Jaguar Animal Health, Inc.
Form S-1/A
September 09, 2014

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As filed with the Securities and Exchange Commission on September 9, 2014.

Registration No. 333-198383

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

Amendment No. 1
FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

JAGUAR ANIMAL HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**46-2956775**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

185 Berry Street, Suite 1300
San Francisco, California 94107
(415) 371-8300

(Address, including zip code, and telephone number, including area code, of registrant's principal executive office)

Lisa A. Conte
Chief Executive Officer and President
Jaguar Animal Health, Inc.
185 Berry Street, Suite 1300
San Francisco, California 94107
(415) 371-8300

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box: o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

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.

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

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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SUBJECT TO COMPLETION DATED SEPTEMBER 9, 2014

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS

Shares

Common Stock
$ per share

This is the initial public offering of Jaguar Animal Health, Inc. We are offering shares of common stock. Prior to this offering, there has been no public market for our common stock. We estimate that the initial public offering price will be between $ and $ per share.

We have applied for listing of our common stock on The NASDAQ Capital Market under the symbol "JAGX."

We are an "emerging growth company" as defined by the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 11.

	Per Share	Total
Initial public offering price	$	$
Underwriting discounts and commissions[(1)]	$	$
Proceeds, before expenses to us	$	$

(1) We refer you to "Underwriting" for additional information regarding underwriter compensation.

We have granted the underwriters a 30-day option to purchase a total of up to additional shares of common stock.

The underwriters expect to deliver shares of common stock to purchasers on or about , 2014.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

BMO Capital Markets **Guggenheim Securities**

Roth Capital Partners

The date of this prospectus is , 2014.

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Until , 2014 (25 days after the commencement of this offering), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under the circumstances and in the jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

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For investors outside the United States: we have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of securities and the distribution of this prospectus outside the United States.

Jaguar Animal Health, our logo, Canalevia and Neonorm are our trademarks that are used in this prospectus. This prospectus also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this prospectus appear without the © and symbols, but those references are not intended to indicate that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the section in this prospectus titled "Risk Factors" and our financial statements and related notes appearing elsewhere in this prospectus, before making an investment decision.

As used in this prospectus, references to "Jaguar," "we," "us" or "our" refer to Jaguar Animal Health, Inc.

Overview

Our Company

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 expect to announce data from our proof-of-concept study of Canalevia for general acute watery diarrhea in dogs in the fourth quarter of 2014. We also expect to initiate filing of a rolling new animal drug application, or NADA, for Canalevia for chemotherapy-induced diarrhea, or CID, in dogs, by 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 U.S. Food and Drug Administration, or 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 address the symptoms of watery diarrhea, or scours, in preweaned dairy calves. We plan to launch Neonorm in the United States by the end of 2014 and expect to launch additional formulations of Neonorm for other animal species beginning in 2015. 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 seven investigational new animal drug applications, or INADs, on file with the FDA and intend to develop species-specific formulations of Neonorm in six additional target species.

Diarrhea is one of the most common reasons for veterinary office visits for dogs and is the second most common reason for visits to the veterinary emergency room, yet there are no FDA-approved anti-secretory products for the treatment of diarrhea. We estimate that in the United States, veterinarians see approximately six million annual cases of acute and chronic watery diarrhea in dogs, approximately two-thirds of which are acute watery diarrhea. We believe Canalevia will be effective in treating watery diarrhea because it acts at the last physiological step, conserved across mammalian species, in the manifestation of watery diarrhea, regardless of cause, by normalizing ion and water flow in the intestinal lumen. We are first seeking a minor use, minor species, or MUMS, designation for Canalevia for CID in dogs to shorten the timeframe to commercialization. If we receive conditional approval pursuant to MUMS designation, we expect to commercialize Canalevia for CID in dogs in early 2016. We are also enrolling a proof-of-concept study of approximately 240 dogs with multiple preselected and distinct types of watery diarrhea. We are conducting this study to support full approval of Canalevia for CID, as well as protocol concurrence discussions with the FDA regarding expansion of labeled indications of watery diarrhea beyond CID to include general acute watery diarrhea. We plan to market Canalevia, if approved, through a focused direct sales force and to complement our internal efforts with distribution partners, although we do not yet have any such agreements in place.

According to the Dairy 2007 study conducted by the United States Department of Agriculture, or USDA, almost one in four preweaned dairy heifer, or female, calves suffers from diarrhea or other digestive problems. The preweaning period is generally the first 60 days after birth. Scours, diarrhea or other digestive problems are responsible for more than half of all preweaned heifer calf deaths, and

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result in supportive care and treatment costs, impaired weight gain and long-term reduction in milk production. We believe the incidence rate of scours and its corresponding financial impact represent a large opportunity and that Neonorm has the potential to effectively meet this need. In our clinical study completed in May 2014, Neonorm demonstrated a statistically significant reduction in the severity of watery diarrhea, reduced morbidity and mortality, and improved weight gain as compared to placebo in newborn dairy calves with scours.

We intend to launch Neonorm for preweaned dairy calves in the United States by the end of 2014 and have commenced initial launch activities. Our commercialization activities will initially focus on large commercial dairy operations and include active ongoing education and outreach to dairy industry key opinion leaders, such as academics involved in dairy cattle research or who advise the dairy cattle industry, as well as veterinarians. We intend to augment these commercialization efforts by working with regional distributors to leverage the geographic concentration of the dairy market in the United States. In August 2014, we entered into our first regional distribution agreement for the Upper Midwest region. We estimate that the commercial launch will cost approximately $1.0 million. We expect the ongoing launch of Neonorm to drive awareness among veterinarians regarding the utility of our first-in-class *Croton lechleri*-derived products, including Canalevia.

We have an exclusive worldwide license to Napo's intellectual property rights and technology related to our products and product candidates, including rights to its library of over 2,300 medicinal plants, for all veterinary treatment uses and indications for all species of animals. This license includes rights to Canalevia, Neonorm and other distinct prescription drug product candidates and non-prescription products in our pipeline along with the corresponding existing pre-clinical and clinical data packages.

Our management team has significant experience in gastrointestinal and animal health product development. This experience includes the development of crofelemer for human use, from discovery and preclinical and clinical toxicity studies, including the existing animal studies to be used for Canalevia regulatory approvals, through human clinical development. Our team also includes individuals who have prior animal health experience at major pharmaceutical companies, including Ciba-Geigy Corp., now Novartis International AG, SmithKline Beecham Corporation, now GlaxoSmithKline LLC, the animal health group of Pfizer Inc., now Zoetis Inc., and Vétoquinol S.A.

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Product Pipeline

We are developing a pipeline of prescription drug product candidates and non-prescription products to address unmet needs in animal health. Our pipeline currently includes prescription drug product candidates for eight indications across multiple species, and non-prescription products targeting seven species.

Prescription Drug Product Candidates

Product Candidates	Species	Indication	Recent Developments[1]	Anticipated Near-Term Milestones
Canalevia	Dogs	CID	INAD filed in November 2013[2] Scheduled MUMS designation / pre-NADA meeting	Initiate rolling NADA filing with the FDA in fourth quarter of 2014
	Dogs	General acute watery diarrhea	INAD filed in February 2014 Initiated proof-of-concept study in June 2014	Proof-of-concept data in fourth quarter of 2014 Top line pivotal efficacy data in 2015
	Horses	Acute colitis	INAD filed in February 2014 Initiated hamster *C. difficile* study in April 2014	Proof-of-concept data in second half of 2014 Apply for MUMS designation in second half of 2014 Safety data in second half of 2015
Species-specific formulations of crofelemer	Horses	Colonic and gastric ulcers[3]		Proof-of-concept data in second half of 2015
	Cats	General acute watery diarrhea	INAD filed in February 2014	Safety data in first half of 2015 Top line pivotal efficacy data in 2015
Virend (topical)	Cats	Herpes virus	INAD filed in July 2014	Proof-of-concept data in first half of 2015 Top line pivotal efficacy data in 2015
	Dogs	Insulin-resistance syndrome	INAD filing expected August 2014	
Species-specific formulations of NP-500	Horses	Metabolic syndrome	INAD filed in March 2014	
	Cats	Type II diabetes	INAD filed in March 2014	

(1) Each INAD was filed by us unless otherwise noted.

(2) Initially filed by Napo; transferred to us in March 2014

(3) In combination with omeprazole.

Non-Prescription Products

Products	Species	Use	Recent Developments	Anticipated Near-Term Milestones
Neonorm	Dairy calves	For scours in preweaned dairy calves	Initiated commercial launch activities in July 2014	Commercial launch by end of 2014 Field study data by end of 2014
	Horse foals	Normalize stool formation	Completed pilot formulation in April 2014	Safety and palatability data in 2014 Efficacy data in first half of 2015 Commercial launch in 2015
Species-specific formulations of Neonorm	Adult horses	Normalize stool formation	Completed pilot formulation in April 2014	Safety and efficacy data in first half of 2015 Commercial launch in 2015
	Sheep and other farm animals	Normalize stool formation	Initiated international market research in New Zealand in May 2014	Initiate proof-of-concept studies in various species based on market research

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Novel Mechanism of Action

Our gastrointestinal products and product candidates act by normalizing the flow of ions and water in the intestinal lumen, the dysregulation of which is the last step common to the manifestation of watery diarrhea. As a result, we believe that our products and product candidates may be effective in addressing watery diarrhea, regardless of cause. In addition, the channels that regulate this ion and water flow, including channels known as CFTR and CaCC (the sites of action of our gastrointestinal products), are generally present in mammals. We therefore expect that the clinical benefit shown in humans and preweaned dairy calves will be confirmed in multiple other species, including dogs. Accordingly, we believe we can bring to market multiple products for a range of species that are first-in-class and effective in preventing the debilitating and devastating ramifications of watery diarrhea in companion and production animals. The following diagram illustrates the mechanism of action of our gastrointestinal products and product candidates, which normalize chloride and water flow and transit time of fluids within the intestinal lumen.

Business Strategy

Our goal is to become a leading animal health company with first-in-class products that address unmet medical needs in both the companion and production animal markets. To accomplish this goal, we plan to:

Leverage our significant gastrointestinal knowledge, experience and intellectual property portfolio to develop a line of products addressing watery diarrhea for both companion and production animals. In addition to Canalevia for dogs and Neonorm for preweaned dairy calves, we are developing formulations of these products across multiple animal species and market channels.

Establish commercial capabilities, including third-party sales and distribution networks and our own targeted commercial efforts, through the launch of Neonorm. We expect to launch Neonorm by the end of 2014, and have already commenced initial launch activities for Neonorm. We intend to establish a focused direct sales force for both the companion and production animal markets, as well as partner with leading distributors to commercialize our products.

Launch Canalevia and our other product candidates for companion animals, if approved, leveraging the commercial capabilities and brand awareness we are currently building. We believe the ongoing Neonorm launch will allow us to establish sales and marketing capabilities in advance of the planned launch of Canalevia in 2016 for both CID (early 2016) and general acute watery diarrhea (2016) in dogs, to build corporate brand identity awareness, and to establish distributor relationships relevant to both our non-prescription and prescription drug product lines.

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Identify market needs that can be readily accessed and develop species-specific products by leveraging our broad intellectual property portfolio, deep pipeline and extensive botanical library. In addition to our gastrointestinal product pipeline, we are also developing products such as Virend for feline herpes and NP-500 for Type II diabetes and metabolic syndrome, both of which have been through Phase 2 human clinical testing. We have exclusive worldwide rights to a library of over 2,300 medicinal plants for all veterinary treatment uses and indications for all species of animals.

Risks Related to Our Business

Our business, and our ability to execute our business strategy, is subject to a number of risks as more fully described in the section titled "Risk Factors." These risks include, among others, the following:

We are a development stage company, have a limited operating history, have not yet generated any revenues, expect to continue to incur significant research and development and other expenses, and may never become profitable. Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

We have never generated any revenue from operations and may need to raise additional capital to achieve our goals.

We are substantially dependent on the success of our current lead prescription drug product candidate, Canalevia, and non-prescription product, Neonorm, and cannot be certain that necessary approvals will be received or that these products will be successfully commercialized.

We are dependent upon our license agreement with Napo, and if this agreement is terminated, we will be unable to commercialize our products and our business will be harmed.

The results of earlier studies may not be predictive of the results of our pivotal trials or other future studies, and we may be unable to obtain any necessary regulatory approvals for our existing or future prescription drug product candidates under applicable regulatory requirements.

Development of prescription drug products, and to a lesser extent, non-prescription products, for the animal health market is inherently expensive, time-consuming and uncertain, and any delay or discontinuance of our current or future pivotal trials, or dosage or formulation studies, would harm our business and prospects.

Even if we obtain any required regulatory approvals for our current or future prescription drug product candidates, they may never achieve market acceptance or commercial success.

We are dependent upon contract manufacturers for supplies of our current prescription drug product candidates and non-prescription products and, in the short term, intend to rely on contract manufacturers for commercial quantities of any of our commercialized products.

If we are not successful in identifying, developing and commercializing additional prescription drug product candidates and non-prescription products, our ability to expand our business and achieve our strategic objectives would be impaired.

Corporate Information

We were founded in San Francisco, California as a Delaware corporation on June 6, 2013. Napo formed our company to develop and commercialize animal health products. As of December 31, 2013, we were a wholly-owned subsidiary of Napo, and as of June 30, 2014, we are a majority-owned subsidiary of Napo. Upon the closing of this offering, we will no longer be majority-owned by Napo. See "Certain Relationships and Related Person Transactions Transactions with Napo" and " Napo Arrangements" for information regarding our transactions with Napo.

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Our executive offices are located at 185 Berry Street, Suite 1300, San Francisco, California 94107, and our telephone number is (415) 371-8300. Our website address is www.jaguaranimalhealth.com. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated by reference into this prospectus and should not be considered to be part of this prospectus.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from specified disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We can take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we were to generate more than $1.0 billion in annual revenues, have more than $700.0 million in market value of our capital stock held by non-affiliates or issue more than $1.0 billion of non-convertible debt over a three-year period. As an emerging growth company, we may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of some reduced reporting burdens in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

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The Offering

Common stock offered by us	shares (or shares if the underwriters exercise their option to purchase additional shares in full)
Common stock to be outstanding after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full)
Option to purchase additional shares	We have granted the underwriters a 30-day option to purchase up to additional shares of our common stock to cover over-allotments, if any.
Use of proceeds	We intend to use the net proceeds from this offering for further development work for Canalevia, for commercial launch activities for Neonorm and associated field studies, for establishing manufacturing capabilities, and for other research and product development activities, working capital and general corporate purposes. See "Use of Proceeds" for a more detailed description of the intended use of proceeds from this offering.
Risk factors	See "Risk Factors" and other information included in this prospectus for a discussion of factors that you should consider carefully before deciding to invest in our common stock.
Proposed NASDAQ Capital Market symbol	"JAGX"

The number of shares of common stock to be outstanding after this offering is based on 4,311,498 shares of common stock outstanding as of June 30, 2014, and excludes:

311,498 shares of common stock issuable upon exercise of outstanding warrants as of June 30, 2014 with an exercise price of $1.6854 per share;

25,000 shares of common stock issuable upon exercise of an outstanding warrant as of June 30, 2014 with an exercise price equal to 90% of the initial public offering price;

50,000 shares of our common stock issuable upon exercise of outstanding warrants issued after June 30, 2014 with an exercise price equal to 80% of the initial public offering price;

1,129,673 shares issuable upon exercise of outstanding options as of June 30, 2014 with a weighted-average exercise price of $1.77 per share;

118,953 shares issuable upon vesting of outstanding restricted stock unit awards as of June 30, 2014;

22,674 shares of common stock reserved for future issuance under our 2013 Equity Incentive Plan as of June 30, 2014; and

500,000 shares of common stock reserved for future issuance under our 2014 Stock Incentive Plan, which will become effective in connection with this offering, as well as any automatic increases in the shares of common stock reserved for future issuance under the 2014 Stock Incentive Plan.

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Unless otherwise indicated, the information in this prospectus assumes the following:

- the filing of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, which will be in effect as of the closing of this offering;
- the conversion of all outstanding shares of Series A preferred stock into 3,015,902 shares of common stock on a one-for-one basis upon the closing of this offering;
- the issuance of shares of common stock upon the conversion of convertible promissory notes in the aggregate principal amount of $450,000 (which includes $150,000 aggregate principal amount of notes issued in July 2014) upon the closing of this offering at a conversion price equal to 80% of the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and which shares will be unregistered;
- no conversion into shares of common stock of up to $1,000,000 aggregate principal amount of borrowings under our standby letter of credit entered into in August 2014;
- no exercise of outstanding options or warrants, or issuance of shares upon the vesting of restricted stock units; and
- no exercise by the underwriters of their option to purchase additional shares of common stock.

Recent Developments

Subsequent to June 30, 2014, we completed the following transactions and issuances of securities.

Convertible Promissory Notes

In July 2014, we issued convertible promissory notes in the aggregate principal amount of $150,000. Upon the closing of this offering, these notes will convert into shares of common stock at a conversion rate equal to 80% of the initial public offering price per share, and which shares will be unregistered.

Standby Line of Credit and Warrant Issuance

In August 2014, we entered into a standby line of credit with an individual, who is an accredited investor, for up to $1.0 million pursuant to a Line of Credit Loan Agreement dated August 26, 2014. The minimum amount of any drawdown is $250,000, the lender has no obligation to fund more than once every 10 calendar days, we must provide 15 business days prior notice for any drawdown and may not drawdown funds after March 31, 2015. Outstanding borrowings bear interest at a rate of 3.0% per annum, and all borrowings are due in full on the one-year anniversary of our first drawdown. Following closing of this offering, outstanding principal amounts borrowed under the standby line of credit may be converted, at the option of the lender, into shares of our common stock at a conversion price equal to 80% of the initial public offering price per share. In connection with the entry into the standby line of credit, we issued the lender a warrant to purchase 50,000 shares of our common stock at an exercise price equal to 80% of the initial public offering price per share, which expires in August 2016.

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Summary Selected Financial Data

The following tables set forth a summary of our selected historical financial data as of and for the periods ended on the dates indicated. We have derived the statements of comprehensive loss data for the period from June 6, 2013 (inception) through December 31, 2013 from our audited financial statements included elsewhere in this prospectus. We have derived the statements of comprehensive loss data for the period from June 6, 2013 (inception) through June 30, 2014 and for the six months ended June 30, 2014, and the balance sheet data as of June 30, 2014 from our unaudited interim financial statements appearing elsewhere in this prospectus. The unaudited interim financial statements have been prepared on the same basis as our audited financial statements and, in our opinion, reflect all adjustments, consisting only of normal and recurring adjustments, which we consider necessary for a fair presentation of our financial position as of June 30, 2014. You should read this data together with our financial statements and related notes appearing elsewhere in this prospectus and the sections in this prospectus titled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The historical results are not necessarily indicative of the results to be expected for any future periods and the results for the six months ended June 30, 2014 should not be considered indicative of results expected for the full year 2014.

	Period from June 6, 2013 (inception) through December 31, 2013	Six Months Ended June 30, 2014 (unaudited)	Period from June 6, 2013 (inception) through June 30, 2014 (unaudited)
Statements of Comprehensive Loss Data:			
Operating expenses:			
General and administrative expense	$ 458,473	$ 1,740,515	$ 2,198,988
Research and development expense	324,479	2,149,555	2,474,034
Total operating expenses	782,952	3,890,070	4,673,022
Loss from operations	(782,952)	(3,890,070)	(4,673,022)
Interest expense, net	(18,251)	(20,164)	(38,415)
Net loss and comprehensive loss	$ (801,203)	$ (3,910,234)	$ (4,711,437)
Accretion of redeemable convertible preferred stock		(285,009)	(285,009)
Net loss attributable to common stockholders	$ (801,203)	$ (4,195,234)	$ (4,996,446)
Net loss per share attributable to common stockholders, basic and diluted[(1)]	$ (0.20)	$ (0.99)	
Weighted-average common shares outstanding, basic and diluted[(1)]	4,000,000	4,250,929	

Pro forma net loss per share, basic and diluted[1]	$ (0.20)	$ (0.67)
Pro forma weighted-average number of common shares outstanding, basic and diluted[1]	4,000,000	6,304,461

(1) See Notes 2 and 12 to our financial statements for a description of the method used to compute basic and diluted net loss per share and pro forma net loss per share.

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	As of June 30, 2014		
	Actual	Pro Forma[1]	Pro Forma, As Adjusted[2][3]
		(unaudited)	
Balance Sheet Data:			
Cash and cash equivalents	$ 4,281,698	$	$
Total assets	6,217,115		
Total liabilities	3,175,169		
Convertible promissory notes	231,250		
Redeemable convertible preferred stock	6,943,250		
Total stockholders' (deficit)	(3,901,304)		

(1) Pro forma column reflects (i) the conversion of all outstanding shares of Series A preferred stock into shares of common stock upon the closing of this offering; (ii) the issuance of shares of common stock upon the conversion of convertible promissory notes in the aggregate principal amount of $450,000 (which includes $150,000 aggregate principal amount of notes issued in July 2014) upon the closing of this offering at a conversion price equal to 80% of the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus; and (iii) the filing and effectiveness of our amended and restated certificate of incorporation upon the closing of this offering.

(2) Pro forma as adjusted column further reflects the sale of shares of common stock that we are offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) each of cash and cash equivalents, total assets and total stockholders' equity (deficit) on a pro forma as adjusted basis by approximately $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) each of cash and cash equivalents, total assets, and total stockholders' equity (deficit) on a pro forma as adjusted basis by approximately $ million, assuming the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions. The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may harm our business, financial condition, results of operations and prospects.

Risks Related to Our Business

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

Since formation in June 2013, our operations have been primarily limited to the research and development of our lead prescription drug product candidate, Canalevia, to treat various forms of watery diarrhea in dogs, and our lead non-prescription product, Neonorm, to address symptoms of scours in preweaned dairy calves. As a result, we have no meaningful historical operations upon which to evaluate our business and prospects and have not yet demonstrated an ability to commercialize any of our products, obtain any required marketing approval for any of our prescription drug product candidates or successfully overcome the risks and uncertainties frequently encountered by companies in emerging fields such as the animal health industry. We also have not generated any revenue to date, and expect to continue to incur significant research and development and other expenses. Our net loss and comprehensive loss for the period from June 6, 2013 (inception) through December 31, 2013 was $801,203 and for the six months ended June 30, 2014 was $3,910,234. As of June 30, 2014, we had a total stockholders' deficit of $3,901,304. We expect to continue to incur losses for the foreseeable future, which will increase significantly from historical levels as we expand our product development activities, seek necessary approvals for our product candidates, conduct species-specific formulation studies for our non-prescription products and begin commercialization activities. Even if we succeed in developing and commercializing one or more of our products or product candidates, we expect to continue to incur losses for the foreseeable future, and we may never become profitable. If we fail to achieve or maintain profitability, then we may be unable to continue our operations at planned levels and be forced to reduce or cease operations.

Our auditors have included an explanatory paragraph in their audit report on our financial statements for the year ended December 31, 2013, 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 that the successful completion of this offering will eliminate the doubt and enable us to continue as a going concern. However, if we are unable to successfully complete this offering, we will need to obtain alternate financing or create operational plans to continue as a going concern.

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

We are an animal health company focused on developing and commercializing prescription drug and non-prescription products for companion and production animals. Since formation in June 2013, we have not generated any revenue from operations. There is no guarantee that our commercial launch of Neonorm for preweaned dairy calves in late 2014 in the United States will be successful or that we will be able to sell any products in the future. Further, in order to commercialize our prescription drug

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product candidates, we must receive regulatory approval from the FDA in the United States and other regulatory agencies in various jurisdictions. We have not yet received any regulatory approvals for our prescription drug product candidates. In addition, certain of our non-prescription products, such as Neonorm, may be subject to regulatory approval outside the United States prior to commercialization. Accordingly, until and unless we receive any necessary regulatory approvals, we cannot market or sell our products. Moreover, even if we receive the necessary approvals, we may not be successful in generating revenue from sales of our products as we do not have any experience marketing or distributing our products. Accordingly, we may never generate any material revenue from our operations.

We expect to incur significant additional costs as we begin commercialization efforts for Neonorm, and undertake the clinical trials necessary to obtain regulatory approvals for Canalevia, which will increase our losses.

We currently anticipate commencing sales of Neonorm for preweaned dairy calves by the end of 2014. To do this, we will need to invest in developing our internal and third-party sales and distribution network and outreach efforts to key opinion leaders in the dairy industry, including veterinarians. We will also need to conduct clinical trials for Canalevia in order to obtain necessary initial regulatory approvals and subsequently broaden Canalevia to additional indications and additional species. We will also need to conduct species-specific testing with Neonorm to expand to additional animal populations.

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

identifying additional potential prescription drug product candidates and non-prescription products;

formulation studies;

conducting pilot, pivotal and toxicology studies;

completing other research and development activities;

payments to technology licensors;

maintaining our intellectual property;

obtaining necessary regulatory approvals;

establishing commercial manufacturing and supply capabilities; and

sales, marketing and distribution of our commercialized products.

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

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

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We may need to raise additional capital to achieve our business goals and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, limit, reduce or terminate one or more of our product development programs or future commercialization efforts.

We believe the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operating plan through the planned commercial launch of Neonorm for preweaned dairy calves and anticipated commercial launch of Canalevia for CID in dogs, as well as for general acute watery diarrhea in dogs. However, we may experience unexpected events that require us to seek additional funds sooner than planned through public or private equity or debt financings or other sources such as strategic collaborations. We do not expect that the net proceeds from this offering will be sufficient to complete the development of all the current products in our pipeline, or any additional products we may identify. We may need to raise additional capital to fund these activities. We have no current agreements or arrangements with respect to any such financings or collaborations, and any such financings or collaborations may result in dilution to our stockholders, the imposition of debt covenants and repayment obligations or other restrictions that may harm our business or the value of our common stock. We may also seek from time to time to raise additional capital based upon favorable market conditions or strategic considerations such as potential acquisitions.

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

- the scope, progress, results and costs of researching and developing our current and future prescription drug product candidates and non-prescription products;
- the timing of, and the costs involved in, obtaining any regulatory approvals for our current and any future products;
- the number and characteristics of the products we pursue;
- the cost of manufacturing our current and future products and any products we successfully commercialize;
- the cost of commercialization activities for Neonorm and Canalevia, if approved, including sales, marketing and distribution costs;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- our ability to establish and maintain strategic collaborations, distribution or other arrangements and the financial terms of such agreements; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing possible patent claims, including litigation costs and the outcome of any such litigation.

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

We are substantially dependent on the success of Canalevia and Neonorm and cannot be certain that Canalevia will be approved or that we can successfully commercialize these products.

We currently do not have any products for sale and do not have regulatory approval for any of our prescription drug product candidates, including Canalevia. Our current efforts are primarily focused on the commercial launch of Neonorm in the United States by the end of 2014,

and development efforts related to Canalevia for CID in dogs. We are also focused on expanding Canalevia's proposed

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indications to cover general acute watery diarrhea in dogs and full FDA approval for CID for dogs. Accordingly, our near-term prospects, including our ability to generate material product revenue, obtain any new financing if needed to fund our business and operations or enter into potential strategic transactions, will depend heavily on the success of Neonorm and, if approved, Canalevia.

Substantial time and capital resources have been previously devoted by third parties in the development of crofelemer, the active pharmaceutical ingredient, or API, in Canalevia, and the botanical extract used in Neonorm. Both crofelemer and the botanical extract used in Neonorm were originally developed at Shaman Pharmaceuticals, Inc., or Shaman, by certain members of our management team, including Lisa A. Conte, our Chief Executive Officer and President, and Steven R. King, Ph.D., our Executive Vice President, Sustainable Supply, Ethnobotanical Research and Intellectual Property. Shaman spent significant development resources before voluntarily filing for bankruptcy in 2001 pursuant to Chapter 11 of the U.S. Bankruptcy Code. The rights to crofelemer and the botanical extract used in Neonorm, as well as other intellectual property rights, were subsequently acquired by Napo from Shaman in 2001 pursuant to a court approved sale of assets. Ms. Conte founded Napo in 2001 and is the current interim chief executive officer of Napo and a member of its board of directors. While at Napo, certain members of our management team, including Ms. Conte and Dr. King, as well as Charles O. Thompson, our Executive Vice President, Chief Financial Officer, Secretary and Treasurer, continued the development of crofelemer. In 2005, Napo entered into license agreements with Glenmark Pharmaceuticals Ltd. and Luye Pharma Group Limited for rights to various human indications of crofelemer in certain territories as defined in the respective license agreements with these licensees. Subsequently, after expending significant sums developing crofelemer, including trial design and on-going patient enrollment in the final pivotal Phase 3 trial for crofelemer for non-infectious diarrhea in adults with HIV/AIDS on antiretroviral therapy, in late 2008, Napo entered into a collaboration agreement with Salix Pharmaceuticals, Inc., or Salix, for development and commercialization rights to certain indications worldwide and certain rights in North American, Europe, and Japan, to crofelemer for human use. 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 crofelemer and the botanical extract used in Neonorm, for all veterinary treatment uses and indications for all species of animals. In February 2014, most of the executive officers of Napo, and substantially all Napo's employees, became our employees. If we are not successful in the development and commercialization of Neonorm and Canalevia, our business and our prospects will be harmed.

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

- the successful completion of the pivotal trials and toxicology studies for Canalevia, which may take significantly longer than we currently anticipate and will depend, in part, upon the satisfactory performance of third-party contractors;
- our ability to demonstrate to the satisfaction of the FDA and any other regulatory bodies, the safety and efficacy of Canalevia;
- our ability and that of our contract manufacturers to manufacture supplies of Neonorm and Canalevia and to develop, validate and maintain viable commercial manufacturing processes that are compliant with current good manufacturing practices, or cGMP, if required;
- the success of Neonorm field studies and acceptance of their results by dairy producers;
- our ability to successfully launch Neonorm, whether alone or in collaboration with others;
- our ability to successfully launch Canalevia assuming approval is obtained, whether alone or in collaboration with others;

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

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

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

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

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

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

Although a substantial amount of our efforts are focused on the commercial launch of Neonorm and the continued development and potential approval of Canalevia, a key element of our strategy is to identify, develop and commercialize a portfolio of products to serve the animal health market. Most of our potential products are based on our knowledge of medicinal plants. Our current focus is primarily on product candidates and products for animals whose active pharmaceutical ingredient or botanical extract has been successfully commercialized or demonstrated to be safe and effective in human trials. In some instances, we may be unable to further develop these potential products because of perceived regulatory and commercial risks. Even if we successfully identify potential products, we may still fail to yield products for development and commercialization for many reasons, including the following:

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

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

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

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

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

While we are developing species-specific formulations, including flavors, methods of administration, new patents and other strategies with respect to our current potential products, we may be unable to prevent competitors from developing substantially similar products and bringing those products to market earlier than we can. If such competing products achieve regulatory approval and commercialization prior to our potential products, our competitive position may be impaired. If we fail

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to develop and successfully commercialize other potential products, our business and future prospects may be harmed and we will be more vulnerable to any problems that we encounter in developing and commercializing our current potential products.

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

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

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

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

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

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

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of animal health products are subject to extensive regulation. We are usually not permitted to market our prescription drug product candidates in the United States until we receive approval of an NADA from the FDA. To gain approval to market an animal prescription drug for a particular species, we must provide the FDA with efficacy data from pivotal trials that adequately demonstrate that our prescription drug product candidates are safe and effective in the target species (*e.g.*, dogs, cats or horses) for the intended indications. In addition, we must provide manufacturing data evidencing that we can produce our product candidates in accordance with cGMP. For the FDA, we must also provide data from toxicology studies, also called target animal safety studies, and in some cases environmental impact data. In addition to our internal activities, we will partially rely on contract research organizations, or CROs, and other third parties to conduct our toxicology studies and for certain other development activities. The results of toxicology studies and other initial development activities, and of any previous studies in humans or animals conducted by us or third parties, may not be predictive of future results of pivotal trials or other future studies, and failure can occur at any time during the conduct of pivotal trials and other development activities by us or our CROs. Our pivotal trials may fail

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to show the desired safety or efficacy of our prescription drug product candidates despite promising initial data or the results in previous human or animal studies conducted by others, and success of a prescription drug product candidate in prior animal studies, or in the treatment of humans, does not ensure success in subsequent studies. Clinical trials in humans and pivotal trials in animals sometimes fail to show a benefit even for drugs that are effective because of statistical limitations in the design of the trials or other statistical anomalies. Therefore, even if our studies and other development activities are completed as planned, the results may not be sufficient to obtain a required regulatory approval for a product candidate.

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

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

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

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

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

Our product pipeline includes a number of species-specific formulations of Neonorm, our lead non-prescription product. The results of our dairy calf studies and other initial development activities and of any previous studies in humans or animals conducted by us or third parties may not be predictive of future results of these formulation studies. Failure can occur at any time during the conduct of these trials and other development activities. Even if our species-specific formulation studies and other development activities are completed as planned, the results may not be sufficient to pursue a particular line extension for Neonorm. Further, even if we obtain promising results from our species-specific formulation studies, we may not successfully commercialize any line extension. Because line extensions are developed for a particular species market, we may not be able to leverage our experience from the commercial launch of Neonorm in new animal species markets. If we are not successful in developing and successfully commercializing these line extension products, we may not be able to grow our revenue and our business may be harmed.

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

Development of prescription drug products for animals remains an inherently lengthy, expensive and uncertain process, and our development activities will be successful. We do not know whether our

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current or planned pivotal trials for any of our product candidates, will begin or conclude on time, and they may be delayed or discontinued for a variety of reasons, including if we are unable to:

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

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

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

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

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

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Even if we obtain regulatory approval for Canalevia or our other product candidates, they may never achieve market acceptance. Further, even if we are successful in commercially launching Neonorm, it may not achieve commercial success.

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

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

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

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

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

- cost containment measures within the dairy industry, in response to international, national and local general economic conditions, which may affect the market adoption of our products;
- state and federal government policies, including government-funded programs or subsidies whose discontinuance or modification could erode the demand for our products;
- a decline in demand for dairy products due to changes in consumer diets away from dairy products, which could adversely affect the demand for production animal health products;

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

disease or other conditions beyond our control.

Animal products, like human products, are subject to unanticipated post-approval safety or efficacy concerns, which may harm our business and reputation.

The success of our commercialization efforts will depend upon the perceived safety and effectiveness of animal health products, in general, and of our products, in particular. Unanticipated safety or efficacy concerns can subsequently arise with respect to approved prescription drug products,

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or non-prescription products, such as Neonorm, which may result in product recalls or withdrawals or suspension of sales, as well as product liability and other claims. Any safety or efficacy concerns, or recalls, withdrawals or suspensions of sales of our products, or human products derived from *Croton lechleri*, if any, could harm our reputation and business, regardless of whether such concerns or actions are justified.

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

Under current federal and state laws, companion and production animals are generally considered to be the personal property of their owners and, as such, the owners' recovery for product liability claims involving their companion and production animals may be limited to the replacement value of the animal. Companion animal owners and their advocates, however, have filed lawsuits from time to time seeking non-economic damages such as pain and suffering and emotional distress for harm to their companion animals based on theories applicable to personal injuries to humans. If new legislation is passed to allow recovery for such non-economic damages, or if precedents are set allowing for such recovery, we could be exposed to increased product liability claims that could result in substantial losses to us if successful. In addition, some horses can be worth millions of dollars or more, and product liability for horses may be very high. While we currently have product liability insurance, such insurance will be sufficient to cover any future product liability claims against us.

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

Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We are highly dependent upon our senior management, particularly Lisa A. Conte, our President and Chief Executive Officer, Serge Martinod, D.V.M., Ph.D., our Chief Veterinary Officer and Charles O. Thompson, our Chief Financial Officer. The loss of services of any of our key personnel would cause a disruption in our ability to develop our current or future product pipeline and commercialize our products and product candidates. Although we have offer letters with these key members of senior management, such agreements do not prohibit them from leaving our employ at any time. We currently do not maintain "key man" life insurance on any of our senior management team. The loss of Ms. Conte, Dr. Martinod, Mr. Thompson or other members of our current senior management could adversely affect the timing or outcomes of our current and planned studies, as well as the prospects for commercializing our products.

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

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

The raw material used to manufacture Canalevia and Neonorm is crude plant latex, or CPL, derived from the *Croton lechleri* tree, which is found in countries in South America, principally Peru. The ability of our contract suppliers to harvest CPL is governed by the terms of their respective agreements with local government authorities. Although CPL is available from multiple suppliers, we

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only have contracts with two suppliers to obtain CPL and arrange the shipment to our contract manufacturer. Accordingly, if our contract suppliers do not or are unable to comply with the terms of our respective agreements, and we are not able to negotiate new agreements with alternate suppliers on terms that we deem commercially reasonable, it may harm our business and prospects. The countries from which we obtain CPL could change the laws and regulations regarding the export of the natural products or impose or increase taxes or duties payable by exporters of such products. Restrictions could be imposed on the harvesting of the natural products or additional requirements could be implemented for the replanting and regeneration of the raw material. Such events could have a significant impact on our cost and ability to produce Canalevia, Neonorm and anticipated line extensions.

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

To date, the CPL, API, botanical extract and some finished products that we have used in our studies and trials were obtained from Napo. We have also contracted with third parties for the formulation of API into finished products for our studies. We have entered into memorandums of understanding with Indena S.p.A. for the manufacture of CPL received from our suppliers into the API in Canalevia from CPL to support our regulatory filings, as well as the botanical extract in Neonorm and agreed to negotiate a commercial supply agreement. Indena S.p.A. has never manufactured either such ingredient. We also plan to contract with different third parties for the formulation and supply of finished products, which we will use in our planned studies and commercialization efforts. However, we have not entered into any definitive agreements with any third parties for the supply of commercial quantities of finished products.

We also intend to use a portion of the net proceeds from this offering to develop our own manufacturing capability for the API in Canalevia. However, we do not yet have such capability, and we cannot be certain that we will have sufficient funds to develop this facility, and we may not be able to successfully manufacture the API in Canalevia. If we are not able to develop our own manufacturing capability, we will be dependent upon our contract manufacturer for the supply of the API in Canalevia. We currently have approximately 2,000 kg of the botanical extract used in Neonorm. However, we will require additional quantities of the botanical extract if our planned 2014 commercial launch of Neonorm is successful. If we are not successful in reaching agreements with third parties on terms that we consider commercially reasonable for manufacturing and formulation, or if our contract manufacturer and formulator are not able to produce sufficient quantities or quality of API, botanical extract or finished product under their agreements, it could delay our plans and harm our business prospects.

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

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facilities for the same product candidate or any approved product. We are also exposed to risk if our third-party contractors do not comply with the negotiated terms of our agreements, or if they suffer damage or destruction to their facilities or equipment.

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

We currently have no sales, marketing or distribution capabilities, and we have no prior experience in the sale, marketing and distribution of animal health products. We intend to launch Neonorm for preweaned dairy calves by the end of 2014 in collaboration with one or more distribution partners. In August 2014, we entered into our first regional distribution agreement for the Upper Midwest region. There are significant risks involved in building and managing a sales organization, including our potential inability to attract, hire, retain and motivate qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively oversee a geographically-dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities and entry into adequate arrangements with distributors would adversely impact the commercialization of Neonorm, and Canalevia, if approved. If we are not successful in commercializing Neonorm, Canalevia or any of our other line extension products, either on our own or through one or more distributors, we may never generate significant revenue and may continue to incur significant losses, which would harm our financial condition and results of operations.

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

In the United States, animal owners typically purchase their animal prescription drugs from their local veterinarians who also prescribe such drugs. There is a trend, however, toward increased purchases of animal prescription drugs from Internet-based retailers, "big-box" retail stores and other over-the-counter distribution channels, which follows an emerging shift in recent years away from the traditional veterinarian distribution channel. It is also possible that animal owners may come to rely increasingly on Internet-based animal health information rather than on their veterinarians. We currently expect to market our animal prescription drugs directly to veterinarians, so any reduced reliance on veterinarians by animal owners could harm our business and prospects, by making it more difficult or expensive for us to distribute our prescription drug products. Animal owners also may substitute human health products for animal prescription drugs if the human health products are less expensive or more readily available, which could also harm our business.

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

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

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

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

As of August 31, 2014, we have 14 employees. Our ability to manage our growth effectively will require us to hire, train, retain, manage and motivate additional employees and to implement and improve our operational, financial and management systems. These demands also may require the hiring of additional senior management personnel or the development of additional expertise by our senior management personnel. If we fail to expand and enhance our operational, financial and management systems in conjunction with our potential future growth, it could harm our business and operating results.

Our research and development relies on evaluations in animals, which is controversial and may become subject to bans or additional regulations.

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

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

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

Under the Animal Medicinal Drug Use Clarification Act of 1994, veterinarians are permitted to prescribe extra-label uses of certain approved animal drugs and approved human drugs for animals under certain conditions. While veterinarians may in the future prescribe and use human-approved products or our products for extra-label uses, we may not promote our products for extra-label uses. If the FDA determines that any of our marketing activities constitute promotion of an extra-label use, we could be subject to regulatory enforcement, including seizure of any misbranded or mislabeled drugs, and civil or criminal penalties, any of which could have an adverse impact on our reputation and expose us to potential liability. We will continue to spend resources ensuring that our promotional claims for our products and product candidates remain compliant with applicable FDA laws and regulations, including materials we post or link to on our website. For example, in 2012, our Chief Executive Officer received an "untitled letter" from the FDA while at Napo regarding preapproval promotion statements constituting misbranding of crofelemer, which was then an investigational drug. These statements were included in archived press releases included on Napo's website. Napo was required to expend time and resources to revise its website to remove the links in order to address the concerns raised in the FDA's letter.

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

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

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

Although we requested MUMS designation for Canalevia for CID in dogs, we may not be granted MUMS designation. Even if granted, we may not receive or maintain the benefits associated with MUMS designation. As the sponsor, we are allowed under FDA regulations to apply for MUMS designation of our product candidate prior to its approval. MUMS designation is a status similar to "orphan drug" status for human drugs. If we are granted MUMS designation, we are eligible for incentives to support the approval or conditional approval of the designated use. This designation does not allow us to commercialize a product until such time as we obtain approval or conditional approval of the product.

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

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

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

It is very difficult to estimate the commercial potential of any of our products because of the emerging nature of our industry as a whole. The animal health market continues to evolve and it is difficult to predict the market potential for our products. The market will depend on important factors such as safety and efficacy compared to other available treatments, changing standards of care, preferences of veterinarians, the willingness of companion and production animal owners to pay for such products, and the availability of competitive alternatives that may emerge either during the product development process or after commercial introduction. If the market potential for our products

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is less than we anticipate due to one or more of these factors, it could negatively impact our business, financial condition and results of operations. Further, the willingness of companion and production animal owners to pay for our products may be less than we anticipate, and may be negatively affected by overall economic conditions. The current penetration of animal insurance in the United States is low, animal owners are likely to have to pay out-of-pocket, and such owners may not be willing or able to pay for our products.

Our largest stockholder, Napo, controls a significant percentage of our common stock, and its interests may conflict with those of our other stockholders.

Upon the closing of this offering, Napo will beneficially own in the aggregate % of our common stock. This concentration of ownership gives Napo significant influence over the way we are managed and the direction of our business. In addition, because we and Napo are party to a license agreement, Napo's interests as the licensor of our technology may be different from ours or those of our other stockholders. As a result, the interests of Napo with respect to matters potentially or actually involving or affecting us, such as future acquisitions, licenses, financings and other corporate opportunities and attempts to acquire us, may conflict with the interests of our other stockholders. In addition, our chief executive officer is also the interim chief executive officer of Napo and her duties as interim chief executive officer of Napo may conflict with her duties as our chief executive officer, and the resolution of these conflicts may not always be in our or your best interest.

Napo's principal business currently consists of, among other activities, the management of its intellectual property portfolio, including rights under license agreements with respect to such intellectual property. Napo has limited assets, and its primary sources of revenues in recent years have been license fees, warrant exercises, equity and debt investments and, since late 2013, the receipt of royalties pursuant to its license agreements, which have been limited to date. If Napo fails to generate sufficient revenues to cover its operating costs, it could revise its business strategy in ways that could affect its relationship with our company. For example, it could decide to divest its assets, including its stock in our company. Napo's interests in managing its business, including its ownership in our company, may conflict with your interests.

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

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

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

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

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

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

Risks Related to Intellectual Property

We are dependent upon our license agreement with Napo and if the agreement is terminated for any reason our business will be harmed.

In January 2014, we entered into a license agreement with Napo, or the Napo License Agreement, which we amended and restated in August 2014. Pursuant to the Napo License Agreement, 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 terms of the Napo License Agreement, we are responsible for, and shall ensure, the development and commercialization of products that contain or are derived from the licensed Napo technology worldwide in the field of veterinary treatment uses and indications for all species of animals. In consideration for the license, we are obligated to pay a one-time non-refundable license fee and royalties. Napo has the right to terminate the Napo License Agreement upon our uncured material breach of the agreement or if we declare bankruptcy. If the Napo License Agreement is terminated for any reason, our business will be harmed.

Napo has also entered into a security and collateral assignment agreement with Nantucket Investments Limited with respect to certain assets, including the intellectual property and technology licensed to us pursuant to the Napo License Agreement. In the event of a bankruptcy of Napo or foreclosure action with respect to Napo's assets, the bankruptcy trustee or any other party to such action may attempt to interfere with or terminate the Napo License Agreement or otherwise require its terms to be changed, which could harm our business. Under the terms of the Napo License Agreement, certain events, such as an acquisition of Napo or a sale by Napo of all of the intellectual property and technology licensed to us pursuant to the Napo License Agreement, should result in a fully-paid up license to us of all of such intellectual property and technology. If for any reason, Napo ceases to be the owner of the intellectual property and technology licensed to us pursuant to the Napo License Agreement in such a manner that did not result in a fully-paid up license provided for therein, the owner of such intellectual property and technology could attempt to interfere with or terminate the Napo License Agreement or otherwise attempt to renegotiate the arrangement, which would harm our business.

If Napo experiences financial difficulties and becomes unable to pay its liabilities when due and declare bankruptcy, its creditors could attempt to asserts claims against Napo relating to the formation of our company and the grant of an exclusive license to us.

Napo formed our company in June 2013, and in January 2014, we entered into the Napo License Agreement. Napo currently has no commercial operations and its potential sources of revenue are limited to the third parties who have licensed or may license Napo's intellectual property and technology, or collaborate with Napo in the future. Napo has been involved in litigation with Salix and has expended significant resources in the litigation. At the time of the formation of our company and the date of the Napo License Agreement, Napo's liabilities exceeded its assets on a balance sheet prepared in conformity with U.S. generally accepted accounting principles. Napo has been able to pay its liabilities when due but if Napo experiences financial difficulties and becomes unable to pay its