Jaguar Animal Health, Inc.
Form S-1/A
April 17, 2015

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As filed with the Securities and Exchange Commission on April 17, 2015.

Registration No. 333-198383

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

Amendment No. 6
To

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)

Copies to:

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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 o (Do not check if a smaller reporting company)	Smaller reporting company ý

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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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 **SUBJECT TO COMPLETION** **DATED APRIL 17, 2015**

3,150,000 Shares
Common Stock

This is a firm commitment initial public offering 3,150,000 shares of our common stock by Jaguar Animal Health, Inc. No public market currently exists for our shares. We anticipate that the initial public offering price of our shares of common stock will be $7.00 per share.

Our common stock has been approved for listing on The NASDAQ Capital Market under the symbol "JAGX."

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

Our business and an investment in our securities involves a high degree of risk. See "Risk Factors" beginning on page 12 of this prospectus for a discussion of information that you should consider before investing in our securities.

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.

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

(1) The underwriters will receive compensation in addition to the underwriting discount. The registration statement, of which this prospectus is a part, also registers for sale warrants to purchase 157,500 shares of our common stock to be issued to the representative of the underwriters. We have agreed to issue the warrants to the representative of the underwriters as a portion of the underwriting compensation payable to the underwriters in connection with this offering. See "Underwriting" beginning on page 125 of this prospectus for a description of compensation payable to the underwriters, including a description of the warrants.

We have granted a 45-day option to the underwriters to purchase up to 472,500 additional shares of common stock solely to cover over-allotments, if any.

The underwriters expect to deliver the shares against payment therefor on or about , 2015.

Sole Book-Running Manager

Aegis Capital Corp

Co-Managers

CRT Capital **Feltl and Company**

, 2015

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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. We are not, and the underwriters are not, making an offer of these securities in any jurisdiction where such offer is not permitted.

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 ©, ® or 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 achieved statistically significant results in a canine proof-of-concept study completed in February 2015, supporting the conclusion that Canalevia treatment is superior to placebo, with 91% of the Canalevia-treated dogs achieving a formed stool during the study versus 50% of the placebo-treated dogs. We also initiated filing of a rolling new animal drug application, or NADA, with the U.S. Food and Drug Administration, or FDA, for Canalevia for chemotherapy-induced diarrhea, or CID, in dogs, at the end of 2014. Canalevia is a canine-specific formulation of crofelemer, an active pharmaceutical ingredient isolated and purified from the *Croton lechleri* tree. A human-specific formulation of crofelemer, Fulyzaq, was approved by the FDA in 2012 for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. Members of our management team developed crofelemer, including while at Napo Pharmaceuticals, Inc., or Napo. Neonorm is our lead non-prescription product to improve gut health and normalize stool formation in animals suffering from watery diarrhea, or scours. We launched Neonorm in the United States at the end of 2014 for preweaned dairy calves under the brand name Neonorm Calf and expect to launch additional formulations of Neonorm for other animal species in 2015. We have already shipped approximately $450,000 of Neonorm Calf to distributors. Neonorm is a botanical extract also derived from the *Croton lechleri* tree. Canalevia and Neonorm are distinct products that are formulated to address specific species and market channels. We have filed nine investigational new animal drug applications, or INADs, with the FDA and intend to develop species-specific formulations of Neonorm in six additional target species.

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 from the FDA 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 completed a canine proof-of-concept study in February 2015, with statistically significant results, in support of protocol concurrence discussions with the FDA regarding expansion of labeled indications of watery diarrhea beyond CID to include general watery diarrhea. We plan to market Canalevia, if approved, through a focused direct sales force and to complement our internal efforts with distribution partners.

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 result in supportive care and treatment costs, impaired weight gain and long-term reduction in milk production.

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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 recently launched Neonorm for preweaned dairy calves under the brand name Neonorm Calf. Our commercialization activities are initially focusing 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 as well as national distributors to provide wider geographic access to our products. We recently signed a distribution agreement with a veterinary biotechnology company in Latin America for exclusive distribution rights of Neonorm Calf in Argentina, Brazil, Paraguay, Uruguay, and Bolivia. In addition, where appropriate, we intend to explore other international distribution and partnership arrangements. In August 2014, we entered into our first regional distribution agreement for the Upper Midwest region, and in September 2014, entered into an agreement with a national master distributor, who also distributes prescription products for the companion animal market. We expect the ongoing launch of Neonorm to drive awareness among veterinarians regarding the utility of our first-in-class anti-secretory *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. We also recently expanded our intellectual property portfolio to include combinations of our proprietary anti-secretory product lines, Canalevia and Neonorm, with the non-absorbed antibiotic, rifaximin, for gastrointestinal indications in all animals.

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 SmithKline Beecham Corporation, now GlaxoSmithKline LLC, the animal health group of Pfizer Inc., now Zoetis Inc., Vétoquinol S.A., Merial Limited, the animal health division of Sanofi S.A., as well as management experience at major veterinary hospital institutions.

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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	Anticipated Near-Term Milestones
Canalevia	Dogs	CID	MUMS designation / pre-NADA meeting in October 2014 Initiated rolling NADA filing in December 2014	Conditional NADA approval in 1st quarter of 2016
	Dogs	General watery diarrhea	INAD filed in February 2014 Statistically significant proof-of-concept data in February 2015	Concurrence meeting with FDA in 2015 Initiation of pivotal trial in 2015 Initiate filing NADA in 1st quarter of 2016
	Horses	Acute colitis	INAD filed in February 2014	Safety data in 2nd half of 2015 Apply for MUMS designation in 2nd half of 2015
Species-specific formulations of crofelemer	Horses	Diarrhea, colonic and gastric ulcers(1)	INAD filed in February 2015	Proof-of-concept data in 2nd half of 2015
	Cats	General watery diarrhea	INAD filed in February 2014 Initiated safety and palatability study in cats with diarrhea in March 2015	Safety and proof-of-concept data in 2nd half of 2015/1st quarter of 2016
Virend (topical)	Cats	Herpes virus	INAD filed in July 2014	Proof-of-concept and top line pivotal efficacy data in 1st quarter of 2016
	Dogs	Obesity-related metabolic dysfunction	INAD filed September 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) In combination with omeprazole and/or sucralfate.

Non-Prescription Products

Products	Species	Use	Recent Developments	Anticipated Near-Term Milestones
Neonorm Calf	Dairy calves	Improve gut health and	National launch in February 2015 U.S. regional and nationwide distribution	Field study results in 2nd quarter of 2015 (study has been ongoing since 4th quarter of 2014);

		normalize stool formation in preweaned dairy calves with scours	agreements signed in 2nd half of 2014 South American distribution agreement signed in 1st quarter of 2015, commercial launch in 2016 Approximately $450,000 of product shipped since commercial launch	includes evaluation of prebiotic effect
	Horse foals	Normalize stool formation	Completed pilot formulation in April 2014 Completed safety and palatability study in November 2014	Safety and efficacy data in 2nd half of 2015 Commercial launch in 2015
Species-specific formulations of Neonorm	Adult horses	Normalize stool formation		Safety and efficacy data in 1st quarter of 2016
	Other farm/production animals	Normalize stool formation	Initiated market research in New Zealand and China in 2014	Initiate proof-of-concept studies based on market research within the next 12 months

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Novel Mechanism of Action

Our anti-secretory 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, preweaned dairy calves and dogs will be confirmed in multiple other species, including cats and horses. 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.

We have recently supplemented our anti-secretory product line by filing intellectual property for combinations with rifaximin, a non-absorbed antibiotic. Rifaximin is approved for human use for the treatment of traveler's diarrhea and chronic administration for hepatic encephalopathy. It is not approved for oral administration in veterinary health, and provides another opportunity for local drug administration (*i.e.*, non-systemic) in the gut of the animal to target bacterial causes of watery diarrhea coincident with an anti-secretory approach to normalization of ion and water flow associated with watery diarrhea.

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 Croton lechleri-derived products for both production and companion 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 recently launched Neonorm in the United States under the brand name Neonorm Calf. We intend to establish a focused direct sales force for both the companion and production animal markets, as well as continue to 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

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planned launch of Canalevia for both CID (early 2016) and general 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.

Expand to international markets. We intend to leverage our proprietary product development in the United States to international markets, with meaningful partnerships to address international requirements for product development, registration, and access to commercialization in relevant markets for each of our prescription and non-prescription products. We may also enter into partnerships that include payment of upfront licensing fees for our products and product candidates for markets outside the United States where appropriate.

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 pipeline product candidates, both *Croton lechleri* and rifaximin-based, 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 have a limited operating history, have not yet generated any material 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 material 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, either by us or any of our partners.

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 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.

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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 December 31, 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.

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	3,150,000 shares (or 3,622,500 shares if the underwriters exercise their option to purchase additional shares in full)
Common stock to be outstanding after this offering	8,409,923 shares (or 8,882,423 shares if the underwriters exercise their option to purchase additional shares in full)
Option to purchase additional shares	We have granted the underwriters a 45-day option to purchase up to 472,500 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 development work for Canalevia and our other prescription drug products, for studies and commercial activities related to Neonorm, for formulation costs and establishing contract manufacturing capabilities, repayment of $1.3 million of indebtedness 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 5,259,923 shares of common stock outstanding as of December 31, 2014, and excludes:

207,664 shares of common stock issuable upon exercise of outstanding warrants as of December 31, 2014 with an exercise price of $2.5281 per share;

16,666 shares of common stock issuable upon exercise of an outstanding warrant as of December 31, 2014 with an exercise price of $6.30 per share;

269,938 shares of our common stock issuable upon exercise of outstanding warrants as of December 31, 2014 with an exercise price of $5.60 per share;

111,605 shares of common stock issuable upon exercise of outstanding warrants issued after December 31, 2014 with an exercise price of $5.60 per share;

659,554 shares issuable upon exercise of outstanding options as of December 31, 2014 with a weighted-average exercise price of $2.67 per share;

68,902 shares issuable upon vesting of outstanding restricted stock unit awards, or RSUs, as of December 31, 2014;

1,484 shares issuable upon vesting of outstanding RSUs issued after December 31, 2014;

203,030 shares issuable upon exercise of stock options, which were authorized after December 31, 2014, and which will be granted effective upon this offering with an exercise price equal to the initial public offering price;

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up to 44,642 shares of common stock issuable upon conversion of outstanding convertible promissory notes in the aggregate principal amount of $250,000 issued after December 31, 2014;

25,197 shares of common stock reserved for future issuance under our 2013 Equity Incentive Plan; and after taking into account the grant of an equity awards for an aggregate of 204,514 shares under our 2013 Equity Incentive Plan after December 31, 2014; and

333,333 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.

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

a 1-for-1.5 reverse stock split of our common stock effected on October 27, 2014;

the filing of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, which will be in effect upon the closing of this offering;

the conversion of all 3,015,902 outstanding shares of Series A preferred stock into 2,010,596 shares of common stock upon the closing of this offering;

the issuance of 374,997 shares of common stock upon the conversion of convertible promissory notes in the aggregate principal amount of $2,100,000 upon the closing of this offering at a conversion price of $5.60 per share (which includes $1,000,000 aggregate principal amount issued after December 31, 2014), and which shares will be unregistered;

no conversion into shares of common stock of up to $1.0 million 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 December 31, 2014, we completed the following transactions and issuances of securities.

In February 2015, we issued an additional $250,000 aggregate principal amount of convertible promissory notes to two accredited investors and amended and restated the terms of the $650,000 convertible promissory notes issued in December 2014 to conform the terms. All $900,000 aggregate principal amount of these notes bear interest at 12% per annum and become payable upon demand by the holders within 30 days following this offering. In the event this offering is consummated on, or prior to, June 30, 2015, the noteholders may convert the notes at a conversion price equal to $5.60 per share (80% of the initial public offering price). If these notes have not been converted prior to July 31, 2015, nor declared due and payable by the holders within 30 days after this offering, the maturity date will automatically be extended to July 31, 2016 if we have not otherwise elected to prepay these notes within 30 days after this offering. We also issued these investors three-year warrants to purchase an aggregate of 80,355 shares of our common stock (determined by dividing 50% of the corresponding original principal amount issued by the current exercise price). If this offering is consummated prior to June 30, 2015, the exercise price will be $5.60 per share. In March 2015, holders of $650,000 aggregate principal amount of these notes issued in December 2014 irrevocably elected to have their notes automatically convert into shares of our common stock upon the closing of this offering at a conversion price of $5.60 per share. Accordingly,

we expect to issue these holders an aggregate of 116,070 shares of our common stock.

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In March 2015, we entered into a non-binding letter of intent with Dechra Pharmaceuticals PLC, pursuant to which we agreed to negotiate a licensing agreement for rights to commercialize our leading prescription drug product candidate, Canalevia, for dogs in the European Union. In connection therewith, Dechra purchased $1.0 million of our convertible promissory notes, the terms of which provide that such notes will automatically convert into shares of our common stock upon the closing of this offering at a conversion price of $5.60 per share. In connection with the purchase of the notes, we also issued Dechra a warrant to purchase approximately 89,285 shares at $5.60 per share, which expires December 31, 2017.

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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 and for the year ended December 31, 2014 from our audited financial statements included elsewhere in this prospectus. 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.

	Period from June 6, 2013 (inception) through December 31, 2013	Year Ended December 31, 2014
Statements of Comprehensive Loss Data:		
Operating expenses:		
General and administrative expense	$ 458,473	$ 4,095,324
Research and development expense	324,479	4,220,338
Total operating expenses	782,952	8,315,662
Loss from operations	(782,952)	(8,315,662)
Interest expense, net	(18,251)	(345,336)
Change in fair value of warrants		51,423
Net loss and comprehensive loss	$ (801,203)	$ (8,609,575)
Accretion of redeemable convertible preferred stock		(646,673)
Net loss attributable to common stockholders	$ (801,203)	$ (9,256,248)
Net loss per share attributable to common stockholders, basic and diluted(1)	$ (0.30)	$ (3.24)
Weighted-average common shares outstanding, basic and diluted(1)	2,666,666	2,854,417
Pro forma net loss per share, basic and diluted(1)	$ (0.30)	$ (2.02)

Pro forma weighted-average number of common shares outstanding, basic and diluted(1)	2,666,666	4,592,283

(1) See Notes 2 and 13 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 December 31, 2014		
	Actual	Pro Forma(1)	Pro Forma, As Adjusted(2)(3)
		(unaudited)	
Balance Sheet Data:			
Cash and cash equivalents	$ 845,192	$ 2,095,192	$ 18,301,692
Total assets	4,506,630	5,756,630	21,963,130
Convertible notes payable	424,674	250,000	250,000
Notes payable	478,709	478,709	
Warrant liability	601,889		
Total liabilities	5,436,964	4,660,401	4,181,692
Redeemable convertible preferred stock	7,304,914		
Total stockholders' equity (deficit)	(8,235,248)	1,096,229	17,781,438

(1) Pro forma column reflects (i) the conversion of all 3,015,902 outstanding shares of Series A preferred stock into 2,010,596 shares of common stock upon the closing of this offering; (ii) the issuance of 374,997 shares of common stock upon the conversion of convertible promissory notes in the aggregate principal amount of $2,100,000 upon the closing of this offering at a conversion price equal to $5.60 per share; (iii) the issuance of $1,250,000 aggregate principal amount of convertible promissory notes after December 31, 2014 ($1,000,000 of which will convert into shares of common stock upon the closing of this offering); (iv) the modification in March 2015 of $650,000 aggregate principal amount of convertible promissory notes issued in December 2014 to automatically convert into shares of common stock upon the closing of this offering at a conversion price equal to $5.60 per share; and (v) 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 (i) the sale of 3,150,000 shares of common stock that we are offering at an initial public offering price of $7.00 per share, after deducting underwriting discounts and estimated offering expenses payable by us and (ii) the repayment of our $1.0 million standby bridge facility.

(3) A $1.00 increase (decrease) in the initial public offering price of $7.00 per share 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 $2.9 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 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 $6.5 million, assuming the initial public offering price remains the same, and after deducting underwriting discounts. 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 improve gut health and normalize stool formation in preweaned dairy calves with scours, and the recent commercial launch of Neonorm. As a result, we have limited meaningful historical operations upon which to evaluate our business and prospects and have not yet demonstrated an ability to broadly commercialize any of our 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 material revenue to date, and expect to continue to incur significant research and development and other expenses. Our net loss and comprehensive loss for the year ended December 31, 2014 was $8,609,575. As of December 31, 2014, we had an accumulated deficit of $9,410,778. 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 though we recently commercially launched Neonorm and if we succeed in developing and broadly commercializing one or more of our products or product candidates, we expect to continue to incur losses for the foreseeable future, and we may never become profitable. If we fail to achieve or maintain profitability, then we may be unable to continue our operations at planned levels and be forced to reduce or cease operations.

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

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

We are 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 material revenue from operations. There is no guarantee that our recent commercial launch of Neonorm for preweaned dairy calves in the United States will be successful or that we will be able to sell any products in the future. Further, in order to commercialize our prescription drug product candidates, we must receive regulatory approval from the FDA in the United States and other regulatory

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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 meaningful experience marketing or distributing our products. Accordingly, we may never generate any material revenue from our operations.

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

We recently commenced sales of Neonorm for preweaned dairy calves in the United States under the brand name Neonorm Calf. We will need to continue to invest in developing our internal and third-party sales and distribution network and outreach efforts to key opinion leaders in the 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 supply capabilities; and

sales, marketing and distribution of our commercialized products.

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

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

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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 April 2016 and anticipated commercial launch of Canalevia for CID in dogs, as well as for the pivotal data and regulatory filing with the FDA to expand the indication to general watery diarrhea in dogs. However, 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. Other than our standby line of credit (under which we had $1.0 million available as of December 31, 2014), 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 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, and development efforts related to Canalevia for CID in dogs.

We are also focused on expanding Canalevia's proposed indications to cover general watery diarrhea in dogs and full FDA approval for CID for dogs. Accordingly, our near-term prospects, including our ability to generate material

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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 and Secretary. Shaman spent significant development resources before voluntarily filing for bankruptcy in 2001 pursuant to Chapter 11 of the U.S. Bankruptcy Code. The rights to crofelemer and the botanical extract used in 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, continued the development of crofelemer. In 2005, Napo entered into license agreements with Glenmark Pharmaceuticals Ltd., or Glenmark, 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 America, 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;
- 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;

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

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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, Nexvet Biopharma and ImmuCell Corporation. We also compete with academic institutions, governmental agencies and private organizations that are conducting research in the field of animal health products.

Although there are currently no FDA-approved anti-secretory products to treat 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 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

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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. We intend to use a portion of the proceeds of this offering for formulation costs associated with developing such species-specific formulations. 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 Calf 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 may not be successful. We do not know whether our current or planned pivotal trials for any of our product candidates, will begin or conclude on time, and they may be delayed or discontinued for a variety of reasons, including if we are unable to:

- address any safety concerns that arise during the course of the studies;
- complete the studies due to deviations from the study protocols or the occurrence of adverse events;
- add new study sites;

address any conflicts with new or existing laws or regulations; or

reach agreement on acceptable terms with study sites, which can be subject to extensive negotiation and may vary significantly among different sites.

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Further, 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.

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;

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- 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 Calf, is heavily dependent on factors that affect the dairy market that are beyond our control, including the following, any of which may harm our business:

- cost containment measures within the dairy industry, in response to international, national and local general economic conditions, which may affect the market adoption of our products;
- state and federal government policies, including government-funded programs or subsidies whose discontinuance or modification could erode the demand for our products;
- a decline in demand for dairy products due to changes in consumer diets away from dairy products, which could adversely affect the demand for production animal health products;
- adverse weather conditions and natural disasters, such as floods, droughts, and pestilence, which can lower dairy yields; and
- disease or other conditions beyond our control.

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, 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 may not be sufficient to cover any future product liability claims against us.

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

Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We are highly dependent upon our senior management, particularly

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Lisa A. Conte, our President and Chief Executive Officer, and John A. Kallassy, our Executive Vice President, Chief Financial Officer, Chief Operating Officer and Treasurer. The loss of services of any of our key personnel would cause a disruption in our ability to develop our current or future product pipeline and commercialize our products and product candidates. Although we have offer letters with these key members of senior management, such agreements do not prohibit them from resigning at any time. For example, the resignation of our former Chief Financial Officer, Charles O. Thompson, in September 2014, and the mutually agreed departure of our former Chief Veterinary Officer, Serge Martinod, D.V.M., Ph.D. in February 2015, caused us to incur additional expenses and expend resources to ensure a smooth transition with their respective successors, which diverted management attention away from executing our operational plan during this period. We currently do not maintain "key man" life insurance on any of our senior management team. The loss of Ms. Conte, Mr. Kallassy 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 field 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 only have contracts with two suppliers to obtain CPL and arrange the shipment to our contract manufacturer. Accordingly, if our contract suppliers do not or are unable to comply with the terms of our respective agreements, and we are not able to negotiate new agreements with alternate suppliers on terms that we deem commercially reasonable, it may harm our business and prospects. The countries from which we obtain CPL could change their laws and regulations regarding the export of the natural products or impose or increase taxes or duties payable by exporters of such products. Restrictions could be imposed on the harvesting of the natural products or additional requirements could be implemented for the replanting and regeneration of the raw material. Such events could have a significant impact on our cost and ability to produce 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 and botanical extract 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 to support our regulatory filings, as well as the botanical extract in Neonorm and agreed to negotiate a commercial supply agreement. Indena S.p.A. has never manufactured either such ingredient to commercial scale. As a second supplier situation, we have entered into a non-binding letter of intent with Glenmark for the supply of the API in Canalevia. Glenmark is the current manufacturer of crofelemer, the active API in Canalevia, for the FDA-approved human anti-secretory product, and the manufacturer on

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file for the NADA to which we have a right of reference. 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 will be dependent upon our contract manufacturers for the supply of the API in Canalevia. We currently have sufficient quantities of the botanical extract used in Neonorm to support initial commercialization of Neonorm. However, we will require additional quantities of the botanical extract if our 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 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 or other revenue.

We currently have limited sales, marketing or distribution capabilities, and prior to our recent launch of Neonorm for preweaned dairy calves, had no experience in the sale, marketing and distribution of animal health products. There are significant risks involved in building and managing a sales organization, including our potential inability to attract, hire, retain and motivate qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively oversee a geographically-dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities and entry into adequate arrangements with distributors or other partners would adversely impact the commercialization of 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, or in generating upfront licensing or other fees, we may never generate significant revenue and may continue to incur significant losses, which would harm our financial condition and results of operations.

Changes in distribution channels for animal 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

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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.

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

As of March 31, 2015, we had 17 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.

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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.

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 conditional approval or approval prior to our product candidate for the same indication or species. In addition, MUMS designation may be withdrawn for a variety of reasons such as where the FDA determines that the request for designation was materially defective, or if the manufacturer is unable to assure sufficient quantity of the prescription drug product to meet the needs of animals with the rare disease or condition. If this designation is lost, it could have a negative impact on the product and 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.

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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 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 31.7% 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. Further, Napo has pledged its interests in our common stock as security for certain of its monetary obligations. Accordingly, Napo's ability to take action with respect to these shares may be limited by its agreements with its secured lenders, which may conflict with your interests or those of our other stockholders. If these secured lenders were to foreclose on such shares, these lenders would have significant influence over the way we are managed and the direction of our business. 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.

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

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

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

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

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 and further amended in January 2015. 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 secured financing agreements with certain secured lenders, for whom Nantucket Investments Limited is acting as collateral agent. The security includes certain assets, including the intellectual property and technology licensed to us pursuant to the Napo License Agreement and Napo's shares of our common stock. Although Napo and Nantucket Investments Limited, on behalf of the secured lenders, have entered into a non-disturbance agreement with respect to the Napo License Agreement, in the event of a bankruptcy of Napo or foreclosure action with respect to Napo's assets, there can be no guarantee that the bankruptcy trustee or any other party to such action will not 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.

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If Napo experiences financial difficulties, becomes unable to pay its liabilities when due, or declares bankruptcy, its creditors could attempt to assert 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, becomes unable to pay its liabilities when due, or declares bankruptcy, a creditor, trustee in bankruptcy, or other representative of a Napo bankruptcy estate could attempt to assert claims against us relating to our formation and Napo's grant of an exclusive license to us. One theory such a party could use to challenge our formation and the license grant is that of fraudulent conveyance. This theory is used by creditors to challenge the transfer of assets made with actual intent to hinder, delay, or defraud creditors, or where a financially distressed entity transfers assets without receiving reasonably equivalent value in exchange, provided such litigation is brought within the applicable statute of limitations. Although we do not believe that our formation or Napo's grant of the license was a fraudulent conveyance, litigation based on such theory, if successful, could result in a court order setting aside the license for the benefit of the creditor pursuing the litigation or all creditors of Napo should it occur in the context of a Napo bankruptcy. Even if unsuccessful, any such action would divert management's attention, potentially be costly to defend and could harm our business.

We currently do not own any issued patents, most of our intellectual property is licensed from Napo and we cannot be certain that our patent strategy will be effective to enhance marketing exclusivity.

The patent prosecution process is expensive and time-consuming, and we may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of inventions made in the course of development and commercialization activities in time to obtain patent protection on them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. In particular, we are dependent upon Napo and its licensees to file, prosecute and maintain the intellectual property we license pursuant to the Napo License Agreement. The patents and patent applications we licensed from Napo, or the Napo Patents, which cover both human and veterinary uses, are also licensed by Napo to Salix for certain fields of human use. Under the terms of the collaboration agreement between Salix and Napo, or the Salix Collaboration Agreement, Napo and Salix agreed on who has the first right and responsibility to file, prosecute and maintain the Napo Patents. As a result, under the Napo License Agreement, we only have the right to maintain any issued patents within the Napo Patents that are not maintained in accordance with the rights and responsibilities of the parties under the Salix Collaboration Agreement. There are three issued Napo Patents in the United States that cover, collectively, enteric protected formulations of proanthocyanidin polymers isolated from *Croton spp.* and methods of treating watery diarrhea using the enteric protected formulations for both human and veterinary uses.

Napo has also licensed its *Croton lechleri* related intellectual property to Salix, Glenmark and Luye Pharma Group Limited to develop and commercialize crofelemer for human indications in various geographies. In May 2011, Napo filed a lawsuit against Salix in the Supreme Court of the State of New York, County of New York, alleging, among other items, that Salix had breached its collaboration agreement with Napo. By orders entered in December 2013 and January 2014, the court granted Salix's motion for partial summary judgment and narrowed the issues for trial. In February 2014, the jury rendered its verdict, concluding that Salix had complied with its contractual obligations in commercializing

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Fulyzaq in the United States, and had not breached the collaboration agreement. In May 2014, Napo filed a notice of appeal from the court's partial summary judgment ruling as well as from certain court rulings and the judgment entered in February 2014. That appeal is pending. Fulyzaq is dependent upon intellectual property protection from the Napo Patents. Salix currently markets Fulyzaq in the United States for human use and has listed the three issued Napo Patents in the FDA's Orange Book for Fulyzaq. We rely on these issued Napo Patents as intellectual property protection for our prescription drug product candidates and non-prescription products. Pending patent applications within Napo Patents either may not be relevant to veterinary indications and/or may not issue as patents. If any patent application within the Napo Patents is not filed or prosecuted as provided in the Salix Collaboration Agreement, including due to a lack of financial resources, and we are not able to file and prosecute such patent application within the Napo Patents, our business may be harmed. Also, under the Salix Collaboration Agreement, Napo and Salix have agreed on who has the first right to enforce the Napo Patents against potential infringers. In addition, as between Napo and us, Napo has the first right to enforce the Napo Patents against potential infringers. If we are not the party who enforces the Napo Patents, we will receive no proceeds from such enforcement action. In each case, such proceeds are subject to reimbursement of costs and expenses incurred by the other party in connection with such action. If our current or future licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated.

We currently do not own any issued patents. We have filed eleven provisional patent applications in the veterinary field, of which we control the filing, prosecution and maintenance; however, patents based on any patent applications we may submit may never be issued. We have an exclusive worldwide license from Napo to various issued patents and pending patent applications in the field of animal health. The strength of patents in the field of animal health involves complex legal and scientific questions and can be uncertain. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents, if issued, and the patents we have licensed may not adequately protect our intellectual property or prevent others from designing around their claims. If we cannot obtain issued patents or the patents we have licensed are not maintained or their scope is significantly narrowed, our business and prospects would be harmed.

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

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

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

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

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

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

There has been substantial litigation regarding patents and other intellectual property rights in the field of therapeutics, as well as patent challenge proceedings, including interference, derivation and administrative law proceedings before the USPTO, and oppositions and other comparable proceedings in

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foreign jurisdictions. Under U.S. patent reform laws, new procedures, including *inter partes* review and post-grant review, were implemented as of September 16, 2012, with post-grant review available for patents issued on applications filed on or after March 16, 2013, and the implementation of such reform laws presents uncertainty regarding the outcome of any challenges to our future patents, if any, and to patents we have in licensed. In addition to possible infringement claims against us, we may be subject to third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review, or other patent office proceedings or litigation in the United States or elsewhere, challenging our patent rights or the patent rights of others. For applications filed before March 16, 2013 or patents issuing from such applications, if third parties have prepared and filed patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO to determine the priority of invention. Because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either file patent applications on or invent any of the inventions claimed in our patent applications. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. We may also become involved in opposition or similar proceedings in patent offices in other jurisdictions regarding our intellectual property rights with respect to our prescription drug or non-prescription products and technology. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our future patent rights, if any, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

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

Composition-of-matter patents on the API in prescription drug products are generally considered to be the strongest form of intellectual property protection because such patents provide protection without regard to any particular method of use or manufacture or formulation of the API used. The composition-of-matter patents for crofelemer, the API in Canalevia, have expired, and we have licensed from Napo patents and applications covering formulations and methods of use for crofelemer and the botanical extract in Neonorm.

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

If our efforts to protect intellectual property are not adequate, we may not be able to compete effectively in our markets.

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

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If the breadth or strength of protection provided by any patents, patent applications or future patents we may own, license, or pursue with respect to any of our current or future product candidates or products is threatened, it could threaten our ability to commercialize any of our current or future product candidates or products. Further, if we encounter delays in our development efforts, the period of time during which we could market any of our current or future product candidates or products under any patent protection we obtain would be reduced.

Given the amount of time required for the development, testing and regulatory review of new product candidates or products, patents protecting such candidates might expire before or shortly after such product candidates or products are commercialized. Patent term extensions have been applied for US 7,323,195 and US 7,341,744 to account for regulatory delays in obtaining human marketing approval for crofelemer, however, only one patent may be extended per marketed compound. If such extensions are received, then US 7,323,195 may be extended to June 2021 or US 7,341,744 may be extended to December 2020. However, the applicable authorities, including the USPTO and the FDA, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to patents, or may grant more limited extensions than requested. If this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

Even where laws provide protection or we are able to obtain patents, costly and time-consuming litigation may be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us, and some of our competitors have substantially greater intellectual property portfolios than we have.

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

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

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

We may be involved in lawsuits to protect or enforce any future patents issued to us, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe upon any patents that may issue to us, or any patents that we may license. To counter infringement or unauthorized use of any patents we may obtain, we may be required to file infringement claims or request that our licensor file an infringement claim, which can be expensive and

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time-consuming to litigate. In addition, if we or one of our future collaborators were to initiate legal proceedings against a third party to enforce a patent covering our current product candidates, or one of our future products, the defendant could counterclaim that the patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as *ex parte* reexaminations, *inter partes* review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party.

Litigation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be unsuccessful, it could have an adverse effect on the price of our common stock. Finally, we may not be able to prevent, alone or with the support of our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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

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

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

Filing, prosecuting and defending patents on prescription drug products, product candidates and non-prescription products throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may

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compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

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

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

In October 2014, our trademark applications for Canalevia and Neonorm were approved for publication. Although we have filed a trademark application for our company name and our logo in the United States, our applications have not been granted and the corresponding marks have not been registered in the United States. We have not filed for these or other trademarks in any other countries. During trademark registration proceedings, we may receive rejections of our trademark applications. If so, we will have an opportunity to respond, but we may be unable to overcome such rejections. In addition, the USPTO and comparable agencies in many foreign jurisdictions may permit third parties to oppose pending trademark applications and to seek to cancel registered trademarks. If opposition or cancellation proceedings are filed against any of our trademark applications or any registered trademarks, our trademarks may not survive such proceedings. Moreover, any name we propose to use with our prescription drug product candidates in the United States, including Canalevia, must be approved by the FDA, regardless of whether we have registered or applied to register as a trademark. The FDA typically conducts a review of proposed prescription drug product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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

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

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Risks Related to Government Regulation

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

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

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, revised labeling, or voluntary or involuntary product recalls;
- fines, warning letters or holds on target animal studies;
- refusal by the FDA, or other regulators to approve pending applications or supplements to approved applications filed by us or our strategic collaborators related to the unknown problems, or suspension or revocation of the problematic product's license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

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

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

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

We intend to seek protocol concurrences with the FDA for the pivotal trial of Canalevia that we plan to conduct for general watery diarrhea in dogs and for future pivotal trials in other indications. A pivotal study protocol is submitted to the FDA voluntarily by a drug sponsor for purposes of obtaining FDA review of the protocol. Prior FDA review of the protocol for a pivotal study makes it more likely that the study will generate information the sponsor needs to demonstrate whether the drug is safe and effective for its intended use. It creates an expectation by the sponsor that the FDA should not later alter its perspectives on these issues unless public or animal health concerns appear that were not recognized at the time of protocol assessment. Even if the FDA issues a protocol concurrence, ultimate approval of an

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NADA by the FDA is not guaranteed because a final determination that the agreed-upon protocol satisfies a specific objective, such as the demonstration of efficacy, or supports an approval decision, will be based on a complete review of all the data submitted to the FDA. Even if we were to obtain protocol concurrence such concurrence does not guarantee that the results of the study will support a particular finding or approval of the new drug.

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

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

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

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

changes to manufacturing methods;

new requirements related to approval to enter the market;

recall, replacement, or discontinuance of certain products; and

additional record keeping.

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

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

The FDA retains jurisdiction over all prescription drug products however, in many instances, the Federal Trade Commission will exercise primary or concurrent jurisdiction with FDA on non-prescription products as to post marketing claims made regarding the product. On April 22, 1996 the FDA published a statement in the Federal Register, 61 FR 17706, that it does not believe that the Dietary Supplement and Health Education Act, or DSHEA, applies to animal health supplement products, such as our non-prescription products. Accordingly, the FDA's Center for Veterinary Medicine only regulates those animal supplements that fall within the FDA's definition of an animal drug, food or feed additive. The Federal Food Drug and Cosmetic Act defines food as "articles used for food or drink for man or other animals and articles used as components of any such article." Animal foods are not subject to pre-market approval and are designed to provide a nutritive purpose to the animals that receive them. Feed additives are defined as those articles that are added to an animal's feed or water as illustrated by the guidance documents. Our non-prescription products are not added to food, are not ingredients in food nor are they added to any animal's drinking water. Therefore, our non-prescription products do not fall within the definition of a food or feed additive. In light of the pronouncement by the FDA that the DSHEA was not intended to apply to animals, the FDA seeks to regulate such supplements as food or food additives depending on the intended use of the product. The intended use is demonstrated by how the article is included in a food, or added to the animals' intake (*i.e.,* through its drinking water). If the intended use of the product does not fall within the proscribed use making the product a food, it cannot be regulated as a food. There is no intent to make our non-prescription products a component of an animal food, either directly or indirectly. A feed additive is a product that is added to a feed for any reason including the top dressing of an already prepared feed. Some additives, such as certain forage, are deemed to be Generally Recognized as Safe, or GRAS, and therefore, not subject to a feed Additive Petition approval prior to use. However, the substances deemed GRAS are generally those that are recognized as providing nutrients as a food does. We do not believe that our non-prescription products fit within this framework either. Finally, a new animal drug refers to drugs intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals. Our non-prescription products are not intended to diagnose, cure, mitigate, treat or prevent disease and therefore, do not fit within the definition of an animal drug. Our non-prescription products are intended to support a healthy gut and normalize stool formation in animals that often contract and suffer from scours, a symptom of which is dehydration. A healthy well-hydrated gut allows them to better fight the scours as they do not also have to struggle with dehydration. Our non-prescription products are not being delivered to treat the disease of scours but rather to provide a more well-hydrated gut and normalize stool formation to better enable the animal to manage the scours. Additionally, because a previously marketed human formulation of the botanical extract in our non-prescription products was regulated as a human dietary supplement subject to the DSHEA (and not regulated as a drug by the FDA), we do not believe that the FDA would regulate the animal formulation used in our non-prescription products in a different manner. We do not believe that our non-prescription products fit the definition of an animal drug, food or food additive and therefore are not regulated by the FDA at this time.

However, despite many such unregulated animal supplements currently on the market, the FDA may choose in the future to exercise jurisdiction over animal supplement products in which case, we may be subject to unknown regulations thereby inhibiting our ability to launch or to continue marketing our non-prescription products. In the past, the FDA has redefined or attempted to redefine some non-prescription non-feed products as falling within the definition of drug, feed or feed additive and therefore subjected those products to the relevant regulations. We have not discussed with the FDA our belief that the FDA currently does not exercise jurisdiction over our non-prescription products. Should the FDA assert regulatory authority over our non-prescription products, we would take commercially reasonable steps to address the FDA's concerns, potentially including but not limited to, seeking

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registration for such products, reformulating such products to further distance such products from regulatory control, or ceasing sale of such products. Further, the Animal and Plant Health Inspection Service, an agency of the USDA, may at some point choose to exercise jurisdiction over certain non-prescription products that are not intended for production animals. We do not believe we are currently subject to such regulation, but could be in the future. If the FDA or other regulatory agencies, such as the USDA, try to regulate our non-prescription products, we could be required to seek regulatory approval for our non-prescription products, which would result in additional expense and could delay or prevent the commercialization of these products.

Risks Related to this Offering and Our Common Stock

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

If a market for our common stock develops following this offering, the trading price of our common stock could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed previously in this "Risk Factors" section of this prospectus and others, such as:

- delays in the commercialization of Neonorm, Canalevia or our other current or future prescription drug product candidates and non-prescription products;
- any delays in, or suspension or failure of, our current and future studies;
- announcements of regulatory approval or disapproval of any of our current or future product candidates or of regulatory actions affecting us or our industry;
- manufacturing and supply issues that affect product candidate or product supply for our studies or commercialization efforts;
- quarterly variations in our results of operations or those of our competitors;
- changes in our earnings estimates or recommendations by securities analysts;
- the payment of licensing fees or royalties in shares of our common stock;
- announcements by us or our competitors of new prescription drug products or product candidates or non-prescription products, significant contracts, commercial relationships, acquisitions or capital commitments;
- announcements relating to future development or license agreements including termination of such agreements;
- adverse developments with respect to our intellectual property rights or those of our principal collaborators;
- commencement of litigation involving us or our competitors;

any major changes in our board of directors or management;

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

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

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

general economic conditions in the United States and abroad.

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

No active market for our common stock exists or may develop, and you may not be able to resell your common stock at or above the initial public offering price.

Prior to this offering, there has been no public market for shares of our common stock. We and the representative of the underwriters determined the initial public offering price of our common stock by arm's-length negotiations, and the initial public offering price does not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. If no active trading market for our common stock develops or is sustained following this offering, you may be unable to sell your shares when you wish to sell them or at a price that you consider attractive or satisfactory. The lack of an active market may also adversely affect our ability to raise capital by selling securities in the future, or impair our ability to license or acquire other product candidates, businesses or technologies using our shares as consideration.

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

The initial public offering price of our common stock is substantially higher than the pro forma net tangible book value per share of our common stock before giving effect to this offering. Accordingly, if you purchase our common stock in this offering, you will incur immediate dilution of approximately $4.86 per share, representing the difference between the initial public offering price of $7.00 per share and our pro forma as adjusted net tangible book value per share as of December 31, 2014. In addition, following this offering, purchasers participating in this offering will have contributed approximately 70.1% of the total gross consideration paid by stockholders to us to purchase shares of our common stock through December 31, 2014, but will own only approximately 37.5% of the shares of common stock outstanding immediately after this offering. Furthermore, if the underwriters exercise their option to purchase additional shares of our common stock or our outstanding stock options are exercised, you will experience further dilution. For a further description of the dilution that you will experience immediately after this offering, see the section in this prospectus titled "Dilution."

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

We do not currently have research coverage by securities and industry analysts, and if no significant coverage is initiated or maintained following this offering, the market price for our stock may be adversely affected. Our stock price also may decline if any analyst who covers us issues an adverse or erroneous opinion regarding us, our business model, our intellectual property or our stock performance, or if our animal studies and operating results fail to meet analysts' expectations. If one or more analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline and possibly adversely affect our ability to engage in future financings.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the expiration or termination of the lock-up and other legal restrictions on resale discussed in this prospectus, the trading price of our common stock could decline. Based upon the

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number of shares outstanding as of December 31, 2014, and an initial public offering price of $7.00 per share, upon the closing of this offering, we will have outstanding a total of 8,115,282 shares of common stock. Of these shares, 3,150,000 shares, plus any shares sold upon exercise of the underwriters' option to purchase additional shares of our common stock, will be freely tradable in the public market immediately following this offering, unless held by our "affiliates," as that term is defined in Rule 144 under the Securities Act. Following this offering, holders of outstanding convertible notes, warrants, or options may also convert or exercise their securities, and outstanding RSUs may vest, all of which will result in additional shares of our common stock being issued, which ultimately may be sold into the market. Further, we may pay licensing fees or royalties due under our license agreement in shares of our common stock, and reach agreement with other creditors to pay fees due in shares of our common stock, all of which could lead to additional shares being available for resale.

The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. After the lock-up agreements expire, up to an additional 5,259,923 shares of common stock outstanding immediately after the offering will be eligible for sale in the public market, 4,517,123 of which shares are held by directors, executive officers and other affiliates and will be subject to vesting schedules or volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. The representative of the underwriters may, in its sole discretion, permit our officers, directors and other stockholders who are subject to lock-up agreements to sell shares even prior to the expiration of the lock-up agreements. In addition, shares of common stock that are subject to outstanding options under our 2013 Equity Incentive Plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. The sale or possible sale of these additional shares may adversely affect the trading price of our common stock.

We will have broad discretion to use the net proceeds from this offering, and may use them in ways that do not enhance our operating results or the market price of our common stock.

Our management will have broad discretion regarding the use of the net proceeds from this offering, and we could spend the net proceeds in ways our stockholders may not agree with or that do not yield a favorable return, if at all. We intend to use the net proceeds from this offering for the research and development of our prescription drug and non-prescription products and product candidates, manufacturing, marketing, distribution and commercialization of any products, repayment of indebtedness and other general corporate and working capital purposes. We may also use a portion of the net proceeds to acquire additional product candidates or complementary assets or businesses; however, we currently have no agreements or commitments to complete any such transaction. Our use of these proceeds may differ substantially from our current plans. If we do not invest or apply the net proceeds from this offering in ways that improve our operating results or our prospects, our stock price could decline.

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

Our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect upon the closing of this offering will contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. We expect these provisions to include the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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we may incur additional costs associated with resolving such matters in other jurisdictions, which could harm our business and financial condition.

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

As described in the section titled "Dividend Policy" in this prospectus, we currently intend to invest our future earnings, if any, to fund our growth and not to pay any cash dividends on our common stock. Because we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market price of our common stock. We cannot be certain that our common stock will appreciate in price.

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

Upon the closing of this offering, based on shares outstanding as of December 31, 2014 and after taking into account the automatic conversion of outstanding notes that will occur in connection with this offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates will beneficially own in the aggregate approximately 55.2% of our outstanding shares of common stock. As a result of their stock ownership, these stockholders may have the ability to influence our management and policies, and will be able to significantly affect the outcome of matters requiring stockholder approval such as elections of directors, amendments of our organizational documents or approvals of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

As a newly public company, we will incur significant additional costs, and our management will be required to devote substantial management time and attention to our public reporting obligations.

As a privately-held company, we have not been required to comply with public reporting, corporate governance and financial accounting practices and policies required of a publicly-traded company. As a publicly-traded company, we will incur significant additional legal, accounting and other expenses compared to historical levels. In addition, new and changing laws, regulations and standards relating to corporate governance and public disclosure, including the Dodd-Frank Wall Street Reform and Consumer Protection Act and the rules and regulations thereunder, as well as under the Sarbanes-Oxley Act, the JOBS Act and the rules and regulations of the U.S. Securities and Exchange Commission, or the SEC, and The NASDAQ Capital Market, may result in an increase in our costs and the time that our board of directors and management must devote to our compliance with these rules and regulations. We expect these rules and regulations to substantially increase our legal and financial compliance costs and to divert management time and attention from our product development and other business activities.

The Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. In particular, Section 404 of the Sarbanes-Oxley Act, or Section 404, requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm potentially to attest to, the effectiveness of our internal control over financial reporting. We will need to expend time and resources on documenting our internal control over financial reporting so that we are in a position to perform such evaluation when required. As an "emerging growth company," we expect to avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption when we cease to be an "emerging growth company." When our independent registered public accounting firm is required to undertake an assessment of our internal

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control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

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

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

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

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing of receipt of clinical trial, field study and other study data, and likelihood of success, commercialization plans and timing, other plans and objectives of management for future operations, and future results of current and anticipated products are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "aim," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this prospectus. Forward-looking statements are subject to inherent risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in a dynamic industry and economy. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties that we may face. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

INDUSTRY DATA

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market share, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates. See "Special Note Regarding Forward-Looking Statements."

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USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of 3,150,000 shares of common stock in this offering will be approximately $17.2 million, after deducting underwriting discounts and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares from us in full, we estimate that the net proceeds from this offering will be approximately $20.3 million, after deducting underwriting discounts and estimated offering expenses payable by us.

A $1.00 increase (decrease) in the initial public offering price of $7.00 per share would increase (decrease) the net proceeds from this offering by approximately $2.9 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 estimated offering expenses payable by us. An increase (decrease) by 1,000,000 shares in the number of shares offered by us would increase (decrease) the net proceeds to us from this offering by approximately $6.5 million, assuming that the initial public offering price remains the same, and after deducting underwriting discounts. We do not expect that a change in the initial public offering price or the number of shares by these amounts would have a material effect on our anticipated uses of the net proceeds from this offering, although it may accelerate the time at which we will need to seek additional capital.

We anticipate that we will use the net proceeds from this offering as follows:

- approximately $2.4 million for clinical studies and regulatory approval costs related to Canalevia for CID ($0.4 million) and general watery diarrhea ($2.0 million) in dogs;

- approximately $2.1 million for clinical studies and regulatory approval costs related to the other prescription drug products in our pipeline, namely species-specific formulations of crofelemer for general watery diarrhea in cats ($0.4 million), acute colitis in horses ($0.7 million), and gastric and colonic ulcers in horses and proof-of-concept studies for NP-500 ($1.0 million);

- approximately $3.5 million for studies and activities inside and outside the United States and for commercial activities related to the launch of Canalevia, our lead prescription drug product candidate for the treatment of various forms of watery diarrhea in dogs and for the continued commercialization efforts related to Neonorm both domestically and internationally;

- approximately $1.0 million for studies and field trials relating to Neonorm Calf and additional non-prescription formulations of Neonorm for other animal species including horse foals and adult horses;

- approximately $2.2 million for costs associated with developing species-specific formulations of our products;

- approximately $2.1 million for establishing third-party manufacturing capability, including the technology transfer at Indena S.p.A. pursuant to our memorandums of understanding;

- Approximately $1.3 million to repay the notes with an aggregate principal amount of $1.0 million that we borrowed in December 2014 pursuant to our Standby Bridge Financing Agreement. These notes had 10% original issue discount, have a stated interest rate of 12%, and provide for payment of 118% of the aggregate amount of principal plus interest, along with any other payments due, at maturity. We used the funds from these notes for working capital. See "Underwriting Certain Relationships"; and

- the remaining funds will be utilized for working capital and general corporate purposes.

A portion of the proceeds of this offering may also be used for repayment of up to $900,000 aggregate principal amount of convertible promissory notes that is currently outstanding if the holders thereof demand payment thereof, which they have the right to do at any time within 30 days following completion of this offering. In addition, we also have the right to prepay these notes at any time within 30 days

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following completion of this offering, although we do not currently have any intention to do so. These notes bear interest at 12% per annum, were issued pursuant to a convertible note and warrant purchase agreement dated December 23, 2014, and the proceeds from their sale was used for working capital purposes.

These expected uses of the net proceeds from this offering represents our intentions based upon our current financial condition, results of operations, business plans and conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

We may also use a portion of the net proceeds from this offering for the acquisition of, or investment in, complementary business, products or technologies, although we have no present commitments or agreements for any specific acquisitions or investments. Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments and U.S. government securities.

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DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2014, as follows:

- on an actual basis;
- on a pro forma basis to give effect to (i) the conversion of all outstanding shares of Series A preferred stock into 2,010,596 shares of common stock upon the closing of this offering; (ii) the issuance of 374,997 shares of common stock upon the conversion of convertible promissory notes in the aggregate principal amount of $2,100,000 upon the closing of this offering at a conversion price equal to $5.60 per share, and which shares will be unregistered; (iii) the issuance of $1,250,000 aggregate principal amount of convertible promissory notes after December 31, 2014 ($1,000,000 of which will convert into shares of common stock upon the closing of this offering); (iv) the modification in March 2015 of $650,000 aggregate principal amount of convertible promissory notes issued in December 2014 to automatically convert into shares of common stock upon the closing of this offering at a conversion price equal to $5.60 per share; and (v) the filing and effectiveness of our amended and restated certificate of incorporation upon the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to (i) the sale of 3,150,000 shares of common stock in this offering at the initial public offering price of $7.00 per share, after deducting underwriting discounts and estimated offering expenses payable by us and (ii) the repayment of our $1.0 million standby bridge facility.

You should read this information in conjunction 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."

	As of December 31, 2014		
	Actual	Pro Forma	Pro Forma As Adjusted(1)
		(unaudited)	
Cash and cash equivalents	$ 845,192	$ 2,095,192	$ 18,301,692
Convertible notes payable	$ 424,674	$ 250,000	$ 250,000
Notes payable	$ 478,709	$ 478,709	$
Series A redeemable convertible preferred stock, par value $0.0001 per share: 3,017,488 shares authorized, 3,015,902 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	7,304,914		
Stockholders' equity (deficit):			
Preferred stock, par value $0.0001 per share; no shares authorized, issued and outstanding, actual; 10,000,000 shares authorized, no shares issued and outstanding pro forma and pro forma as adjusted			
Common stock, par value $0.0001 per share: 10,000,000 shares authorized, 2,874,330 shares issued and outstanding, actual; 50,000,000 shares authorized, 5,259,923 shares issued and outstanding, pro forma; 8,409,923 shares issued and outstanding, pro forma as adjusted	288	525	840
Additional paid-in capital	1,175,242	12,181,808	29,387,993
Accumulated deficit	(9,410,778)	(11,086,104)	(11,607,395)

Total stockholders' equity (deficit)	(8,235,248)	1,096,229	17,781,438
Total capitalization	$ (26,951)	$ 1,824,938	$ 18,031,438

(1) A $1.00 increase (decrease) in the initial public offering price of $7.00 per share would increase (decrease) each of cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization

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by approximately $2.9 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 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) cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately $6.5 million, assuming the initial public offering price remains the same, and after deducting underwriting discounts. 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.

The outstanding share information in the table above is based on 5,259,923 shares of common stock outstanding as of December 31, 2014, and excludes:

207,664 shares of common stock issuable upon exercise of outstanding warrants as of December 31, 2014 at an exercise price of $2.5281 per share; and

16,666 shares of common stock issuable upon exercise of an outstanding warrant as of December 31, 2014 with an exercise price of $6.30 per share;

269,938 shares of our common stock issuable upon exercise of outstanding warrants as of December 31, 2014 with an exercise price of $5.60 per share;

111,605 shares of common stock issuable upon exercise of outstanding warrants issued after December 31, 2014 with an exercise price of $5.60 per share;

659,554 shares issuable upon exercise of outstanding options as of December 31, 2014 with a weighted-average exercise price of $2.67 per share;

68,902 shares issuable upon vesting of outstanding restricted stock unit awards, or RSUs, as of December 31, 2014;

1,484 shares issuable upon vesting of outstanding RSUs issued after December 31, 2014;

203,030 shares issuable upon exercise of stock options, which were authorized after December 31, 2014, and which will be granted effective upon this offering with an exercise price equal to the initial public offering price;

up to 44,642 shares of common stock issuable upon conversion of outstanding convertible promissory notes in the aggregate principle amount of $250,000 issued after December 31, 2014;

25,197 shares of common stock reserved for future issuance under our 2013 Equity Incentive Plan; and after taking into account the grant of an equity awards for an aggregate of 204,514 shares under our 2013 Equity Incentive Plan after December 31, 2014; and

333,333 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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DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

As of December 31, 2014, our historical net tangible book value was $(8.2) million, or $(2.87) per share of common stock. Our historical net tangible book value per share represents the amount of our total tangible assets less total liabilities divided by the number of shares of common stock outstanding as of December 31, 2014.

Our pro forma net tangible book value as of December 31, 2014 was $1.3 million or $0.26 per share of common stock, after giving effect to (i) the conversion of all outstanding shares of Series A preferred stock into 2,010,596 shares of common stock upon the closing of this offering; (ii) the issuance of 374,997 shares of common stock upon the conversion of convertible promissory notes in the aggregate principal amount of $2,100,000 upon the closing of this offering at a conversion price equal to $5.60 per share, and which shares will be unregistered; (iii) the issuance of $1,250,000 aggregate principal amount of convertible promissory notes after December 31, 2014 ($1,000,000 of which will convert into shares of common stock upon the closing of this offering); (iv) the modification in March 2015 of $650,000 aggregate principal amount of convertible promissory notes issued in December 2014 to automatically convert into shares of common stock upon the closing of this offering at a conversion price equal to $5.60 per share; and (v) the filing and effectiveness of our amended and restated certificate of incorporation upon the closing of this offering.

After giving further effect to (i) the sale of the 3,150,000 shares of common stock in this offering at the initial public offering price of $7.00 per share, after deducting underwriting discounts and estimated offering expenses payable by us and (ii) the repayment of our $1.0 million standby bridge facility, our pro forma as adjusted net tangible book value as of December 31, 2014 would have been approximately $18.0 million, or $2.14 per share. This amount represents an immediate increase in pro forma net tangible book value of $1.88 per share to our existing stockholders, and an immediate dilution in pro forma net tangible book value of approximately $4.86 per share to new investors purchasing shares of common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution:

Initial public offering price per share		$ 7.00
Historical net tangible book value per share as of December 31, 2014	$ (2.87)	
Increase attributable to conversion of all outstanding shares of Series A preferred stock and $2,100,000 of convertible promissory notes	3.13	
Pro forma net tangible book value per share as of December 31, 2014	0.26	
Increase in net tangible book value per share attributable to new investors	1.88	
Pro forma as adjusted net tangible book value per share after this offering		2.14
Dilution per share to new investors		$ 4.86

If the underwriters exercise their option to purchase additional shares in full, the pro forma as adjusted net tangible book value will increase to $2.38 per share, representing an immediate dilution of $4.62 per share to new investors.

A $1.00 increase (decrease) in the initial public offering price of $7.00 per share would increase (decrease) our pro forma as adjusted net tangible book value per share after this offering by $0.35 per

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share and the dilution to new investors by $0.65 per share, 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 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) the pro forma as adjusted net tangible book value by $0.47 and $0.59 per share, respectively, and the dilution to new investors by $0.47 and $0.59 per share, respectively, assuming the initial public offering price remains the same and after deducting underwriting discounts. 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.

The following table summarizes, on a pro forma as adjusted basis as of December 31, 2014, the differences between the number of shares of common stock purchased from us, the total consideration and the average price per share paid by existing stockholders and by investors participating in this offering, before deducting underwriting discounts and estimated offering expenses payable by us, at an initial public offering price of $7.00 per share.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	5,259,923	62.5%	$ 9,402,738	29.9%	$ 1.79
New investors	3,150,000	37.5%	22,050,000	70.1%	7.00
Total	8,409,923	100%	$ 31,452,738	100%	

The number of shares of common stock to be outstanding after this offering excludes:

207,664 shares of common stock issuable upon exercise of outstanding warrants as of December 31, 2014 with an exercise price of $2.5281 per share; and

16,666 shares of common stock issuable upon exercise of an outstanding warrant as of December 31, 2014 with an exercise price of $6.30 per share;

269,938 shares of our common stock issuable upon exercise of outstanding warrants as of December 31, 2014 with an exercise price of $5.60 per share;

111,605 shares of common stock issuable upon exercise of outstanding warrants issued after December 31, 2014 with an exercise price of $5.60 per share;

659,554 shares issuable upon exercise of outstanding options as of December 31, 2014 with a weighted-average exercise price of $2.67 per share;

68,902 shares issuable upon vesting of outstanding RSUs as of December 31, 2014;

1,484 shares issuable upon vesting of outstanding RSUs issued after December 31, 2014;

203,030 shares issuable upon exercise of stock options, which were authorized after December 31, 2014, and which will be granted effective upon this offering with an exercise price equal to the initial public offering price;

up to 44,642 shares of common stock issuable upon conversion of outstanding convertible promissory notes in the aggregate principle amount of $250,000 issued after December 31, 2014;

25,197 shares of common stock reserved for future issuance under our 2013 Equity Incentive Plan; and after taking into account the grant of an equity awards for an aggregate of 204,514 shares under our 2013 Equity Incentive Plan after December 31, 2014; and

333,333 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.

To the extent any of these outstanding options or warrants are exercised or RSUs vest, there will be further dilution to new investors. If all of such outstanding options or warrants had been exercised or RSUs vested as of December 31, 2014, the pro forma as adjusted net tangible book value after this offering would be $2.28 per share, and total dilution to new investors would be $4.72 per share.

If the underwriters exercise their option to purchase additional shares of common stock in full:

the percentage of shares of common stock held by existing stockholders will decrease to approximately 59.2% of the total number of shares of common stock outstanding after this offering; and

the number of shares held by new investors will increase to 3,622,500, or approximately 40.8% of the total number of shares of common stock outstanding after this offering.

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SELECTED FINANCIAL DATA

You should read the following selected financial data together with our financial statements and related notes appearing elsewhere in this prospectus and the section in this prospectus titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." 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 December 31, 2014, we are a majority-owned subsidiary of Napo.

The following tables set forth our selected statements of comprehensive loss data since inception in June 2013 and our selected balance sheet data as of December 31, 2014. We are a development stage company. Data for the period from June 6, 2013 (inception) through and as of December 31, 2013 and 2014 is derived from our audited financial statements included elsewhere in this prospectus. The historical results are not necessarily indicative of the results to be expected for any future periods.

	Period from June 6, 2013 (inception) through December 31, 2013	Year Ended December 31, 2014
Statements of Comprehensive Loss Data:		
Operating expenses:		
General and administrative expense	$ 458,473	$ 4,095,324
Research and development expense	324,479	4,220,338
Total operating expenses	782,952	8,315,662
Loss from operations	(782,952)	(8,315,662)
Interest expense, net	(18,251)	(345,336)
Change in fair value of warrants		51,423
Net loss and comprehensive loss	$ (801,203)	$ (8,609,575)
Accretion of redeemable convertible preferred stock		(646,673)
Net loss attributable to common stockholders	$ (801,203)	$ (9,256,248)
Net loss per share attributable to common stockholders, basic and diluted(1)	$ (0.30)	$ (3.24)
Weighted-average common shares outstanding, basic and diluted(1)	2,666,666	2,854,417
Pro forma net loss per share, basic and diluted(1)	$ (0.30)	$ (2.02)

Pro forma weighted-average number of common shares(1)	2,666,666	4,592,283

(1) See Notes 2 and 13 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.

	As of December 31, 2014
Balance Sheet Data:	
Cash and cash equivalents	$ 845,192
Total assets	4,506,630
Convertible notes payable	424,674
Notes payable	478,709
Warrant liability	601,889
Total liabilities	5,436,964
Redeemable convertible preferred stock	7,304,914
Total stockholders' (deficit)	(8,235,248)

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MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this prospectus for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are an animal health company focused on developing and commercializing first-in-class gastrointestinal products for companion and production animals. Canalevia is our lead prescription drug product candidate for the treatment of various forms of watery diarrhea in dogs. We achieved statistically significant results in a canine proof-of-concept study completed in February 2015, supporting the conclusion that Canalevia treatment is superior to placebo, with 91% of the Canalevia-treated dogs achieving a formed stool during the study versus 50% of the placebo-treated dogs. We also initiated filing of a rolling new animal drug application, or NADA, with the U.S. Food and Drug Administration, or FDA, for Canalevia for chemotherapy-induced diarrhea, or CID, in dogs, at the end of 2014. Canalevia is a canine-specific formulation of crofelemer, an active pharmaceutical ingredient isolated and purified from the *Croton lechleri* tree. A human-specific formulation of crofelemer, Fulyzaq, was approved by the FDA in 2012 for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. Members of our management team developed crofelemer, including while at Napo Pharmaceuticals, Inc., or Napo. Neonorm is our lead non-prescription product to improve gut health and normalize stool formation in animals suffering from watery diarrhea, or scours. We launched Neonorm in the United States at the end of 2014 for preweaned dairy calves under the brand name Neonorm Calf and expect to launch additional formulations of Neonorm for other animal species in 2015. We have already shipped approximately $450,000 of Neonorm Calf to distributors. Neonorm is a botanical extract also derived from the *Croton lechleri* tree. Canalevia and Neonorm are distinct products that are formulated to address specific species and market channels. We have filed nine investigational new animal drug applications, or INADs, with the FDA and intend to develop species-specific formulations of Neonorm in six additional target species.

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

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

In consideration for the license from Napo, we are obligated to pay a one-time non-refundable license fee of $1.75 million, less an option fee of $100,000 we paid in July 2013. In December 2014, we paid Napo

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an additional $25,000, and in January 2015, agreed that the remaining license fee payment will be paid in cash, or if mutually agreed with Napo, in shares of our common stock according to the following schedule:

Payment Date	License Fee Amount
Amendment Date	$ 25,000
March 31, 2015	$ 25,000
June 30, 2015	$ 150,000
September 30, 2015	$ 500,000
December 31, 2015	$ 500,000
March 31, 2016	$ 425,000
Total	$ 1,625,000

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

Financial Operations Overview

We were incorporated in June 2013 in Delaware. Napo formed our company to develop and commercialize animal health products. Prior to our incorporation, the only activities of Napo related to animal health were limited to the retention of consultants to evaluate potential strategic alternatives. As of December 31, 2013, we were a wholly-owned subsidiary of Napo, and as of December 31, 2014, we are a majority-owned subsidiary of Napo. Upon the closing of this offering, we will no longer be majority-owned by Napo.

We have presented our financial statements on a standalone basis without predecessor or carve-out financial information because we do not have a "predecessor" within the meaning of Rule 405 of Regulation C under the Securities Act. We did not succeed to a major portion of the business or assets of Napo, nor a separately identifiable line of business of Napo. Prior to our formation, Napo's operations did not include an animal health business and we were formed for the purpose of developing and commercializing products in the animal health field. Napo's business was focused on the development of human-specific formulations of its product, as well as licensing activities related to its intellectual property. Since early 2011, Napo's business activities have been limited to activities related to the licensing of its intellectual property, which we did not acquire or succeed to, and there were no predecessor operations of the animal health business in Napo prior to our formation. For these reasons, we did not succeed to substantially all of the business of Napo nor a separately identifiable line of business of Napo.

In July 2013, we entered into an employee leasing and overhead allocation agreement with Napo, or the Service Agreement. The term of the Service Agreement was from July 1, 2013 through February 28, 2014. Pursuant to the Service Agreement, Napo provided us the services of certain Napo employees, and on March 1, 2014, these employees joined our company. In addition, we also agreed to pay Napo for a portion of its overhead costs during the term of the agreement. We agreed to pay Napo for the months from July 2013 through February 2014 as follows: (1) for the period from July 2013 through November 2013, in 2,666,666 shares of common stock and (2) for the period from December 2013 through February 2014, $71,811 per month (consisting of $65,811 for employee services and $6,000 for overhead costs) in cash.

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We have not generated any material revenue to date and expect to continue to incur significant research and development and other expenses. Our net loss attributable to common stockholders for the year ended December 31, 2014 was $9,256,248. As of December 31, 2014, we had a total stockholders' deficit of $8,235,248. We expect to continue to incur losses for the foreseeable future as we expand our product development activities, seek necessary approvals for our product candidates, conduct species-specific formulation studies for our non-prescription products, establish API manufacturing capabilities and begin commercialization activities.

Operating Expenses

The majority of our operating expenses to date have been for research and development activities related to Canalevia and Neonorm and for costs associated with our formation, including legal, recruiting, travel and financing activities. During 2013, we did not incur any stock-based compensation expense. For the year ended December 31, 2014, operating expenses includes $164,156 of stock-based compensation expense.

Research and Development Expense

Research and development costs are expensed as incurred. Research and development expense consists primarily of third-party consultant fees, expenses attributable to services received from Napo under the Service Agreement and expenses related to our clinical studies. Beginning January 1, 2014, research and development expense also includes personnel-related costs, including salaries and benefits, and other operational costs related to our research and development activities, including costs of studies, raw material acquisition costs, contract manufacturers and service providers, regulatory, professional and consulting fees, and travel costs.

We typically use our employee and infrastructure resources across multiple development programs. We track outsourced development costs by prescription drug product candidate and non-prescription product but do not allocate personnel or other internal costs related to development to specific programs or development compounds.

The timing and amount of our research and development expenses will depend largely upon the outcomes of current and future trials for our prescription drug product candidates as well as the related regulatory requirements, the outcomes of current and future species-specific formulation studies for our non-prescription products, manufacturing costs and any costs associated with the advancement of our line extension programs. We cannot determine with certainty the duration and completion costs of the current or future development activities.

The duration, costs and timing of trials, formulation studies and development of our prescription drug and non-prescription products will depend on a variety of factors, including:

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

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

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

General and Administrative Expense

General and administrative expense consists of personnel-related costs, including salaries and benefits, and also includes expenses attributable to services received from Napo under the Service Agreement, rent and other facilities costs and professional and consulting fees for legal, accounting, tax services and other general business services. During 2013, we did not incur any stock-based compensation expense. For the year ended December 31, 2014, general and administrative expense includes $106,701 of stock-based compensation expense.

We expect general and administrative expense to increase significantly as we incur operating costs related to being a public company, including building our corporate infrastructure.

Interest (Expense) Income, Net

Interest (expense) income, net consists primarily of interest expense related to our convertible promissory notes and standby bridge financing commitment. It also includes interest expense and the amortization of a beneficial conversion feature related to convertible promissory notes issued in June and December 2014.

Results of Operations