt and unpaid accrued end-of-term payment	\$ 2,993,473

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.

20

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

# Table of Contents

	Three Months Ended June 30,			Six Months Ended June 30,			ed
	 2017		2016		2017		2016
Nominal interest	\$ 67,273	\$	112,374	\$	146,134	\$	261,000
Accretion of debt discount	9,961		16,640		21,639		35,051
Accretion of end-of-term payment	41,505		69,331		90,160		146,027
Accretion of debt issuance costs	31,085		51,924		67,524		87,940
	\$ 149,824	\$	250,269	\$	325,457	\$	530,018

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

## 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, 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 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 \$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 \$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 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 A warrants and placement agent warrants were revalued on March 31, 2017 at \$1,252,620 which is included in the Company's balance sheet, and the \$453,419 increase is included in the Company's statements of operations and comprehensive loss. The stock price was \$0.75 per share, the expected life was 5.16 years, the volatility was 78.33% and the risk free rate was 1.95%. 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 reduction of \$700,740 from the March 31, 2017 valuation of \$1,252,620 and a decrease of \$247,321 decrease from the \$799,201 December 31, 2016 valuation. The changes are included in the Company's statements of operations and comprehensive loss. The stock price of \$1.00, the strike price was \$0.75 per share, the expected life was 5.16 years, the volatility was 78.33% and the risk free rate was 1.95%. The series B and C warrants were classified as equity, and as such were not subject to revaluation at year enduction of \$700,740 from the March 31, 2017 valuation of \$1,252,620 and a decrease of \$247,321 decrease from the \$799,201 December 31, 2016 valuation. The changes are included i

21

#### Table of Contents

The Company's warrant activity is summarized as follows:

	Six Months Ended June 30, 2017	Year Ended December 31, 2016
Beginning balance	5,968,876	748,872
Warrants granted	370,916	5,253,337
Warrants cancelled	—	(33,333)
Ending balance	6,339,792	5,968,876

#### 8. Redeemable Convertible Preferred Stock

In February, April and May of 2014, the Company issued 3,015,902 shares of convertible preferred stock in exchange for \$6,777,338. The redemption value of the convertible preferred stock was \$9.0 million. The differences between the respective redemption values/liquidation preference and carrying values are being accreted over the period from the date of issuance to the earliest possible redemption date, February 2017. The Company has recorded accretion of \$263,060 for the year ended December 31, 2015.

Costs incurred in connection with the issuance of Series A redeemable convertible preferred stock during the year ended December 31, 2014 were \$119,097 which have been recorded as a reduction to the carrying amounts of convertible preferred stock and are being accreted to the carrying value of the applicable preferred stock to the redemption date. The Company has recorded accretion of \$83,334 for the year ended December 31, 2015.

On May 18, 2015, the Company completed its IPO. In connection with the IPO, all of the Company's 3,015,902 outstanding shares of convertible preferred stock were automatically converted into 2,010,596 shares of common stock. Prior to this conversion event, Convertible Preferred Stock had been classified outside of stockholders' deficit in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities.

#### 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.

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.

#### Table of Contents

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 six months ended June 30, 2017, the Company sold another 3,375,369 shares of the Company's common stock in exchange for \$2,071,317 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, which is referred to herein as 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 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 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 B 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	I	ssuance Costs (allocated)
Common Stock	\$ 156,522	16%	\$	50,522
Warrants (Series A)	700,001	70%		225,944
Warrants (Series B and C)	143,478	14%		46,311
Total	\$ 1,000,001	100%	\$	322,777

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

In exchange for the extension of the maturity date of the outstanding 2015 Convertible Note, on, November 8, 2016, the Company's board of directors granted the lender a warrant to purchase 120,000 shares of the Company's common stock for \$0.01 per share. The warrant is exercisable at any time on or before July 28, 2022, the expiration date of the warrant. The amendment and related warrant issuance resulted in the Company treating the debt as having been extinguished and replaced with new debt for accounting purposes due to meeting the 10% cash flow test. The Company calculated a loss on the extinguishment of debt of \$108,000, or the equivalent to the fair value of the warrants granted, which is included in other expense in the Company's statements of operations and comprehensive loss. The warrants were valued on November 8, 2016 using the Black-Scholes-Merton model with

#### Table of Contents

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.

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

	June 30, 2017	June 30, 2016
Options issued and outstanding	2,440,851	1,464,265
Options available for grant	450,499	1,146,943

RSUs issued and outstanding	20,789	20,789
Warrants issued and outstanding	6,339,792	748,872
Convertible notes	2,196,533	26,785
Total	11,448,464	3,407,654

#### **Preferred Stock**

The Company's second 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 June 30, 2017 or December 31, 2016.

#### 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 June 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 six months ended June 30, 2017:

Table of Contents						
	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	<u>\$                                    </u>
2013 Equity Incentive Plan Activity: None						
2014 Stock Incentive Plan Activity:						
Additional shares authorized	280,142					
Q1 Options granted	(18,000)	18,000		0.71		
Q1 Options cancelled	60,570	(60,570)		1.67		
Q2 Options granted	(20,000)	20,000		0.79		
Q2 Options cancelled	107,799	(107,799)		1.47		
Combined Incentive Plan Balance—						
June 30, 2017	450,499	2,440,851	20,789	\$ 2.56	8.44	\$ —
Options vested and exercisable—						
June 30, 2017		1,297,589		\$ 3.21	7.93	\$ —
Options vested and expected to vest—						
June 30, 2017		2,128,319		\$ 2.60	8.38	\$

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

The weighted average grant date fair value of stock options granted was \$0.50 and \$1.04 during the six months ended June 30, 2017 and 2016.

The number of option shares that vested in the six months ended June 30, 2017 and 2016 was 375,011 shares and 242,239 shares. The grant date weighted average fair value of option shares that vested in the six months ended June 30, 2017 and 2016 was \$383,370 and \$283,219, respectively.

24

#### Tab

No options were exercised in the six months ended June 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 \$1.00 on March 31, 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.

### **Stock-Based Compensation**

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

	Three Mor Jun	nths End e 30,	Six Mont Jun	hs Ende e 30,	ed	
	2017		2016	2017		2016
Research and development expense	\$ 58,173	\$	37,284	\$ 123,972	\$	62,617
Sales and marketing expense	7,711			15,369		8,681
General and administrative expense	150,250		88,238	304,829		157,766
Total	\$ 216,134	\$	125,522	\$ 444,170	\$	229,064

As of June 30, 2017, the Company had \$878,446 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 1.75 years.

25

#### Table of Contents

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

		onths Ended ne 30,		ths Ended 1e 30,	
	2017	2016	2017	2016	
Weighted-average volatility	76.75%	66.25-69.14%	74.26-76.75%	66.25-69.14%	
Weighted-average expected term (years)	5.82	5.67-5.82	5.82	5.67-5.82	
Risk-free interest rate	1.97%	1.36-1.49%	1.97-1.98%	1.36-1.49%	
Expected dividend vield					

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:

		lonths Ended 1ne 30,		onths Ended une 30,
	2017	2016	2017	2016
Weighted-average volatility		78.30-80.04%	_	78.30-80.04%
Weighted-average expected term (years)		9.19-9.25	—	9.19-9.44
Risk-free interest rate	—	1.44-1.66%		1.44-1.74%
Expected dividend yield			—	

Note: All non-employee options were cancelled prior to June 30, 2017.

## 11. Net 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 six months ended June 30, 2017 and 2016:

	Three Months Ended June 30,			Six Months Ende June 30,			ed	
		2017		2016		2017		2016
Net loss attributable to common shareholders	\$	(1,805,642)	\$	(3,657,475)	\$	(6,521,000)	\$	(7,641,679)
Shares used to compute net loss per common share, basic and diluted		14,694,316		10,314,106		14,427,317		9,810,730
Net loss per share attributable to common shareholders, basic and								
diluted	\$	(0.12)	\$	(0.35)	\$	(0.45)	\$	(0.78)

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company's potentially dilutive securities which include stock options, convertible preferred stock and common stock warrants have been excluded from the computation of diluted net loss per share as they would be anti-dilutive. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares outstanding due to the Company's net loss position.

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

	June 30, 2017	June 30, 2016
Options issued and outstanding	2,440,851	1,464,265
Warrants to purchase common stock	6,339,792	748,872
Restricted stock units	20,789	20,789
Total	8,801,432	2,233,926

#### 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 June 30, 2017.

#### Table of Contents

#### 13. Subsequent Events

The Company completed an evaluation of the impact of subsequent events through August 14, 2017, the date these financial statements were issued.

#### Merger Agreement

As discussed in Note 1, the Company completed its acquisition of Napo on July 31, 2017. 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 (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 exinguishment 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 resele 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).

#### **CSPA**

In July 2017, pursuant to the CSPA, the Company sold an additional 497,141 shares of the Company's common stock in exchange for \$277,528 of cash proceeds.

## **PIPE Financing**

On July 13, 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.

#### Long term Debt

On July 7, 2017, the Company amended loan and security agreement with the lender providing for a \$1.0 million principal payment in July 2017, and interest only payments only beginning August 1, 2017 and extending to November 1, 2017 when principal and interest payments of \$141,204.40 will be made until August 1, 2018, the maturity date of the loan. The Company made the \$1.0 million principal payment in accordance with the terms of the amended agreement.

#### Warrant Exercise Agreements

As previously reported, on November 22, 2016, the entered into a securities purchase agreement (the "Securities Purchase Agreement") with certain investors pursuant to which the Company agreed, among other things, to issue warrants to purchase up to an aggregate of 1,666,668 shares of Common Stock at an exercise price of \$1.00 per share (the "Series C Warrants").

On July 31, 2017, the Company enetered 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.

## 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. Mytesi is currently indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). 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 for its current, FDA-approved specialty indication. Jaguar holds global unencumbered right to key indications for Mytesi, and is pursuing a follow-on indication for Mytesi in chemotherapy-induced diarrhea (CID), an important supportive care indication for patients undergoing primary or adjuvant chemotherapy for cancer treatment. Mytesi is in development as a second-generation anti-secretory agent for use in cholera patients; for supportive care for irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD), as well as for orphan-drug indications for infants and children with short bowel syndrome (SBS) and congenital diarrheal disorders (CDD). Mytesi has shown activity in IBS-D patients in published Phase 2 studies. Napo recently received orphan-drug designation from the U.S. Food and Drug Administration (FDA) for the treatment of SBS.

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. Canalevia is our lead prescription drug product candidate, intended for treatment of various forms of diarrhea in dogs. we achieved statistically significant results in a multicenter canine proof-of-concept study completed in February 2015, supporting the conclusion that Canalevia treatment is superior to placebo. As we announced in December 2015, the pivotal clinical field study to evaluate the safety and effectiveness of Canalevia for acute diarrhea in dogs completed enrollment in January 2017. We have received Minor Use in a Minor Species (MUMS) designation for Canalevia for Chemotherapy-Induced Diarrhea (CID) in dogs, and Jaguar is pursuing MUMS designation for Canalevia for the indication of exercise-induced diarrhea (EID) in dogs. Canalevia is a canine-specific formulation of crofelemer, an active pharmaceutical ingredient isolated and purified from the *Croton lechleri* tree, which is sustainably harvested. A human-specific formulation of crofelemer, Mytesi, was approved by the FDA in 2012 for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. Members of our management team developed crofelemer while at Napo, which was Jaguar Health's parent company until May 13, 2015. The reception among users of our lead non-prescription products—Neonorm Calf and Neonorm Foal, an anti-diarrheal product we launched for newborn horses in early 2016—has been quite positive, and in June 2017 we launched neonorm.com, a commercial website for both Neonorm products. As we announced on June 14, 2017, 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 National Organic Program. OMRI is an international nonprofit organization that determines which input products are allowed for use in organ

The clinically-proven performance of Neonorm Foal, in combination with our heightened understanding of market needs within the global equine space, is driving our increased focus on equine product development. Equilevia is our non-prescription product for total gut health in equine athletes. Equilevia is a pharmaceutical formulation of a standardized botanical extract. Neonorm is a standardized botanical extract derived from the *Croton lechleri* tree. We launched Neonorm Calf in the United States at the end of 2014 for preweaned dairy calves. Canalevia, Equilevia and Neonorm are distinct products formulated to address specific species and market channels. We have filed nine investigational new animal drug applications, or INADs, with the FDA and intend to develop species-specific formulations of Neonorm in six additional target species, and Canalevia for both cats and dogs.

As we announced in December 2016, we signed a distribution agreement with Henry Schein, Inc., the world's largest provider of health care products and services to office-based dental, animal health and medical practitioners, for exclusive distribution of our Neonorm Foal product to all segments of the U.S. equine market. Henry Schein's animal health business, Dublin, Ohio-based Henry Schein Animal Health, employs approximately 900 team members and had 2015 net sales of \$2.9 billion. The agreement became effective on December 9, 2016, and, subject to provisions specified in the agreement, shall continue in force for an initial period of

#### Table of Contents

one year. Thereafter, unless either party notifies the other of its intent not to renew the term of the agreement at least 30 days prior to the end of the then current term, the term shall be automatically renewed upon expiration for successive renewal terms of one year.

In July 2016 we released data from two China-based studies sponsored by Fresno, California-based Integrated Animal Nutrition and Health Inc. showing remarkable resolution of diarrhea and cure of piglets afflicted with diarrhea following treatment with a *Croton lechleri* botanical extract administered in water. As we announced in September 2016, we signed an exclusive supply and distribution agreement for this botanical extract with Integrated Animal Nutrition and Health Inc. for dairy cattle and pigs in the Chinese marketplace. According to Index Muni, swine production is projected to reach 672.5 million head in 2017 in China, where pork is still the main protein source for many consumers. According to New Zealand-based NZX Agri, in 2017 there will be seven

million cows "in milk" (lactating cows) in China. Integrated Animal Nutrition and Health, Inc. has minimum purchase requirements of the botanical extract to maintain their exclusivity.

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

#### 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 Merger, we changed our name from "Jaguar Animal Health, Inc." to "Jaguar Health, Inc." Napo now operates as a wholly-owned subsidiary of Jaguar focused on human health and the ongoing commercialization of Mytesi, a Napo drug product approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy.

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

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.

#### Table of Contents

We have not generated any material revenue to date and expect to continue to incur significant research and development and other expenses. Our net loss and comprehensive loss was \$6.5 million and \$7.6 million for the six months ended June 30, 2017 and 2016, respectively. As of June 30, 2017, we had total stockholders' deficit of \$6.3 million and cash and cash equivalents of \$2.8 million. We expect to continue to incur losses for the foreseeable future as we expand our product development activities, seek necessary approvals for our product candidates, conduct species-specific formulation studies for our non-prescription products, establish API manufacturing capabilities and begin commercialization activities. As a result, we expect to experience increased expenditures for 2017.

#### **Revenue Recognition**

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

We recognize revenue under its licensing, development, co-promotion and commercialization agreement from milestone payments when: (i) the milestone event is substantive and its achievability has substantive uncertainty at the inception of the agreement, and (ii) it does not have ongoing performance obligations related to the achievement of the milestone earned. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment (a) is commensurate with either our performance subsequent to the inception of the arrangement to achieve the milestone or

the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from our performance subsequent to the inception of the arrangement to achieve the milestone, (b) relates solely to past performance, and (c) is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

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

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

## **Product Revenue**

Sales of Neonorm Calf and Foal to distributors are made under agreements that may provide distributor price adjustments and rights of return under certain circumstances. Until we develop sufficient sales history and pipeline visibility, revenue and costs of distributor sales will be deferred until products are sold by the distributor to the distributor's customers. Revenue recognition depends on notification either directly from the distributor that product has been sold to the distributor's customer, when we have access to the data. Deferred revenue on shipments to 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 \$61,445 and \$24,143 for the three months ended June 30, 2017 and 2016, and \$105,989 and \$62,289 for the six months ended June 30, 2017 and 2016.

Sales of Botanical Extract are recognized as revenue when delivered to the customer. We had Botanical Extract revenues of \$0 and \$0 in the three months ended June 30, 2017 and 2016, and \$30,000 and \$0 in the six months ended June 30, 2017 and 2016.

#### Table of Contents

#### **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 chemotherapyinduced 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 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 \$835,076 and \$1,582,942 in collaboration revenue in the three and six months ended June 30, 2017 which are included in our statements of operations and comprehensive loss. The difference of \$1,451,789 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 had \$197,876 of unreimbursed expenses as of June 30, 2017, which is included in Other Receivables on our balance sheet. We included the \$197,876 and \$486,042 in collaboration revenue in the three and six months ended June 30, 2017 which are included in our statements of operations and comprehensive loss.

#### **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, stockbased 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:

#### Table of Contents

- the scope, rate of progress, and expense of our ongoing, as well as any additional clinical trials, formulation studies and other research and development activities;
- · future clinical trial and formulation study results;
- potential changes in government regulations; and
- the timing and receipt of any regulatory approvals.

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

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

#### Sales and Marketing Expense

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

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

#### **General and Administrative Expense**

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

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

#### **Interest Expense**

Interest expense consists primarily of interest on convertible promissory notes, the standby bridge financing commitment and the loan and security agreement (long-term debt arrangement). It also includes interest expense and the amortization of a beneficial conversion feature related to convertible promissory notes issued in June and December 2014 and in February and March 2015.

#### **Results of Operations**

#### Comparison of the six months ended June 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 six months ended June 30, 2017 and 2016 together with the change in such items in dollars and as a percentage:

32

#### Table of Contents

	_				
		2017	 2016	 Variance	Variance %
Revenue	\$	135,989	\$ 62,289	\$ 73,700	118.3%
Collaboration revenue		1,582,942		1,582,942	N/A
Total revenue		1,718,931	 62,289	 1,656,642	2659.6%
Operating Expenses					
Cost of revenue		40,907	27,009	13,898	51.5%
Research and development expense		2,182,243	3,705,388	(1,523,145)	(41.1%)
Sales and marketing expense		280,143	218,463	61,680	28.2%

General and administrative expense	5,441,493	3,204,544	2,236,949	69.8%
Total operating expenses	 7,944,786	7,155,404	789,382	11.0%
Loss from operations	 (6,225,855)	(7,093,115)	867,260	12.2%
Interest expense, net	(336,201)	(538,994)	202,793	37.6%
Other income	1,448	(9,570)	11,018	115.1%
Change in fair value of warrants	247,321	—	247,321	N/A
Loss on extinguishment of debt	 (207,713)		(207,713)	N/A
Net loss and comprehensive loss	\$ (6,521,000)	\$ (7,641,679)	\$ 1,120,679	14.7%

## **Revenue and Cost of Revenue**

## **Neonorm Calf and Foal**

Our revenue of \$105,989 and \$62,289 and related cost of revenue of \$40,907 and \$27,009 for the six months ended June 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. We experienced a significant increase in unit sales in the six months ended June 30, 2017 compared to the same period in 2016 resulting in the increase in revenue. 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 December 2016. The revenue from these sales, which totaled \$30,000 in the six months ended June 30, 2017, is recognized upon shipment to the distributor as no return rights are provided to this distributor. 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 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 s 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 \$1,096,900 in collaboration revenue in the six months ended

#### Table of Contents

June 30, 2017. We included \$486,042 of the additional expense reimbursements in the six months ended June 30, 2017 as collaboration revenue.

#### **Research and Development Expense**

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

	Six Mont Jun				
	 2017	2016		 Variance	Variance %
R&D:					
Personnel and related benefits	\$ 888,077	\$	1,426,021	\$ (537,944)	(37.7%)
Materials expense and tree planting	63,531		45,977	17,554	38.2%
Travel, other expenses	123,010		223,328	(100,318)	(44.9%)
Clinical and contract manufacturing	436,210		1,323,338	(887,128)	(67.0%)
Stock-based compensation	123,972		62,617	61,355	98.0%
Other	547,443		624,107	(76,664)	(12.3%)
Total	\$ 2,182,243	\$	3,705,388	\$ (1,523,145)	(41.1%)

Our research and development expense decreased \$1,523,145 from \$3,705,388 in the six months ended June 30, 2016 to \$2,182,243 for the same period in 2017. Personnel and related benefits decreased \$537,944 from \$1,426,021 in the six months ended June 30, 2016 to \$888,077 in the same period in 2017 due to \$509,620 employee leasing chargebacks to Napo for services rendered in Q1 2017 net of a decrease of \$28,324 due to changes in headcount personnel and related salaries year over year. Travel expenses decreased \$100,317 from \$223,328 in the six months ended June 30, 2016 to \$123,010 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 \$887,128 from \$1,323,338 in the six months ended June 30, 2016 to \$436,210 in the same period in 2017. Clinical expenses decreased \$461,686 from \$994,014 in the six months ended June 30, 2016 to \$532,328 in the same period in 2017, and contract manufacturing expense decreased \$425,442 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 Q2 2017. Stock-based compensation increased \$61,355 from \$62,617 in the six months ended June 30, 2016 to \$123,972 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

<sup>33</sup> 

consulting and formulation expenses, decreased \$76,664 from \$624,107 in the six months ended June 30, 2016 to \$547,443 in the same period in 2017. Consulting expenses decreased \$53,338 from \$387,185 in the six months ended June 30, 2016 to \$333,847 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 increased \$17,369 from \$133,500 in the six months ended June 30, 2016 to \$116,131 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.

We increased support for the reforestation of croton lechleri trees in South America, which is reflected in an increase in our spend by almost 40% from \$45,977 in the six months ended June 30, 2016 to \$63,531 in the same period in 2017. We value and take to heart the responsibility to replenish trees consumed in order to extract the raw material to manufacture our primary commercial product and the drug product for use in clinical trials.

#### Sales and Marketing Expense

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

#### Table of Contents

		Six Mont June		1		
	2017 2016			2016	 Variance	Variance %
S&M:						
Personnel and related benefits	\$	130,436	\$	89,579	\$ 40,857	45.6%
Stock-based compensation		15,369		8,681	6,688	77.0%
Direct Marketing Fees		59,208		56,926	2,282	4.0%
Other		75,130		63,277	11,853	18.7%
Total	\$	280,143	\$	218,463	\$ 61,680	28.2%

Our sales and marketing expense increased \$61,680 from \$218,463 in the six months ended June 30, 2016 to \$280,143 in the same period in 2017. Personnel and related benefits increased \$40,857 from \$89,579 in the three months ended June 30, 2016 to \$130,436 in the same period in 2017 due primarily to an increase in headcount from no employees for more than half of the first six months of 2016 to three employees in the first six months of 2017, net of \$42,355 employee leasing chargebacks to Napo for services rendered in the six months ended June 30, 2017. Stock based compensation expense increased \$6,688 from \$8,681 in the six months ended June 30, 2016 to \$15,369 in the same period in 2017 due to headcount increases. Direct marketing and sales expense increased \$2,282 from \$56,926 in the six months ended June 30, 2016 to \$59,208 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 \$11,853 from \$63,277 in the six months ended June 30, 2016 to \$75,130 in the same period in 2017. We plan to expand sales and marketing spend to promote our Neonorm products.

#### General and Administrative Expense

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

	Six Mont Jun					
	 2017	2016		Variance		Variance %
G&A:						
Personnel and related benefits	\$ 786,163	\$	1,268,680	\$	(482,517)	(38.0)%
Accounting fees	336,651		168,613		168,038	99.7%
Third-party consulting fees and Napo service fees	1,007,779		153,786		853,993	555.3%
Legal fees	2,004,492		383,523		1,620,969	422.7%
Travel	105,669		181,004		(75,335)	(41.6)%
Stock-based compensation	304,829		157,766		147,063	93.2%
Rent and lease expense	156,999		212,973		(55,974)	(26.3)%
Public company expenses	335,546		186,317		149,229	80.1%
Other	403,365		491,882		(88,517)	(18.0)%
Total	\$ 5,441,493	\$	3,204,544	\$	2,236,949	69.8%

Our general and administrative expenses increased \$2,236,949 from \$3,204,544 in the six months ended June 30, 2016 to \$5,441,493 for the same period in 2017 due primarily to \$2,450,919 in merger related expenses incurred in the six months ended June 30, 2017, including \$858,103 in consulting services for a fairness opinion, \$1,306,791 in estimated legal fees and \$136,529 in estimated audit fees, and \$135,000 in estimated printer and filing fees. Personnel and related benefits decreased \$482,517 from \$1,268,680 in the six months ended June 30, 2016 to \$786,163 in the same period in 2017. We reduced headcount significantly from eleven in the six months ended June 30, 2016 to seven in the same period in 2017, which resulted in a \$376,657 decrease in expense. In addition, we charged back Napo \$105,860 in employee leasing chargebacks for services rendered in the six months ended June 30, 2017. Stock-based compensation increased \$147,063 from \$157,766 in the six months ended June 30, 2016 to \$304,829 in the same period in 2017 due primarily to expense associated with new grants to existing employees. Our public company expenses decreased

## Table of Contents

\$149,229 from \$186,317 in the six months ended June 30, 2016 to \$335,546 in the same period in 2017. In addition to the \$136,529 of audit related merger fees discussed above, our annual and other audit fees increased by another \$31,509 resulting in an aggregate \$168,038 increase in accounting fees from \$168,613 in the six months ended June 30, 2016 to \$336,651 in the same period in 2017. In addition to the \$1,306,791 of legal related merger fees, our

general corporate and public securities legal fees increased an additional \$314,178 resulting in an aggregate increase of \$1,620,969 in legal fees from \$383,523 in the six months ended June 30, 2016 to \$2,004,492 in the same period in 2017. In addition to the \$858,103 in merger related consulting fees, our non-merger related consulting expenses actually decreased by \$4,110 resulting in aggregate increase of \$853,993 from \$153,786 in the six months ended June 30, 2016 to \$1,007,779 in the same period in 2017. Rent expense decreased \$55,974 from \$212,973 in the six months ended June 30, 2016 to \$156,999 in the same period in 2017 due primarily to \$63,983 in employee leasing chargebacks to Napo for space used in connection with our employees providing services to Napo in the six months ended June 30, 2017, offset in part by three months of company apartment rent (monthly rent began April of 2016) of approximately \$4,000 per month in the six months ended June 30, 2017. Other expenses, including insurance costs, office and facilities expenses decreased \$88,517 from \$491,882 in the six months ended June 30, 2016 to \$403,365 in the same period in 2017 primarily due to a reduction of \$92,875 in recruiting fees. 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.

#### Comparison of the three months ended June 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 June 30, 2017 and 2016 together with the change in such items in dollars and as a percentage:

	Three Mon June				
	 2017 2016		 Variance	Variance %	
Revenue	\$ 61,445	\$	24,143	\$ 37,302	154.5%
Collaboration revenue	835,076			835,076	0.0%
Total revenue	896,521		24,143	 872,378	3613.4%
Operating Expenses					
Cost of revenue	24,762		8,641	16,121	186.6%
Research and development expense	926,791		1,953,647	(1,026,856)	(52.6%)
Sales and marketing expense	157,231		54,050	103,181	190.9%
General and administrative expense	2,137,990		1,416,159	721,831	51.0%
Total operating expenses	 3,246,774		3,432,497	 (185,723)	(5.4%)
Loss from operations	 (2,350,253)		(3,408,354)	1,058,101	31.0%
Interest expense, net	(156,129)		(254,758)	98,629	38.7%
Other income	_		5,637	(5,637)	(100.0%)
Change in fair value of warrants	700,740			700,740	0.0%
Net loss and comprehensive loss	\$ (1,805,642)	\$	(3,657,475)	\$ 1,851,833	50.6%

## **Revenue and Cost of Revenue**

#### **Neonorm Calf and Foal**

Our revenue of \$61,445 and \$24,143 and related cost of revenue of \$24,762 and \$8,641 for the three months ended June 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. We experienced a significant increase in unit sales in the six months ended June 30, 2017 compared to the same period in 2016 resulting in the increase in revenue. The increase in cost of revenue was consistent with the increase in sales. We continue to increase our efforts to promote sales growth.

## Table of Contents

#### **Botanical extract**

We began selling botanical extract to a distributor for use exclusively in China beginning in December 2016. Revenue from these sales is recognized upon shipment to the distributor as no return rights are provided to this distributor. There was no revenue in the three months ended June 30, 2017 and 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 Mareement 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 June 30, 2017. We included \$197,876 of the additional expense reimbursements in the three mon

#### **Research and Development Expense**

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

	Three Mor Jun	nths End e 30,				
	2017		2016		Variance	Variance %
R&D:						
Personnel and related benefits	\$ 427,458	\$	763,921	\$	(336,463)	(44.0%)
Materials expense and tree planting	25,430		14,178		11,252	79.4%
Travel, other expenses	50,440		115,147		(64,707)	(56.2%)
Clinical and contract manufacturing	140,706		620,134		(479,428)	(77.3%)
Stock-based compensation	58,173		37,284		20,889	56.0%
Other	224,584		402,983		(178,399)	(44.3%)
Total	\$ 926,791	\$	1,953,647	\$	(1,026,856)	(52.6%)

Our research and development expense decreased \$1,026,856 from \$1,953,647 in the three months ended June 30, 2016 to \$926,791 for the same period in 2017. Personnel and related benefits decreased \$336,463 from \$1,426,021 in the three months ended June 30, 2016 to \$888,077 in the same period in 2017 due to \$231,747 employee leasing chargebacks to Napo for services rendered in Q2 2017 net of a decrease of \$104,716 due to changes in headcount personnel and related salaries year over year. Travel expenses decreased \$64,707 from \$115,147 in the three months ended June 30, 2016 to \$50,440 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 \$479,428 from \$620,134 in the three months ended June 30, 2016 to \$140,706 in the same period in 2017. Clinical expenses decreased \$383,310 from \$620,134 in the three months ended June 30, 2016 to \$236,824 in the same period in 2017, and contract manufacturing expense decreased \$96,118 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 Q2 2017. Stock-based compensation increased \$20,889 from \$37,284 in the three months ended June 30, 2016 to \$58,173 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 \$178,399 from \$402,983 in the three months ended June 30, 2016 to \$224,584 in the same period in 2017. Consulting

37

#### Table of Contents

expenses decreased \$90,797 from \$213,633 in the three months ended June 30, 2016 to \$122,836 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 increased \$80,835 from \$133,500 in the three months ended June 30, 2016 to \$52,665 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.

We increased support for the reforestation of croton lechleri trees in South America, which is reflected in an increase in our spend by almost 80% from \$11,252 in the three months ended June 30, 2016 to \$25,430 in the same period in 2017. We value and take to heart the responsibility to replenish trees consumed in order to extract the raw material to manufacture our primary commercial product and the drug product for use in clinical trials.

#### Sales and Marketing Expense

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

_			led			
	2017		2016		Variance	Variance %
\$	65,546	\$	543	\$	65,003	11971.1%
	7,711				7,711	N/A
	29,332		19,621		9,711	49.5%
	54,642		33,886		20,756	61.3%
\$	157,231	\$	54,050	\$	103,181	190.9%
	\$	<b>3017</b> \$ 65,546 7,711 29,332 54,642	June 30,           2017           \$ 65,546 \$           7,711           29,332           54,642	2017         2016           \$ 65,546         \$ 543           7,711         —           29,332         19,621           54,642         33,886	June 30,           2017         2016           \$         65,546         \$         543         \$           7,711         —	June 30,         Variance           2017         2016         Variance           \$         65,546         \$         543         \$         65,003           7,711         —         7,711         29,332         19,621         9,711           54,642         33,886         20,756         20,756

Our sales and marketing expense increased \$103,181 from \$54,050 in the three months ended June 30, 2016 to \$157,231 in the same period in 2017. Personnel and related benefits increased \$65,003 from \$543 in the three months ended June 30, 2016 to \$130,436 in the same period in 2017 due primarily to an increase in headcount from no employees in the three months ended June 30, 2016 to three employees in the same period in 2017, net of \$22,588 employee leasing chargebacks to Napo for services rendered in the three months ended June 30, 2017. Stock based compensation expense increased \$7,711 from \$0 in the three months ended June 30, 2016 to \$29,332 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 \$20,756 from \$33,886 in the three months ended June 30, 2016 to \$54,642 in the same period in 2017. We plan to expand sales and marketing spend to promote our Neonorm products.

#### General and Administrative Expense

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

	ths End 30,	led					
	2017 2016			Variance	Variance %		
G&A:							
Personnel and related benefits	\$	404,051	\$	583,525	\$	(179,474)	(30.8%)
Accounting fees	159,473			47,115		112,358	238.5%
Third-party consulting fees and Napo service fees		63,518		31,755		31,763	100.0%
Legal fees	803,277			196,919		606,358	307.9%
Travel		38,288		76,225		(37,937)	(49.8%)
Stock-based compensation		150,250		88,238		62,012	70.3%
Rent and lease expense		78,012		111,803		(33,792)	(30.2%)
Public company expenses	256,122			88,659		167,462	188.9%
Other	184,999			191,920		(6,921)	(3.6%)
Total	\$	\$ 2,137,990		\$ 1,416,159		721,831	51.0%

Our general and administrative expenses increased \$721,831 from \$1,416,159 in the three months ended June 30, 2016 to \$2,137,900 for the same period in 2017 due primarily to \$795,423 in merger related expenses incurred in the three months ended June 30, 2017, including \$543,894 in estimated legal fees and \$116,529 in estimated audit fees, and \$135,000 in estimated printer and filing fees. Personnel and related benefits decreased \$179,474 from \$583,525 in the three months ended June 30, 2016 to \$404,051 in the same period in 2017. We reduced headcount significantly from nine in the three months ended June 30, 2016 to seven in the same period in 2017, which resulted in a \$133,652 decrease in expense. In addition, we charged back Napo \$45,822 in employee leasing chargebacks for services rendered in the three months ended June 30, 2017. Stock-based compensation increased \$62,012 from \$88,238 in the three months ended June 30, 2016 to \$150,250 in the same period in 2017 due primarily to expense associated with new grants to existing employees. Our public company expenses decreased \$167,462 from \$88,659 in the three months ended June 30, 2016 to \$256,122 in the same period in 2017. In addition to the \$116,529 of audit related merger fees discussed above, our annual and other audit fees increased by only another \$4,171 resulting in an aggregate \$112,358 increase in accounting fees from \$47,115 in the three months ended June 30, 2016 to \$159,473 in the same period in 2017. In addition to the \$543,894 of legal related merger fees, our general corporate and public securities legal fees increased an additional \$62,464 resulting in an aggregate increase of \$606,358 in legal fees from \$196,919 in the three months ended June 30, 2016 to \$803,277 in the same period in 2017. Our non-merger related consulting expenses increased by \$31,763 from \$31,755 in the three months ended June 30, 2016 to \$63,518 in the same period in 2017. Rent expense decreased \$33,792 from \$111,803 in the three months ended June 30, 2016 to \$78,012 in the same period in 2017 due primarily to \$32,117 in employee leasing chargebacks to Napo for space used in connection with our employees providing services to Napo in the three months ended June 30, 2017. Other expenses, including insurance costs, office and facilities expenses decreased \$6,921 from \$191,920 in the three months ended June 30, 2016 to \$184,999 in the same period in 2017. We expect to incur additional general and administrative expense as a result of operating as a public company and as we grow our business, including expenses related to compliance with the rules and regulations of the SEC, additional insurance expenses, investor relations activities and other administrative and professional services.

#### Liquidity and Capital Resources

#### Sources of Liquidity

We had an accumulated deficit of \$47.0 million as a result of incurring net losses since our inception as we have not generated significant revenue through the current fiscal year. Our net loss and comprehensive loss was \$801,000 for the period from inception to December 31, 2013, \$8.6 million for the year ended December 31, 2014, \$16.3 million for the year ended December 31, 2015, \$14.7 million for the year ended December 31, 2016, and \$6.5 million for the six months ended June 30, 2017. We expect to continue to incur additional losses through the end of fiscal year 2017 and in future years due to expected significant expenses for toxicology, safety and efficacy clinical trials of our products and product candidates, for establishing contract manufacturing capabilities, and for the commercialization of one or more of our product candidates, if approved.

We had cash and cash equivalents of \$2,760,848 as of June 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 regarding our assessment of

#### Table of Contents

substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty.

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

- In 2013, we received \$400 from the issuance of 2,666,666 shares of common stock to our parent Napo Pharmaceuticals, Inc. We also received \$519,000 of net cash from the issuance of convertible promissory notes in an aggregate principal amount of \$525,000. These notes were all converted to common stock in 2014.
- In 2014, we received \$6.7 million in proceeds from the issuance of convertible preferred stock. Effective as of the closing of our initial public offering, the 3,015,902 shares of outstanding convertible preferred stock were automatically converted into 2,010,596 shares of common stock. Following our initial public offering, there were no shares of preferred stock outstanding.
- In 2014, we received \$1.1 million from the issuance of convertible promissory notes in an aggregate principal amount of \$1.1 million. These notes were converted to common stock upon the 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 \$54,130 offering expenses under the CSPA in the year ended December 31, 2016. And in the three months ended March 31, 2017, we sold another 416,996 shares of the Company's common stock in exchange for \$550,434 of cash proceeds. Of the \$15.0 million available under the CSPA, we have received \$3,227,134 as of March 31, 2017.

40

#### Table of Contents

- 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 (iii) 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 \$0.90 per share, or the Series B Warrants, and (iii) warrants to purchase up to an aggregate 1,666,668 shares of our common stock, at an exercise price of \$1.00 per share, or the Series C Warrants and, together with the Series A Warrants and the Series B Warrants, the 2016 Warrants.
- On January 27, 2017, we entered into a licensing, development, co-promotion and commercialization agreement with Elanco to license, develop and commercialize Canalevia, our drug product candidate under investigation for treatment of acute and chemotherapy-induced diarrhea in dogs, and other drug product formulations of crofelemer for treatment of gastrointestinal diseases, conditions and symptoms in cats and other companion animals. The Elanco Agreement grants Elanco exclusive global rights to Canalevia, a product whose active pharmaceutical ingredient is sustainably isolated and purified from the Croton lechleri tree, for use in companion animals. Pursuant to the Elanco Agreement, Elanco will have exclusive rights globally outside the U.S. and co-exclusive rights with us in the U.S. to direct all marketing, advertising, promotion, launch and sales activities related to the Licensed Products.

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

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

basis of a 360-day year comprised of twelve (12) thirty (30) day months compounded daily and payable in accordance with the terms of the Note. All principal and interest on the debt is due in full on August 2, 2018.

We expect our expenditures will continue to increase as we continue our efforts to develop animal health products, expand our commercially available Neonorm product and continue development of our pipeline in the near term. We do not believe our current capital is sufficient to fund our operating plan through June 2018. We will need to seek additional funds through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. We may also not be successful in entering into partnerships that include payment of upfront licensing fees for our products and product candidates for markets outside the United States, where appropriate. If we do not generate upfront fees from any anticipated arrangements, it would have a negative effect on our operating plan. We plan to finance our operations and capital funding needs through equity and/or debt financing as well as revenue from future product sales. However, there can be no assurance that additional funding will be available to us on acceptable terms on a timely basis, if at all, or that we will generate sufficient cash from operations to adequately fund operating needs or ultimately achieve profitability. If we are unable to

41

#### Table of Contents

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 Six Months Ended June 30, 2017 Compared to the Six Months Ended June 30, 2016

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

	Six Mont June	ed		
	 2017	 2016		
Total cash used in operations	\$ (1,466,211)	\$ (8,303,055)		
Total cash provided by investing activities	511,293	1,757,437		
Total cash provided by financing activities	2,764,787	2,723,131		
	\$ 1,809,869	\$ (3,822,487)		

## Cash Used in Operating Activities

During the six months ended June 30, 2017, cash used in operating activities of \$1,466,211 resulted from our net loss of \$6.5 million, offset by non-cash accretion of end of term payment, debt discounts and debt issuance costs of \$181,000, stock-based compensation of \$444,000, reduction in the fair value of warrants of \$247,000, loss on extinguishment of debt of \$208,000, depreciation expense of \$30,000, net of changes in operating assets and liabilities of \$4.4 million.

During the six months ended June 30, 2016, cash used in operating activities of \$8,303,055 resulted from our net loss of \$7.6 million, offset by non-cash accretion of debt discounts and debt issuance costs of \$269,000, stock-based compensation of \$229,000, depreciation expense of \$17,000, net of changes in operating assets and liabilities of \$1.2 million.

## Cash Provided by Investing Activities

During the six months ended June 30, 2017, cash provided by investing activities of \$511,293 consisted of \$511,000 of a release of restricted cash that resulted from a reduction in our long-term debt.

During the six months ended June 30, 2016, cash provided by investing activities of \$1,757,437 primarily consisted of \$1.9 million of a release of restricted cash that resulted from principal payments on our long-term debt, net of \$98,000 in purchases of property and equipment.

#### Cash Provided by Financing Activities

During the six months ended June 30, 2017, cash provided by financing activities of \$2,764,787 primarily consisted of \$2.0 million in net proceeds received in the CSPA, \$47,000 in net proceeds received in a PIPE financing, \$1.7 million received in the issuance of convertible debt, offset by \$992,000 in principal payments on our long-term debt.

During the six months ended June 30, 2016, cash provided by financing activities of \$2,723,131 primarily consisted \$4.1 million in net cash received in our secondary public offering, net of commissions and certain offering expenses, and \$448,732 in net cash received in the initial sale under the Common Stock Purchase Agreement, net of fees and certain offering expenses, offset by \$1.9 million in principal payments on our long-term debt.

#### Standby Lines of Credit, Convertible Notes and Warrant Issuances

#### **Convertible Notes and Warrants**

#### 2013 Convertible Notes

From July through September 2013, we issued four convertible promissory notes (collectively the "Notes") for gross aggregate proceeds of \$525,000 to various third-party lenders. The Notes bore interest at 8% per annum. The Notes automatically matured and the entire outstanding principal amount, together with accrued interest, was due and payable in cash at the earlier of

#### Table of Contents

July 8, 2015 (the "Maturity Date") or ten business days after the date of consummation of the initial closing of a first equity round of financing. We consummated a first equity round of financing prior to the Maturity Date with a pre-money valuation of greater than \$3.0 million, and, accordingly, principal and accrued interest was converted into shares of common stock at 75% of the purchase price paid by such equity investors. These notes were all converted to common stock in February 2014 upon the issuance of the convertible preferred stock. In February 2014, in connection with the first equity round of financing and issuance of the Series A convertible preferred stock, the noteholders exercised their option to convert their Notes into 207,664 shares of common stock and accrued interest was paid in cash to the noteholders. The accreted interest expense related to the discount on the Notes was \$1,443 for the period from January 1, 2014 to the conversion date of the Notes. Upon conversion, the entire remaining debt discount of \$4,071 was recorded as interest expense.

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

#### 2014 Convertible Notes

On June 2, 2014, pursuant to a convertible note purchase agreement, we issued convertible promissory notes in the aggregate principal amount of \$300,000 to two accredited investors, including a convertible promissory note for \$200,000 to a board member to which Series A preferred stock was sold. These notes accrued interest at 3% per annum and automatically were to mature on June 1, 2015. We had unpaid accrued interest of \$8,507, which is included in accrued liabilities in the balance sheet. All interest was to be paid in cash upon maturity. No interest was incurred for the three and six months ended June 30, 2017 and 2016. Upon the closing of the IPO, the outstanding principal amount automatically converted into 53,571 shares common stock at \$5.60, as amended in March 2015. Upon issuance, we analyzed the beneficial nature of the conversion terms and determined that a beneficial conversion feature ("BCF") existed because the effective conversion price on issuance of the notes was less than the fair value at the time of the issuance. We calculated the value of the BCF using the intrinsic method and recorded a BCF of \$75,000 as a discount to notes payable and to additional paid-in capital. The full amount of the BCF was amortized to interest expense by the end of May 2015 when the notes were converted to equity.

On July 16, 2014, pursuant to a convertible note purchase agreement, we issued a convertible promissory note in the principal amount of \$150,000 to an accredited investor. This note accrued interest at 3% per annum and automatically was to mature on June 1, 2015. We had unpaid accrued interest of \$3,711, which is included in accrued liabilities in the balance sheet. All interest was to be paid in cash upon maturity. No interest was incurred for the three and six months ended June 30, 2017 and 2016. Upon the closing of the IPO, the outstanding principal amount automatically converted into 26,785 shares of common stock at \$5.60, as amended in March 2015. Upon issuance, we analyzed the beneficial nature of the conversion terms and determined that a BCF existed because the effective conversion price was less than the fair value at the time of the issuance. We calculated the value of the BCF using the intrinsic method and recorded a BCF of \$37,500 as a discount to the notes payable and to additional paid-in capital. The full amount of the BCF was amortized to interest expense by the end of May 2015 when the notes were converted to equity.

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

On December 23, 2014, pursuant to a convertible note purchase agreement, we issued convertible promissory notes in the aggregate principal amount of \$650,000 to three accredited investors, including a convertible promissory note for \$250,000 to the same board member to which the June 2, 2014 \$200,000 convertible promissory note was issued and to which Series A preferred stock was sold. These notes accrued interest at 12% per annum and became payable within thirty days following the IPO. We had unpaid accrued interest of is \$30,132, which is included in accrued liabilities in the balance sheet. All interest was to be paid in cash upon maturity. No interest expense was accrued for the three and six months ended June 30, 2017 and 2016. Upon consummation of our IPO, the noteholders converted the notes into 116,070 shares of common stock at a conversion price equal to 80% of the IPO price, amended to \$5.60 in March 2015. In connection with these notes, we also issued the lenders a fully vested warrant to purchase shares of the Company's common stock at an exercise price equal to 80% of the IPO price, amended to \$5.60 in March 2015. The fair value of the warrants, \$147,943, was recorded as a debt discount and liability at December 23, 2014. Our fully amortized the discount by the end of May 2015 when the notes were converted to equity. The warrants were originally valued using the Black-Scholes-Merton model with the following assumptions: stock price of \$4.59, exercise price of \$4.15, term of three years expiring December 2017, volatility of 49%, dividend yield of 0%, and risk-free interest rate of 1.10%. Based on the circumstances, the value derived using the Black-Scholes-Merton model approximated

## Table of Contents

that which would be obtained using a lattice model. The debt discount was amortized as interest expense over the one hundred ninety days from issuance of the notes through their first maturity date of July 31, 2015, beginning in January 2015. We analyzed the beneficial nature of the conversion terms and determined that a BCF existed because the effective conversion price was less than the fair value at the time of the issuance. We calculated the value of the BCF using the intrinsic method. A BCF of \$502,057 was recorded as a discount to the notes payable and to additional paid-in capital. The full amount of the BCF was amortized to interest expense by the end of May 2015 when the notes were converted to equity.

## 2015 Convertible Notes

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

recorded as a discount to the notes payable and to additional paid-in capital. The full amount of the BCF was amortized to interest expense by the end of June 2015.

The remaining outstanding 2015 convertible 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 our common stock for \$0.01 per share. The warrant is exercisable at any time on or before July 28, 2022, the expiration date of the warrant. The amendment and related warrant issuance resulted in our treating the debt as having been extinguished and replaced with new debt for accounting purposes due to meeting the 10% cash flow test. We 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 our statements of operations and comprehensive loss in the three months ended December 31, 2017.

### Extinguishment of debt

On January 31, 2017, we entered into an 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 other expense in our statements of operations and comprehensive loss in the six months ended June 30, 2017.

The \$150,000 note is included in notes payable in current liabilities on our balance sheet. We had unpaid accrued interest of \$42,855 and \$33,929, which is included in accrued liabilities on our balance sheet as of June 30, 2017 and December 31, 2016, respectively, and incurred interest expense of \$4,488 in the three months ended June 30, 2017 and 2016, and \$8,926 and \$8,975 in the six months ended June 30, 2017 and 2016 which is included in interest expense in the statement of operations and comprehensive loss.

In March 2015, we entered into a non-binding letter of intent with an investor. In connection therewith, the investor paid us \$1.0 million. At March 31, 2015, we had recorded this amount as a loan advance on the balance sheet. In April 2015, the investor purchased \$1.0 million of convertible promissory notes from us, the terms of which provided that such notes were to be converted into shares of our common stock upon the closing of an IPO at a conversion price of \$5.60 per share. In connection with the purchase of the notes, we issued the investor a warrant to purchase 89,285 shares at \$5.60 per share, which expires December 31, 2017. The notes accrued simple interest of 12% per annum and, upon consummation of our IPO in May 2015, converted into 178,571 shares of our common stock. We analyzed the beneficial nature of the conversion terms and determined that a BCF existed because the effective conversion price was less than the fair value at the time of the issuance. We calculated the value of the BCF using the intrinsic method. A BCF of for the full face value was recorded as a discount to the notes payable and to additional paid-in capital. The full amount of the BCF was amortized to interest expense by the end of June 2015. While the note was converted to equity, we have not yet remitted the related accrued interest of \$17,753, which is included in accrued liabilities in our balance sheet. No interest expense was accrued in the three months ended June 30, 2017 and 2016.

## 44

#### Table of Contents

#### 2017 Convertible Notes

On June 29, 2017, we issued a secured convertible promisorry note ("Note") to a lendor in the aggregate principal amount of \$2,155,000 less an original issue discount of \$425,000 and less \$30,000 to cover the lender's legal fees for net cash proceeds of \$1,700,000. Interest on the outstanding balance will be paid 8% per annum from the purchase price date until the balance is paid in full. All interest calculations are computed on the basis of a 360-day year comprised of twelve (12) thirty (30) day months compounded daily and payable in accordance with the terms of the Note. All principal and interest on the debt is due in full on August 2, 2018. We accrued interest of \$472 at June 30, 2017 which is included in accrued expenses on our balance sheet and in interest expense in our statement of operations and comprehensive loss. We also recorded \$1,346 in interest expense in our statement of operations and comprehensive loss for the accretion of the debt discount. The lender has the right to convert all or any portion of the outstanding balance into our common stock at \$1.00 per share.

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

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

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

We computed fair values 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 balance of the note payable of \$1,627,346, 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 \$1,346 in June of 2017, is included in notes

payable in current liabilities on the balance sheet.

As of June 30, 2017 and December 31, 2016, the aggregate convertible notes payable obligations were as follows:

	June 30, 2017	Ľ	December 31, 2016
Notes payable	\$ 2,285,000	\$	150,000
Unamortized note discount and debt issuance costs	(507,654)		—
Net debt obligation	\$ 1,777,346	\$	150,000

Interest payable on the convertible notes at June 30, 2017 and December 31, 2016 was \$103,446 and \$94,048, respectively and are included in accrued expenses on the balance sheet.

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

		Three Months Ended June 30,			Six Months Ended June 30,			
	2	2017		2016		2017		2016
Nominal interest	\$	4,960	\$	4,487	\$	9,398	\$	8,975
Amortization of debt discount		1,346				1,346		—
	\$	6,306	\$	4,487	\$	10,744	\$	8,975

#### Notes Payable—Bridge Loans

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

#### Standby Line of Credit

In August 2014, we entered into a standby line of credit with an accredited investor for up to \$1.0 million pursuant to a Line of Credit and Loan Agreement dated August 26, 2014. In connection with the entry into the standby line of credit, we issued the lender a fully vested warrant to purchase 33,333 shares of common stock at an exercise price equal to 80% of the IPO price, amended to \$5.60 in March 2015, which expires in August 2016. The fair value of the warrants, \$114,300, was recorded as interest expense and additional paid-in capital in August 2014. The warrants were originally valued using the Black-Scholes-Merton model with the following assumptions: stock price of \$8.00, exercise price of \$6.40, term of two years, volatility of 52%, dividend yield of 0%, and

## Table of Contents

risk-free interest rate of 0.52%. The line of credit expired on March 31, 2015 and there were no drawdowns under the facility. The warrants expired in August 2016.

## 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. This debt discount is being recorded as interest expense, using the interest method, over the term of the loan agreement, we are entitled to prepay principal and accrued interest upon five days prior notice to the lender. In the event of prepayment, we are obligated to pay a prepayment charge. If such prepayment is made during any of the first twelve months of the loan agreement, the prepayment charge will be (a) during such time as we are required to maintain a minimum cash balance, 2% of the minimum cash balance amount plus 3% of the difference between the amount being prepaid and the minimum cash balance, and (b) after such time as we are no longer required to maintain a minimum cash balance, 3% of the amount being prepaid. If such prepayment is made during any time after the first twelve months of the loan agreement, 1% of the amount being prepaid.

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

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

	June 30, 2017	December 31, 2016
Debt and unpaid accrued end-of-term payment	\$ 2,993,473	\$ 3,894,320
Unamortized note discount	(20,854)	(42,493)

Unamortized debt issuance costs	(64,997)	 (114,626)
Net debt obligation	\$ 2,907,622	\$ 3,737,201
Current portion of long-term debt	\$ 2,071,646	\$ 1,919,675
Long-term debt, net of discount	835,976	1,817,526
Total	\$ 2,907,622	\$ 3,737,201

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

Years ending December 31	 Amount
2017 - July through December	\$ 1,041,040
2018	1,479,246
Total future principal payments	2,520,286
2018 end-of-term payment	560,000
	3,080,286
Less: unaccreted end-of-term payment at June 30, 2017	(86,813)
Debt and unpaid accrued end-of-term payment	\$ 2,993,473

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.

46

## Table of Contents

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

	 Three Months Ended June 30,				Six Months Ended June 30,			
	2017		2016		2017		2016	
Nominal interest	\$ 67,273	\$	112,374	\$	146,134	\$	261,000	
Accretion of debt discount	9,961		16,640		21,639		35,051	
Accretion of end-of-term payment	41,505		69,331		90,160		146,027	
Accretion of debt issuance costs	31,085		51,924		67,524		87,940	
	\$ 149,824	\$	250,269	\$	325,457	\$	530,018	

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

#### Warrants

On November 22, 2016, we entered into a Securities Purchase Agreement, or the 2016 Purchase Agreement, with certain institutional investors, pursuant to which we sold securities to such investors in a private placement transaction, which we refer to herein as the 2016 Private Placement. In the 2016 Private Placement, we sold an aggregate of 1,666,668 shares of our common stock at a price of \$0.60 per share for gross proceeds of approximately \$1.0 million. The investors in the 2016 Private Placement also received (i) warrants to purchase up to an aggregate of 1,666,668 shares of our common stock, at an exercise price of \$0.75 per share, or the Series A Warrants, and the Placement Agent received warrants to purchase 133,333 shares of our common stock, 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 \$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 \$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 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 on our balance sheet. The series A warrants and placement agent warrants were revalued on December 31, 2016 at \$799,201 which is included on our balance sheet, and the \$43,200 increase is included in our 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 A warrants and placement agent warrants were revalued on March 31, 2017 at \$1,252,620 which is included on our balance sheet, and the \$453,419 increase is included in our statements of operations and comprehensive loss. The stock price was \$1.00, the strike price was \$0.75 per share, the expected life was 5.16 years, the volatility was 78.33% and the risk free rate was 1.95%. 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 again on June 30, 2017 at \$551,880, which is included on our balance sheet, which reflects a reduction of \$700,740 from the March 31, 2017 valuation of \$1,252,620 and a decrease of \$247,321 decrease from the \$799,201 December 31, 2016 valuation. The changes are included in our statements of operations and comprehensive loss. The strike price was \$0.75 per share, the expected life was 5.16 years, the volatility was 78.33% and the risk free rate was 1.95%. The series B and C warrants were revalued as a decrease of \$247,321 decrease from the \$799,201 December 31, 2016 valuation. The changes are included in our statements of operations and comprehensive

## Table of Contents

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.

Warrant activity is summarized as follows:

	Six Months Ended June 30, 2017	Year Ended December 31, 2016
Beginning balance	5,968,876	748,872
Warrants granted	370,916	5,253,337
Warrants cancelled	—	(33,333)
Ending balance	6,339,792	5,968,876

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

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

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

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

#### **Revenue Recognition**

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

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

#### 48

## Table of Contents

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

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

#### **Product Revenue**

Sales of Neonorm Calf and Foal to distributors are made under agreements that may provide distributor price adjustments and rights of return under certain circumstances. Until we develop sufficient sales history and pipeline visibility, revenue and costs of distributor sales will be deferred until products are sold by the distributor to the distributor's customers. Revenue recognition depends on notification either directly from the distributor that product has been sold to the distributor's customer, when we have access to the data. Deferred revenue on shipments to 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 \$61,445 and \$24,143 for the three months ended June 30, 2017 and 2016, and \$105,989 and \$62,289 for the six months ended June 30, 2017 and 2016.

Sales of Botanical Extract are recognized as revenue when delivered to the customer. We had Botanical Extract revenues of \$0 and \$0 in the three months ended June 30, 2017 and 2016, and \$30,000 and \$0 in the six months ended June 30, 2017 and 2016.

#### **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 chemotherapyinduced 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 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 \$835,076 and \$1,582,942 in collaboration revenue in the three and six months ended June 30, 2017 which are included in our statements of operations and comprehensive loss. The difference of \$1,451,789 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 had \$197,876 of unreimbursed expenses as of June 30, 2017, which is included in Other Receivables on our balance sheet. We included the \$197,876 and \$486,042 in collaboration revenue in the three and six months ended June 30, 2017 which are included in our statements of operations and comprehensive loss.

#### Table of Contents

#### **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.
- 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.

50

## Table of Contents

- Dividend yield—We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.
- Forfeitures—We estimate forfeitures at the time of grant and revise those estimates periodically in subsequent periods. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest.

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

- the prices, rights, preferences and privileges of our Series A preferred stock relative to those of our common stock;
- · lack of marketability of our common stock;
- · our actual operating and financial performance;
- · current business conditions and projections;
- · hiring of key personnel and the experience of our management;
- · our stage of development;
- · illiquidity of share-based awards involving securities in a private company;
- the U.S. capital market conditions; and
- the likelihood of achieving a liquidity event, such as an offering or a merger or acquisition of our company given prevailing market conditions.

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

#### **Classification of Securities**

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

## Table of Contents

amended, limits the use of net operating loss and tax credit carryforward in certain situations where changes occur in the stock ownership of a company. Utilization of the domestic NOL and tax credit forwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by the Internal Revenue Code Section 382, as well as similar state provisions.

#### **Recent Accounting Pronouncements**

In November 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update, or 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 equivalents in the statement of cash flows. When cash, cash equivalents, 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, 2018 and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted, including adoption in an interim period. We are currently evaluating the impact of the adoption of ASU No. 2016-15 on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, which simplifies several aspects of the accounting for employee stock-based payment transactions. The areas for simplification in ASU No. 2016-09 include the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Effective January 1, 2017, we adopted ASU No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. Among other requirements, the new guidance requires all tax effects related to share-based payments at settlement (or expiration) to be recorded through the income statement. Previously, tax benefits in excess of compensation cost ("windfalls") were recorded in equity, and tax deficiencies ("shortfalls") were recorded in equity to the extent of previous windfalls, and then to the income statement. Under the new guidance, the windfall tax benefit is to be recorded when it arises, subject to normal valuation allowance considerations. The adoption of this standard did not have any impact to the Statement of Operations or the Statement of Cash Flows for the three-month periods ended March 31, 2016 or 2017. 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

#### Table of Contents

periods presented, and plan to adopt the standard as of January 1, 2018. We are currently evaluating the new guidance, however we do not believe the impact will be significant.

#### **JOBS** Act

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended

transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

#### 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 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.

53

#### Table of Contents

## PART II. — OTHER INFORMATION

#### Item 1. Legal Proceedings.

We are not currently involved in any material legal proceedings. However, from time to time, we may become subject to legal proceedings, claims, and litigation arising in the ordinary course of business.

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

On June 28, 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. The issuance of the securities is deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering. The investor is acquiring the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends will be affixed to the securities issued in this transaction. The investor is 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.

#### Item 6. Exhibits

Exhibit Number	Description
4.1++	Secured Convertible Promissory Note, dated June 29, 2017, by and between Jaguar Health, Inc. (f/k/a Jaguar Animal Health, Inc.) and
	Chicago Venture Partners, L.P. (incorporated by reference to Ex. 4.1 to the Current Report on Form 8-K filed on July 3, 2017).
10.1++	Amendment, Waiver & Consent, dated June 27, 2017, by and among Jaguar Health, Inc. (f/k/a Jaguar Animal Health, Inc.), Nantucket
	Investments Limited, and Napo Pharmaceuticals, Inc. (incorporated by reference to Ex. 10.83 of the Company's Registration Statement
	on Form S-4 (Registration No. 333-217364) filed on July 5, 2017)
10.2++	Securities Purchase Agreement, dated June 29, 2017, by and between Jaguar Health, Inc. (f/k/a Jaguar Animal Health, Inc.) and Chicago
	Venture Partners, L.P. (incorporated by reference to Ex. 10.1 to the Current Report on Form 8-K filed on July 3, 2017)
10.3++	Subordination Agreement and Right to Purchase Debt, dated June 29, 2017, by and between Chicago Venture Partners, L.P., Jaguar
	Health, Inc. (f/k/a Jaguar Animal Health, Inc.) and Hercules Capital, Inc. (incorporated by reference to Ex. 10.2 to the Current Report on
	Form 8-K filed on July 3, 2017).
10.4++	Security Agreement, dated June 29, 2017, by and between Jaguar Health, Inc. (f/k/a Jaguar Animal Health, Inc.) and Chicago Venture
	Partners, L.P. (incorporated by reference to Ex. 10.3 to the Current Report on Form 8-K filed on July 3, 2017).
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

## ++ Previously filed.

\*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.

54

Table of Contents

## SIGNATURE

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

Date: August 9, 2017

JAGUAR HEALTH, INC.

By: /s/ Karen S. Wright

Karen S. Wright Chief Financial Officer Principal Financial and Accounting Officer

55

## 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 June 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: August 9, 2017

/s/ Lisa A. Conte

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

1

## 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 June 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: August 9, 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 June 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: August 9, 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 June 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: August 9, 2017

/s/ Karen S. Wright Karen S. Wright Chief Financial Officer (Principal Financial and Accounting Officer)