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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

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 ANIMAL HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

**201 Mission Street, Suite 2375
San Francisco, California 94105**
(Address of principal executive offices, zip code)

(415) 371-8300
(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

As of November 13, 2015, there were 8,124,923 shares of common stock, par value \$0.0001 per share, outstanding.

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PART I. — FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

JAGUAR ANIMAL HEALTH, INC.

CONDENSED BALANCE SHEETS

	September 30, 2015 (Unaudited)	December 31, 2014 (1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,377,483	\$ 845,192
Accounts receivable	8,698	—
Due from related party	4,209	—
Inventory	256,129	198,029
Deferred offering costs	—	2,480,049
Prepaid expenses	353,944	24,170
Deferred finance charges	102,226	86,667
Total current assets	11,102,689	3,634,107
Property and equipment, net	834,387	872,523
Restricted cash	4,500,000	—
Deferred finance charges	82,083	—
Other assets	122,163	—
Total assets	\$ 16,641,322	\$ 4,506,630
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 276,767	\$ 698,318
License fee payable to related party	950,000	—
Due to related party	—	16,581
Deferred revenue	336,712	23,802
Convertible notes payable	150,000	424,674
Notes payable	—	478,709
Warrant liability	—	601,889
Accrued expenses	648,357	1,317,991
Long-term debt — current portion	1,454,030	—
Total current liabilities	3,815,866	3,561,964
Long-term debt, net of discount	4,457,994	—
License fee payable to parent	—	1,875,000
Deferred rent	1,660	—
Total liabilities	\$ 8,275,520	\$ 5,436,964

Commitments and Contingencies (See note 7)

Series A redeemable convertible preferred stock; \$0.0001 par value, 0 and 3,017,488 shares authorized at September 30, 2015 and December 31, 2014, respectively; 0 and 3,015,902 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively; (liquidation preference of \$0 and \$6,777,338 at September 30, 2015 and December 31, 2014, respectively)	—	7,304,914
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Stockholders' Equity (Deficit):

Common stock: \$0.0001 par value, 50,000,000 and 15,000,000 shares authorized at September 30, 2015 and December 31, 2014, respectively; 8,124,923 and 2,874,330 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	812	288
Additional paid-in capital	29,936,497	1,175,242
Accumulated deficit	(21,571,507)	(9,410,778)
Total stockholders' equity (deficit)	8,365,802	(8,235,248)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 16,641,322	\$ 4,506,630

(1) The condensed balance sheet at December 31, 2014 is derived from the audited financial statements at that date included in the Company's prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b)(4) on May 14, 2015.

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

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JAGUAR ANIMAL HEALTH, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue	\$ 77,666	\$ —	\$ 203,195	\$ —
Operating Expenses				
Cost of revenue	36,634	—	87,889	—
Research and development expense	1,239,831	1,126,436	4,414,162	3,275,991
Sales and marketing expense	165,745	—	519,275	—
General and administrative expense	1,390,429	1,455,605	3,784,272	3,196,120
Total operating expenses	2,832,639	2,582,041	8,805,598	6,472,111
Loss from operations	(2,754,973)	(2,582,041)	(8,602,403)	(6,472,111)
Interest expense, net	(163,594)	(148,220)	(3,033,238)	(168,384)
Other income	(42,104)	—	(23,471)	—
Change in fair value of warrants	—	—	(501,617)	—
Net loss and comprehensive loss	(2,960,671)	(2,730,261)	(12,160,729)	(6,640,495)
Accretion of redeemable convertible preferred stock	—	(180,832)	(346,374)	(465,841)
Net loss attributable to common stockholders	\$ (2,960,671)	\$ (2,911,093)	\$ (12,507,103)	\$ (7,106,336)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.36)	\$ (1.01)	\$ (2.28)	\$ (2.49)
Weighted-average common shares outstanding, basic and diluted	8,123,293	2,874,330	5,488,655	2,848,467

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

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JAGUAR ANIMAL HEALTH, INC.

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

(Unaudited)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balances December 31, 2013	—	\$ —	2,666,666	\$ 267	\$ 366,083	\$ (801,203)	\$ (434,853)
Stock-based compensation	—	—	—	—	164,156	—	164,156
Conversion of notes payable	—	—	207,664	21	524,979	—	525,000
Series A issuance	3,015,902	6,658,241	—	—	—	—	—
Beneficial conversion feature on notes payable	—	—	—	—	614,557	—	614,557
Warrant, line of credit	—	—	—	—	114,300	—	114,300
Warrant, transfer agreement	—	—	—	—	37,840	—	37,840
Deemed dividends on Series A	—	610,889	—	—	(610,889)	—	(610,889)
Accretion of issuance costs	—	35,784	—	—	(35,784)	—	(35,784)
Net and comprehensive loss	—	—	—	—	—	(8,609,575)	(8,609,575)
Balances December 31, 2014	3,015,902	\$ 7,304,914	2,874,330	\$ 288	\$ 1,175,242	\$ (9,410,778)	\$ (8,235,248)
Issuance of common stock in initial public offering, net of discounts and commissions of \$1,209,802 and offering costs of \$2,897,825	—	—	2,860,000	286	15,912,374	—	15,912,660
Conversion of preferred stock into common stock upon	(3,015,902)	(7,651,288)	2,010,596	201	7,651,087	—	7,651,288

initial public offering								
Conversion of preferred stock warrant liability into additional paid-in capital	—	—	—	—	1,150,985	—	—	1,150,985
Conversion of convertible notes into common stock upon initial public offering	—	—	374,997	37	2,099,963	—	—	2,100,000
Stock-based compensation	—	—	—	—	828,049	—	—	828,049
Beneficial conversion feature on notes payable	—	—	—	—	1,202,521	—	—	1,202,521
Deemed dividends on Series A	—	263,060	—	—	(263,060)	—	—	(263,060)
Accretion of issuance costs	—	83,314	—	—	(83,314)	—	—	(83,314)
Napo license fee abatement	—	—	—	—	250,000	—	—	250,000
Issuance of common stock upon exercise of stock options	—	—	5,000	—	12,650	—	—	12,650
Net and comprehensive loss	—	—	—	—	—	(12,160,729)	—	(12,160,729)
Balances September 30, 2015	—	\$ —	\$ 8,124,923	\$ 812	\$ 29,936,497	\$ (21,571,507)	—	\$ 8,365,802

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

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JAGUAR ANIMAL HEALTH, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30,	
	2015	2014
Cash Flows from Operating Activities		
Net loss	\$ (12,160,729)	\$ (6,640,495)
Adjustments to reconcile net loss to net cash used in operating activities:		
(Gain)/loss on disposal of fixed assets	34,549	—
Materials cost in connection with license activity	6,287	1,082,626
Warrants issued in connection with transfer agreement	—	37,840
Warrants issued in connection with line of credit	—	114,300
Stock-based compensation	828,049	105,610
Amortization of beneficial conversion feature	—	36,981
Accretion of debt discount	2,493,074	5,514
Revaluation of warrant liability	501,617	—
Amortization of deferred finance charge	99,882	3,894
Changes in assets and liabilities		
Accounts receivable	(8,698)	—
Inventory	(58,100)	—
Prepaid license fee	—	100,000
Prepaid expenses	(329,774)	(66,743)
Deferred finance charges	(197,524)	—
Other long-term assets	(122,163)	—
Due to/from parent	(20,790)	(44,622)
Deferred revenue	312,910	—
Deferred rent	1,660	—
License fee payable	(675,000)	—
Accounts payable	(421,551)	617,057
Accrued expenses	(669,634)	1,028,781
Total Cash Used in Operations	<u>(10,385,935)</u>	<u>(3,619,257)</u>
Cash Flows from Investing Activities		
Purchase of equipment	(23,300)	(55,149)
Sale of equipment	20,600	—
Change in restricted cash	(4,500,000)	—
Total Cash used in Investing Activities	<u>(4,502,700)</u>	<u>(55,149)</u>
Cash Flows from Financing Activities		
Proceeds from issuance of long-term debt	5,865,567	—
Proceeds from issuance of redeemable convertible preferred stock, net	—	6,658,241
Repayment of convertible notes payable	(100,000)	—
Repayment of notes payable	(1,000,000)	—
Proceeds from issuance of redeemable convertible notes payable, net	1,250,000	450,000
Proceeds from issuance of common stock in initial public offering, net	18,810,484	—
Deferred offering costs	(417,775)	(1,954,007)
Proceeds from exercise of common stock options	12,650	—
Total Cash Provided by Financing Activities	<u>24,420,926</u>	<u>5,154,234</u>
Net increase in cash and cash equivalents	<u>9,532,291</u>	<u>1,479,828</u>
Cash and cash equivalents, beginning of period	<u>845,192</u>	<u>185,367</u>
Cash and cash equivalents, end of period	<u>\$ 10,377,483</u>	<u>\$ 1,665,195</u>
Supplemental Schedule of Non-Cash Financing and Investing Activities		
Interest paid on long-term debt	23,100	—
Offering costs not paid during the nine months	\$ 1,401,253	—
Equipment received in connection with license agreement	\$ —	\$ 817,374
Note payable converted into common stock	\$ —	\$ 525,000

Warrants issued in connection with convertible notes payable	\$ 47,479	\$ —
Conversion of convertible preferred stock to common stock	\$ 7,651,288	\$ —
Conversion preferred stock warrant liability to common stock warrants	\$ 1,150,985	\$ —
Conversion of convertible notes to common stock	\$ 2,100,000	\$ —
Accretion of redeemable convertible preferred stock	\$ 346,374	\$ 465,841
Abatement of license fee payable to Napo	\$ 250,000	\$ —

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

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JAGUAR ANIMAL HEALTH, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

1. Organization and Business

Jaguar Animal Health, Inc. (“Jaguar” or the “Company”) was incorporated on June 6, 2013 (inception) in Delaware. The Company, a majority-owned subsidiary of Napo Pharmaceuticals, Inc. (“Napo” or the “Parent”) until May 13, 2015, was formed to develop and commercialize gastrointestinal products for companion and production animals. The Company is an animal health company whose activities since inception have consisted principally of raising capital, recruiting management, and performing research and development. The Company’s activities are subject to significant risks and uncertainties, including failing to secure additional funding to complete the development and commercialization of its products before another company develops similar products. The Company operates in one segment and is headquartered in San Francisco, California.

The following series of transactions between Jaguar and Napo were executed in order to separate the Company’s business from Napo:

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 Jaguar with the services of certain Napo employees for research and development and the general administrative functions of Jaguar. 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 Notes 4 and 5 for the Service Agreement and license agreement details, respectively.

Reverse Stock Split

In October 2014, the Board of Directors and stockholders approved a 1-for-1.5 reverse stock split (the “Reverse Split”) of the Company’s outstanding shares of common stock and increased the number of authorized shares of common stock from 10,000,000 shares to 15,000,000 shares. The Company effected the Reverse Split on October 27, 2014. Under the terms of the Reverse Split, each share of common stock, issued and outstanding as of such effective date, was automatically reclassified and changed into two-thirds of one share of common stock, without any action by the stockholder. Fractional shares were rounded down to the nearest whole share. All share and per share amounts have been restated to reflect the Reverse Split.

Initial Public Offering

In May 2015, the Company completed an initial public offering (“IPO”) of its common stock. In connection with its IPO, the Company issued 2,860,000 shares of its common stock at a price to the public of \$7.00 per share. The Company’s shares of common stock began trading on the NASDAQ Capital Market on May 13, 2015. As a result of the IPO, the Company received approximately \$15.9 million in net proceeds, after deducting underwriting discounts and commissions of \$1.2 million and offering expenses of \$2.9 million. At the closing of the IPO, 3,015,902 shares of outstanding convertible preferred stock were automatically converted into 2,010,596 shares of common stock. Following the IPO, there were no shares of preferred stock outstanding. In connection with the IPO, the Company amended its Amended and Restated Certificate of Incorporation to change the authorized capital stock to 50,000,000 shares designated as common stock and 10,000,000 shares designated as preferred stock, all with a par value of \$0.0001 per share.

Liquidity

The accompanying condensed 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 \$21,571,507 as of September 30, 2015. 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. 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 as well as revenue from future product sales. However, there can be no assurance that additional funding will be available to the Company on acceptable terms on a timely basis, if at all, or that the Company will generate sufficient cash from operations to adequately fund operating needs or ultimately achieve profitability. If the Company is unable to obtain an adequate level of financing needed for the long-term development and commercialization of its products, the Company will need to curtail planned activities and reduce costs. Doing so will likely have an adverse effect on the Company’s ability to execute on its business plan. These matters raise substantial doubt about the ability of the Company to continue in existence as a going concern. The accompanying condensed financial statements do not include any adjustments that might result from the outcome of these uncertainties.

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2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”) for Quarterly Reports on Form 10-Q and do not contain all of the information and footnotes required by U.S. generally accepted accounting principles (“U.S. GAAP”) for complete financial statements. The accompanying unaudited condensed financial statements and notes thereto should be read in conjunction with the audited financial statements and notes thereto included in the prospectus that forms part of the Company’s Registration Statement on Form S-1 (File No. 333-198383), which prospectus was filed with the SEC pursuant to Rule 424 on May 14, 2015. In the opinion of management, the accompanying unaudited Condensed Financial Statements reflect all adjustments, which include only normal recurring adjustments necessary to present fairly the Company’s interim financial information. The results for the nine months ended September 30, 2015 are not necessarily indicative of the results to be expected for the year ending December 31, 2015 or for any other period. The balance sheet as of December 31, 2014 has been derived from the audited financial statements as of that date but it does not include all of the information and notes required by U.S. GAAP.

The Company has evaluated events and transactions subsequent to the balance sheet date and has disclosed all events or transactions that occurred subsequent to the balance sheet date but prior to filing this Quarterly Report on Form 10-Q that would require recognition or disclosure in the unaudited Condensed Financial Statements.

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; 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; and evaluation and measurement of contingencies. Those estimates could change, and as a result, actual results could differ materially from those estimates.

Revenue Recognition

Sales 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. The Company will maintain system controls to verify that the reported distributor and third party data is accurate. Deferred revenue on shipments to distributors will reflect the estimated effects of distributor price adjustments, if any, and the estimated amount of gross margin expected to be realized when the distributor sells through product purchased from the Company. Accounts receivable from distributors will be recognized and included in deferred revenue when shipped to the distributor. Inventory will be relieved and revenue recognized, typically upon shipment by the distributor to their customer. The Company had no revenue for the nine months ended September 30, 2014 and \$203,195 for the nine months ended September 30, 2015.

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.

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The following table presents information about the Company’s liability that is measured at fair value on a recurring basis as of September 30, 2015 and December 31, 2014 and indicates the fair value hierarchy of the valuation:

	Level 1	Level 2	Level 3	Total
As of December 31, 2014 Warrant liability	\$ —	\$ —	\$ 601,889	\$ 601,889
As of September 30, 2015 Warrant liability	\$ —	\$ —	\$ —	\$ —

The change in the estimated fair value of the warrant liability is summarized below:

	Beginning Value of Level 3 Liability	Issuance of Common Warrants	Change in Fair Value of Level 3 Liability	Conversion into Additional Paid-in Capital	Ending Fair Value of Level 3 Liability
For the nine months ended September 30, 2015	\$ 601,889	\$ 47,479	\$ 501,617	(1,150,985)	\$ —

The change in the fair value of the level 3 warrant liability is reflected in the statement of operations and comprehensive loss for the nine months ended September 30, 2015. The liability was converted into additional paid-in capital upon the Company's initial public offering.

There were no other assets or liabilities measured at fair value on a recurring basis at September 30, 2015.

4. Employee Leasing and Overhead Allocation Agreement

Effective July 1, 2013, the Company entered into an employee leasing and overhead allocation agreement (the "Service Agreement") with its parent, Napo. The term of the Service Agreement was from July 1, 2013 through February 28, 2014. In connection with the Service Agreement, Napo provided the Company with the services of Napo employees. The Service Agreement also stipulated that Jaguar would pay for a portion of Napo's overhead costs. The Company agreed to pay Napo \$71,811 per month (consisting of \$38,938 for executive compensation, \$26,873 for employee services, and \$6,000 for overhead costs) for the months from July 2013 through February 2014 as follows: (1) for the period from July 2013 through November 2013, in 2,666,666 shares of common stock and (2) for the period from December 2013 through February 2014, in cash. Commencing March 1, 2014, the relevant Napo employees became employees of the Company and all overhead costs related to the animal health business will be paid by the Company.

General and administrative expense recognized under the Service Agreement was \$114,858 for the nine months ended September 30, 2014.

Research and development expense recognized under the Service Agreement \$28,764 for the nine months ended September 30, 2014.

5. License 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).

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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. 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 products that are not derived from *Croton lechleri* and a 1% royalty on annual net sales of nonprescription 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 nonprescription products derived from *Croton lechleri* and no milestone payment will be due and no royalties will be owed on any additional products developed. As of September 30, 2015, \$2,214 is the amount of royalties due Napo.

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. Materials transferred from Napo have been included in research and development expense on the statements of operations and comprehensive loss during the year ended December 31, 2014. Equipment of \$817,374 related to the License is included on the balance sheet at September 30, 2015 at the cost paid by Napo, which approximates fair value. As of September 30, 2015, the equipment has not been placed into service. The Company will begin depreciating the equipment on a straight-line basis over its estimated life of 10 years at the time it is placed into service.

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.

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. In 2015, payments totalling \$1,175,000 will be made, with the balance paid during the first quarter of 2016. Additionally, the terms of the License Agreement were amended to require the mutual agreement of the parties for payment of the license fee to be remitted in the form of the Company's common stock. The Company may also, at its sole discretion, elect to remit any milestone payments and/or royalties in the form of the Company's common stock. 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.

6. Accrued Expenses

Accrued expenses at September 30, 2015 and December 31, 2014 consist of the following:

	September 30, 2015	December 31, 2014
Accrued legal costs	\$ —	\$ 738,600
Accrued printing costs	—	275,000
Accrued interest	120,962	29,292
Accrued vacation	173,473	140,408
Accrued compensation and related expense	137,630	—
Other	216,292	134,691
	<u>\$ 648,357</u>	<u>\$ 1,317,991</u>

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7. Commitments and Contingencies

Since March 1, 2014, the date the Service Agreement terminated (Note 4), the Company paid Napo \$33,897 for rent related to the office space utilized by the Company for the months of March, April and May of 2014.

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 €500,000, €250,000 of which was to be paid at the earlier of September 15, 2014 or the closing date of an initial public offering and €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, €620,000, €310,000 of which was paid subsequent to the signature of the Transfer Agreement and €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, €100,000 was to be paid within five days of the signature of the Transfer Agreement, and (4) a €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 €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 €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. (Note 8)

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 €500,000 start-up fee was due by the end of April 2015 and has been paid during the nine months ended September 30, 2015, (ii) related to the technology transfer, of the remaining €310,000, €215,000 was due April 2015 and €95,000 was due June 30, 2015, both of which were paid during the nine months ended September 30, 2015, (iii) related to the design of a portion of the Manufacturer’s facility, the payment has increased to €170,000, €150,000 of which was due at the end of April 2015 and €20,000 was due on June 30, 2015, both of which have been paid during the nine months ended September 30, 2015 (iv) the fees linked to the deliverables are now due €250,000 on December 31, 2015 and €250,000 on March 31, 2016, 2015, (v) the bonus fee payable of €300,000, €150,000 was due at the end of April 2015 and has been paid during the nine months ended September 30, 2015 and €150,000 due at December 31, 2015. In May 2015, the Company paid the start-up fee of €500,000 and the technology transfer fee of €215,000. In accordance with the terms of the Memorandum of Understanding, the Manufacturer will supply 400Kg of SB300 at no cost in anticipation of the future deduction by December 2015.

In September 2015, the Company entered into a four year manufacture and supply agreement (the “Supply Agreement”) with a contract manufacturer in India for the manufacture and supply of active pharmaceutical ingredient (“API”). For each calendar year, the Company and the manufacturer will agree to a minimum annual quantity that the Company will purchase. In connection with the Supply Agreement, the Company paid \$49,090 in September 2015 as an advance payment for the API, which has been included in prepaid expenses at September 30, 2015.

In accordance with a sublease assignment, effective in June 19, 2015, the Company leased 6,008 square feet of office space. The term of the sublease began upon the delivery of the premises, which was July 1, 2015, and will expire on August 31, 2018. The base rent is \$29,539 with \$500 annual increases. In addition, the Company will be responsible for certain costs and charges specified in the sublease, including operating expenses and taxes. Future minimum lease payments will total \$1,054,909.

8. Debt and Warrants

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 \$3,000,000, and, accordingly, principal and accrued interest was converted into shares of common stock at 75% of the purchase price paid by such equity investors.

In connection with the Notes, the Company issued to the noteholders warrants, 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 are fully exercisable from the initial date of the first equity round of financing and have a five-year term subsequent to that date.

In February 2014, the Company closed its first equity round of financing and sold 2,224,991 shares of Series A convertible preferred stock at a price of \$2.2472 per share. The pre-money valuation was in excess of \$3,000,000 setting the exercise price of the Warrants at 75% of the purchase price paid by the investors, or \$2.5281 (as adjusted for the 1-for-1.5 reverse stock split approved in October 2014) per share. As such, the fair value of the Warrants, \$6,895, was recorded as equity in February 2014. The Warrants were valued at \$6,895 using the Black-Scholes model with the following assumptions: exercise price of \$2.5281, term of five years, volatility of 64%, dividend yield of 0%, and risk-free interest rate of 1.82%. Based on the fair value of the Warrants, the Company used the residual value of the total proceeds from the issuance of the Notes and Warrants to record the Notes on the balance sheet as of issuance of the Notes. Thus, the amount recorded, in the aggregate, for the Notes on issuance was \$518,105, net. The debt discount of \$6,895 is recorded as interest expense over the five-year term of the Warrants.

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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.

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. Accrued interest was to be paid in cash upon maturity. Upon the closing of the IPO, the outstanding principal amount automatically converted into 53,571 shares common stock at \$5.60, as amended in March 2015. Upon issuance, 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 the notes payable and to additional paid-in capital. For the nine months ended September 30, 2015 and 2014, the Company amortized \$31,250 and \$6,250, respectively, of the discount, which has also been recorded as interest expense.

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. Accrued interest was to be paid in cash upon maturity. Upon the closing of the IPO, the outstanding principal amount automatically converted into 26,785 shares of common stock at \$5.60, as amended in March 2015. Upon issuance, 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. For the nine months ended September 30, 2015, the Company amortized \$17,857 of the discount, which has also been recorded as interest expense.

In connection with the Transfer Agreement (Note 7) 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 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%.

In August 2014, the Company entered into a standby line of credit with an accredited investor for up to \$1,000,000 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 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 have been no drawdowns under the facility.

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 \$1,000,000 (the “Bridge”). Proceeds to the Company were net of a \$100,000 debt discount under the terms of the Bridge. This debt discount was 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 paid in May 2015, including interest thereon in an amount of \$321,600. In connection with the Bridge, the lenders were granted warrants to purchase that number of shares of the Company’s common stock determined by dividing \$1,000,000 by the exercise price of 80% of the IPO price, amended to \$5.60 in March 2015. The fair value of the warrants, \$505,348, was originally recorded as a debt discount and liability at December 3, 2014. The warrants were originally valued using the Black-Scholes model with the following assumptions: stock price of \$5.01, exercise price of \$5.23, term of five years, volatility of 63%, dividend yield of 0%, and risk-free interest rate of 1.61%. Based on the circumstances, the value derived using the Black-Scholes model approximated that which would be obtained using a lattice model. The debt discount was recorded as interest expense over the six month term of the Bridge. Of the aggregate debt discount of \$605,348 (warrants and original \$100,000 discount), \$521,291 was recorded as interest expense during the nine months ended September 30, 2015. Additional financing costs of \$104,000 were incurred related to the Bridge and deferred on closing. These are being recognized as interest expense over the six-month term of the Bridge using the effective interest method. During the nine months ended September, 2015, the remaining \$86,667 of these deferred financing charges was recorded as interest expense.

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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. 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 amortized the remaining \$141,890 of this discount during the nine months ended September 30, 2015. The warrants were originally valued using the Black-Scholes model with the following assumptions: stock price of \$4.59, exercise price of \$4.15, term of three years, volatility of 49%, dividend yield of 0%, and risk-free interest rate of 1.10%. Based on the circumstances, the value derived using the Black-Scholes model approximated that which would be obtained using a lattice model. The debt discount was recorded 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 has been recorded as a discount to the notes payable and to additional paid-in capital. For the nine months ended September 30, 2015, the Company amortized the remaining \$484,326 of the BCF which has also been recorded as interest expense.

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. Principal and interest of \$103,912 was paid in May 2015 for \$100,000 of these notes.

In March 2015, the Company entered into a non-binding letter of intent with Dechra Pharmaceuticals PLC (“Dechra”). In connection therewith, Dechra paid the Company \$1,000,000. At March 31, 2015, the Company had recorded this amount as a loan advance on the balance sheet. In April 2015, Dechra purchased \$1,000,000 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 Dechra 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. For the nine months ended June 30, 2015, the Company amortized the entire BCF of \$1,000,000 which has also been recorded as interest expense.

In August 2015, the Company entered into a loan and security agreement with a lender for up to \$8,000,000, which provided for an initial loan commitment of \$6,000,000. The loan agreement requires the Company to maintain \$4,500,000 of the proceeds in cash, which amount may be reduced or eliminated on the achievement of certain milestones. An additional \$2,000,000 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%. 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.

9. Common Stock

On May 18, 2015, the Company filed an amended and restated certificate of incorporation was amended and restated authorizing the Company to issue 50,000,000 of common stock \$0.0001 par value.

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10. Stock-Based Awards

2013 Equity Incentive Plan

Effective November 1, 2013, the Company's board of directors and sole stockholder adopted the Jaguar Animal 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 are contingent on the IPO, the 2013 Plan was terminated and no additional stock awards will be granted under the 2013 Plan.

2014 Equity Incentive Plan

In July 2014, the Company adopted the Jaguar Animal Health, Inc. 2014 Stock Incentive Plan ("2014 Plan"). The 2014 Plan provides for the grant of incentive stock options to eligible employees, and for the grant of nonstatutory stock options, restricted stock, and RSUs to eligible employees, directors and consultants. The Company has reserved 333,333 shares of common stock for issuance pursuant to the 2014 Plan. During the nine months ended September 30, 2015, 147,500 options were granted, 90,000 of which were granted to members of the Company's board of directors, 25,000 to an outside consultant and 32,500 to employees. Following the effective date of the IPO, any stock awards granted by the Company will be under the 2014 Plan. The Company has 185,833 shares available for grant at September 30, 2015.

Stock-Based Compensation

The Company recognizes compensation expense for only the portion of the awards that are expected to vest. The Company recorded stock-based compensation expense of \$429,468 as research and development expense, \$44,462 as selling and marketing expense and \$354,119 as general and administrative expense for the nine months ended September 30, 2015.

11. Related Party Transactions

The Company was a majority-owned subsidiary of Napo until its IPO. The Company had total outstanding receivables from Napo in the amount of \$4,209 as of September 30, 2015. The Company had outstanding liabilities to Napo in the amount of \$16,581 as of December 31, 2014. Additionally, Lisa A. Conte, Chief Executive Officer of the Company, is also the interim Chief Executive Officer of Napo Pharmaceuticals, Inc.

12. Net Loss Per Share Attributable to Common Stockholders

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. 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 shares of common stock equivalents have been excluded from diluted net loss per common share for the nine months ended September 30, 2015 and 2014 because their inclusion would be anti-dilutive:

	<u>Nine Months Ended September 30,</u>	
	<u>2015</u>	<u>2014</u>
Shares of common stock issuable upon conversion of preferred stock	—	2,010,596

Shares of common stock subject to outstanding options and restricted stock units	905,302	832,407
Warrants to purchase common stock	605,872	257,663
Total shares of common stock equivalents	1,511,174	3,100,666

13. Subsequent Events

The Company completed an evaluation of the impact of subsequent events through November 13, 2015, the date these financial statements were issued.

In October 2015, the Company entered into a formulation development and manufacturing contract with a manufacturer, whereby the manufacturer will provide enteric-coated tablets to the Company for use in animals. The total amount committed to be paid by the Company during 2015 and 2016 under this contract is estimated to be approximately \$850,000.

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

The following discussion and analysis of the financial condition and results of operations should be read together with the condensed financial statements and the related notes included in Item 1 of Part I of this Quarterly Report on Form 10-Q and with the audited financial statements and the related notes thereto and management’s discussion and analysis of financial condition and results of operations for the year ended December 31, 2014 included in the prospectus dated May 13, 2015 and filed with the Securities and Exchange Commission pursuant to Rule 424(b)(4) on May 14, 2015, which we refer to as the Prospectus.

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 Prospectus, that could cause our actual commercialization efforts, financial condition and results of operations, and business prospects and opportunities to differ materially from those 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

We are an animal health company focused on developing and commercializing first-in-class gastrointestinal products for companion and production animals. Canalevia is our lead prescription drug product candidate for the treatment of various forms of watery diarrhea in dogs. We achieved statistically significant results in a canine proof-of-concept study completed in February 2015, supporting the conclusion that Canalevia treatment is superior to placebo, with 91% of the Canalevia-treated dogs achieving a formed stool during the study versus 50% of the placebo-treated dogs. We also initiated filing of a rolling new animal drug application, or NADA, with the U.S. Food and Drug Administration, or FDA, for Canalevia for chemotherapy-induced diarrhea, or CID, in dogs, at the end of 2014. Canalevia is a canine-specific formulation of crofelemer, an active pharmaceutical ingredient isolated and purified from the *Croton lechleri* tree. A human-specific formulation of crofelemer, Fulyzaq, was approved by the FDA in 2012 for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. Members of our management team developed crofelemer, including while at Napo Pharmaceuticals, Inc., or Napo. Neonorm is our lead non-prescription product to improve gut health and normalize stool formation in animals suffering from watery diarrhea, or scours. We launched Neonorm in the United States at the end of 2014 for preweaned dairy calves under the brand name Neonorm Calf and expect to launch additional formulations of Neonorm for other animal species in 2015. We have already shipped approximately \$508,000 of Neonorm Calf to distributors. Neonorm is a botanical extract also derived from the *Croton lechleri* tree. Canalevia and Neonorm are distinct products that are 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.

Since inception, we have been primarily focused on designing protocols for studies of Canalevia to treat multiple preselected and distinct types of watery diarrhea in dogs and for Neonorm to improve gut health and normalize stool formation in preweaned dairy calves suffering from scours. We have also conducted a clinical study of Neonorm in preweaned dairy calves with scours. A portion of our activities has also been focused on other efforts associated with being a newly formed company, including securing necessary intellectual property, recruiting management and key employees and initial financing activities.

Financial Operations Overview

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

We have not generated any material revenue to date and expect to continue to incur significant research and development and other expenses. Our net loss attributable to common stockholders for the year ended December 31, 2014 was \$9.3 million and \$12.5 million for the nine months ended September 30, 2015. As of September 30, 2015, we had a total stockholders’ equity of \$8.4 million and cash and cash equivalents of \$10.4 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 2015.

Recent Developments

In May 2015, we completed the initial public offering of our common stock. In connection with our initial public offering, we issued 2,860,000 shares of our common stock at a price to the public of \$7.00 per share. Our shares of common stock began trading on the NASDAQ Capital Market on May 13, 2015. As a result of the initial public offering, we received approximately \$15.9 million in net proceeds, after deducting underwriting discounts and commissions of \$1.2 million and estimated offering expenses of \$2.9 million.

In September 2015, the Company entered into a four year manufacture and supply agreement (the “Supply Agreement”) with a contract manufacturer in India for the manufacture and supply of active pharmaceutical ingredient (“API”). For each calendar year, the Company and the manufacturer will agree to a minimum annual quantity that the Company will purchase. In connection with the Supply Agreement, the Company paid \$49,090 in September 2015 as an advance payment for the API, which has been included in prepaid expenses at September 30, 2015.

In October 2015, the Company entered into a formulation development and manufacturing contract with a manufacturer, whereby the manufacturer will provide enteric-coated tablets to the Company for use in animals. The total amount committed to be paid by the Company during 2015 and 2016 under this contract is estimated to be approximately \$850,000.

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Critical Accounting Policies and Significant Judgments and Estimates

Our management’s discussion and analysis of financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of our condensed financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, and revenue, costs and expenses and related disclosures during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those described below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no significant changes to our critical accounting policies since the filing of the Prospectus. Our critical accounting policies are described in the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of the Prospectus.

Results of Operations

The following table summarizes the results of our operations for the periods indicated:

	Nine Months Ended September 30,	
	2015	2014
	(unaudited, in thousands)	
Revenue:	\$ 203	\$ —
Operating expenses:		
Cost of revenue	88	—
Research and development expense	4,414	3,276
Sales and marketing expense	520	—
General and administrative expense	3,784	3,196
Total operating expenses	8,806	6,472
Loss from operations	(8,603)	(6,472)
Interest expense, net	(3,033)	(168)
Change in fair value of warrants	(501)	—
Other income	(24)	—
Net loss and comprehensive loss	\$ (12,161)	\$ (6,640)

Revenue and Cost of Revenue

Revenue and related cost of revenue for the nine months ended September 30, 2015 is for sales of Neonorm to a distributor. We defer revenue and cost of revenue until products are sold by the distributor to the distributor’s end customers and recognition will depend on notification from the distributor that product has been sold to the distributor’s end customer.

Research and Development Expense

The following table presents the components of research and development expense for the periods indicated:

	Nine Months Ended September 30,	
	2015	2014
	(unaudited, in thousands)	
Personnel and related benefits	\$ 1,295	\$ 731
Materials expense and tree planting	116	1,385
Travel, other expenses	241	294
Clinical and contract manufacturing	2,109	572
Stock-based compensation	429	37
Other	224	257
Total	\$ 4,414	\$ 3,276

We plan to increase our research and development expense as we continue develop our drug candidates.

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Research and development expense for the nine months ended September 30, 2015 includes expenses associated with clinical studies and manufacturing related activities and personnel and related benefits.

Research and development expense for the nine months ended September 30, 2014 primarily consists of materials for studies and pre-commercial manufacturing that were transferred to our company as part of the Napo License Agreement, and expensed. Research and development expenses also include payroll and related benefits for research and development personnel, the costs of a study of Neonorm in preweaned dairy calves, services provided by Napo personnel before they became employees of our company in March 2014, consultants, and manufacturing and raw material supply costs and related activities.

Sales and Marketing Expense

Sales and marketing expense for the nine months ended September 30, 2015 and 2014 consisted of personnel costs, direct marketing, travel and consulting expenses.

General and Administrative Expense

The following table presents the components of general and administrative expense for the periods indicated:

	Nine Months Ended September 30,	
	2015	2014
(unaudited, in thousands)		
Personnel and related benefits	\$ 1,453	\$ 1,226
Accounting fees	317	190
Third-party consulting fees and Napo service fees	108	378
Legal fees	437	365
Travel	311	446
Stock-based compensation	354	69
Other	804	522
Total	<u>\$ 3,784</u>	<u>\$ 3,196</u>

We expect to incur additional general and administrative expense as a result of operating as a public company, 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.

During the nine months ended September 30, 2015, general and administrative expense primarily consists of salaries and related benefits, accounting, legal, and travel. Legal fees were related to general corporate activities. Other expenses included costs related to marketing studies and business development consultants.

During the nine months ended September 30, 2014 general and administrative expense primarily consists of salaries and related benefits for employees, third-party consulting fees, legal fees, travel expenses, including hotel and airfare, and two months of services provided by Napo personnel pursuant to the Service Agreement, as well as Napo overhead allocation expense and legal costs related to intellectual property development and general corporate activities. In March 2014, upon the conclusion of the Service Agreement with Napo, four Napo employees joined us as our employees.

The following table summarizes the results of our operations for the periods indicated:

	Three Months Ended September 30,	
	2015	2014
(unaudited, in thousands)		
Revenue:	\$ 78	\$ —
Operating expenses:		
Cost of revenue	37	—
Research and development expense	1,240	1,126
Sales and marketing expense	166	—
General and administrative expense	1,390	1,456
Total operating expenses	<u>2,833</u>	<u>2,582</u>
Loss from operations	(2,755)	(2,582)
Interest expense, net	(163)	(148)
Change in fair value of warrants	—	—
Other income	(43)	—
Net loss and comprehensive loss	<u>\$ (2,961)</u>	<u>\$ (2,730)</u>

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Revenue and Cost of Revenue

Revenue and related cost of revenue for the three months ended September 30, 2015 is for sales of Neonorm to a distributor. We defer revenue and cost of revenue until products are sold by the distributor to the distributor's end customers and recognition will depend on notification from the distributor that product has been sold to the distributor's end customer.

Research and Development Expense

The following table presents the components of research and development expense for the periods indicated:

Three Months Ended
September 30,

	2015	2014
	(unaudited, in thousands)	
Personnel and related benefits	\$ 460	\$ 350
Materials expense and tree planting	116	34
Travel, other expenses	127	140
Clinical and contract manufacturing	439	493
Stock-based compensation	83	3
Other	15	106
Total	<u>\$ 1,240</u>	<u>\$ 1,126</u>

We plan to increase our research and development expense as we continue develop our drug candidates.

Research and development expense for the three months ended September 30, 2015 includes expenses associated with clinical studies and manufacturing related activities and personnel and related benefits.

Research and development expense for the three months ended September 30, 2014 primarily consists of materials for studies and pre-commercial manufacturing that were transferred to our company as part of the Napo License Agreement, and expensed. Research and development expenses also include payroll and related benefits for research and development personnel, the costs of a study of Neonorm in preweaned dairy calves, services provided by Napo personnel before they became employees of our company in March 2014, consultants, and manufacturing and raw material supply costs and related activities.

Sales and Marketing Expense

Sales and marketing expense for the three months ended September 30, 2015 and 2014 consisted of personnel costs, direct marketing, travel and consulting expenses.

General and Administrative Expense

The following table presents the components of general and administrative expense for the periods indicated:

	Three Months Ended September 30,	
	2015	2014
	(unaudited, in thousands)	
Personnel and related benefits	\$ 458	\$ 546
Accounting fees	50	43
Third-party consulting fees and Napo service fees	37	127
Legal fees	130	138
Travel	125	285
Stock-based compensation	107	12
Other	483	305
Total	<u>\$ 1,390</u>	<u>\$ 1,456</u>

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We expect to incur additional general and administrative expense as a result of operating as a public company, 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.

During the three months ended September 30, 2015, general and administrative expense primarily consists of salaries and related benefits, accounting, legal, and travel. Legal fees were related to general corporate activities. Other expenses included costs related to marketing studies and business development consultants.

During the three months ended September 30, 2014 general and administrative expense primarily consists of salaries and related benefits for employees, third-party consulting fees, legal fees, travel expenses, including hotel and airfare, and two months of services provided by Napo personnel pursuant to the Service Agreement, as well as Napo overhead allocation expense and legal costs related to intellectual property development and general corporate activities. In March 2014, upon the conclusion of the Service Agreement with Napo, four Napo employees joined us as our employees.

Liquidity and Capital Resources

We have not generated any material revenue to date and expect to continue to incur significant research and development and other expenses. Our net loss attributable to common stockholders was \$12.5 million for the nine months ended September 30, 2015. As of September 30, 2015, we had a total stockholders' equity of \$8.4 million and cash and cash equivalents of \$10.4 million. We anticipate that we will continue to incur losses for at least the next two years due to expenses relating to:

- trials of our products and product candidates;
- toxicology studies for our product candidates;
- establishing contract manufacturing capabilities; and
- commercialization of one or more of our prescription drug product candidates, if approved, and commercialization of our non-prescription products.

As of September 30, 2015, we had cash and cash equivalents of \$10.4 million. In the nine months ended September 30, 2015 we issued \$250 thousand, \$1.0 million and \$6.0 million aggregate principal amounts of promissory notes in February 2015, March 2015, and August 2015 respectively. Additionally, we received net cash of approximately \$15.9 million as a result of our initial public offering, net of offering cost and underwriters discounts.

Our auditors have included an explanatory paragraph in their audit report on our financial statements for the year ended December 31, 2014, regarding our assessment of substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty.

We believe the net proceeds from our initial public offering, our existing cash and cash equivalents, together with the achievement of certain milestones which will allow us to access an additional \$1.5 million from the restricted cash portion of our senior secured loan facility with Hercules Technology Growth Capital, Inc. (announced on August 19, 2015) will be sufficient to fund our operating plan through April 2016 and anticipated commercial launch of Canalevia for CID in dogs, as well as for the pivotal data and regulatory filing with the FDA to expand the indication to general watery diarrhea in dogs. However, our operating plan may change due to many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. We may also not be successful in entering into partnerships that include payment of upfront licensing fees for our products and product candidates for markets outside the United States, where appropriate. If we do not generate upfront fees from any anticipated arrangements, it would have a negative effect on our operating plan.

We expect that we will increase our expenditures in the future in order to continue our efforts to develop animal health products, continue to commercially launch Neonorm and continue development of Canalevia in the near term. We have agreed to pay Indena S.p.A. aggregate fees of approximately €2.1 million under memorandums of understanding relating to the establishment of our commercial manufacturing arrangement. The exact amounts and timing of any expenditures may vary significantly from our current intentions.

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Cash Flows

The following table shows a summary of cash flows for the periods set forth below:

	Nine Months Ended September 30,	
	2015	2014
	(unaudited, in thousands)	
Cash used in operating activities	\$ (10,386)	\$ (3,619)
Cash used in investing activities	(4,503)	(55)
Cash provided by financing activities	24,421	5,154

Cash Used in Operating Activities

During the nine months ended September 30, 2015 cash used in operating activities was the result of our net loss of \$12.2 million, offset by non-cash accretion of debt discounts of \$2.5 million, non-cash revaluation of warrant liability of \$502 thousand and stock-based compensation of \$828 thousand, and amortization of deferred finance charges of \$100 thousand, \$35 thousand loss on the sale of property and equipment, net of changes in operating assets and liabilities of \$2.2 million.

During the nine months ended September 30, 2014, cash used in operating activities was the result of our net loss of \$6.6 million, offset by and non-cash expense of the write-off of certain materials received from Napo of \$1.1 million, warrants issued in connection with transfer agreement and line of credit of \$85 thousand, and stock-based compensation of \$106 thousand, offset by changes in operating assets and liabilities of \$1.6 million.

Cash Used in Investing Activities

During the nine months ended September 30, 2015 cash used in investing activities primarily consisted of \$4.5 million in restricted cash that resulted from our issuance of long-term debt.

Cash Provided by Financing Activities

During the nine months ended September 30, 2015, cash provided by financing activities primarily consisted of the gross proceeds from the issuance of \$5.9 million in long-term debt, net of discounts, and \$1.3 million in convertible promissory notes, offset by \$1.1 million in repayments thereof. Additionally, \$15.9 million in cash was provided related to our IPO, net of commissions certain deferred offering costs.

During the nine months ended September 30, 2014, cash provided by financing activities consisted of net proceeds of \$6.7 million from the issuance of Series A preferred stock and \$450 thousand for the issuance of convertible notes payable, offset by \$2.0 million of offering costs.

Description of Indebtedness.

Standby Lines of Credit, Convertible Notes and and Warrant Issuances

In August 2014, the Company entered into a standby line of credit with an accredited investor for up to \$1,000,000 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 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 have been no drawdowns under the facility.

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 \$1,000,000 (the "Bridge"). Proceeds to the Company were net of a \$100,000 debt discount under the terms of the Bridge. This debt discount was 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 paid in May 2015, including interest thereon in an amount of \$321,600. In connection with the Bridge, the lenders were granted warrants to purchase that number of shares of the Company's common stock determined by dividing \$1,000,000 by the exercise price of 80% of the IPO price, amended to \$5.60 in March 2015. The fair value of the warrants, \$505,348, was originally recorded as a debt discount and liability at December 3, 2014. The warrants were originally valued using the Black-Scholes model with the following assumptions: stock price of \$5.01, exercise price of \$5.23, term of five years, volatility of 63%, dividend yield of 0%, and risk-free interest rate of 1.61%. Based on the circumstances, the value derived using the Black-Scholes model approximated that which would be obtained using a lattice model. The debt discount was recorded as interest expense over the six month term of the Bridge. Of the aggregate debt discount of \$605,348 (warrants and original \$100,000 discount), \$521,291 was recorded as interest expense during the nine months ended September 30, 2015. Additional financing costs of \$104,000 were incurred related to the Bridge and deferred on closing. These are being recognized as interest expense over the six-month term of the Bridge using the effective interest method. During the nine months ended September 30, 2015, the remaining \$86,667 of these deferred financing charges was recorded as interest expense.

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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. 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 amortized the remaining \$141,890 of this discount during the nine months ended September 30, 2015. The warrants were originally valued using the Black-Scholes model with the following assumptions: stock price of \$4.59, exercise price of \$4.15, term of three years, volatility of 49%, dividend yield of 0%, and risk-free interest rate of 1.10%. Based on the circumstances, the value derived using the Black-Scholes model approximated that which would be obtained using a lattice model. The debt discount was recorded 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 has been recorded as a discount to the notes payable and to additional paid-in capital. For the nine months ended September 30, 2015, the Company amortized the remaining \$484,326 of the BCF which has also been recorded as interest expense.

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. Principal and interest of \$103,912 was paid in May 2015 for \$100,000 of these notes.

In March 2015, the Company entered into a non-binding letter of intent with Dechra Pharmaceuticals PLC ("Dechra"). In connection therewith, Dechra paid the Company \$1,000,000. At March 31, 2015, the Company had recorded this amount as a loan advance on the balance sheet. In April 2015, Dechra purchased \$1,000,000 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 Dechra 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. For the nine months ended September 30, 2015, the Company amortized the entire BCF of \$1,000,000 which has also been recorded as interest expense.

In August 2015, the Company entered into a loan and security agreement with a lender for up to \$8,000,000, which provided for an initial loan commitment of \$6,000,000. The loan agreement requires the Company to maintain \$4,500,000 of the proceeds in cash, which amount may be reduced or eliminated on the achievement of certain milestones. An additional \$2,000,000 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%. 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 effective 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.

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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.

Commitments and Contingencies

Since March 1, 2014, the date the service agreement with Napo terminated, we paid Napo \$33 thousand for rent related to the office space we utilized for the months of March, April and May, 2014.

Effective on June 1, 2014, we assumed the existing sublease from Napo. The term of the sublease was from June 1, 2014 through June 30, 2015. Minimum lease payments paid during 2015 totaled \$68 thousand.

In accordance with a sublease assignment, effective in June 19, 2015, the Company leased 6,008 square feet of office space. The term of the sublease began upon the delivery of the premises, which was July 1, 2015, and will expire on August 31, 2018. The base rent is \$29,539 with \$500 annual increases. In addition, the Company will be responsible for certain costs and charges specified in the sublease, including operating expenses and taxes. Future minimum lease payments will total \$1,143,526.

In January 2014, we entered into the Napo License Agreement, pursuant to which we acquired an exclusive worldwide license to Napo's intellectual property rights and technology, including rights to its library of over 2,300 medicinal plants, for all veterinary treatment uses and indications for all species of animals. Under the Napo License Agreement, Napo also assigned to us equipment, inventory and granted us a right to cross-reference any regulatory submissions or drug-matter files for which Napo has rights and access.

In consideration for the license from Napo, we are obligated to pay a one-time non-refundable license fee of \$1.75 million, less an option fee of \$100 thousand we paid in July 2013. In December 2014, we paid Napo an additional \$25 thousand, and in January 2015, agreed that the remaining license fee payment will be paid in cash, or if mutually agreed with Napo, in shares of our common stock according to the following schedule:

Payment Date	License Fee Amount (in thousands)
December 31, 2015	\$ 500
March 31, 2016	\$ 450
Total	\$ 950

For products derived from *Croton lechleri*, we owed Napo a 2% royalty on annual net sales of all products that are prescription drugs (such as Canalevia and any line extensions) approved by the FDA or the equivalent regulatory agency in another country, and, 1% of net sales of non-prescription products (such as Neonorm and any line extensions) that do not require pre-marketing approval from the FDA or the equivalent regulatory agency in another country. Following the closing of the offering, we do not owe Napo any royalties on sales of non- *Croton lechleri* products.

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 €500,000, €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 €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, €620,000, €310,000 of which was paid subsequent to the signature of the Transfer Agreement and €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, €100,000 was to be paid within five days of the signature of the Transfer Agreement, and (4) a €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 €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 €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. (Note 8)

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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 €500,000 start-up fee was due by the end of April 2015 and has been paid during the nine months ended September 30, 2015, (ii) related to the technology transfer, of the remaining €310,000, €215,000 was due April 2015 and €95,000 was due June 30, 2015, both of which were paid during the nine months ended September 30, 2015, (iii) related to the design of a portion of the Manufacturer's facility, the payment has increased to €170,000, €150,000 of which was due at the end of April 2015 and €20,000 was due on June 30, 2015, both of which have been paid during the nine months ended September 30, 2015 (iv) the fees linked to the deliverables are now due €250,000 on December 31, 2015 and €250,000 on March 31, 2016, 2015, (v) the bonus fee payable of €300,000, €150,000 was due at the end of April 2015 and has been paid during the nine months ended September 30, 2015 and €150,000 due at December 31, 2015. In May 2015, the Company paid the start-up fee of €500,000 and the technology transfer fee of €215,000. In accordance with the terms of the Memorandum of Understanding, the Manufacturer will supply 400Kg of SB300 at no cost in anticipation of the future deduction by December 2015.

The following table summarizes remaining payments due to the Manufacturer:

Payment Date	Payment Amount (in thousands)
December 31, 2015	€ 400
March 31, 2016	€ 250
Total	€ 650

In September 2015, the Company entered into a four year manufacture and supply agreement (the "Supply Agreement") with Glenmark Pharmaceuticals Ltd., a contract manufacturer in India, for the manufacture and supply of crofelemer, an active pharmaceutical ingredient ("API") for animal use. For each calendar year, the Company and the manufacturer will agree to a minimum annual quantity that the Company will purchase. In connection with the Supply Agreement, the Company paid \$49,090 in September 2015 as an advance payment for the API, which has been included in prepaid expenses at September 30, 2015.

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, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

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

Changes in internal control over financial reporting.

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

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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.

None

Item 6. Exhibits

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the registrants’s current report on Form 8-K, filed May 18, 2015)
3.2	Bylaws (incorporated herein by reference to Exhibit 3.2 to the registrant’s current reported on Form 8-K, filed May 18, 2015)
10.1	Loan and Security Agreement between Jaguar Animal Health, Inc., Qualified Subsidiaries thereof, the several banks and other financial institutions or entities from time to time parties thereto as lenders and Hercules Technology Growth Capital, Inc., dated as of August 18, 2015 (incorporated herein by reference to Exhibit 10.2 to the registrant’s current report on Form 8-K, filed August 20, 2015)
10.2**	Manufacture and Supply Agreement by and between Jaguar Animal Health, Inc. and Glenmark Pharmaceuticals Ltd., dated as of September 22, 2015 (filed herewith)
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

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

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SIGNATURE

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

Date: November 13, 2015

JAGUAR ANIMAL HEALTH, INC.

By: /s/ John A. Kallassy

John A. Kallassy

Chief Financial Officer

Principal Financial and Accounting Officer

*** TEXT OMITTED AND SUBMITTED SEPARATELY PURSUANT
TO CONFIDENTIAL TREATMENT REQUEST

MANUFACTURE AND SUPPLY AGREEMENT

This **MANUFACTURE AND SUPPLY AGREEMENT** (“**Agreement**”) is entered into as of the date of the last signature below (the “**Effective Date**”) between:

(i) **Glenmark Pharmaceuticals, Ltd.** incorporated under laws of India under the provisions of the Companies Act, 1956 and having its registered office at B/2, Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai-400 026, India, (“**Glenmark**”); and

(ii) **Jaguar Animal Health Inc.** incorporated under laws of Delaware and having its registered office/place of business at 185 Berry, Suite 1300, (201 Mission Street) San Francisco, California 94107, USA (“**Jaguar**”)

“**Glenmark**” and “**Jaguar**” may be referred to herein from time to time individually as a “**Party**,” and collectively as the “**Parties**”.

RECITALS:

WHEREAS Glenmark and Salix are parties to an Amended and Restated Manufacturing and Supply Agreement, dated July 18, 2011 (the “**Salix API Supply Agreement**”), whereby, among other things, Glenmark agreed to manufacture and supply Crofelemer API (as defined below) to Salix;

WHEREAS, Napo Pharmaceuticals, Inc. (“**Napo**”) and Glenmark entered into and executed a Collaboration Agreement dated 2nd July, 2005 and various amendments thereto and further entered a Settlement Agreement dated 9th December, 2013 (“**the Glenmark-Napo Agreements**”) whereby, among other things, Glenmark agreed to manufacture and supply Crofelemer API to Napo;

WHEREAS, Jaguar being desirous of using the Crofelemer Animal API (as defined below) for the development, manufacture and marketing of a Crofelemer Animal Product (as defined below) for non-human use and has approached Glenmark for manufacture and supply of such Crofelemer Animal API;

WHEREAS, certain officers of Jaguar are or were officers of Napo and possess knowledge and documentation of Glenmark Intellectual Property (as defined below) relating to the manufacture of Crofelemer API;

WHEREAS, the license and relationship between Jaguar and Napo is outlined in **Appendix 1**;

WHEREAS, Glenmark is willing to manufacture and supply Crofelemer Animal API to Jaguar from their Ankleshwar Facility, on the terms and conditions set forth below including, without limitation, terms relating to protecting the continued confidentiality of Glenmark Intellectual Property,

NOW THEREFORE, in consideration of the mutual promises and agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

1.1 “Affiliate” of a Party shall mean any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such Party, as the case may be, but for only so long as such control exists. As used in this Section 1.1, “control” shall mean (a) direct or indirect beneficial ownership of at least 50% (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in such Person or (b) the power to direct the management of such Person by contract or otherwise.

1.2 “Applicable Laws” shall mean the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, permits (including Marketing Approvals) of or from any court, arbitrator, Regulatory Authority or governmental agency or authority having jurisdiction over or related to the subject item.

1.3 “Ankleshwar Facility” means the Manufacturing facility of Glenmark’s Affiliate, Glenmark Pharmaceuticals Ltd., located at 3109, GIDC Industrial Estate, Ankleshwar 393 002, Gujarat, India.

1.4 “Business Day” shall mean a day other than a Saturday or Sunday or any public holiday in the San Francisco, CA, USA or Mumbai, India. For the avoidance of doubt, references in this Agreement to “days” shall mean calendar days.

1.5 “Calendar Year” shall mean a period of twelve (12) consecutive months beginning on and including January 1st.

1.6 “cGMP” shall mean the then-current good manufacturing practices required by the FDA, as set forth in the United States Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder.

1.7 “Crofelemer API” means oligomeric proanthocyanidin (OPC) of varying chain lengths [***], as per the current specifications approved by US FDA.

1.8 “Crofelemer Animal API” means oligomeric proanthocyanidin (OPC) of varying chain lengths [***], for use in animal health pharmaceutical preparations as per Specifications

1.9 “Crofelemer Animal Product” means a pharmaceutical animal product containing Crofelemer Animal API and that has received Marketing Approval for the treatment of animals.

1.10 “CPL” means crude plant latex of *croton lechleri* that meets Specifications.

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1.11 “Confidential Information” means the Glenmark and Jaguar Disclosed Information and the Glenmark Intellectual Property or Jaguar Intellectual Property but shall not include: (a) information which was already in the public domain or became publically available through no breach of this Agreement or the Related Confidentiality Agreements, or (b) information already in the possession of a Party that is not subject to any confidential obligations under any of the Related Confidentiality Agreements.

1.12 “Disclosing Party” means the Party disclosing Confidential Information.

1.13 “Facility” means the Ankleshwar Facility.

1.13a “Full Product Lot” means milled and blended lot size of Crofelemer Animal API at Ankleshwar Facility of approximately 10kg.

1.14 “FDA” shall mean the U.S. Food and Drug Administration or similar federal, state or local Regulatory Authorities.

1.15 “FD&C Act” shall mean the United States Food, Drug and Cosmetic Act, as amended, and any regulations promulgated thereunder.

1.16 “Field Of Use” All indications (prevention, treatment and/or diagnosis) for non-human use in the Territory.

1.17 “Firm Forecast” has the meaning set forth in Section 2.2.

1.18 “Fully-Allocated Manufacturing Cost” or **“FAMC”** has the meaning set forth in **Appendix 5**.

1.19 “Glenmark and Jaguar Disclosed Information” means any and all information or material that, at any time before or after the Effective Date, has been or is provided or communicated to the receiving Party by or on behalf of the disclosing Party pursuant to this Agreement or in connection with the transactions contemplated hereby or any discussions or negotiations with respect thereto.

1.20 “Glenmark Intellectual Property” means all technical, scientific and other know-how and information, trade secrets, inventions, patents, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, technical assistance, designs, assembly procedures, specifications, assays, test methods, analytical methods, and other material or information developed by Glenmark that: (a) relates to the development and Manufacture of Crofelemer API and (b) is owned in whole or in part by Glenmark or its Affiliates.

1.20A “Jaguar Intellectual Property” means all technical, scientific and other know-how and information, trade secrets, inventions, patents, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, technical assistance, designs, assembly procedures, specifications, test methods, analytical methods, and other material or information that: (a) relates to the development of Jaguar’s animal products containing Crofelemer Animal API and (b) is owned in whole or in part by Jaguar or its Affiliates.

1.21 “Governmental Authority” shall mean any court, agency, department, authority or other instrumentality of any national, supranational, state, county, city or other political subdivision.

1.22 “Indemnified Party” has the meaning set forth in Section 7.3(a).

1.23 “Indemnifying Party” has the meaning set forth in Section 7.3(a).

1.24 “Jaguar-Supplied CPL” means the CPL supplied by Jaguar to Glenmark hereunder and used by Glenmark in connection with Manufacturing of the Crofelemer Animal API.

1.25 “Manufacture” shall mean to manufacture, process, formulate, package, label, hold and/or store, warehouse, quality control release and deliver the Crofelemer Animal API or Crofelemer Animal Product (or any component thereof).

1.26 “Marketing Approval” and **“MAA Approval”** means an approved New Animal Drug Application (NADA) as defined in the FD&CA and the regulations promulgated thereunder, or any corresponding foreign application, registration or certification, necessary or reasonably useful to market any Crofelemer Animal Product in the Territory, including applicable pricing and reimbursement approvals.

1.27 “Minimum Annual Purchase Quantity” has the meaning set forth in Section 2.2.

1.28 “NADA” of the Crofelemer Animal Product shall mean a New Animal Drug Application as defined in Title 21 of the U.S. Code of Federal Regulations, §321(v) et seq., and all amendments and supplements thereto, which is filed with the FDA, including all documents, data, and other information concerning such Crofelemer Animal Product thus filed that are necessary or useful for gaining Marketing Approval for such Crofelemer Animal Product.

1.29 “Person” shall mean any individual, corporation, partnership, limited liability company, trust, governmental entity, or other legal entity of any nature whatsoever.

1.30 “Purchase Price” has the meaning set forth in Section 4.1.

1.31 “Purchase Order” means a written purchase order that sets forth, with respect to the period covered thereby, (a) the quantities of Crofelemer Animal API to be delivered by Glenmark to Jaguar, (b) the required delivery dates therefor, (c) the port of entry and terminal for DAT delivery as specified in Section 3.5, and (d) any special instructions or invoicing information.

1.32 “Quality Agreement” has the meaning set forth in Section 3.2.

1.33 “Regulatory Authority” shall mean any national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity (a) whose review and/or approval is necessary (i) for the Manufacture, packaging, use, storage, import, export, distribution, promotion, marketing, offer for sale and sale of the Crofelemer Animal API or Crofelemer Animal Product, and/or (ii) for reviewing regulatory filings for the Crofelemer Animal API or the Crofelemer Animal Product (or a component thereof); and/or (b) having authority to review and enforce cGMP and/or other Applicable Laws relating to the Crofelemer Animal API or the Crofelemer Animal Product or the Manufacture, development, commercialization, use or sale thereof.

1.34 “Regulatory Requirements” shall mean (a) all specifications, methods of Manufacture, and other information in one or more regulatory submissions related in any way to the Crofelemer Animal API or Crofelemer Animal Product, and (b) all laws, rules, regulations, applicable regulatory guidance documents, and other requirements of any Regulatory Authority that govern the Crofelemer Animal API or Crofelemer Animal Product, including its Manufacture, customs requirements and delivery.

1.35 “Related Confidentiality Agreements” shall mean any and all agreements between Glenmark and Napo that provide restrictions on the disclosure of information regarding or relating to Crofelemer API and any and all agreements between Salix and Napo that provide restrictions on the disclosure of information regarding or relating to Crofelemer API.

1.36 “Rolling Forecast” has the meaning set forth in Section 2.2.

1.37 “Specifications” shall mean, with respect to the Crofelemer Animal API, those Crofelemer Animal API related Specifications set forth in **Appendix 2 Part A** and with respect to CPL, those CPL-related specifications set forth in **Appendix 2 Part B**, which shall specifications shall be provided by Jaguar to Glenmark. Any amendment to **Appendix 2 Part A** or **Part B** shall be agreed between the parties.

1.38 “Term” has the meaning set forth in Section 8.1.

1.39 “Territory” means worldwide.

1.40 “Third Party” shall mean any Person other than Glenmark, Jaguar and their respective Affiliates.

ARTICLE 2

SUPPLY AND PURCHASE OF CROFELEMER ANIMAL API AND FIELD OF USE RESTRICTION

2.1 Supply and Purchase of the Crofelemer Animal API. Subject to the terms of this Agreement, during the Term, Glenmark shall Manufacture and supply Crofelemer Animal API to Jaguar, and Jaguar shall purchase from Glenmark, its requirements of Crofelemer Animal API in such quantities as Jaguar shall order pursuant to and in accordance with Section 2.

2.2 Development and Commercial Phase. For each Calendar Year Jaguar and Glenmark shall agree to a minimum annual quantity of Crofelemer Animal API that will be purchased by Jaguar for the Calendar Year (the “**Minimum Annual Purchase Quantity**”) after considering Jaguar’s requirements for the Crofelemer Animal API and Glenmark’s available manufacturing capacity at its Facility. After the development of the Minimum Annual Purchase Quantity and not less than 120 Business Days prior to the first anticipated delivery of the Crofelemer Animal API to Jaguar, Jaguar shall provide Glenmark its rolling forecast (“**Rolling Forecast**”) in writing estimating the quantities of Crofelemer Animal API that Jaguar expects to purchase from Glenmark for each quarter during the following six (6) quarters and thereafter update the same within ten (10) Business Days of the beginning of each Quarter. For each Calendar Year the Minimum Annual Purchase Quantity shall not be less than thirty (30%) percent of the Rolling Forecast for the first two (2) years of commercial supply and fifty (50%) percent of the Rolling Forecast for each year thereafter of commercial supply. The initial three (3) months of each Rolling Forecast shall be a firm forecast (“**Firm Forecast**”) for the purchase of the Crofelemer Animal API. Each Firm Forecast shall be accompanied by a Purchase Order for Crofelemer Animal API to be delivered to Jaguar during each of the first three (3) months, respectively, set forth in such Firm Forecast. Under no circumstances shall Glenmark be obligated to agree to minimum quantities that are greater than its capacity to supply the Crofelemer Animal API.

2.3 Failure To Meet Minimum Annual Purchase Quantities. During each Calendar Year, if Jaguar fails to purchase the Minimum Annual Purchase Quantity, then Jaguar shall be liable to pay to Glenmark the Overheads relating to and apportioned to the non-purchased Minimum Annual Purchase Quantity. At the end of each Calendar Year, Glenmark shall submit an invoice, if applicable, relating to the Overhead in respect of non-purchased Minimum Annual Purchase Quantity which shall be due and payable within thirty (30) Calendar Days. For removal of doubt, the Parties have included the illustration relating to this Section has been elaborated in **Appendix 4**. The term Overheads shall be construed in accordance with meaning attributed to it under **Appendix 5** — Fully Allocated Manufacturing Costs.

2.4 Supply During Development Phase. With respect to the development phase, Jaguar’s forecasts for [***] are set forth at **Appendix 6** attached hereto, which may be amended by Jaguar provided that Glenmark is provided sufficient lead time to meet the amended forecast and has the available capacity if the forecast is increased. Glenmark will initiate the planning of the manufacturing campaigns upon execution of a Purchase Order and payment in accordance with Section 4.2.

2.5 Purchase Orders.

(a) Each Purchase Order for the Crofelemer Animal API to be delivered to Jaguar in any month (i) shall be in multiples of the Full Product Lot of the Crofelemer Animal API and (ii) shall not be less than 80% nor more than one hundred twenty percent (120%) of the quantities specified in any

previous Firm Forecast applicable to such month. In no event shall the delivery date of Crofelemer Animal API for any Purchase Order be less than six (6) months from the date of the Purchase Order; provided however, that such period shall be shortened to three (3) months so long as Jaguar has fulfilled its obligations under Section 2.6 to provide to Glenmark the Jaguar-Supplied CPL in respect of such Purchase Order.

(b) Each Purchase Order shall specify the quantity of Crofelemer Animal API ordered, the required delivery date, the port of entry and terminal for DAT delivery as specified in Section 3.5, and any special instructions or invoicing information.

(c) Glenmark shall acknowledge and accept the Purchase Order from Jaguar made in accordance with and governed by this Agreement, and any terms or conditions of such Purchase Order which conflict or are inconsistent with the terms of the Agreement are void and hereby rejected.

(d) Jaguar shall be obligated to purchase and take delivery of, and Glenmark shall be obligated to deliver by the required delivery date set forth therein, such quantities of Crofelemer Animal API as are set forth in each accepted Purchase Order.

(e) Glenmark shall deliver the quantities of Crofelemer Animal API set forth in each accepted Purchase Order by the required delivery date set forth in such Purchase Order.

2.6 Jaguar-Supplied CPL

(a) Jaguar shall supply to Glenmark an amount of Jaguar-Supplied CPL that is sufficient to manufacture one hundred twenty percent (120%) of the Crofelemer Animal API specified in any Firm Forecast applicable to such month. The Jaguar-Supplied CPL shall conform to the Specifications and shall be delivered on a schedule consistent with Glenmark's need for Jaguar-Supplied CPL in order to meet the Firm Forecast.

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(b) Jaguar's obligations with respect to the Jaguar-Supplied CPL shall include the responsibility for complying with all Regulatory Requirements obligations associated with the delivery of the Jaguar-Supplied CPL to the Facility and Jaguar shall bear all costs associate thereto.

(c) In the event Jaguar fails to deliver Jaguar -Supplied CPL in quantities that meet Specifications for CPL necessary for Glenmark to Manufacture Crofelemer Animal API in accordance with the applicable Purchase Order, such failure shall excuse Glenmark's obligation to supply Crofelemer Animal API to Jaguar until such failure has been corrected by Jaguar.

2.7 Field of Use Restriction. Jaguar agrees that the development and commercial uses of Crofelemer Animal API and Crofelemer Animal Product shall be solely limited to the Field of Use and that any development or commercial uses of Crofelemer Animal API and Crofelemer Animal Product for purpose other than the Field of Use shall constitute a material breach of the Agreement.

ARTICLE 3

MANUFACTURING

3.1 Manufacture of Crofelemer Animal API. Glenmark shall Manufacture the Crofelemer Animal API to meet the Specifications and in accordance with applicable Regulatory Requirements in the Territory, as then in effect. Amendments to the Specifications will be handled in accordance with Section 3.6(a)-(d).

3.2 Quality Agreement. Not later than 10 Business Days after the Effective Date of this Agreement, Glenmark and Jaguar shall enter into the quality agreement ("**Quality Agreement**") attached here to as **Appendix 3**, which sets forth the quality assurance arrangements, responsibilities and procedures with respect to the Manufacture of the Crofelemer Animal API, and the conducting of timely investigations & closure of issues with respect to the Crofelemer Animal API.

3.3 Regulatory Inspections; cGMP and QA Audits. Glenmark shall cooperate with any inspection of its facilities by the FDA relating to this Agreement and, if applicable, by any Regulatory Authority or respective notified bodies overseeing the Manufacture of Crofelemer Animal API for the Territory. Any costs associated with such inspections shall be borne completely by Jaguar.

3.4 Compliance with Laws. Glenmark and Jaguar shall comply with all applicable Regulatory Requirements and laws of any Regulatory Authority in the Territory.

3.5 Delivery and Acceptance.

(a) **Delivery.** Subject to the terms and conditions of this Agreement, Glenmark shall deliver all Crofelemer Animal API ordered by Jaguar on the requested delivery date set forth in the applicable Purchase Order in compliance with Section 2.5(b). Deliveries shall be made DAT (INCOTERMS 2010) to the port of entry and terminal as specified in the applicable Purchase Order at Jaguar's expense and risk provided, however: (i) Glenmark shall only engage such carriage, insurance or other providers in connection with such delivery as are approved by Jaguar in the applicable Purchase Order, (ii) Jaguar shall bear costs and expenses for (A) carriage and insurance of the Crofelemer Animal API from the Facility and (B) clearance of Crofelemer Animal API through customs in the destination country and (iii) in the event any claim arises against Glenmark in respect of any such carriage, insurance or other provider, or under Applicable Law in relation to the delivery, Glenmark, as promptly as possible, shall assign such claim to Jaguar and Jaguar undertakes to defend and hold Glenmark harmless against all such claims in accordance with Section 7.2. All Crofelemer Animal API shall be labeled in accordance with

Applicable Law of the Territory and packed for shipping in accordance with packing instructions provided by Jaguar. Title to and risk of loss of Crofelemer Animal API shall pass to Jaguar at the time and place of delivery.

(b) Certificate of Analysis; Certificate of Conformance. Each delivery of Crofelemer Animal API, shall be accompanied by a (i) Certificate of Analysis; (ii) Certificate of Conformance, (ii) such other documents as may be required pursuant to the Quality Agreement and (iv) documentation necessary for the sale or import of the Crofelemer Animal API.

(c) Acceptance upon Delivery. Jaguar shall be under no obligation to accept any shipment of Crofelemer Animal API for which Glenmark has not provided a Certificate of Analysis or a Certificate of Conformance, as applicable. Jaguar shall inspect all shipments of the Crofelemer Animal API promptly upon receipt, and Jaguar may reject any shipment of the Crofelemer Animal API which is nonconforming to the Specifications. In order to reject delivery of a shipment of the Crofelemer Animal API, Jaguar must give written notice to Glenmark of Jaguar's rejection of any delivery **thirty (30) days** after receipt of such delivery. If no such notice of rejection is received, Jaguar shall be deemed to have accepted such Crofelemer Animal API on the thirtieth (30th) day after delivery, subject to later detection of hidden defects which in no event shall be more than twelve (12) months after the delivery of Crofelemer Animal API by Glenmark.

(i) After timely notice of rejection is received by Glenmark, Jaguar shall cooperate with Glenmark in determining whether rejection is appropriate or justified. Glenmark will evaluate process issues and other reasons for any alleged nonconformity to the Specifications. Glenmark shall notify Jaguar as promptly as reasonably possible whether it accepts Jaguar's basis for any rejection, but not later than thirty (30) **business days** after the respective notification. If Glenmark agrees with Jaguar's determination that the rejected Crofelemer Animal API does not meet the Specifications, promptly on receipt of a notice of rejection of a shipment of Crofelemer Animal API and no later than **120 Business Days** after receipt of such notice, Glenmark shall use commercially reasonable efforts to replace such rejected Crofelemer Animal API with Crofelemer Animal API conforming Crofelemer Animal API to the Specifications. If Glenmark disagrees with Jaguar's determination that certain Crofelemer Animal API is nonconforming to Specifications, (x) promptly on receipt of a notice of rejection of a shipment of Crofelemer Animal API but no later than **120 Business Days** after receipt of such notice, at Jaguar's request, Glenmark shall use commercially reasonable efforts at Jaguar's request to replace such rejected Crofelemer Animal API and (y) the rejected Crofelemer Animal API shall be submitted to a mutually acceptable Third Party laboratory in the Territory, which shall determine whether such Crofelemer Animal API is nonconforming to Specifications. The Parties agree that such Third Party laboratory's determination shall be final and binding on the Parties absent manifest error. The Party against whom the Third Party laboratory rules shall bear the reasonable costs of the Third Party testing. If the Third Party laboratory rules that the Crofelemer Animal API in question meets Specifications, Jaguar shall purchase that batch at the agreed-upon price, irrespective of whether Glenmark has provided replacement Crofelemer Animal API, provided that in such event Jaguar shall also pay for any replacement Crofelemer Animal API delivered if not previously paid. Otherwise the replacement delivery shall be at no charge to Jaguar.

(ii) Jaguar shall not destroy any rejected Crofelemer Animal API until it receives written notification from Glenmark that Glenmark does not dispute that the rejected Crofelemer Animal API fails to meet Specifications. At Glenmark's election and upon instruction from Glenmark, Jaguar shall either (a) destroy the Crofelemer Animal API received in the rejected delivery promptly at Glenmark's cost and provide Glenmark with certification of such destruction, or (b) return such Crofelemer Animal API to Glenmark at Glenmark's cost.

(iii) Notwithstanding any other provisions hereinabove, Glenmark shall have no liability hereunder to the extent any such liability is attributable to (i) failure of Jaguar-Supplied CPL to

conform to applicable Specifications as of its time of delivery to Glenmark or (ii) Jaguar-Supplied CPL having been adulterated (as such term is defined in FD&C) prior to the time of delivery to Glenmark.

3.6 Change in Specifications; Other Modifications.

(a) Changes in Specifications. In the event that an amendment to the Specifications, the Manufacturing process, or the test methods for the Crofelemer Animal API is (i) required in writing by any Regulatory Authority, or (ii) requested by Jaguar, Jaguar promptly shall provide Glenmark with appropriate documentation relating to any such changes to the Specifications or Manufacturing process to the extent that such changes affect Glenmark's Manufacturing of the Crofelemer Animal API hereunder. If the requested changes can be made without modification to the existing process capability, Glenmark shall implement such changes in accordance with the change control procedures applicable under GMP and per agreement between the Parties regarding the timing of the changes. It shall be within Glenmark's sole discretion to determine whether or not the requested change can be made without modification to the existing process capability. In the event that Glenmark determines that the requested change cannot be made without modification to the existing process capability, then Glenmark, in its sole discretion, shall have the right to reject any request for changes to the Specifications or Manufacturing process. Glenmark shall not, in any respect, amend, modify or supplement the Specifications, the Manufacturing process, or the test methods for the Crofelemer Animal API or any Jaguar-Supplied CPL or sources of Jaguar-Supplied CPL used in connection with Manufacturing the Crofelemer Animal API without the prior written consent of Jaguar.

(b) Costs to Implement Changes. Jaguar shall be solely responsible for any additional costs incurred to implement changes to the Specifications or the Manufacturing process as required by Jaguar or any Regulatory Authority, including reasonable costs of capital equipment and process upgrades and obsolescence of Jaguar-Supplied CPL, not suitable for other use in the business or operations of Glenmark or any of its Affiliates.

(c) Costs. Glenmark shall be solely responsible for any and all increased costs or expenses incurred by it or Jaguar as a result of any amendment of the Specifications or the Manufacturing process for the Crofelemer Animal API (i) requested by Glenmark and consented to by Jaguar or (ii) required by Jaguar as a result of Glenmark's failure to Manufacture the Crofelemer Animal API in conformity with the Specifications; provided however that such failure is not as a result of Jaguar-Supplied CPL or otherwise due to default of Jaguar.

(d) Records. Glenmark shall keep complete, accurate and authentic accounts, notes, data and records pertaining to the Manufacture and supply of each batch of the Crofelemer Animal API, for the minimum period provided in 21 CFR Part 211, or longer if required by Regulatory Requirements in the Territory or country of Manufacture, and upon Jaguar's reasonable request and at its expense, shall make available to Jaguar copies of or access to such records. Notwithstanding the foregoing, Glenmark shall at all times maintain such records and systems for the Parties to investigate causes of a Recall of the Product and conduct a Recall of the Product in compliance with all Applicable Laws.

3.7 Complaints Handling and Reporting. The Parties shall agree upon a procedure for handling complaints in the Quality Agreement.

3.8 Stability. Glenmark shall, during the Term, take such quantities of quality control stability samples, from batches of Crofelemer Animal API intended for delivery to Jaguar, as are required by cGMP and applicable Regulatory Requirements and establish appropriate stability studies, in each case to support the claimed expiration dating for the Crofelemer Animal API delivered to Jaguar.

3.9 Records.

(a) Glenmark shall generate, retain and maintain:

(i) all records necessary to comply with GMP and all other Applicable Law relating to the Manufacture of the Crofelemer Animal API. Without limiting the foregoing, records shall be made concurrently with the performance of each step in the Manufacture of the Crofelemer Animal API and in such a manner that at any time successive steps in the Manufacture and distribution of any batch may be traced by an inspector. Such records shall be legible and indelible, shall identify the person immediately responsible, shall include dates of the various steps and be as detailed as necessary for a clear understanding of each step by an individual experienced in the manufacture of pharmaceutical products;

(ii) all Manufacturing records, standard operating procedures, equipment log books, batch manufacturing records, laboratory notebooks and all raw data and electronic data relating to the Manufacturing of the Crofelemer Animal API;

(iii) samples of each batch and Materials. Samples shall include a quantity of representative material of each batch and Materials sufficient to perform at least full duplicate quality control testing, and shall specify the dates of Manufacture and packaging thereof. Samples so retained shall be selected at random from either final container material or from bulk and final containers; provided that they include at least one final container as a final package, or package-equivalent of such filling of each batch. Such sample shall be stored at temperatures and under conditions which will maintain the identity and integrity of the relevant sample; and

(iv) such other records and samples that Glenmark maintains in the ordinary course of business, as Jaguar reasonably may require in order to ensure compliance by Glenmark with the terms of this Agreement and Applicable Law.

(b) Without prejudice to Glenmark's obligations pursuant to Section 3.9(a) Glenmark shall diligently complete the master batch record for the Crofelemer Animal API during the Manufacture of such Crofelemer Animal API.

(c) All materials, samples, records and other items referred to in Section 3.9(a) shall be retained by Glenmark for the longer of (i) such period as may be required by GMP and all other Applicable Law and (ii) five (5) years.

3.10 Legal Changes. Each Party shall immediately advise the other if it becomes aware of any legislation or Applicable Laws (including, all health and safety, environmental, custom, trade, tariff or other import laws, approvals process or vigilance reporting requirements) which is in effect or which may come into effect after this Agreement becomes effective and which affects the obligations of the Parties hereunder.

ARTICLE 4

PAYMENT

4.1 Purchase Price for Supply.

(a) Glenmark shall Manufacture and supply the Crofelemer Animal API under this Agreement at the purchase price ("Purchase Price") specified herein. The Purchase Price shall be equal to the sum of (i) Glenmark's Fully-Allocated Manufacturing Cost [***] (ii) Glenmark's cost of importing the CPL to comply with local regulations. Along with each acceptance of a Purchase Order pursuant to Section 2.5(c), Glenmark shall also confirm the Purchase Price applicable for such Purchase Order, based on the formula set forth in this Section 4.1(a).

(b) In any event, if there is a net increase in the Manufacturing costs incurred by Glenmark in connection with the Manufacture and supply of the Crofelemer Animal API hereunder, the Parties shall in good faith negotiate a new Purchase Price to prevent Glenmark having to Manufacture and sell Crofelemer Animal API to Jaguar at a loss under this Agreement. Conversely, in the event of a reduction in the Fully-Allocated Manufacturing Cost, the then current Purchase Price shall be reduced to reflect such reduced Fully-Allocated Manufacturing Cost.

4.2 Payment Terms for Purchases.

(a) **Invoice and Payment.** For any Purchase Order, Glenmark shall invoice Jaguar and Jaguar shall pay [***]% of the estimated value of the Purchase Order in advance at the time of acceptance of such Purchase Order and balance shall be paid to Glenmark within thirty (30) Business days after issuance of such invoice to Jaguar. For removal of any doubts, Glenmark shall issue the invoice before the release of the Crofelemer Animal API underlying the said Purchase Order. If any shipment is rejected under Section 3.5(c) then in such case any payment made by Jaguar towards such rejected shipment Crofelemer Animal API shall be adjusted: (a) for any replacement Crofelemer Animal API; and/or (b) for such original shipment after a Third Party laboratory, pursuant to Section 3.5(c), confirms that the Crofelemer Animal API originally delivered complies with the Specifications and not subject to rejection.

(b) **Currency.** All references to "Dollars" or "\$" shall mean the legal currency of the United States. All payments to be made under this Agreement shall be made in Dollars, unless expressly specified to the contrary herein.

(c) **Late Payments.** Any amounts not paid when due under this Agreement shall be subject to interest beginning 60 days after the foregoing due date through and including the date upon which payment is received, calculated at the interest rate equal to U.S. Prime Rate per year effective for the applicable days of the period of default, on the last business day of the applicable Calendar Quarter prior to the date on which such payment is due, calculated daily on the basis of a 365-day year, or, if lower, the highest rate permitted under Applicable Law.

ARTICLE 5

REPRESENTATIONS AND WARRANTIES

5.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as of the Effective Date as follows:

(a) The execution, delivery, and performance of this Agreement have been duly authorized by all necessary corporate actions;

(b) This Agreement constitutes a valid obligation of such Party and is binding and enforceable against such Party in accordance with the terms hereof; and

(c) Such Party has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and there is no contractual restriction or obligation binding on such Party which would be materially contravened by execution and delivery of this Agreement or by the performance or observance of its terms.

5.2 Crofelemer Animal API Warranties. Glenmark represents and warrants that the Crofelemer Animal API supplied to Jaguar:

(a) complies with the Specifications;

(b) has been Manufactured and stored in compliance with the Specifications and Regulatory Requirements;

(c) is not unfit for commerce under any Regulatory Requirements; and

(e) assuming payment in full by Jaguar, is free and clear of all security interests, liens and other encumbrances of any kind or character.

5.3 Limitation of Liability. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, NEITHER PARTY NOR ANY OF THEIR RESPECTIVE AFFILIATES, DIRECTORS, OFFICERS, EMPLOYEES, OR AGENTS SHALL HAVE ANY LIABILITY OF ANY TYPE (INCLUDING, BUT NOT LIMITED TO, CLAIMS IN CONTRACT, NEGLIGENCE AND TORT LIABILITY) FOR ANY SPECIAL, INCIDENTAL, INDIRECT, PUNITIVE OR CONSEQUENTIAL DAMAGES, INCLUDING, BUT NOT LIMITED TO, THE LOSS OF OPPORTUNITY, LOSS OF USE OR LOSS OF REVENUE OR PROFIT IN CONNECTION WITH OR ARISING OUT OF THIS AGREEMENT, EVEN IF SUCH DAMAGES MAY HAVE BEEN FORESEEABLE. THE FOREGOING SHALL NOT LIMIT EITHER PARTY'S INDEMNIFICATION OBLIGATIONS UNDER ARTICLE 7 NOR SHALL IT APPLY TO DAMAGES ARISING FROM EITHER PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 6. NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT. THE TOTAL LIABILITY OF GLENMARK UNDER THIS AGREEMENT SHALL NOT EXCEED THE AMOUNT OF ALL PAYMENTS RECEIVED BY GLENMARK FROM JAGUAR UNDER THIS AGREEMENT.

5.4 Insurance.

(a) Jaguar shall maintain (i) comprehensive general liability insurance written on an occurrence basis with a combined single limit for bodily injury and property damage of not less than [***] and (ii) product liability/completed operations coverage with a per claim limit of not less than [***].

(b) Glenmark shall maintain (i) comprehensive general liability insurance in the amount of [***] and (ii) public liability insurance in the amount of [***].

(c) The insurance policies referenced in Sections 5.4(a) and (b) above ("Policies") shall (i) be provided by an insurance carrier(s) acceptable to the other Party and (ii) show the other Party as additional named insured and loss payee, as its interests may appear. Certificates of insurance for the Policies shall be furnished to the other Party within ten (10) days after the Effective Date. The Policies shall remain in effect throughout the Term of this Agreement and shall not be canceled or subject to a reduction of coverage or any other modification without the prior written authorization of the other Party.

(d) It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under Article 7.

5.5 Warranty Limitations or Disclaimers. THE WARRANTIES, LIMITATIONS AND DISCLAIMERS DESCRIBED IN THIS ARTICLE 5 SUPERSEDE ANY OTHER WARRANTY LIMITATIONS AND DISCLAIMERS GIVEN BY EITHER PARTY, WHETHER WRITTEN OR ORAL. EXCEPT FOR THE EXPRESS WARRANTIES IN SECTIONS 5.1 and 5.2 GLENMARK MAKES NO WARRANTIES OF ANY KIND WITH RESPECT TO THE CROFELEMER ANIMAL API, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OF FITNESS FOR A PARTICULAR PURPOSE, OR ANY IMPLIED WARRANTIES ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING, OR USAGE OF TRADE.

ARTICLE 6

CONFIDENTIALITY

6.1 Confidential Information. Except as provided in Section 6.2, the Parties shall not publish or otherwise disclose Confidential Information to a Third Party and shall not use Confidential Information directly or indirectly for any purpose other than performing its obligations or exercising its rights hereunder.

6.2 Authorized Disclosure.

(a) Each Party may disclose Confidential Information to the extent that such disclosure is made in response to a valid order of a court of competent jurisdiction or other governmental body of a country or any political subdivision thereof of competent jurisdiction; provided, however, that the Party under court order shall, to the extent possible under such order, first have given notice and a reasonable opportunity for the other Party to quash such order or to obtain a protective order requiring that the Confidential Information or documents that are the subject of such order be held in confidence by such court or governmental body or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to that information that is legally required to be disclosed in such response to such court or governmental order.

(b) Jaguar may disclose Confidential Information to the extent that such disclosure is made to Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information.

(c) Jaguar may disclose Jaguar Confidential Information to its suppliers, commercial partners and others to be able to use Crofelemer Animal API in the field of animal health.

(d) If Jaguar wishes to disclose Glenmark Confidential Information to its suppliers, commercial partners and others to be able to use Crofelemer Animal API in the field of animal health, then Jaguar shall seek prior written consent of Glenmark, which consent shall not be unreasonably withheld.

6.3 Notification. Upon a Party's discovery of loss or compromise of the other Party's Confidential Information, the Party discovering the loss shall notify the other Party immediately, and cooperate as reasonably requested.

6.4 Remedies. Each Party agrees that the unauthorized use or disclosure of Confidential Information in violation of this Agreement will cause severe and irreparable damage. In the event of any violation of this Section, the Parties agree that the Party whose Confidential Information has been disclosed shall be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, without the necessity of proving irreparable harm or actual damages, as well as any other relief permitted by Applicable Law. The Party sought to be enjoined agrees to waive any requirement that the Party seeking the injury post bond as a condition for obtaining any such relief.

6.5 Use of Names. Neither Party shall mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other Party (or any abbreviation or adaptation thereof) in any publication, press release, promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 6.5 shall not prohibit either Party from making any disclosure identifying the other Party that is required by applicable law; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information.

6.6 Press Releases. Neither Party shall make a press release or other public announcement regarding this Agreement, the terms hereof or the transactions contemplated hereby without the prior written approval of the other Party. Each Party shall provide the other with the proposed text of any such

press release or public announcement for review and approval, which approval shall not be unreasonably withheld, conditioned or delayed, as early as possible, but in no event less than four (4) business days in advance of the publication, communication or dissemination thereof; provided, however, that the receiving Party shall be deemed to have approved any such press release or public announcement if it fails to notify the proposing Party in writing of any objections to such press release or public announcement within three (3) business days after receipt by the receiving Party of the text of such public announcement. Notwithstanding the foregoing, but subject to Section 6.4 above, this Section 6.6 shall not be applicable to filings and disclosures required by Applicable Laws.

ARTICLE 7

INDEMNIFICATION

7.1 Indemnification by Glenmark. Glenmark shall indemnify, defend and hold Jaguar and its Affiliates and their respective officers, directors, employees and agents ("Jaguar Indemnitees") harmless from and against any and all losses, damages, liabilities, assessments, costs, charges, or claims ("Losses") arising out of or resulting from any Third Party claims made or suits brought against Jaguar which arise or result from: (1) the breach of any of Glenmark's representations and warranties set forth in this Agreement; (2) Glenmark's negligence or willful misconduct in the performance of this Agreement, or material breach of this Agreement; except in each case of clauses (1)-(2) to the extent caused by any Jaguar Indemnitee's negligence or willful misconduct or material breach of this Agreement.

7.2 Indemnification by Jaguar. Jaguar shall indemnify, defend and hold Glenmark and its Affiliates and their respective officers, directors, employees and agents ("Glenmark Indemnitees") harmless from and against any and all Losses arising out of or resulting from any Third Party claims made or suits brought against Glenmark which arise or result from: (1) the breach of any of Jaguar's representations and warranties set forth in this Agreement; (2) a claim by a Third Party that the filing of a dossier, or the marketing and sale of any finished Crofelemer Animal Product by Jaguar or its Affiliates or licensees pursuant to this Agreement infringes such Third Party's intellectual property rights or (3) Jaguar's negligence or willful misconduct in the performance of this Agreement, or material breach of this Agreement; (4) any personal injury or death associated with the animal studies or clinical trials conducted by Jaguar or conducted on behalf of Jaguar by a Jaguar licensee or distribution partner; or (5) product recall or product liability claims; or (6) any claims that arise in respect of the delivery under Section 3.5(a); except in each case of clauses (1)- (6) to the extent caused by any Glenmark Indemnitee's negligence or willful misconduct or material breach of this Agreement.

7.3 Procedures.

(a) A party making a claim for indemnity under this Article 7 hereinafter is referred to as an "Indemnified Party" and the party against whom such claim is asserted is hereinafter referred to as the "Indemnifying Party." All claims by any Indemnified Party under this Section shall be asserted and resolved in accordance with the following provisions. If any claim or demand for which an Indemnifying Party would be liable to an Indemnified Party is asserted against or sought to be collected from such Indemnified Party by a Third Party, said Indemnified Party shall with reasonable promptness notify in writing the

Indemnifying Party of such claim or demand stating with reasonable specificity the circumstances of the Indemnified Party's claim for indemnification; provided, however, that any failure to give such notice will not waive any rights of the Indemnified Party except to the extent the rights of the Indemnifying Party are actually prejudiced. After receipt by the Indemnifying Party of such notice, then upon reasonable notice from the Indemnifying Party to the Indemnified Party, or upon the written request of the Indemnified Party, the Indemnifying Party shall defend, manage and conduct any proceedings,

negotiations or communications involving any claimant whose claim is the subject of the Indemnified Party's notice to the Indemnifying Party as set forth above, and shall take all actions necessary, including the posting of such bond or other security as may be required by any governmental authority, so as to enable the claim to be defended against or resolved without expense or other action by the Indemnified Party.

(b) In any such proceeding, any Indemnified Party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the sole expense of such Indemnified Party

(c) Upon written request of the Indemnifying Party, the Indemnified Party shall, to the extent it may legally do so and to the extent that it is compensated in advance by the Indemnifying Party for any costs and expenses thereby incurred, (1) take such action as the Indemnifying Party may reasonably request in connection with such action, (2) allow the Indemnifying Party to dispute such action in the name of the Indemnified Party and to conduct a defense to such action on behalf of the Indemnified Party, or (3) render to the Indemnifying Party all such assistance as the Indemnifying Party may reasonably request in connection with such dispute and defense.

(d) The Indemnifying Party shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent, or if there be a final judgment for the plaintiff, the Indemnifying Party shall indemnify and hold harmless such Indemnified Parties from and against any Losses (to the extent stated above) by reason of such settlement or judgment. Without the prior written consent of the Indemnified Party, no Indemnifying Party shall effect any settlement of any pending or threatened proceeding in respect of which any Indemnified Party is or could have been a party and indemnity could have been sought hereunder by such Indemnified Party, unless such settlement includes an unconditional release of such Indemnified Party from all liability arising out of such proceeding.

ARTICLE 8

TERM

8.1 Term. This Agreement shall become effective upon the Effective Date and shall remain in full force and effect until the 4th anniversary unless earlier terminated pursuant to Section 8.2 below (the "Initial Term"). At the end of the Initial Term, the Parties may extend the term of this Agreement by mutual written agreement.

8.2 Termination.

In addition to any other provision of this Agreement expressly providing for termination of this Agreement, this Agreement may be terminated as follows:

(a) Jaguar may terminate this Agreement immediately upon notice to Glenmark in the event that Regulatory Authorities cause the withdrawal of any Crofelemer Animal Product from the Territory for safety reasons.

(b) Either Party may terminate this Agreement:

(i) immediately upon written notice if the other Party shall (a) file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction a petition in bankruptcy or insolvency or for reorganization or for arrangement or for the appointment of a receiver or trustee of that Party or of its assets, (b) propose a written agreement of composition or extension of its debts, (c) be served with an

involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, (d) propose or be a party to any dissolution or liquidation, (e) make an assignment for the benefit of its creditors, or (f) admit in writing its inability generally to pay its debts as they fall due in the general course;

(ii) immediately upon written notice in the event of any material breach by the other Party in the performance of any of its obligations herein contained that has not been cured by the defaulting Party within ninety (90) days after receiving written notice thereof from the non-breaching Party;

(iii) Either party may terminate this Agreement for any reason with ninety (90) day notice subject to Section 2.3.

(iv) immediately upon written notice in the event that, as a result of an order of government or any other official authority, the continued operation of this Agreement in its entirety or in substantial part is prevented or delayed for an unspecified and indeterminate period.

8.3 Effect of Expiration or Termination.

(a) Survival. The expiration or earlier termination of this Agreement shall be without prejudice to any rights or obligations of the Parties that may have accrued prior to such termination or expiration, and the provisions of Articles 1 (Definitions), 4 (Payment) 5 (Representations and Warranties), 6 (Confidentiality), 7 (Indemnification), 8 (Term), and 9 (Miscellaneous) shall survive the expiration or termination of this Agreement. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available at law or in equity.

(b) Return of Confidential Information. Upon expiration or earlier termination of this Agreement, each Party, at the request of the other, shall return all data, files, records and other materials in its possession or control containing or comprising the other Party's Confidential Information except that the legal department of such Party may retain one copy for archival purposes.

(c) Actions. Upon termination of this Agreement for any reason, (i) Glenmark immediately shall cease all Manufacturing of the Crofelemer Animal API pursuant to this Agreement, (ii) all submitted but unfilled Purchase Orders automatically shall be cancelled, and (iii) Glenmark promptly shall return any remaining Jaguar-Supplied CPL to Jaguar or its designee at Jaguar's costs. For purposes of clarification, termination of this Agreement does not preclude Glenmark from manufacturing Crofelemer API for its own use and the use of its Affiliates or Salix.

(d) Cumulative Remedies. Except as expressly stated otherwise herein, remedies hereunder are cumulative, and nothing in this Agreement shall prevent either Party, in the case of a breach, from not terminating this Agreement and seeking to enforce its rights hereunder.

(e) Accrued Obligations. Except as set forth herein, any termination or expiration of this Agreement shall not relieve either Party of any obligation which has accrued prior to the effective date of such termination or expiration (including the costs of any Jaguar-Supplied CPL maintained for the Crofelemer Animal Product ordered by Jaguar hereunder, which are unique to the manufacture of Crofelemer Animal API, and any remedy of Jaguar relating to Article 3 with respect to Crofelemer Animal API Manufactured and supplied prior to the effective date of termination), which obligations shall remain in full force and effect for the period provided therein. However, both Parties will make best commercial efforts to cancel and limit the amount of any accrued obligations. Either Party shall not be liable for any amount that could have been avoided if cancelled upon notice of termination.

(f) No Waiver. The termination or expiration of this Agreement, as the case may be, shall not act as a waiver of any breach of this Agreement and shall not act as a release of either Party from any liability or obligation incurred under this Agreement through the date of such termination or expiration, including payments due to Glenmark pursuant to this Agreement.

ARTICLE 9

MISCELLANEOUS

9.1 Notices. Any notice, request, demand, waiver, consent, approval or other communication which is required or permitted to be given to any Party shall be in writing and shall be deemed given only if delivered to the Party personally or sent to the Party by registered mail, return receipt requested, postage prepaid, sent by a nationally recognized courier service guaranteeing next-day or second-day delivery, charges prepaid, addressed to the Party at its address set forth below, or sent by facsimile transmission to the number set forth below, or at such other address or fax number as such Party may from time to time specify by notice given in the manner provided herein to the Party entitled to receive notice hereunder:

For Glenmark: **Glenmark Pharmaceuticals Ltd.,**
Glenmark House,
B. D. Sawant Marg,
Chakala, Andheri East,
Mumbai 400099,
India

Attention: General Counsel
[***]

For Jaguar: **Jaguar Animal Health Inc.**
Suite 2375,
201 Mission Street,
San Francisco,
CA 94105,
USA

Attention: General Counsel

[***]

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9.2 Entire Agreement and Inconsistency. This Agreement (including any other attachments hereto), together with the Quality Agreement, constitutes the entire agreement between the Parties with respect to the subject matter hereof, and no oral or written statement may be used to interpret or vary the meaning of the terms and conditions hereof. In the event of a conflict or inconsistency between the provisions of this Agreement and the provisions of the Quality Agreement, this Agreement will prevail. In the event of a conflict or inconsistency between the provisions of this Agreement and any legal or regulatory requirements applicable for the Territory, amendments to this Agreement shall be considered promptly in good faith in order to meet such requirements.

9.3 Assignment. Neither Party may assign or otherwise transfer this Agreement without the prior written consent of the other Party; provided, however, that either Party may assign this Agreement without the consent of the other Party to any Affiliate or in connection with the acquisition of such Party or the sale of all or substantially all of the business or assets of the assigning Party relating to the subject matter of this Agreement, whether by merger, acquisition or otherwise. Subject to the foregoing, this Agreement shall inure to the benefit of each Party, its successors and permitted assigns. Any assignment of this Agreement in violation of this Section shall be null and void.

9.4 Force Majeure. Failure of any Party to perform its obligations under this Agreement (other than of the obligations to make any payments or of confidentiality) shall not subject such Party to any liability or place them in breach of any term or condition of this Agreement to the other Party if, and solely to the extent, such failure is caused by Force Majeure. The corresponding obligations of the other Party will be suspended to the same extent. **"Force**

Majeure” shall mean any unanticipated event, reason or cause beyond the reasonable control of a Party (including fire, flood, embargo, power shortage or failure, acts of war, insurrection, riot, terrorism, strike, lockout or other labor disturbance, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, or storm or like catastrophe, acts of God or any acts, omissions or delays in acting of the other Party); provided, however, that the Party affected shall promptly notify the other Party of the condition constituting Force Majeure as defined herein and shall exert commercially reasonable efforts to eliminate, cure and overcome any such causes and to resume performance of its obligations with all possible speed. If a condition constituting Force Majeure as defined herein prevents, or would likely prevent, a Party from performing its obligations under this Agreement for more than [one hundred twenty (120) days], the Parties shall meet to negotiate a mutually satisfactory solution to the problem, if practicable, including the use of a Third Party to fulfill the obligations hereunder of the Party invoking the Force Majeure.

9.5 Headings. The descriptive headings contained in this Agreement are for convenience of reference only and shall not affect in any way the meaning or interpretation of the Agreement.

9.6 Independent Contractor. Each Party shall be acting as an independent contractor in performing under this Agreement and shall not be considered or deemed to be an agent, employee, joint venturer or partner of the other Party. Neither Party to this Agreement shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, or to bind the other Party to any contract, agreement or undertaking with any Third Party.

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

9.8 No Third Party Beneficiaries. Nothing in this Agreement, either express or implied, is intended to or shall confer upon any Third Party any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

9.9 Amendment. This Agreement may not be amended or modified except by an instrument in writing signed by authorized representatives of Jaguar and Glenmark.

9.10 Governing Law. This Agreement and all questions regarding the existence, validity, interpretation, breach or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the laws of State of New York, New York, without reference to its conflicts of law principles.

9.11 Dispute Resolution. (a) In the event of any dispute between the Parties that relates to interpretation of a Party’s rights and/or obligations hereunder or any alleged breach of this Agreement, such dispute shall be resolved in accordance this Section. Notwithstanding the provisions of this Section, however, nothing herein contained shall preclude a party from seeking equitable remedies in any court of competent jurisdiction.

(b) Any dispute, controversy or claim arising out of or relating to this Agreement or the breach, termination or validity thereof (hereinafter referred to as “Dispute”), shall be referred for decision forthwith to a senior executive of each Party not involved in the Dispute. If no agreement is reached within thirty (30) days of the request by one Party to the other to refer the same to such senior executive, then the Parties agree to attempt to settle such Dispute through good faith non-binding mediation efforts. If after a period of thirty (30) days, the Parties have not settled the Dispute by non-binding mediation, then any such Dispute which does not involve a claim for equitable relief shall be settled by Arbitration according to the provisions of Section 9.11(c).

(c) Any Dispute that is not resolved in accordance with Section 9.11(b), shall be decided by arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association (“AAA”); such arbitration to be held in Newark, New Jersey on an expedited basis. Each Party hereby expressly waives any right to object to such jurisdiction on the basis of venue or forum non-conveniens. Any arbitration shall be conducted by three arbitrators. One arbitrator shall be selected by Jaguar, one arbitrator shall be selected by Glenmark and the third arbitrator shall be selected by the two arbitrators so selected. The arbitrators shall have no power to change the provisions of this Agreement nor to make an award of reformation. The award rendered by the arbitrators shall be final and binding upon the Parties hereto, and judgment upon the award rendered may be entered by either Party in any court that has jurisdiction over the Parties or the subject matter of the controversy or claim. The expense of such arbitration, including attorneys’ fees, shall be allocated between the Parties as the arbitrators shall decide. The arbitration panel shall prepare and deliver to the Parties a written, reasoned opinion conferring its decision. Both Parties, solely for the purpose of collection of a judgment against them, consent to jurisdiction and venue in New York, New York, USA.

9.12 No Waiver. The failure of either Party to enforce at any time for any period the provisions of or any rights deriving from this Agreement shall not be construed to be a waiver of such provisions or rights or the right of such Party thereafter to enforce such provisions.

9.13 Counterparts. This Agreement may be executed in one or more counterparts, and by the respective Parties in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one and the same Agreement.

[Signature page on the next page]

IN WITNESS WHEREOF, each Party hereto has executed or caused this Agreement to be executed on its behalf as of the Effective Date.

GLENMARK PHARMACEUTICALS LTD.

JAGUAR ANIMAL HEALTH, INC.

By: /s/ Meera Vanjari

By: /s/ Steven R. King

Name: Meera Vanjari

Name: Steven R. King

Appendix 1 — License and Relationship between Napo Pharmaceuticals and Jaguar Animal Health

Napo Pharmaceuticals formed Jaguar Animal Health to develop and commercialize animal health products. Jaguar Animal Health has obtained an exclusive worldwide license to Napo Pharmaceuticals intellectual property rights and technology for veterinary treatment uses and indications for all species of animals.

Appendix 2**Part A: Crofelemer Animal API related specifications****Specification for Animal Drug Substance (Crofelemer) for filing in NADA (Canalevia, 125mg)**

Effective: August 05, 2015

Test	Analytical Procedure	Acceptance Criteria
Appearance	Visual [***]	[***]
Solubility	[***]	[***]
Identification	IR	[***]
Infrared Absorption	USP <197K>	
UV Absorption	[***]	
Retention Time on Assay	UV USP <197U> [***]	
Assay (Anhydrous Basis)	HPLC [***]	[***]
CFTR Inhibitory Potency*	Using Epithelial Voltage [***]	25% - 120% relative potency
Residual Solvents	GC	[***]
[***]	[***]	[***]
Acetone		[***]
[***]		[***]
[***]		[***]
Water Content	Karl Fischer USP <921>, Method Ia [***]	[***]
Microbial Limits	USP <61> and USP <62>	[***]
Total Aerobic Microbial Count	[***]	[***]
Total Combined Yeasts and Molds	[***]	[***]
Count		[***]
<i>S. aureus</i>		[***]
<i>E. coli</i>		[***]
<i>P. aeruginosa</i>		[***]
Salmonella spp.		[***]
[***]	HPLC [***]	NMT 1000 ppm
Heavy Metals	USP <231> Method II [***]	[***]

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Test	Analytical Procedure	Acceptance Criteria
Related Substances	HPLC	[***]
[***]	[***]	[***]
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]
Gallocatchin		[***]
[***]		[***]
[***]		[***]
[***]		[***]

[***]		
[***]		
[***]	[***]	[***]
[***]	[***]	[***]
[***]		[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]		[***]
[***]		[***]
[***]		[***]
DP 4		[***]
[***]		[***]
[***]		[***]
Aflatoxins Content	USP <561>	[***]
Aflatoxin B ₁		[***]
Sum of Aflatoxins B ₁ B ₂ G ₁ G ₂		[***]
pH of Solution (1.25% Solution)	USP <791>	[***]
	[***]	

[***]

[***]

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Part B: CPL related specifications

Specification for Crude Plant Latex (CPL) for filing in NADA (Canalevia, 125mg)

Effective: August 05, 2015

Test	Analytical Procedure	Acceptance Criteria
[***]	[***] [***]	[***]
[***]	[***] [***]	[***]
[***]	[***] [***]	[***]
[***]	[***] [***]	[***]
[***]	[***] [***] [***]	[***]
[***]	[***] [***] [***]	[***]
[***]	[***] [***] [***]	[***]
[***]	[***] [***] [***]	[***]
[***]	[***] [***] [***] [***]	[***]
[***]	[***] [***] [***] [***]	[***]
[***]	[***] [***] [***] [***]	[***]
[***]	[***] [***] [***]	[***]
[***]	[***] [***] [***]	[***]
[***]	[***] [***] [***]	[***]
[***]	[***] [***] [***]	[***]
[***]	[***] [***] [***]	[***]
[***]	[***] [***] [***]	[***]
[***]	[***] [***] [***]	[***]
[***]	[***] [***] [***]	[***]
[***]	[***] [***] [***]	[***]

[***]

[***]

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QUALITY AGREEMENT

for

API MANUFACTURING

BETWEEN:

hereinafter referred to as *Jaguar*

AND:

Glenmark Pharmaceuticals Limited,

Glenmark House,

B. D. Sawant Marg, Chakala,

Andheri (East),

Mumbai 400 099

India

hereinafter referred to as *Glenmark*

Authorization

Name	Function name	Signature	Date
<i>Jaguar</i>			
Quality Assurance			
<i>Glenmark Pharmaceuticals Limited</i>			
Quality Assurance			

Introduction

This Quality Agreement has been entered into by the parties in order to ensure compliance with the applicable guidance and directives set forth in applicable sections 21CFR Parts 210 & 211 laying down the principles and guidelines of good manufacturing practice for medicinal products for animal use and ICH Q7 Good Manufacturing Practice Guide For Active Pharmaceutical Ingredients, providing guidance regarding good manufacturing practice for the manufacturing of active pharmaceutical ingredients under an appropriate system for managing quality. This Quality Agreement applies to the API manufacturing of specified Crofelemer Animal API for *Jaguar*.

Scope

This Quality Agreement establishes the roles, responsibilities, deliverables and time requirements with respect to the Quality Assurance of the manufacture and supply of the Crofelemer Animal API for *Jaguar*. It is an appendix to and an integral part of the Manufacture and Supply Agreement to be executed / executed by *Jaguar* and *Glenmark* (further referred as the "Agreement") dated []. *Glenmark* will operate a GMP quality controlled operation regarding (where applicable) manufacture, testing, holding, packaging, labelling, shipping and/or distribution of the Crofelemer Animal API for *Jaguar*. The Appendices attached hereto are an integral part of the Quality Agreement and shall, for all purposes, be considered as part thereof.

General

This Quality Agreement may be revised on an "as-needed or appropriate" basis or whenever the Agreement is renegotiated. Prior to implementation, any proposed changes to this Quality Agreement must be reviewed and approved in writing by authorized representatives of Quality Assurance from *Jaguar* and *Glenmark* (collectively, "Authorized Quality Representatives"). If appropriate, the Agreement shall be amended accordingly. Unless otherwise defined specifically in this Quality Agreement, all general terms used herein will be interpreted in accordance with the definitions provided in the Agreement. Any terms not so defined will be interpreted in a manner consistent with the definitions set forth in the relevant guidelines of the USA where applicable.

The Authorized Quality Representatives will address and resolve any disputes or conflicts relating to this Quality Agreement in a timely and equitable manner and in compliance with all applicable quality and regulatory requirements. Such resolutions shall be made in writing and shall be signed by the Authorized Quality Representatives. If any issue remains unresolved for more than twenty (20) business days, or any other mutually agreed timeline, the senior corporate Quality officials from *Jaguar* and *Glenmark* shall be contacted to resolve this issue.

All communication affecting the contents of this Quality Agreement will be between the Authorized Quality Representatives, as set forth below:

For *Jaguar*

Head of Quality, Jaguar

For *Glenmark*

Head of Quality, API, GPL

In the event of a change, temporary or otherwise, of either Party's Authorized Quality Representative, the relevant Party shall promptly notify the other in writing of such change, and if temporary, shall state the duration of the change.

This Quality Agreement confirms the responsibilities of *Jaguar* and *Glenmark* with regard to the quality activities described in the quality criteria tabulated below:

1. Regulatory Authorizations & GMP Compliance

No.	Responsibilities	***	***
1.1	***		***
1.2	***		***
1.3	***	***	***
1.4	***	***	
1.5	***	***	
1.6	***	***	***

2. Regulatory Actions & Inspections

No.	Responsibilities	***	***
2.1	***		***
2.2	***		***
2.3	***		***
2.4	***	***	

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No.	Responsibilities	***	***
2.5	***		***
2.6	***	***	
2.7	***	***	***

3. Facilities, Equipment and Utilities

No.	Responsibilities	***	***
3.1	***		***
3.2	***	***	***
3.3	***		***
3.4	***		***
3.5	***		***
3.6	***		***
3.7	***		***
3.8	***		***
3.9	***		***
3.10	***		***

4. Personnel

No.	Responsibilities	***	***
4.1	***		***
4.2	***		***

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No.	Responsibilities	***	***
4.3	***		***
4.4	***		***
4.5	***		***

4.6 [***]

[***]

5. Documentation for Safety

		Responsibilities	[***]	[***]
5.1	[***]			[***]
5.2	[***]			[***]

6. Manufacturing

		Responsibilities	[***]	[***]
6.1	[***]		[***]	[***]
6.2	[***]		[***]	[***]
6.3	[***]		[***]	[***]
6.4	[***]			[***]
6.5	[***]		[***]	[***]

7. Materials and consumables

		Responsibilities	[***]	[***]
7.1	[***]			[***]
7.2	[***]			[***]
7.3	[***]		[***]	
7.4	[***]		[***]	[***]

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		Responsibilities	[***]	[***]
7.5	[***]			[***]

8. Samples

		Responsibilities	[***]	[***]
8.1	[***]			[***]
8.2	[***]			[***]
8.3	[***]			[***]
8.4	[***]		[***]	[***]
8.5	[***]		[***]	[***]
8.6	[***]		[***]	[***]

9. Testing & Analysis

		Responsibilities	[***]	[***]
9.1	[***]		[***]	[***]
9.2	[***]		[***]	[***]
9.3	[***]		[***]	[***]
9.4	[***]			[***]
9.5	[***]		[***]	[***]
9.6	[***]		[***]	[***]
9.7	[***]		[***]	[***]
9.8	[***]		[***]	[***]
9.9	[***]		[***]	[***]
9.10	[***]		[***]	[***]
9.11	[***]			[***]

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10. Release

		Responsibilities	[***]	[***]
10.1	[***]		[***]	[***]
10.2	[***]		[***]	[***]
10.3	[***]		[***]	
10.4	[***]		[***]	[***]

11. Storage and Shipment

		Responsibilities	[***]	[***]
11.1	[***]		[***]	[***]

11.2	[***]	[***]
11.3	[***]	[***]

12. Returned Goods

		Responsibilities	[***]	[***]
12.1	[***]		[***]	[***]

13. Records

		Responsibilities	[***]	[***]
13.1	[***]		[***]	[***]
13.2	[***]			[***]
13.3	[***]		[***]	[***]

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14. Deviations

		Responsibilities	[***]	[***]
14.1	[***]		[***]	[***]
14.2	[***]		[***]	[***]

15. Change Management

		Responsibilities	[***]	[***]
15.1	[***]		[***]	[***]
15.2	[***]		[***]	[***]
15.3	[***]			[***]
15.4	[***]		[***]	[***]

16. Jaguar Audits

		Responsibilities	[***]	[***]
16.1	[***]		[***]	
16.2	[***]		[***]	
16.3	[***]		[***]	[***]
16.4	[***]			[***]
16.6	[***]		[***]	[***]

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17. Complaints, Recalls, Withdrawals

		Responsibilities	[***]	[***]
17.1	[***]		[***]	
17.2	[***]		[***]	[***]
17.3	[***]			[***]
17.4	[***]		[***]	[***]
17.5	[***]		[***]	[***]
17.6	[***]		[***]	[***]

18. Sub contracting

		Responsibilities	[***]	[***]
18.1	[***]		[***]	[***]
18.2	[***]		[***]	[***]
18.3	[***]		[***]	[***]

19. Stability Support

		Responsibilities	[***]	[***]
19.1	[***]		[***]	[***]
19.2	[***]		[***]	[***]
19.3	[***]		[***]	[***]
19.4	[***]		[***]	[***]

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20. Validation Support

	Responsibilities	***	***
20.1	***	***	***
20.2	***	***	***
20.3	***	***	***
20.4	***	***	***
20.5	***	***	***
20.6	***	***	***

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Definitions

Approval The term “Approval” is defined as concurrence between *Jaguar* and *Glenmark*, such as agreement on a proposed Critical Change, as evidenced in writing and signed by both companies’ Authorized Quality Representatives.

Approved Vendor A vendor who has met minimum approval standards and who has been approved by both parties to provide required items or services that may impact Crofelemer Animal API quality.

Active Pharmaceutical Ingredient

Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that when used in the production of a drug becomes active ingredient of the Finished Animal Drug Product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body of animals.

Authorized Quality Representative

An individual named within the Quality Agreement with the authority to resolve any disputes or conflicts relating to this Quality Agreement in a timely and equitable manner and in compliance with all applicable quality and regulatory requirements.

Batch A specific quantity of material produced in a process or fraction of a process. Batches are defined as the material represented at the end of the intermediate processing steps and the material represented at the end of the processing step(s).

CFR Code of Federal Regulations

COA Certificate of Analysis: An authentic document that certifies that a specific Batch of material has been evaluated in accordance with the Specifications outlined in the Supply Agreement.

Crofelemer Animal API means oligomeric proanthocyanidin (OPC) of varying chain lengths [***], for use in animal health pharmaceutical preparations as per Specifications outlined in the Supply Agreement.

Consumables Materials used as an aid in the manufacture of an Active Pharmaceutical Ingredient or Finished Animal Drug Substance that do not themselves participate in a chemical or biological reaction or being part of the Finished Animal Drug Substance, but having contact with the Finished Animal Drug Substance or Active Pharmaceutical Ingredient, as well as critical components of analytical methods

Date of Manufacture At *Glenmark* site, the date of completion for the final drying process will be classified as the Date of Manufacturing.

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Disposition Decision by *Glenmark* Quality on the suitability of the Crofelemer Animal API for further processing.

Final Release Release by *Jaguar* for final processing or use in the formulation of a Finished Animal Drug Product.

Finished Drug Product The product in it’s agreed upon finished form, ready for release. When the product is packed and labelled as registered as being an Active Pharmaceutical it is referred to as “Crofelemer Animal API”.

For Cause Visit	The term “for cause visit” is used to describe site visits, other than audits or business discussions, for the purpose of reviewing documentation, facilities or processes related to a specific deviation affecting Crofelemer Animal API disposition.
GMP / cGMP	Good Manufacturing Practice, including Current Good Manufacturing Practice: The essential rules governing the production, distribution and use of medicinal products, to safeguard public health. In this Agreement GMP means both GMP and/or cGMP.
Lot number	A unique code for each batch of Materials received. Reference is made to Part Number.
Materials	Raw materials, Consumable and/or Packaging Materials, reference is made to “Raw Materials” hereunder.
Master Batch Record	A detailed description of <i>Glenmark</i> specific production process outlining the different actions an operator has

to perform to complete the production process. A scaled copy of the Master Batch Record is the Batch production record.

OOS	Out of Specification
Part Number	A unique item number for each type of Raw Material or Consumable for identification and specification purposes. After receiving of a specific Material a Lot number might be assigned to identify individual lots of a specific Material
Raw Material	Any ingredient intended for use in the manufacture of an Active Pharmaceutical Ingredient or Finished Animal Drug Product, including those that may not appear in the final formulation. These include chemicals used directly and/or indirectly in the manufacturing process, reference is made to “Materials”
Specification	A set of criteria, limited to Critical In-Process Tests or Finished Animal Drug Substance, which must conform, to be considered acceptable for its intended use.

Details of Contact Persons

AREA	Jaguar Pharmaceuticals Inc.	Glenmark Pharmaceuticals Ltd.
Overall Quality Approval	Name: [***] Tel.: e-mail:	
General Quality Assurance	Name: [***] Tel.: e-mail:	
Audit Scheduling/Issues	Name: [***] Tel.: e-mail:	
Regulatory	Name: [***] Tel.: e-mail:	
Product Complaint	Name: [***] Tel.: e-mail:	
General Quality Control	Name: [***] Tel.: e-mail:	

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Appendix 1

- List of all Batch related Deviations
- Executive summary of all Deviations closed out as Minor,
- Reports for all Deviations closed out as Major Deviation or Critical Deviation
- Certificate of Analysis
- Certificate of Conformity
- Copies of any change controls associated with the Master Batch Record
- Copies of any validation reports associated with the Master Batch Record
- Completed copy the [***] Record

End of Quality Agreement

Appendix 4 - Illustration for Failure to Purchase Minimum Annual Quantities

The below illustration assumes commercial launch Crofelemer Animal API supplies are required [***]. The quantities and \$ values outlined in the below table are for illustration purposes only and are aimed to outline the formula for calculating the amount payable by Jaguar to Glenmark in the event the actual purchased quantity is below the Minimal Annual Purchase Quantity.

<u>Calendar Year</u>	<u>[***]</u>	<u>[***]</u>	<u>[***]</u>
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Appendix 5 — FAMC

Fully-Allocated Manufacturing Costs

As used in this Agreement, “Fully-Allocated Manufacturing Costs” or “FAMC” means:

I. FAMC includes the costs of all direct materials, direct labor and direct manufacturing overheads consumed, and allocable manufacturing overheads consumed by a manufacturing facility in the manufacture of the Crofelemer Animal API, together with appropriate: (i) allowances for manufacturing variances, (ii) allowances for inventory carrying charges, (iii) adjustments for inventory valuations as calculated using International Financial Reporting Standards (“IFRS”). FAMC shall not include license fees, royalties and other amounts paid to third parties with respect to a license or rights to or under intellectual property or proprietary rights.

For such purposes:

A. Direct material costs include:

1. The cost of raw materials, import duties and other charges (including freight) incurred by Glenmark in respect of Jaguar-Supplied CPL following its delivery by Jaguar to Glenmark, excipients, process consumables [***] to the extent not renewable and depreciable and more appropriately captured by Item I.B.2.a (below), containers, container components, packaging, labels and other printed materials used in the production of a Crofelemer Animal API.
2. Costs attributable to yield loss (Scrap of raw materials, work in progress and finished goods), exclusive of losses in excess of a reasonable allowance for wastage limits within normal industry standards for Crofelemer Animal API.

B. Direct labor costs and direct manufacturing overheads include:

1. Salaries and fringe benefits for personnel directly involved in the manufacturing process of Crofelemer Animal API at the Facility.
2. Direct manufacturing overheads consumed in the manufacturing process of Crofelemer Animal API at the Facility. Such costs may include:
 - a. Manufacturing overheads, including, but not limited to, utilities (e.g., oil, electric, steam, water), indirect manufacturing materials and supplies, consumables (e.g., production supply materials, tools, spare parts), supervision, production management, plant management, taxes (excluding income taxes) and insurance with respect to the Crofelemer Animal API at the Facility.
 - b. Maintenance and repair of the production plant and production equipment
 - c. Allowances for manufacturing variances (including yield variances within GMP tolerances)

- d. Allowances for adjustments to inventory, valuation, including reasonable charges for spoilage, expiration of shelf life and like charges related to the Crofelemer Animal API Manufactured at the Facility.

C. Allocable manufacturing overheads are limited to costs that can be identified in a practical manner with specific units of production in accordance with IFRS but cannot be included in specific direct material or direct labor and direct manufacturing overhead costs. Such overhead costs may include:

1. Engineering and development support
2. Overhead allocations of costs from service areas directly involved in the manufacture of products at the Facility, including human resources, IT, quality assurance analysis of raw materials in production, including analysis of semi-finished and finished goods produced, materials management (including wages and salaries relating to materials administration, purchasing and warehousing), regulatory affairs, validation, inventory storage, process documentation, and other services required to be performed in connection with the Manufacture of the Crofelemer Animal API at the Facility.
3. Overhead allocations of costs from service areas indirectly involved in the manufacture of Crofelemer Animal API, including finance, business development and other allied services required to be performed in connection with the Manufacture of the Crofelemer Animal API at the Facility.
4. Rent and other costs allocable to the lease of facilities, equipment or materials used to Manufacture the Crofelemer Animal API at the Facility, but only to the extent mutually agreed between the Parties in each Party's sole discretion.
5. Property and sales taxes on shipment and warehousing related to finished goods and logistics cost during shipment.

“Overheads” means the direct manufacturing overheads as listed in I B(2) and allocable manufacturing overheads as stated in I C, above.

- D. Direct labour costs and direct manufacturing overheads, as well as allocable manufacturing overheads are calculated considering the expected annual capacity utilization of the Facility, basis the Rolling Forecast shared by Jaguar for each Calendar Year.
- E. Glenmark shall, on an annual basis (at a time mutually agreed upon by the Parties), calculate the sum of (i) its actual Fully-Allocated Manufacturing Cost of manufacturing Crofelemer Animal API supplied to Jaguar in the previous twelve (12) months [***] (ii) its actual Jaguar-Supplied Material Cost of manufacturing Crofelemer Animal API supplied to Jaguar in the previous twelve (12) months (the “Actual Cost”).
- F. If the Purchase Price paid by Jaguar for Crofelemer Animal API is within five percent (5%) of the Actual Cost, then no reconciliation of the Purchase Price will be made between the Parties. If the Purchase Price paid by Jaguar for Crofelemer Animal API is greater than the Actual Cost by more than five percent (5%), then Glenmark shall reimburse Jaguar for such amount in excess of five percent (5%) within thirty (30) days of such determination. If the Purchase Price paid by Jaguar for Crofelemer animal API is less than the Actual Cost by

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more than five percent (5%), then Jaguar shall reimburse Glenmark for such amount in excess of five percent (5%) within thirty (30) days of such determination.

II. FAMC does *not* include (such costs will be charged to Jaguar post reconciliation of expenses on an annual basis or as mutually agreed upon by the Parties):

A. Cost of Jaguar-Supplied CPL.

In compliance with local regulations, it is mandatory for Glenmark to purchase the Jaguar-Supplied CPL during import. The cost towards such import will be cross-charged to Jaguar as part of the invoice for each shipment of Crofelemer Animal API to Jaguar.

B. Costs incurred due to Crofelemer Animal API rework, except the reasonable allowance included under item I.A.2.

C. The value of Crofelemer Animal API discarded in the manufacturing operation (other than process related to scrap as stated above).

D. Research and development costs.

E. Costs associated with the change of site of manufacture and the change of container, including, without limitation, the costs of satisfying registration and other requirements of regulatory authorities, re-testing of Crofelemer Animal API, reference standard qualification

F. Intercompany margins/markups on intercompany transfers between or among manufacturing plants or Affiliates.

G. Insurance related to product liability.

· [***]

· [***]

· [***]

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**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 Animal Health, Inc.;

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)) 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) Not applicable;

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

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

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

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

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

Date: November 13, 2015

/s/ Lisa A. Conte

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

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

I, John A. Kallassy, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Jaguar Animal Health, Inc.;

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)) 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) Not applicable;

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

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

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

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

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

Date: November 13, 2015

/s/ John A. Kallassy

John A. Kallassy
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 Animal Health, Inc. (the "Company") on Form 10-Q for the nine months ended September 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

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

Date: November 13, 2015

/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 Animal Health, Inc. (the "Company") on Form 10-Q for the nine months ended September 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

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

Date: November 13, 2015

/s/ John A. Kallassy

John A. Kallassy

Chief Financial Officer

(Principal Financial and Accounting Officer)
