Jaguar Animal Health, Inc.
Form 10-K
March 29, 2016

Use these links to rapidly review the document

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2015

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

For the transition period from to
COMMISSION FILE NO. 001-36714

JAGUAR ANIMAL HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**46-2956775**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

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

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

Title of each class	**Name of each exchange on which registered**
Common Stock, Par Value $0.0001 Per Share	The NASDAQ Capital Market

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ý

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes o No ý

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

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

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

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

As of June 30, 2015, the aggregate market value of the registrant's common stock held by non-affiliates was approximately $10,480,126 based upon the closing sales price of the registrant's common stock on The NASDAQ Global Market on such date.

The number of shares of the registrant's Common Stock outstanding as of March 15, 2016 was 10,142,519.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement for the registrant's 2016 Annual Meeting of Stockholders, or Proxy Statement, to be filed within 120 days of the end of the fiscal year ended December 31, 2015 are incorporated by reference in Part III hereof. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as a part hereof.

Table of Contents

TABLE OF CONTENTS

Table of Contents

PART I

Forward-looking statements

This Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Form 10-K, 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 Form 10-K 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 Form 10-K and are subject to a number of risks, uncertainties and assumptions described under the sections in this Form 10-K titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Form 10-K. 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.

ITEM 1. BUSINESS

BUSINESS

Overview

We are an animal health company focused on developing and commercializing first-in-class gastrointestinal products for companion and production animals and horses. Canalevia is our lead prescription drug product candidate for the treatment of various forms of diarrhea in dogs. We achieved statistically significant results in a canine proof-of-concept study completed in February 2015, suggesting 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. In December 2015 we initiated a pivotal trial to evaluate the safety and effectiveness of Canalevia for the treatment of acute diarrhea in dogs. Additionally, we are seeking a first to market introduction of Canalevia with a conditional approval for the indication of CID. In June 2015 we completed a multi-site pilot safety study involving the anticipated commercial formulation of Canalevia for CID, and in August 2015 we completed submission of all required major technical sections for a conditional approval new drug application, or CNADA, for Chemotherapy-Induced Diarrhea (CID) to the FDA for a phased review. 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

Table of Contents

the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. Members of our management team developed crofelemer, while at Napo Pharmaceuticals, Inc., which was Jaguar's parent company until May 13, 2015. Neonorm is our lead non-prescription product to support gut health thereby normalizing fecal 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 in 2015 we launched Neonorm in the United States for foals under the brand name Neonorm Foal. We expect to launch additional formulations of Neonorm in the next years. As of March 1, 2016, we have shipped $638,000 of Neonorm Calf to distributors. Neonorm is a standardized 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 submitted nine active investigational new animal drug applications, or INADs, to the FDA and intend to develop species-specific formulations of Neonorm in six additional target species.

We intend to develop a species-specific formulation of crofelemer to treat diarrhea associated with acute colitis in horses. We believe colitis affects thousands of horses in the United States each year, and in December 2015 we completed a pilot safety study to evaluate crofelemer in adult horses, the first step in the development program for acute colitis. Acute colitis can cause sudden, massive fluid loss and severe electrolyte imbalances that can result in death in a matter of hours.

We are also developing a formulation of a *Croton lechleri* product for the treatment of ulcers in horses. In January 2016 we announced positive topline results from the proof-of-concept study we initiated in November 2015 to evaluate the safety and effectiveness of this investigational new animal drug, currently referred to as SB-300, for the treatment of gastrointestinal ulcers in horses. SB-300 contains ingredients isolated and purified from the *Croton lechleri* tree.

Ulcers are lesions of the lining of the digestive tract and are very common in horses used for many competitive activities. We believe that because *Croton lechleri*-derived products have been shown to act locally in the gut and have traditional use and rodent model benefit for ulcers, SB-300 has the potential to address ulcers in horses, as well as diarrhea. We are initially developing this product for the indication of equine gastric ulcer syndrome (EGUS), and we plan to investigate the possible efficacy of this product candidate for treatment of colonic ulcers in horses as a potential follow on indication following the anticipated launch of SB-300. Both colonic and gastric ulcers can negatively impact the performance of horses which are expected to perform at peak efficiency, including show horses and race horses. We believe a significant market exists for a product that treats both ulcers in horses without altering stomach pH. According to a 2005 study, 54% of performance horses have both colonic and gastric ulcers and 97% of performance horses have either a gastric (87%) or a colonic (63%) ulcer. Data from the American Horse Council states that there are currently 9.2 million horses in the U.S., a population that includes 844,531 race horses, more than 2.7 million show horses, and more than 3.9 million recreational horses. Data from the Food and Agriculture Organization of the United Nations indicate that there were approximately 5.7 million horses in Europe in 2013 and nearly 60 million horses in 2013 worldwide. Our goal is to see SB-300 serve as an important tool in the standard of care for equine ulcers.

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 in animals. 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 diarrhea. We believe that Canalevia will be effective in treating acute diarrhea because it acts at the last physiological step, conserved across mammalian species, in the manifestation of acute diarrhea, regardless of cause, by normalizing ion and water flow in the intestinal lumen. We have received MUMS designation for Canalevia for the treatment of CID in dogs which provides an opportunity 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 the second half of 2016. We completed a canine proof-of-concept study in February 2015, with statistically

Table of Contents

significant results, in support of protocol concurrence discussions with the FDA regarding expansion of labeled indications of watery diarrhea beyond CID, to include acute diarrhea as a secondary indication. We plan to market Canalevia, if approved, through our focused direct sales force and to complement our relationships with distribution partners.

According to the Dairy 2007 study conducted by the 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 impaired weight gain and long-term reduction in milk production. We believe that the incidence rate of scours and its corresponding financial impact represent a health and business opportunity and that Neonorm Calf has the potential to effectively meet this need.

A challenge clinical study was completed in May 2014 by researchers from Cornell, and published in 2015 in the official journal of the American Dairy Science Association, *Journal of Dairy Science*. The results of this study suggest that Neonorm Calf can significantly increase the fecal dry matter of neonatal calves with experimentally-induced enterotoxigenic *E. coli* diarrhea, and suggest a potential benefit of Neonorm Calf in supporting weight gain in calves.

A further analysis, completed in October 2015, of the above-referenced Cornell study supports a benefit of Neonorm Calf on the optimization of the intestinal microbiome profile in preweaned dairy calves, a potential prebiotic benefit. The microbiome is a community of microorganisms that live normally in the gut and are vital to maintenance of gut health.

We recently initiated a placebo-controlled study in conjunction with researchers from Cornell to evaluate the efficacy of the prophylactic use of a second-generation formulation of Neonorm Calf administered in liquid on naturally occurring diarrhea in preweaned dairy calves and investigate the possible prebiotic benefit of the product. This double-blinded, randomized study will involve 40 Holstein bull calves affected with naturally occurring diarrhea. This study will generate data that we expect will enlighten the mechanism by which the prophylactic use of the second-generation formulation of Neonorm Calf may support the gut health of preweaned calves herd-wide during naturally occurring diarrhea. Additionally, characterization of the fecal microbiome throughout the preweaning period will allow us to demonstrate that, under natural conditions, the product may positively alter the intestinal microbiome to the benefit of the host. The possible beneficial prebiotic mechanism of Neonorm Calf would supplement and is potentially synergistic with the anti-secretory and weight gain benefits of the product. We expect results from this study to be available in 2016.

In November 2015 we completed an initial proof-of-concept study (NEO101) of Neonorm Foal that involved 60 foals. The objective of this randomized, multi-site, blinded, placebo-controlled study was to evaluate the safety and performance of the product for treatment of foals suffering from secretory diarrhea, and the treated animals received Neonorm Foal in combination with a third-party probiotic. In December 2015 we announced positive results for an exploratory, investigator-initiated follow-up study (ARG102) which assessed the safety and performance of Neonorm Foal, without inclusion of a probiotic, in preweaned foals with watery diarrhea. The results of a meta-analysis between the two studies demonstrated a significantly higher percentage of foals with clinical response and resolution of diarrhea for Neonorm Foal, from either ARG102 or NEO101, compared with the placebo group in NEO101.

During the 72-hour administration period, 35% of foals receiving the placebo in NEO101 were identified as clinical responders, compared with 85% of foals treated with Neonorm Foal in ARG102. For the purposes of both studies, clinical responders were defined as foals that achieved a formed stool by the end of the reported period.

During the 72-hour administration period, resolution of diarrhea was observed in 41% of placebo-treated foals in NEO101 compared with 85% of foals receiving Neonorm Foal in ARG102. For the

Table of Contents

purposes of both studies, resolution of diarrhea was defined as a foal that produced a formed stool at any point during the reported period.

We expect the ongoing launch of Neonorm Calf promoting normal fecal formation and reducing fluid loss in preweaned calves and Neonorm Foal to drive awareness among veterinarians regarding the utility of our first-in-class anti-secretory *Croton lechleri*-derived products, including our prescription product, 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 includes rights to Neonorm, Canalevia, and other distinct prescription drug product candidates in our pipeline along with the corresponding existing preclinical 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, Zoetis Inc., Vétoquinol S.A., Merial Inc., the animal health division of Sanofi S.A., Morris Animal Foundation, Virbac Animal Health, and Merck Animal Health, as well as management experience at major veterinary hospital institutions and experience at the FDA's Center for Veterinary Medicine.

Product Pipeline

We are developing a pipeline of prescription drug product candidates and non-prescription (non-drug) products to address unmet needs in animal health. Our pipeline currently includes prescription drug product candidates for nine 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		
			Completed safety study with commercial formulation in June 2015	Possible conditional approval filed in second half of 2016
			Submitted all required major technical sections of new animal drug application (NADA) in August 2015	
	Dogs	Acute diarrhea		
			Product development meeting with FDA in 2015	Complete clinical development program fourth quarter of 2016
			Initiated pivotal trial to evaluate safety and effectiveness in December 2015	Initiate NADA in 2016

Table of Contents

Product Candidates	Species	Indication	Recent Developments	Anticipated Near-Term Milestones
Species-specific formulations of crofelemer	Horses	Diarrhea associated with acute colitis	Completed pilot safety study in December 2015	Product development meeting with FDA first half of 2016
				Commence clinical development program under CVM concurred protocols first half of 2016
	Horses	Ulcers		
			INAD opened in October 2015	Product development meeting with FDA in first half of 2016
			Proof-of-concept safety and effectiveness results in January 2016	Commence clinical development program under CVM concurred protocols second half of 2016
	Cats	Acute diarrhea		
			INAD opened in 2014	Safety and proof-of-concept results first half of 2016
Virend (topical)	Cats	Herpes virus		
			INAD opened in 2014	Safety and proof-of-concept results in 2016
Species-specific formulations of NP-500	Dogs	Obesity-related metabolic dysfunction	INAD opened in 2014	
	Horses	Metabolic syndrome	INAD opened in 2014	
	Cats	Type II diabetes	INAD opened in 2014	

Table of Contents

Non-Prescription Products

Products	Species	Use	Recent Developments	Anticipated Near-Term Milestones
Neonorm Calf	Dairy calves	Supports gut health and normalizing fecal formation in preweaned dairy calves with scours	Initiated study in December, 2015 to investigate possible prophylactic and prebiotic benefits	Launch second generation formulation for administration in liquid
			South American distribution agreement signed in first quarter of 2015	Commercial launch in South America
			Shipped $638,000 of product to distributors since commercial launch	
			Analysis completed in October 2015 supports prebiotic effect	
			Field study completed in September 2015 supports beneficial effect of on prewean weight gain	
Species-specific formulations of Neonorm	Horse foals	Supports gut health normalizing fecal formation	Completed proof-of-concept study in November 2015	Commercial launch in first quarter of 2016
			Soft-launched product in December 2015	
			Shipped $25,000 of product to distributors since commercial launch	
	Other farm/production animals	Supports gut health normalizing fecal formation	Conducted market research in 2015 which was initiated in New Zealand and China in 2014 for global market opportunities	Initiate proof-of-concept studies and partnering discussions based on market research within the next 12 months

Canalevia is our lead prescription drug product candidate for CID and general watery diarrhea in dogs. Neonorm Calf and Neonorm Foal are our lead non-prescription products to improve gut health and normalize stool formation for preweaned dairy calves with scours, and to promote normal fecal formation and reduce fluid loss in foals, respectively. Both Canalevia and Neonorm are derived from the *Croton lechleri* tree and act at the same last step in a physiological pathway generally present in mammals. However, they are distinct products based on species-specific formulations of such derivatives and have distinct chemical compositions as well as different levels of purification. Canalevia is a canine-specific formulation of crofelemer, an active pharmaceutical ingredient that is an isolated and purified compound. Neonorm is a formulation of a standardized botanical extract that is less refined than crofelemer and includes other chemical constituents.

Table of Contents

We are developing Canalevia as a prescription drug product and Neonorm as a non-prescription product due to differences between the companion and production animal markets. Companion animal owners generally visit veterinarians, who prescribe a product to treat a disease or condition. We believe the ability to make a disease treatment claim is important in this market, and such a claim is only possible with FDA approval as a prescription product. In contrast, dairy farmers and other production animal owners generally make purchasing decisions based on a product's ability to demonstrate an economic benefit from health endpoints, such as weight gain.

We are initially pursuing conditional FDA approval for Canalevia for CID in dogs pursuant to MUMS designation, and are conducting studies to broaden the Canalevia label to include acute diarrhea in dogs as a secondary indication. A MUMS designation is a status similar to the orphan drug designation in humans. In the case of major animal species such as dogs, cats and horses, MUMS designations are typically limited to drugs that are used to treat a small number of animals each year. For dogs and cats that number is no more than 70,000 and 120,000 animals, respectively. MUMS designation can potentially expedite the process of product approval and therefore availability to the patient. A sponsor of a MUMS drug can apply for conditional approval, which allows the sponsor to make the drug commercially available before collecting all necessary effectiveness data, but after proving the drug is safe and showing that there is a reasonable expectation of effectiveness.

We also plan to expand our gastrointestinal product line to other animals by developing species-specific formulations, including formulations of Neonorm for sheep and other farm animals. We are seeking protocol concurrences with the FDA where appropriate. For example, we are planning a trial to develop a formulation of crofelemer for acute diarrhea in cats, and in December 2015 we completed a pilot safety study to evaluate the safety of crofelemer in adult horses, the first step in a planned development program for diarrhea associated with acute colitis.

A protocol concurrence in animal drug development means that the FDA agrees that the design and analyses proposed in a protocol are acceptable to support regulatory approval of the product candidate with respect to effectiveness of the indication studied and will not change its view of these matters, unless public or animal health concerns arise that were not recognized at the time of concurrence or we change the protocol. We plan to seek concurrence on all major regulatory trials.

We have licensed intellectual property from Napo to develop prescription drug product candidates for diabetes and metabolic syndrome for dogs, cats and horses, as well as a topical herpes product for cats. Similar to our lead prescription drug product candidate, these products were tested in animals for safety to support their development for use in humans. We recently expanded our gastrointestinal product line to include combinations of our proprietary anti-secretory products derived from *Croton lechleri* with the non-absorbed antibiotic, rifaximin, a human approved product, for gastrointestinal indications in all animals. We are leveraging the data and knowledge gained during the development of human therapeutics into veterinary applications.

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, and the horse market. 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 production and companion animals, and horses.

Our management team collectively has more than 100 years of experience in the development of gastrointestinal prescription drug and non-prescription products. This experience covers all aspects of product development, including discovery, preclinical and clinical development and regulatory strategy.

Table of Contents

In addition to our near-term development efforts advancing Canalevia for dogs, Neonorm Calf for preweaned dairy calves, and Neonorm Foal for young horses, we are developing formulations of Canalevia and Neonorm to address the unmet medical need for the treatment of acute diarrhea and to improve gut health and normalize fecal formation across multiple animal species and market channels. The development of a full suite of products to support and improve gastrointestinal health in adult horses is one of our core focus areas. Gastrointestinal conditions such as acute diarrhea, ulcers and diarrhea associated with acute colitis can be extremely debilitating for horses, and present a significant economic and emotional burden for veterinarians and horse owners around the world. Our products are designed with a thorough understanding of not only species-specific health issues, but also market practices, the economics of current treatment strategies, competitive dynamics, government initiatives such as concern for extensive antibiotic usage, and effective channels for new product introductions. Many of our products are being formulated into separate and distinct gastrointestinal products accounting for multiple specific species, markets and regulatory dynamics.

Establish commercial capabilities, including third-party sales and distribution networks and our own targeted commercial efforts, through the launch of Neonorm Calf and Neonorm Foal.

In 2014 we launched Neonorm in the United States under the brand name Neonorm Calf, and in December 2015 we conducted the soft launch of Neonorm Foal. We intend to establish a focused direct sales force, initially for the production animal markets, and have hired our first sales representatives. We will direct our sales and marketing efforts on educational activities and outreach to key opinion leaders and decision makers at targeted regional and global accounts and also plan to continue to partner with leading distributors to commercialize our products. We expect that our current and future distribution partners will have the presence, name recognition, reputation and reach in the veterinary markets and in both key urban and rural centers, as appropriate. We believe this overall approach is scalable and transferable as we expand our commercialization efforts to companion animals, as well as when we expand internationally.

Launch Canalevia and our other product candidates for companion animals, if approved, leveraging the commercial capabilities and brand awareness we are currently building.

We expect to receive FDA acknowledgment of the completion of all required technical sections in support of conditional approval of Canalevia in 2016 for CID in dogs, leveraging the sales and marketing capabilities established from our launch of Neonorm Calf and Neonorm Foal. As our focus shifts to companion animals and in anticipation of crofelemer development and registration for acute diarrhea in dogs and cats, our direct sales force will also increasingly target high-prescribing veterinarians for companion animals with relevant indications. We believe the third-party sales and distribution networks we establish in connection with our launch of Neonorm Calf and Neonorm Foal will be highly relevant for the companion animal market as well. In addition, while we believe Neonorm Calf and Neonorm Foal address smaller market opportunities than our companion animal product candidates, these are first-in-class products with the same novel mechanism of action as Canalevia. As such, Neonorm Calf and Neonorm Foal provide a scientific and promotional foundation that we believe we can leverage for our companion animal prescription product development and launch events.

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. As an example, in February 2015 we signed a distribution agreement with Biogenesis Bagó, a large veterinary biotechnology company in Latin America, a region that contained approximately 401 million dairy and beef cattle in 2009 and produces approximately 11% of the world's

Table of Contents

milk supply. The distribution agreement provides Biogenesis Bagó with exclusive distribution rights for Neonorm Calf in Argentina, Brazil, Paraguay, Uruguay, and Bolivia. Further, certain markets, such as high performance horses, have strong international synergies benefiting market awareness and demand. 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 anti-secretory gastrointestinal product development efforts, we have expanded the depth of our gastrointestinal pipeline product candidates to include combinations of our proprietary anti-secretory products derived from *Croton lechleri* with the non-absorbed antibiotic, rifaximin, a human approved product, for gastrointestinal indications in all animals. We are also developing products such as Virend for feline herpes and NP-500 for Type II diabetes and metabolic syndrome. Both of these product candidates have been through Phase 2 human clinical testing. In addition, we have exclusive worldwide rights to Napo's library of over 2,300 medicinal plants for veterinary use in all species. We believe we have the product candidates and expertise to address many unmet animal health needs for both companion and production animals. We believe our extensive library of medicinal plants will enable us to develop first-in-class products that address significant health issues and concerns of many markets and geographies.

Products in Development

Market Background Acute Diarrhea

We believe there is an unmet medical need for the treatment of acute diarrhea. The devastating dehydration that often occurs as a result of acute diarrhea in animals, including dogs, horses and preweaned dairy calves, can manifest quickly, have long-term health implications and result in death. Other than the FDA-approved human formulation of crofelemer, there are currently no approved anti-secretory agents we are aware of that directly address the water loss associated with acute diarrhea. Current treatments for acute diarrhea include oral rehydration solution, or ORS, anti-motility agents, absorbents and antibiotics. However, each of these approaches has known limitations. While ORS replaces the water loss associated with diarrhea, it can often extend the duration and severity of diarrhea. Anti-motility agents work by the mechanism of constipation, or temporarily paralyzing normal intestinal contractions, or peristaltic activity. These agents are contraindicated for chronic use and are therefore inappropriate for certain conditions, such as chronic CID. Anti-motility agents can also cause pain, cramping, and rebound diarrhea. Absorbents simply attempt to absorb the toxin in the gut, often causing additional pain and cramping, and do not directly address the water loss. Antibiotics attempt to treat the infectious agent releasing the toxin, but do not directly address water loss and carry a risk of altering gut flora, which alteration itself can cause diarrhea. Systemic antibiotic usage has also come under increased scrutiny by the FDA due to problems associated with antibiotic resistance.

We believe that an ideal treatment for acute diarrhea would directly address water loss without causing constipation, affecting normal peristaltic activity or altering normal body absorption of other drugs or normal physiological function of the gut. We believe addressing water loss associated with acute diarrhea will improve the quality of life of dogs and provide attendant benefits to the dog owner, improve the health and productivity of dairy cattle and provide similar health and economic benefits in multiple other species. Our gastrointestinal products and product candidates act by normalizing the flow of ions and water in the intestinal lumen, the dysregulation of which is the last step common to the manifestation of acute diarrhea. As a result, we believe that our products and product candidates may be effective in addressing acute 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, foals, and dogs will be confirmed in multiple other species, including cats and

Table of Contents

adult horses. Accordingly, we believe we can bring to market multiple products among multiple species that are first-in-class and effective in preventing the debilitating and devastating ramifications of acute diarrhea in animals.

The following diagram illustrates the mechanism of action of our gastrointestinal products, which normalize chloride and water flow and transit time of fluids within the intestinal lumen.

Canalevia Chemotherapy-Induced Diarrhea in Dogs

Overview

Canalevia is a three day, twice daily formulation of crofelemer that we are developing for the treatment of CID in dogs. Canalevia is enteric coated for targeted release of crofelemer, the active pharmaceutical ingredient, or API, in Canalevia, in the intestine. We have received MUMS designation for Canalevia for the treatment of CID in dogs which provides an opportunity to shorten the timeframe to commercialization. In June 2015 we completed a multi-site pilot safety study involving the anticipated commercial formulation of Canalevia for CID, and in August 2015 we completed submission of all required major technical sections for the NADA for CID to the FDA for phased review. We expect to receive FDA acknowledgment of the completion of all required technical sections in support of conditional approval of Canalevia in 2016 for CID in dogs. Under MUMS designation, we would be required to initiate a pivotal study in the five years following conditional approval to generate the data required for full approval. We expect to meet this requirement with data generated concurrent with our ongoing clinical development program for the expanded indication of acute diarrhea in dogs. Canalevia 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.

Market Opportunity

We believe there is a significant unmet medical need for the treatment of CID in dogs. There is currently no FDA-approved anti-secretory product that we are aware of to treat CID in dogs. We estimate that there are over 230,000 dogs receiving chemotherapy treatment for cancer each year in the United States, with over 25% suffering from CID. Severe diarrhea is a frequent side effect of the most commonly administered chemotherapy drugs. Similar to the effects in humans, we believe that if left untreated, CID in dogs can result in:

- fluid and electrolyte losses, which can cause dehydration, electrolyte imbalance and renal insufficiency;
- nutritional deficiencies from alteration of gastrointestinal transit and digestion; and
- increased risk of infectious complication.

Table of Contents

Efficacy of the underlying cancer treatment may also be jeopardized if CID severity requires reductions in the absorption, frequency and/or dosage of chemotherapy. From the dog owner's perspective, there are significant practical implications of CID in dogs that may affect living arrangements, as well as the cost, time and attention required to clean and care for the dog and its surroundings on a daily basis. Veterinarians sometimes prescribe human drugs in an effort to treat CID in dogs, but do not have the benefit of clinical support with respect to efficacy or dosing. In addition, administering a potentially unpalatable human formulation is often difficult and may lead to further uncertainty of the amount actually ingested by the dog.

Our Solution

We believe that Canalevia is an ideal treatment for CID in dogs because of its demonstrated novel anti-secretory mechanism of action. Canalevia acts locally in the gut and is minimally absorbed systemically. It does not alter gastrointestinal motility, has no significant effects on normally functioning intestinal ion channels and electrolyte or fluid transport, and has no side effects different from placebo. These features are further augmented by its lack of effects on the absorption and/or metabolism of co-administered chemotherapy drugs, orally or by other routes of administration. Canalevia acts by normalizing the flow of excess ions and water in the intestinal lumen. The flow of excess ions and water into the intestinal lumen is the last step common to the manifestation of acute diarrhea. As a result, we believe Canalevia may be effective in the treatment of acute diarrhea, regardless of cause, including CID.

Human formulations of crofelemer have been studied and found effective in human patients with various types of watery diarrhea, including traveler's diarrhea, HIV-related diarrhea and other acute infectious diarrheas, including cholera. Crofelemer has been clinically demonstrated to have a safety profile not different from placebo in humans and several animal species, including dogs.

Clinical Data

Canalevia is a canine-specific formulation of crofelemer. 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. A number of clinical studies of crofelemer were conducted by Napo in dogs in support of this approval that included dose toxicity studies. Safety was established by conducting a series of toxicity studies involving a total of 32 dogs six months of age and older. Dosage levels varied within and across the studies: two single dose acute toxicity studies were conducted on four dogs each; two seven-day repeat administration studies were conducted on four dogs each; one 30-day repeat administration study was conducted on four dogs; and one nine-month repeat administration study on eight dogs. The toxicology studies in dogs showed minimal to no adverse effects following dosing up to approximately 50 times the anticipated efficacious dose. The clinical studies previously conducted in dogs also included multiple dose studies. We believe these studies will meet FDA requirements for a pivotal safety package and will support our anticipated dosing of Canalevia in dogs with CID. We expect to conduct safety studies in dogs as young as eight weeks of age to expand the labelled indication of Canalevia to include acute diarrhea.

In multiple third-party human clinical trials involving approximately 2,400 patients, enteric-coated crofelemer showed statistically significant results relative to placebo in normalizing stool formation and improvements in other endpoints related to treating watery diarrhea. In these trials, the "p" values were statistical calculations to determine whether the effects of crofelemer were significant in comparison to placebo based on pre-specified statistical targets. Depending on the trial design, we specified that any result less than p=0.05 would be significant. In a pivotal trial in support of approval for human use, crofelemer demonstrated significant benefit in the chronic indication of diarrhea in adults with HIV/AIDS on anti-retroviral therapy, achieving highly significant results (p=0.0096) in the primary endpoint measuring frequency of diarrhea.

Table of Contents

In addition to the pivotal trial in HIV/AIDS associated diarrhea, human clinical trials included double-blind, placebo-controlled chronic and acute studies, across different human patient populations, and included safety studies in pediatric patients as young as three months of age. For example, in a 3-day treatment study of approximately 100 adult human patients with acute watery diarrhea of multiple and/or unknown etiologies, crofelemer achieved clinical success in 79% of the patients, compared to 28% receiving placebo ($p<0.05$). Clinical success was defined as the complete cessation of diarrhea for 12 hours or two consecutive normal stools within 48 hours of first dose. Crofelemer also achieved statistical significance across each of the seven other endpoints measured in that study, including a 96% reduction in watery stools from baseline, compared to 54% for placebo ($p<0.05$) and an 89% reduction in urgency compared to 43% for placebo ($p<0.05$). Across the diseases and human patient populations studied to date with crofelemer, there have been no drug related serious adverse events or safety profile different from placebo.

In June 2015 we completed a pilot safety study involving the anticipated commercial formulation of Canalevia in dogs suffering from CID. The objective of the multi-site study was to determine the safety and tolerability of enteric-coated crofelemer tablets in dogs with CID when administered orally twice daily for six treatments at the recommended dose range of 2-4mg/kg. The eight dogs that participated in the study were enrolled based on current or historical episodes of diarrhea correlating to chemotherapy treatment. The study was a safety assessment as requested by the FDA, and diarrhea or unformed stool consistency was not an eligibility criteria. However, 25% of the dogs entered the study with unformed stools and responded during the treatment with formed or amorphous stools or no stool. None of the remaining dogs progressed to unformed stools.

Next Steps and Commercialization Plans

We have received MUMS designation for Canalevia for the treatment of CID in dogs which provides an opportunity to shorten the timeframe to commercialization. We are relying on previously conducted toxicology studies in dogs that were required for FDA approval of the human formulation of crofelemer to provide required safety data. We have established a safety database that we believe meets the qualifications for MUMS designation. We had meetings with the FDA in October and June 2014 to reach agreement on the timing for submissions of the technical sections of an NADA filing. In August 2015 we completed submission of all required major technical sections for the NADA for CID to the FDA for phased review. We expect to receive FDA acknowledgment of the completion of all required technical sections in support of conditional approval of Canalevia in 2016 for CID in dogs. With conditional approval under MUMS designation, we would be required to initiate a pivotal study in the five years following such conditional approval to generate the data required for full FDA approval. We expect to meet this requirement with data generated concurrent with our ongoing clinical development program for the expanded indication of acute diarrhea in dogs.

We plan to market Canalevia, if conditionally approved by the FDA, through a focused direct sales force and to complement our relationships with distribution partners.

Canalevia Expansion to Acute Diarrhea in Dogs

Overview

We are also developing Canalevia for acute diarrhea in dogs, regardless of cause. In December 2015 we initiated a pivotal field study to evaluate the safety and effectiveness of Canalevia for the treatment of acute diarrhea in dogs. According to the American Veterinary Medical Association, there were approximately 70.0 million dogs in the United States in 2012. In February 2015 we completed a randomized, blind, multicenter proof-of-concept study of Canalevia in dogs, with statistically significant results. Crofelemer, the API in Canalevia, demonstrated efficacy in numerous human clinical trials of acute watery diarrhea induced by various infectious pathogens, including *E. coli*, *V. cholera* and non-specific pathogens (*e.g.*, Traveler's). Following oral dosing for two or three days, crofelemer, together with ORS,

Table of Contents

produced significant reduction in watery diarrhea, as demonstrated by the reduction of watery stool passage as well as reduced duration of diarrhea, urgency and dehydration.

Market Opportunity

Diarrhea is one of the most common reasons for veterinary office visits for dogs and the second most common reason for visits to the veterinary emergency room, yet there are currently no FDA-approved anti-secretory agents we are aware of to treat the indication. We estimate that veterinarians see approximately six million annual cases of acute and chronic diarrhea in dogs in the United States, approximately two-thirds of which are acute diarrhea.

Veterinarians typically treat acute diarrhea in dogs with antibiotics, probiotics, dietary restrictions and products approved and formulated for humans, such as Imodium and other anti-motility agents, as well as binding agents that absorb water such as Kaopectate and Pepto-Bismol. None of these treatment options address the water loss associated with acute diarrhea. Further, because none of the human products are FDA approved for animal use, veterinarians do not have the benefit of clinical support with respect to efficacy or dosing. Moreover, administering a potentially unpalatable human formulation is often difficult and may lead to further uncertainty of the amount actually ingested by the dog.

We believe that Canalevia is an ideal treatment for acute diarrhea in dogs because of its demonstrated novel anti-secretory mechanism of action. If approved for use in acute diarrhea in dogs, we believe Canalevia will be the only FDA-approved anti-secretory agent to treat diarrhea in dogs.

Clinical Data

Overview. Canalevia demonstrated a statistically significant clinical response and resolution of diarrhea in a randomized, blind, multicenter study, which assessed the clinical efficacy in alleviating clinical signs associated with watery diarrhea in dogs. The five-month trial was completed in February 2015. This was a proof of concept study with the goal of defining endpoint assessments and statistical analyses to inform a trial design to FDA for a pivotal regulatory dog Canalevia study for the more general watery diarrhea indications.

Study Protocol. The goal of the study was to investigate the treatment group differences in change from baseline fecal consistency and frequency in dogs with watery diarrhea during a three-day exposure to either Canalevia or placebo. Veterinarians or trained veterinary technicians conducted this blinded, randomized, placebo-controlled, proof-of-concept study over a five-month period using animals obtained through rescue organizations, shelters and from client owners. There were 39 dogs enrolled in the study based on a score of stool formation (described in the chart below). Dogs were enrolled in the trial if they were determined to have a baseline fecal score of 4 or 5. Dogs with bloody diarrhea (*i.e.,* fecal score of 6) and/or suspicion of parvovirus were excluded. Subsequent to enrollment, the dog was confined and treatment was administered at the beginning of the score confirmation.

Fecal Scoring Chart Purina Dog Scale

Score	Description
1	Well-formed, moist stools
2	Soft, moist, amorphous
3	Viscous liquid with some particulate matter
4	Watery, liquid stool with little particulate matter
5	Severe watery diarrhea; no particulate matter visible
6	Hemorrhagic diarrhea

Dogs were randomly allocated in a 1:1 ratio to one of two treatments. The treatments were Canalevia (crofelemer) ~2 mg/kg BID (actually dosed at 40 mg packet for animals weighing 2 - 20 kg and two 40 mg

Table of Contents

packets for dogs 20 - 40 kg) and placebo. Each dog was treated twice a day for three days so that six doses of test article were received. For the shelters, it was planned that six assessments of fecal scores would be taken per day for each of the three treatment days and one additional follow-up day. For dogs enrolled at clinics, there could be less data because animals can be released after four treatments if the diarrhea had resolved. Treatment was assigned as A and B, but statistical analyses were blinded as to whether the treatment assignments correspond to Canalevia or placebo.

Fecal scoring endpoints were defined using the chart above.

Fecal Score Analysis. A total of 39 dogs were analyzed: 23 on Canalevia and 16 on placebo. The mean baseline fecal score in both treatment groups is 4.2. The proportion of dogs with alleviated signs of acute watery diarrhea was analyzed. Resolution of diarrhea was defined as a fecal score of 1 or 2 at any post-baseline time. Dogs that did not have a score of 1 or 2 recorded were considered not resolved.

Resolution of Diarrhea. Using a definition of diarrhea resolution being a fecal score of 1 or 2 at any post-baseline time, 21 of 23 (91.3%) dogs on Canalevia responded. This contrasts with placebo, where 8 of 16 (50.0%) dogs responded. These response rates support the conclusion that a larger proportion of dogs on Canalevia respond as compared to placebo. The two-sided p-value from Fisher's Exact test is 0.0073.

Clinical Responder Evaluation. Under the framework of the endpoint definitions, each dog was coded as a responder or nonresponder on each day. As seen in the table below, response in the Canalevia arm is greater than placebo on all days by at least 10%. A responder is a dog who had formed stools with no follow up unformed stool, day by day.

A Cochran-Mantel-Haenszel test stratified by day provides evidence that the clinical response in Canalevia is greater than placebo (p=0.013).

Using a Fisher's Exact test a significant difference occurs after the treatment period, on Day 4 (p=0.046).

Clinical Response by Day

Table of Contents

The protocol for this study is based on our experience and success in previous human and dairy calf studies evaluating *Croton lechleri* derivatives and their effect on acute diarrhea. Based on the results, we are seeking protocol concurrence from the FDA and anticipate completing the pivotal trial to evaluate the safety and effectiveness of Canalevia for the indication of acute diarrhea in dogs in 2016. In December 2015 we initiated this pivotal trial. The prospective, blinded, randomized, placebo-controlled study will be conducted on an inpatient basis at private veterinary practices, animal shelters and animal rescues across the U.S. A single protocol will be followed at all sites, and enrolled dogs will remain on-site and be individually housed for the duration of the study. The study will enroll at least 150 dogs exhibiting secretory, or watery, diarrhea. Participating dogs will be randomized to receive either Canalevia or a placebo orally twice daily for three days. The study's primary endpoint will be to demonstrate a resolution of diarrhea. The study period will be divided into three 24-hour treatment periods followed by a 24-hour observation period, and fecal assessments will be completed at least six times daily. Study completion testing will include a physical examination, clinical pathology testing and a final fecal assessment.

Equine Product Candidates

Jaguar is developing a full suite of products to support and improve gastrointestinal health in foals and adult horses. Gastrointestinal conditions such as acute diarrhea, ulcers and diarrhea associated with acute colitis can be extremely debilitating for horses, and present a significant economic and emotional burden for veterinarians and owners around the world.

We intend to develop a species-specific formulation of crofelemer to treat diarrhea associated with acute colitis in horses. We believe colitis affects thousands of horses in the United States each year, and in December 2015 we completed a pilot safety study in conjunction with Louisiana State University to evaluate crofelemer in adult horses, the first step in the development program for acute colitis. The study involved three healthy horses treated with three consecutive, three-day cycles of escalating dose levels (up to approximately eight times the proposed dosage in horses) of an oral crofelemer paste. Clinical observations, vital signs, biochemical changes (complete blood count, serum chemistry and urinalysis) and adverse events were evaluated for dose-limiting toxicity after each dose level. The study concluded that dose-limiting toxicities were not observed at any of the three dose levels.

We are also developing a formulation of a *Croton lechleri* product for the treatment of ulcers in horses. Ulcers are lesions of the lining of the digestive tract and are very common in horses used for many competitive activities including racing, dressage, show jumping, endurance events, and western performance. Diarrhea is often a coincident problem. We believe that because *Croton lechleri*-derived products have been shown to act locally in the gut and have traditional use and rodent model benefit for ulcers, this equine formulation of a *Croton lechleri*-derived product has the potential to address ulcers in horses, as well as diarrhea. Data from the American Horse Council states that there are currently 9.2 million horses in the U.S., a population that includes 844,531 race horses, more than 2.7 million show horses, and more than 3.9 million recreational horses. Data from the Food and Agriculture Organization of the United Nations indicate that there were approximately 5.7 million horses in Europe in 2013 and nearly 60 million horses in 2013 worldwide. We believe that many owners give their horses daily doses of omeprazole and/or sucralfate to treat and prevent ulcers, which practice can cost up to $50 per day.

In January 2016 we announced positive topline results from the proof-of-concept study we initiated in November 2015 to evaluate the safety and effectiveness of our investigational new animal drug, currently referred to as SB-300 for the treatment of EGUS (DEFINE) in horses.

In this prospective, blinded, randomized, negative controlled study, Standardbred or Thoroughbred racehorses were randomized to one of three groups (10 horses per group) and treated for 28 days: horses in the placebo group received water-filled syringes every 6 hours; those in the TRT5 group received 5 grams of SB-300 divided into 2 doses per day; and those in the TRT40 group received 40 grams of SB-300 divided into 4 doses per day. Strict enrollment criteria required patients to have both squamous (non-glandular) and glandular gastric ulcerations. All horses were examined by gastroscopy (stomach

Table of Contents

endoscope) by blinded equine investigators on Day 0 (prior to treatment; baseline), and on Day 14 (mid-study), Day 28 (last day of treatment) and Day 35 (7 days after last treatment). Treatment-related adverse events were not observed.

With respect to glandular ulcerations, a statistically significantly greater number of horses in both the TRT40 (89%) and the TRT5 (78%) group had an improvement or a resolution of glandular ulcerations, compared with the placebo (25%) group as soon as Day 14. By Day 35, all of the SB-300 treated horses had experienced improvement or resolution, whereas 25% of horses in the placebo group still had not improved or resolved during the study.

With respect to squamous ulcerations, a non-statistically significant dose-dependent effect was observed with 40% and 33% of horses achieving an improvement or a resolution by Day 14 in the TRT40 and TRT5 groups, respectively, compared with 11% of placebo horses. By Day 35, numerically more horses in the TRT40 (60%) and TRT5 (55%) groups had achieved an improvement or a resolution compared with 33% of placebo horses.

In February 2016 we announced that further analysis of the study results indicates that SB-300 did not alter gastric pH during the trial, or for 7 days after therapy. Gastric pH during therapy was observed to be similar to baseline gastric pH at all measured study time points. Whereas other ulcer treatments (e.g. proton pump inhibitors like omeprazole) rely on a mechanism of action that blocks gastric acid secretion for the treatment and prevention of equine gastric ulcer syndrome (EGUS), our preliminary data indicate that SB-300 may have advantages. Treatments for EGUS that do not alter gastric pH are important because maintaining low gastric pH is essential for digestion, for gut immunity and first line defense against pathogens, for the absorption of vitamins and minerals, and for potentially other downstream effects.

SB-300 may offer horse owners an additional advantage over omeprazole in the competition horse world, where the requirement exists for equine athletes to compete free from the effect of any drugs. International screening limits for horse racing state that omeprazole has a 72-hour detection time. Detection time is defined as the first observed time point at which urine and/or plasma samples collected from a horse are negative for the presence of a specified drug. Because SB-300 acts locally in the gut and is minimally absorbed, it is unlikely that use of this drug product candidate will present any issues related to detection time. We intend to demonstrate that SB-300 is not systemically absorbed in horses, thereby providing a treatment regimen that can continue without mandatory withdrawal prior to competition. Moreover, we also aim to demonstrate that SB-300 can be administered in the presence of feed, another constraint of omeprazole administration.

Following the late stage development toward anticipated FDA approval of SB-300, Jaguar plans to focus initial promotional efforts on the segment of the equine market that is most likely to seek treatment for EGUS: owners and caregivers of high-value horses, equine athletes, and horses that are insured. According to the American Veterinary Medical Association, an estimated 9% of horse owners in the U.S. have insurance for the animals.

The U.S. patent for use of omeprazole to treat equine ulcers expired in 2015.

Until recently, treatment recommendations for equine ulcers have not differentiated between squamous and glandular disease. However, a series of recent third-party studies indicate considerably lower healing rates for glandular ulcers with standard of care (e.g. omeprazole). Subclinically, these lesions can compromise athletic performance.

It is clear that development of a natural alternative treatment for EGUS that maintains stomach health without altering stomach pH is desirable. We are planning to initiate a dose determination study in the second quarter of this year to determine the minimum effective dose of SB-300 for the treatment of EGUS and to support development of the optimal commercial formulation. We also plan to initiate a field study for SB-300 later in 2016, timed to take place during horse racing off-season, when race horses are available to participate.

Table of Contents

Our goal is to see SB-300 serve as an important tool in the standard of care of horses with all types of ulcers. Additionally, we believe a significant market exists for a product that treats both gastric and colonic ulcers in horses without altering stomach pH. According to a 2005 study, 54% of performance horses have both colonic and gastric ulcers and 97% of performance horses have either a gastric (87%) or a colonic (63%) ulcer. While we are initially developing SB-300 for the indiction of EGUS, we plan to investigate the possible efficacy of this product candidate for treatment of colonic ulcers as a follow on indication in horses following the anticipated launch of SB-300.

Crofelemer Cats

According to the American Veterinary Medical Association, there were approximately 74.0 million cats in the United States in 2012. We estimate that veterinarians see approximately 2.9 million annual cases of general watery diarrhea in cats. Veterinarians typically treat watery diarrhea in cats with the same treatments used for dogs, namely antibiotics, probiotics, dietary restrictions and products approved and formulated for humans, such as Imodium and other anti-motility agents, as well as binding agents that absorb water such as Kaopectate and Pepto-Bismol.

We are currently developing a species-specific formulation of crofelemer, Felevia, for cats. We intend to conduct proof-of-concept and pivotal studies in cats in 2016. If data is positive, we anticipate initiating NADA filing in 2017.

Neonorm Calf Improve Gut Health in Preweaned Dairy Calves with Scours

Overview

This formulation of Neonorm is an enteric-coated tablet designed to be orally administered to preweaned dairy calves twice daily for three days. In our clinical study completed in May 2014, Neonorm demonstrated a statistically significant reduction in morbidity, as well as reduced mortality and improved weight gain as compared to placebo in newborn dairy calves with scours. We recently launched Neonorm for preweaned dairy calves in the United States under the brand name Neonorm Calf. We do not believe that Neonorm Calf fits within the FDA's definition of an animal drug, food or feed additive. Thus, we do not believe that it is regulated by the FDA at this time. The FDA previously regulated a human-specific formulation as a dietary supplement, rather than as a drug. To support the commercial launch, we completed field studies of Neonorm Calf involving approximately 400 preweaned dairy calves in total with Cornell University and in collaboration with our distributor, Animart.

Scours Market Opportunity

Scours refers to watery diarrhea in production animals, including dairy calves, which results from infectious agents that cause the secretion of ions and water into the intestinal lumen. Animals with scours may experience severe dehydration and electrolyte imbalance, which can lead to renal insufficiency, nutritional deficiencies, lower production in dairy cattle and even death. Current therapy include fluid and electrolyte replacement, continuous milk feeding, antibiotics (for calves with systemic involvement (*e.g.*, fever) with an increased risk of bacteremia), non-steroidal anti-inflammatory drug therapy and vaccines.

According to the USDA, there are approximately 9.2 million lactating dairy cows in the United States. We estimate from USDA sources that there were over 11.0 million dairy calves born in 2013. Dairy cows are continuously bred, both to maintain lactation and to produce dairy calves to maintain the herd. Dairy calves are separated from their mothers shortly after birth and raised on commercial milk replacers until weaned at about 60 days of age. Almost one in four, or 23.9%, of dairy heifer calves had diarrhea or other digestive problems according to the USDA Dairy 2007 study. Scours, diarrhea or other digestive problems are responsible for more than half of all preweaned calf deaths, and result in supportive care and treatment costs, impaired weight gain and long-term reduction in milk production. Of dairy farm

Table of Contents

operations surveyed in the Dairy 2007 study, 62.1% used antibiotics for diarrhea or other digestive problems, including preweaned heifer calves not reporting diseases or disorders. Of preweaned calves that were affected by diarrhea or other digestive problems, almost three-fourths, or 74.5%, were treated with an antibiotic.

Our Solution

We believe Neonorm Calf is an ideal solution to improve gut health and normalize stool formation in dairy calves suffering from scours. Neonorm Calf has been formulated and clinically tested to improve gut health by specifically addressing the normalization of stool formation and ion and water flow in the intestinal lumen of newborn dairy calves with scours. Like Canalevia, Neonorm Calf acts locally in the gut and is minimally absorbed systemically. It does not alter gastrointestinal motility, has no significant effects on normally functioning intestinal ion channels and electrolyte or fluid transport, and has no side effects different from placebo. As a result, stool formation is normalized in a short period of time, weight loss is mitigated, supportive care costs and rehydration therapies such as ORS are reduced, and the risk of mortality is minimized.

Clinical Data

A challenge clinical study was completed in May 2014 by researchers from Cornell, and published in 2015 in the official journal of the American Dairy Science Association, *Journal of Dairy Science*. The results of this study suggest that Neonorm Calf can significantly increase the fecal dry matter of neonatal calves with experimentally-induced enterotoxigenic *E. coli* diarrhea, and suggest a potential benefit of Neonorm Calf in supporting weight gain in calves.

A further analysis, completed in October 2015, of the above-referenced Cornell study supports a benefit of Neonorm Calf on the optimization of the intestinal microbiome profile in preweaned dairy calves, a potential prebiotic benefit. The microbiome is a community of microorganisms that live normally in the gut and are vital to maintenance of gut health.

We recently initiated a placebo-controlled study in conjunction with researchers from Cornell to evaluate the efficacy of the prophylactic use of a second-generation formulation of Neonorm Calf administered in liquid on naturally occurring diarrhea in preweaned dairy calves and investigate the possible prebiotic benefit of the product. This double-blinded, randomized study will involve 40 Holstein bull calves affected with naturally occurring diarrhea. This study will generate significant amounts of data that we expect will enlighten the mechanism by which the prophylactic use of the second-generation formulation of Neonorm Calf may support the gut health of preweaned calves herd-wide during naturally occurring diarrhea. Additionally, characterization of the fecal microbiome throughout the preweaning period will allow us to demonstrate that, under natural conditions, the product may positively alter the intestinal microbiome to the benefit of the host. The possible beneficial prebiotic mechanism of Neonorm Calf would supplement and is potentially synergistic with the anti-secretory and weight gain benefits of the product. We expect results from this study to be available in 2016.

Neonorm Line Extensions

We believe that due to Neonorm Calf's mechanism of action and our data in preweaned dairy calves, we will be able to develop and commercialize species-specific formulations of Neonorm for the estimated approximately 22.0 million beef calves in the United States, and multiple other animal species, such as horses, goats and sheep. Published sources indicate that approximately 2.4% of beef calves younger than three weeks old suffer from diarrhea. We believe that there is an opportunity to target large-scale commercial livestock operations, first in the United States, and later, internationally. In less developed nations, where not only dairy and beef cattle but also buffalo, goat and sheep provide livelihoods for local populations, reducing losses related to diarrhea can provide significant monetary, social and health

Table of Contents

benefits. Today, these groups are already accessed by distributors with whom we intend to work to extend the reach of Neonorm Calf and line extension products.

In December 2015 we conducted the soft launch of Neonorm Foal, our lead non-drug product to promote normal fecal formation and reduce fluid loss in foals. We are planning studies of an equine formulation of Neonorm for adult horses with episodic diarrhea. Published studies estimate that there were 9.2 million horses in the United States in 2005. Diarrhea is among the most common clinical complaints in foals. Often, diarrhea occurs in the first 30 days of the foal's life, both from infections and non-infectious causes, such as lactose intolerance and overfeeding. Some cases are severe and life threatening. A majority of foals will exhibit diarrhea at some point within the first two months of life. In adult horses, episodic diarrhea is mostly associated with diseases of the large intestine and damage to the colon or disturbance of colonic function. Typically, diarrhea in horses is treated with fluid replenishment and electrolytes, deworming agents and antibiotics, and intestinal protectants and absorbents, as well as anti-motility agents. To our knowledge there are currently no anti-secretory products approved by the FDA for veterinary use.

In December 2015 we announced positive results for an exploratory, investigator-initiated follow-up study which assessed the safety and performance of Neonorm Foal, without inclusion of a probiotic, in pre-weaned foals with watery diarrhea. This six-day, multi-site study (ARG102) involved 20 foals suffering from secretory, or watery, diarrhea, all of which were placed into one treatment group. During the treatment period, which lasted 72 hours, Neonorm Foal was administered orally, in paste formulation, twice daily for six treatments. In this study, a non-enteric form of Neonorm Foal was used. The treatment period was followed by a 72-hour observation period. Fecal scoring was conducted every six hours during both the treatment and observation periods. The study took place in Argentina, during the southern hemisphere foaling season.

In November 2015 we completed an initial proof-of-concept study (NEO101) of Neonorm Foal in Argentina that involved 60 foals. The objective of this earlier, randomized, multi-site, blinded, placebo-controlled study was to evaluate the safety and performance of the product for treatment of foals suffering from secretory diarrhea, and the treated animals received Neonorm Foal in combination with a third-party probiotic. The results of a meta-analysis between the two studies demonstrated a significantly higher percentage of foals with clinical response and resolution of diarrhea for Neonorm Foal, from either ARG102 or NEO101, compared with the placebo group in NEO101.

During the 72-hour treatment period, 35% of placebo-treated foals in NEO101 were identified as clinical responders, compared with 85% of foals treated with Neonorm Foal in ARG102. For the purposes of both studies, clinical responders were defined as foals that achieved a formed stool by the end of the reported period.

During the 72-hour treatment period, resolution of diarrhea was observed in 41% of placebo-treated foals in NEO101 compared with 85% of foals treated with Neonorm Foal in ARG102. For the purposes of both studies, resolution of diarrhea was defined as a foal that produced a formed stool at any point during the reported period.

Other Product Candidates and Development

We have planned multiple clinical studies over the next 12 to 18 months, to expand Canalevia and Neonorm to additional species. We believe that we will be successful because:

- we have existing safety and efficacy data for our products and product candidates in dogs, dairy calves and/or humans;
- each of these products works through the normalization of ion and water flow into the intestinal lumen; and

Table of Contents

this physiological pathway is generally present in mammals.

Additionally, we plan to initiate clinical studies for Virend and NP-500 in 2016 and beyond, both of which have been through Phase 2 human clinical testing by third parties and studies with combinations of rifaximin and *Croton lechleri* derived products. NP-500 is isolated and purified from a plant indigenous to the southwestern United States, and in traditional medicine, the plant was brewed as a tea and used for the treatment of diabetes and other various illnesses. We are currently developing species-specific formulations of NP-500 to treat obesity-related metabolic dysfunction in dogs, Type II diabetes in cats and metabolic syndrome in horses, and have filed three INADs for these indications.

According to a 2013 national survey of veterinarians, approximately 17% of dogs in the United States are obese. Studies show that obesity is more common in elderly dogs, as well as in neutered dogs. Obesity-related metabolic dysfunction manifests in altered lipid profiles, insulin resistance and mild hypertension, which could decrease a dog's lifespan. There are currently no FDA-approved products for the treatment of metabolic syndrome or insulin resistance in dogs. In cats, the prevalence of obesity-related diabetes or Type II diabetes is high and increasing. In horses, insulin resistance is associated with an equine metabolic syndrome characterized by obesity, regional adiposity and hypertriglyceridaemia. It is also known to be a risk factor for laminitis. Various studies report the prevalence of insulin resistance as 10% and 28% in horses and ponies, respectively. There are also currently no FDA-approved products for the treatment of metabolic syndrome in horses.

We anticipate that our development activities will benefit from centralized activities, including shared use of the manufacturing and regulatory documentation for chemistry, manufacturing and controls, or CMC. We also anticipate being able to enter into combined clinical research agreements and activities with companion animal clinical trial sites for dogs and cats.

Sales and Distribution

In September 2014, we launched Neonorm for preweaned dairy calves under the brand name Neonorm Calf in the Upper Midwest region, and expanded the launch nationwide in early 2015. In December 2015 we conducted the soft launch of Neonorm Foal, our non-prescription product, to promote normal fecal formation and reduce fluid loss in foals. We expect to launch Canalevia in 2016. We intend to establish a focused direct sales force for both the production and companion animal markets, and we have already hired our first sales representatives for Neonorm Calf. We will focus our sales and marketing efforts on educational activities and outreach to key opinion leaders and decision makers at key regional and global accounts for production animals and high prescriber veterinarians for companion animals. 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. In February 2015, we entered into a five-year distribution agreement with Biogenesis Bagó for sale and distribution of Neonorm Calf in South America. Biogenesis Bagó is the largest veterinary biotechnology company in Latin America, a region that contained approximately 401 million dairy and beef cattle in 2009 and produces approximately 11% of the world's milk supply. Biogenesis Bagó recently won "Best Animal Health Company in Latin/South America," awarded by a publication called Animal Pharm. Our distribution agreement provides Biogenesis Bagó with exclusive distribution rights for Neonorm Calf in Argentina, Brazil, Paraguay, Uruguay, and Bolivia. Under the terms of the distribution agreement, we can terminate the agreement if Biogenesis Bagó fails to meet annual sales goals for each year of the five-year agreement, and we may revoke exclusivity if Biogenesis Bagó fails to meet guaranteed minimum sales. We also agreed to additional incentive payments if stretch goals are exceeded.

We plan to partner with other leading distributors to deliver our products to customers both in the United States and internationally, and may also explore entering into partnerships that include payment of upfront licensing fees for our products and product candidates for markets outside the United States

Table of Contents

where appropriate. For example, 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. We expect that our current and future partners will have the presence, name recognition, reputation and reach in the veterinary markets and in both key urban and rural centers, as appropriate. We believe this overall approach is scalable and transferable as we expand our commercialization efforts, as well as when we further expand internationally including to resource-constrained countries where food safety issues are emerging global challenges.

Manufacturing

The plant material used to manufacture Canalevia, Neonorm and related products is crude plant latex, or CPL, extracted and purified from *Croton lechleri*, a widespread and naturally regenerating tree in the rainforest that is managed as part of sustainable harvesting programs. The tree is found in several South American countries and has been the focus of long-term sustainable harvesting research and development work. Our collaborating suppliers obtain CPL and arrange for the shipment of CPL to our third party contract manufacturer. CPL will also be shipped to us for manufacturing after we establish our own API manufacturing capability.

Our third-party contract manufacturer will process CPL into both crofelemer, the API in Canalevia, and the botanical extract used in both Neonorm Calf and Neonorm Foal. This manufacturing process uses exclusive Napo intellectual property licensed pursuant to the Napo License Agreement. Canalevia will be manufactured by the same process used to manufacture the API that was used in the animal safety studies and the human studies in support of the approval of Fulyzaq. Napo has also licensed this intellectual property to third parties in connection with its licenses related to the development and commercialization of crofelemer for human use. While we believe these third parties have developed their own proprietary manufacturing specifications pursuant to their license agreements, such third-party intellectual property is unknown to us, is not licensed to us pursuant to the Napo License Agreement, and is not part of the intellectual property that we intend to use for the manufacture of API in our licensed field of use. Similarly, the manufacture of Neonorm depends only on technology licensed from Napo. The license grant specifically excludes intellectual property rights developed pursuant to a prior collaboration agreement between Napo and Glenmark Pharmaceuticals, Ltd., or Glenmark, the manufacturer of the API in Fulyzaq. In May 2014 and June 2014, and as amended in February 2015, we entered into binding memorandums of understanding with Indena S.p.A. to negotiate a definitive commercial supply agreement for the manufacture of the API in Canalevia and the botanical extract in Neonorm. We have furnished equipment to Indena S.p.A. for use in a facility that will be dedicated to the manufacture of crofelemer and the botanical extract.

In December 2015, Indena delivered 360 kilos of the standardized botanical extract to us. We currently own enough of the Neonorm standardized botanical extract to formulate a combination of approximately one million treatments of Neonorm Calf or Neonorm Foal. Indena S.p.A. has agreed to supply us with two pilot lots (approximately 60 kg) of botanical extract, as well as the API in Canalevia (approximately 3 kg) and data to support our anticipated regulatory filings.

Pursuant to the memorandums of understanding as amended, we agreed to pay Indena S.p.A. the following fees in connection with the establishment of our manufacturing arrangement:

- a start-up fee equal to €500,000, payable in two equal installments, both of which were paid in May 2015;

- fees associated with the technology transfer and manufacturing process adaptation equal to €620,000 for API which was paid in May and July 2015;

Table of Contents

fees for the design and set up of a dedicated suite qualified for pharmaceutical and veterinary products equal to €170,000 which was paid in May 2015;

deliverables fees equal to €500,000, €250,000 of which was paid in December 2015, and €250,000 of which is payable by the end of March 2016, with the understanding that these fees will be credited against payments agreed to under the future commercial supply agreement; and

a €300,000 bonus fee payable in two equal installments, the first of which was paid in March 2015, with the remainder paid by the end of March 2016.

In March 2015, Indena S.p.A. agreed to delay payment of the fees payable by the end of March 2015 until the earlier of April 30, 2015 or the completion of our initial public offering. In July 2015 and December 2015 Indena S.p.A agreed to delay payment of certain fees payable until March 2016. As of December 2015 we owe Indena S.p.A €400,000 or $440,000 converted at $1.10 per Euro. In June 2014, as contemplated by the memorandums of understanding, we also issued Indena S.p.A. a warrant to acquire 16,666 shares our common stock at an exercise price per share equal to 90% of the initial public offering price, which expires in June 2019.

In September, 2015 we entered into a distribution agreement with Glenmark Pharmaceuticals Ltd., or Glenmark. With the execution of the agreement, we intend to use Glenmark as our primary manufacturer of crofelemer for animal health use. Our agreement with Glenmark supplements our previously announced manufacturing agreement with Indena S.p.A for the standardized botanical extract in Neonorm Calf and Neonorm Foal. We intend to eventually use Indena as an alternative supplier for crofelemer.

In October 2015, we announced that we signed a crofelemer formulation development and manufacturing contract with Patheon Pharmaceuticals Inc., or Patheon, a leading global provider of drug development and delivery solutions to the global pharmaceutical and biopharma industries. Under the terms of the contract, Patheon will provide enteric-coated crofelemer tablets for Jaguar for use in animals. The tablets will be used in our pivotal efficacy trial for Canalevia, which began in the fourth quarter of 2015. We expect to use safety and effectiveness data from this trial in support of the initiation of the filing of a NADA with the FDA for Canalevia in 2016 for the indication of acute diarrhea in dogs.

Patheon is the manufacturer of Fulyzag, a human-specific, enteric-coated formulation of crofelemer that was approved by the FDA in 2012 for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. Members of our management team developed crofelemer while working at Napo where the drug was initially developed.

We also plan to enter into agreements with third parties for the formulation of the API and botanical extracts into finished products to be used for planned studies and commercialization.

The facilities of our third-party contract manufacturers that will manufacture our API and botanical extract, as well as formulate our finished products, comply with cGMP and other relevant manufacturing requirements.

Competition

The animal health industry is dominated by large independent companies such as Zoetis Inc., a standalone animal health company that was spun out from Pfizer, Inc. in 2013, as well as subsidiaries of large pharmaceutical companies, including Novartis Animal Health Inc., a subsidiary of Novartis International AG., Merck Animal Health, the animal health division of Merck & Co., Inc., Merial Inc., the animal health division of Sanofi S.A., Elanco Animal Health, the animal health division of Eli Lilly and Company, Bayer Animal Health GmbH, a subsidiary of Bayer AG, and Boehringer Ingelheim Animal Health, the animal health division of Boehringer Ingelheim GmbH. There are also animal health companies based in Europe, including Vétoquinol S.A., Virbac S.A., Dechra Pharmaceuticals PLC and Ceva Animal Health S.A.

Table of Contents

Additionally, smaller animal health companies, such as Aratana Therapeutics, Inc., Kindred Biosciences, Inc., Phibro Animal Health Corporation, Nexvet Biopharma and Parnell Pharmaceuticals Holdings Ltd, recently completed initial public offerings of their stock in the United States and may choose to develop competitive products. We believe that the large human pharmaceutical companies may also decide to spin out their animal health subsidiaries into standalone companies.

Although, to our knowledge, there are currently no FDA-approved anti-secretory products to treat acute 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. We are aware that veterinarians typically treat acute diarrhea in dogs with antibiotics, probiotics, dietary restrictions and products approved and formulated for humans, such as Imodium and other anti-motility agents, as well as binding agents that absorb water, such as Kaopectate and Pepto-Bismol. None of these treatment options address the water loss associated with acute diarrhea. We are not aware of any veterinarians prescribing Fulyzaq extra-label for use in dogs, and the indication of Fulyzaq is for a disease that does not occur in dogs. Further, because none of the human products are FDA approved for animal use, veterinarians, although allowed to dispense human products for animal use, do not have the benefit of clinical support with respect to efficacy or dosing. Moreover, administering a potentially unpalatable human formulation is often difficult and may lead to further uncertainty of the amount actually ingested by the dog. However, this practice may continue and Canalevia may face competition from these products. Canalevia could also potentially face competition from Fulyzaq were veterinarians to prescribe it extra-label. 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.

Intellectual Property

Napo License Agreement

In January 2014, we entered into the Napo License Agreement, which we amended and restated in August 2014 and further amended in January 2015, pursuant to which we acquired an exclusive, sublicensable, transferable, worldwide license to certain intellectual property rights of Napo and its affiliates to research, develop, formulate, make, have made, use, have used, market, offer for sale, sell, have sold, and import, and to otherwise exploit products of Napo and its other affiliates for all veterinary treatment uses and indications for all species of animals. The license grant specifically excludes intellectual property rights developed pursuant to a prior collaboration agreement between Napo and Glenmark Pharmaceuticals, Ltd., the manufacturer of the API in Fulyzaq. Under the Napo License Agreement, Napo also assigned to us certain raw materials and equipment and granted us a right of reference to the entirety of the information included in the human approved new drug application of crofelemer.

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 (collectively referred to herein as the Products) 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 of $1.75 million, less the option fee of $100,000 paid in July 2013 pursuant to a term sheet we signed with Napo. We paid $25,000 to Napo towards the license fee in December 2014 and in January 2015, agreed

Table of Contents

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

In 2015, we paid $1.2 million in accordance with the agreement and owe $425,000 as of December 31, 2015.

Pursuant to the Napo License Agreement,, 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 a 1% royalty of annual 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. Upon agreement with Napo, we may elect to remit any milestone payments and/or royalties in the form of our common stock.

The royalty term expires on a country-by-country and Product-by-Product basis on the later of: (i) 10 years from the first sale of a Product in such country, on an animal by animal basis; and (ii) the first date on which there is no longer (A) a valid claim within the licensed patent rights covering the use, manufacture or sale of such Product, or (B) any data exclusivity with respect to such Product in such country conferred by the applicable regulatory authority, and in each case of (A) and (B), a competitive product has been introduced into the market in such country. The royalties payable to Napo are subject to reduction, capped at a specified percentage, for any third-party payments made to obtain a license or other rights to issued patents that might present a commercial obstacle to the development, manufacture, use, or sale of a Product in a country. Additionally, if the royalty term for a Product is ongoing post-expiration of the last valid claim within the licensed patent rights that covers such product in any given country, then the royalties we owe Napo will be reduced by a specified percentage until expiration of the royalty term for such Product in such country. Upon the expiration of each royalty term, on a country-by-country and Product-by-Product basis, the license grants shall be fully paid up and we will have perpetual non-exclusive licenses for such Products in such countries. At any time during the term of the agreement, if Napo sells all of its assets relating to the use, production or exploitation of *Croton lechleri* derivative products to a third party, all of the rights granted to us relating to *Croton lechleri* derivative products under the license shall become exclusive in the field of veterinary treatment uses and indications for all species of animals, perpetual, fully paid-up, royalty-free and irrevocable, with the right to grant sublicenses.

Under the terms of the Napo License Agreement, we own all rights, title and interest in our intellectual property and any joint intellectual property developed under the license. We granted Napo a non-exclusive, paid-up, irrevocable worldwide license to our intellectual property developed under the Napo License Agreement for use outside the veterinary field, and an exclusive, paid-up worldwide license to any joint intellectual property developed under the Napo License Agreement outside the veterinary field. We agreed to defend, indemnify and hold Napo, its affiliates, and its officers, directors, employees, consultants and contractors harmless from and against any losses, costs, damages, liabilities, fees and expenses arising out of any third-party claim related to our gross negligence or willful misconduct, breach of our representations, warranties or covenants or the manufacture, sale or use of the Product or Products, in each case, unless such third-party claim is subject to indemnification by Napo. Napo agreed to defend,

Table of Contents

indemnify and hold us, our affiliates, and our officers, directors, employees, consultants and contractors harmless from and against any losses, costs, damages, liabilities, fees and expenses arising out of any third-party claim related to Napo's, its affiliate's or its licensees' (except for us) gross negligence or willful misconduct, or Napo's breach of its representations, warranties or covenants.

We may terminate the Napo License Agreement upon Napo's uncured material breach, bankruptcy or at will after certain notification periods. Napo may terminate the Napo License Agreement upon our uncured material breach or bankruptcy after certain notification periods.

Jaguar and Napo are also engaged in preliminary exploratory discussions to review a potential merger and/or other ways to cooperate with their respective business endeavors.

Patent Portfolio

Under the Napo License Agreement, we have exclusive rights in the veterinary field to an international patent family related to International Patent Application WO1998/16111. The patents and patent applications in this family are directed to enteric protected formulations of proanthocyanidin polymers isolated from *Croton spp* or *Calophyllum spp.* (such as crofelemer and Neonorm), and methods of treating watery diarrhea using the enteric protected formulations for both human and veterinary uses. As such, the patents and patent applications of this family cover certain formulations of crofelemer, including Canalevia, as well as the standardized botanical extract in Neonorm, and methods of treating diarrhea using these formulations. There are three U.S. patents and a pending U.S. patent application in this family, including, US 7,323,195, which has a term until at least June 7, 2018, US 7,341,744, which has a term until at least January 11, 2018, and US 8,574,634, which has a term until at least January 11, 2018. The term of one of US 7,323,195 or US 7,341,744 may be extended to June 2021 and December 2020, respectively, to account for regulatory delay in obtaining human marketing approval for crofelemer (such potential extensions have been filed for and only one of the patents can be extended). Patent protection for enteric protected formulations of crofelemer and methods of use has also been obtained outside the United States, including in Europe, Australia, Canada, India, Japan, Korea, Mexico, New Zealand and Taiwan, with terms extending until at least October 14, 2017 in these jurisdictions. In particular, European patent EP 0 935 417 and Japanese patent no. 4195728 provide protection for enteric protected formulations of crofelemer and the standardized botanical extract in Neonorm in Europe and Japan, respectively, with terms that extend until at least October 14, 2017.

The patents and patent applications we licensed from Napo, or the Napo Patents, are also licensed by Napo to Salix Pharmaceuticals, Inc., or 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 have 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. US 7,323,195; US 7,341,744; and US 8,574,634 are issued Napo Patents. Salix has licensed rights only to human use in certain territories and for certain indications, and currently markets crofelemer (Fulyzaq) for human use and has listed US 7,323,195; US 7,341,744; and US 8,574,634 (along with US 8,962,680, covering treatment of diarrhea in HIV positive subjects) in the FDA's Orange Book for Fulyzaq. We rely on these issued Napo Patents as intellectual property protection for our veterinary prescription drug product candidates and non-drug products. Pending patent applications within Napo Patents either may not be relevant to veterinary indications and/or may not issue as patents. Similarly, under the Salix Collaboration Agreement, Napo and Salix agreed on who has the first right to enforce the Napo Patents against potential infringers, even in our field of use. 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.

Table of Contents

We have filed and have currently pending three applications under the PCT, one U.S. non-provisional patent application and eight provisional patent applications relating to veterinary uses of *Croton* proanthocyanidin polymer compositions, including crofelemer, Neonorm and Canalevia, and product combinations under development. These applications are directed to treatment of watery diarrhea in newborn and young animals, including methods of improving mortality and weight gain in newborn animals, treatment of stress-induced diarrhea in animals, and treatment of watery diarrhea caused by salmonella in animals. These applications also focus on the treatment of diarrhea in companion animals such as dogs and cats. In addition, an application has been submitted for the treatment of ulcers and related symptoms in animals with an emphasis on ulcers in horses. An application has also been filed on a surprising prebiotic effect of crofelemer in bovine and other animal species based on unexpected research findings that indicate a prebiotic enhancement of the gut bacteria in animals. One other patent application has been filed combining crofelemer with rifaximin, a non-absorbed antibiotic for the treatment of bacteria induced diarrhea in multiple animal species. Patents that may issue based upon applications filed claiming benefit of these provisional patent applications should have terms that extend until at least May 2035.

In October 2015 we announced that the U.S. Patent and Trademark Office (USPTO) issued Notices of Allowance in two pending patent applications, one of which has issued a U.S. patent, licensed exclusively from Napo to Jaguar for veterinary use, covering NP-500 and its use. NP-500 is the API in Jaguar's drug product candidates to treat and manage diseases related to insulin-resistance, such as obesity-related metabolic dysfunction in dogs and cats, diabetes mellitus, and potentially equine laminitis. The two NP-500 pending patent applications claim benefit to a provisional application submitted to the USPTO by Napo in April 2011. Per the terms of the license agreement between Napo and us, we have an exclusive license to these intellectual property for all veterinary treatment uses and indications for all species of animals except humans.

Trademarks

We plan to market our products under a trademark or trademarks we select and we will own all rights, title and interest, including all goodwill, associated with such trademarks.

Government Regulation

The development, approval and sale of animal health products are governed by the laws and regulations of each country in which we intend to seek approval, where necessary, to market and subsequently sell our prescription drug and non-drug products. To comply with these regulatory requirements, we are establishing processes and resources to provide oversight of the development, approval processes and launch of our products and to position those products in order to gain market share in each respective market.

United States

Certain federal regulatory agencies are charged with oversight and regulatory authority of animal health products in the United States. These agencies, depending on the product and its intended use may include the FDA, the USDA and the Environmental Protection Agency. In addition, the Drug Enforcement Administration regulates animal therapeutics that are classified as controlled substances. In addition, the Federal Trade Commission may in the case of non-drug products, regulate the marketing and advertising claims being made.

The approval of prescription drugs intended for animal use is regulated by the FDA's Center for Veterinary Medicine, or CVM. The CVM consists of six offices that work together to, in part, approve new drugs for commercialization and thereafter monitor those commercialized drugs once in the market. The Office of New Animal Drug Evaluation, or ONADE, is the lead office for reviewing novel drug candidates. We, as the sponsor of a novel drug candidate, commence the development and approval process by

Table of Contents

initiating communication with the ONADE and opening an INAD file. As part of this process, we will also schedule a discussion of the novel drug's development plan in order to obtain agreement from the CVM for the number, type and design of studies needed to obtain FDA approval of the novel drug.

As required by the FDA, new animal drug products must obtain marketing approval through the NADA process. Under the Administrative New Animal Drug Application, or Administrative NADA, process, a sponsor can engage in a phased submission of the required technical sections of an NADA, known as a rolling NADA, as opposed to submitting the entire application at once with a standard NADA. The requirements for all NADAs are the same regardless of whether a sponsor chooses the rolling NADA or the standard NADA submission. Under the phased review, once all technical sections have been submitted and reviewed, the sponsor submits an Administrative NADA to reflect that all technical sections of the NADA have been submitted and reviewed, each such technical section meets the requirements for approval and the CVM has issued technical section complete letters for each technical section. The phased review and Administrative NADA allow a drug sponsor to engage with the FDA as to each technical section to ensure that each section meets all requirements prior to submission of the application for approval. Phasing of NADA submissions is a voluntary process.

Once the tasks set forth in the development plan have been completed, including the clinical work as well as the chemistry and manufacturing work (feasibility, validation and stability of the drug inclusive), we, as the novel drug sponsor will need to provide to the FDA through the application process, information as to the safety and efficacy of the drug candidate, and, if needed, human food safety studies. These food safety studies are only required for drugs intended for use in production animals, and we currently have no plans to develop drugs for production animals. Additionally, the application will contain a module on CMC, which describes the plan for manufacturing the drug including the API, the final formulation, where it will be made, how it will be made, how the drug will be packaged, how it can be stored, the conditions required for storage and how long it can be stored before expiry. A major part of the CMC section is the analysis we employ to ensure that the manufactured drug is of a high quality, is consistently manufactured under cGMP and is stable. Other significant components to the application we have to complete before receiving drug approval includes a draft label that will list specific information such as dosing information, intended use, warnings, directions for use, and other information as required by the regulations. The package insert that will contain information on studies, warnings, drug interactions, intended use and dosing is considered part of the label in addition to that which is adhering to the container itself. The CVM ensures that the labeling provides all the necessary information to use the drug safely and effectively, and that it clearly discloses the risks associated with the drug.

MUMS Designation

The Minor Use and Minor Species Animal Health Act, or MUMS Act, became effective in August 2004. The purpose of the MUMS Act was twofold: first, to encourage the development and availability of more animal drugs that are intended to be used in a major species defined as dogs, cats, cattle, horses, chickens, turkeys and pigs to treat diseases which occur infrequently or in limited geographic areas, therefore having an impact on a smaller number of animals on a yearly basis; and second, to encourage the development and availability of animal drugs for use in minor species (defined as all animals other than humans that are not one of the major species). The drug sponsor may seek conditional approval of the drug product provided the Office of Minor Use Minor Species, or "OMUMS" acknowledges that the intended use fits within a small number of animals treated per annum. A drug does not have to be designated to be eligible for conditional approval, however if OMUMS designates a MUMS drug, certain incentives and exclusivities are available to the sponsor. The MUMS designation is modeled on the orphan drug designation for human drug development and has certain financial incentives available to encourage MUMS drug development such as the availability of grants to help with the cost of the MUMS drug development. Also, drug developers of MUMS drugs are eligible to apply for a waiver of the user fees once the MUMS designation has been given by OMUMS. We believe that we qualify for MUMS designation for

Table of Contents

Canalevia as a minor use in a major species because the estimated total number of dogs in the United States affected by CID is less than 70,000. To obtain conditional approval of a MUMS drug, the company must submit CMC and safety data similar to that required for an NADA, as well as data suggesting a reasonable expectation of effectiveness. After the submission and the review of the application, the FDA through the CVM can then grant a conditional approval (CA-1). This approval allows for a commercialization of the product, while the sponsor continues to collect the substantial evidence of effectiveness required for a full NADA approval. The sponsor has up to five years to demonstrate substantial evidence of effectiveness for a previously conditionally approved drug. Ideally, MUMS designation helps move the product forward in development; however it may not shorten the time to full commercialization. A sponsor that gains approval or conditional approval for a MUMS designated drug receives seven years of marketing exclusivity.

Protocol Concurrence

We pursued protocol concurrence from the FDA for the pivotal trial of Canalevia that we initiated in December 2015 for acute diarrhea in dogs, and plan to pursue protocol concurrences from the FDA for future pivotal trials in this and other indications. Under this process, a protocol is submitted to the FDA voluntarily by a drug sponsor. The 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 will 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 FDA issues a protocol concurrence, ultimate approval of an NADA by the FDA is not guaranteed because a final determination that the agreed-upon protocol satisfies a specific objective, such as the demonstration of efficacy, or supports an approval decision, will be based on a complete review of all the data submitted to the FDA. 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.

Marketing Exclusivity

We are currently planning on seeking MUMS designation for some of our prescription drug products and if we receive such a designation, we will be entitled to a seven-year marketing exclusivity, which means that we will face no competition from another sponsor marketing the same drug in the same dosage form for the same intended use. If we were to lose such designation or not receive such designation but our application as a new animal drug is found to be a new chemical entity that meets the criteria described by the FDA, we would be entitled to a five-year marketing exclusivity. In order to receive this five-year exclusivity, the FDA would have to find in its approval of our application that our NADA contains an API not previously approved in another application, that the application itself is an original application, not a supplemental application, and that our application included the following studies: one or more investigations to demonstrate substantial evidence of effectiveness of the drug for which we are seeking approval; animal safety studies and human food safety studies (where applicable). If the NADA is seeking approval of a drug for which we have received conditional approval, we, upon approval would still be entitled to a five-year marketing exclusivity provided it meets the criteria as set forth above. If however, our NADA is for a drug for which the FDA has determined that the drug contains an API that has previously been approved, regardless of whether the original approval was for use in humans or not, we may only be entitled to a three-year marketing exclusivity provided that the NADA is an original, not supplemental, application and contains both safety and efficacy studies demonstrating the safety and efficacy of the drug which is the subject of the application.

Table of Contents

European Union

The European Union, or EU, definition of a veterinary medicinal product closely matches the definition of an animal drug in the United States. In the EU, a company can market a veterinary medicinal product only after a marketing authorization has been issued by an EU member state, (*i.e.*, approval on a country-by-country basis) or by the EU Commission through the European Medicines Agency, or the EMA. Before the EU member state or the EU Commission issues marketing authorization, we must submit a marketing authorization application, known as the dossier. The dossier includes data from studies showing the product's quality, safety, and efficacy and is similar to an NADA filed with the FDA.

For an animal drug, the Committee for Medicinal Products for Veterinary Use, or CVMP, is responsible for the scientific evaluation. Experts from all EU member states are on the CVMP. The Rapporteur, or lead reviewer on the dossier, prepares an overview of the committee's scientific evaluation, called the CVMP Assessment Report.

The CVMP Assessment Report:

- summarizes the data submitted by the company on the product's quality, safety, and efficacy;
- explains the assessment done by the CVMP to support the committee's recommendation to the EU Commission to issue a marketing authorization; and
- is the basis for the European Public Assessment Report published on the EMA's website.

Labeling

The FDA plays a significant role in regulating the labeling, advertising and promotion of animal drugs. This is also true of regulatory agencies in the EU and other territories. In addition, advertising and promotion of animal health products is controlled by regulations in many countries. These rules generally restrict advertising and promotion to those claims and uses that have been reviewed and approved by the applicable agency. We will conduct a review of advertising and promotional material for compliance with the local and regional requirements in the markets where we eventually may sell our product candidates.

Our non-prescription products will be labeled in accordance with the health guidelines outlined by the National Animal Supplements Council, an industry organization that sets industry standards for certain non-prescription animal products, including but not limited to product labeling.

Other Regulatory Considerations

We believe regulatory rules relating to human food safety, food additives, or drug residues in food will not apply to the products we currently are developing because our prescription drug product candidates are not intended for use in production animals, with the exception of horses, which qualify as food animals in Europe and Canada; and our non-prescription products are not regulated by section 201(g) of the Federal Food, Drug, and Cosmetic Act, which the FDA is authorized to administer.

Our prescription drug product candidates currently in development, if approved, may eventually face generic competition in the United States and in the EU after the period of exclusivity has expired. In the United States, a generic animal drug may be approved pursuant to an abbreviated new animal drug application, or ANADA. With an ANADA, a generic applicant is not subject to the submission of new clinical and safety data but instead must only show that the proposed generic product is a copy of the novel drug product, and bioequivalent to the approved novel product. However, if our product candidates are the first approved by the FDA or the EMA as applicable for use in animals, they will be eligible for a five-year marketing exclusivity in the United States and 10 years in the EU thereby prohibiting generic entry into the market. If the product has MUMS designation it has a seven-year marketing exclusivity.

Table of Contents

We do not believe that our non-prescription products are currently subject to regulation in the United States. 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. 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 suffering from scours. Additionally, because a previously marketed human formulation of the botanical extract in our non-prescription products was considered a dietary supplement subject to the Dietary Supplement Health and Education Act of 1994 (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.

In addition to the foregoing, we may be subject to state, federal and foreign healthcare and/or veterinary medicine laws, including but not limited to anti-kickback laws, as we may from time to time enter consulting and other financial arrangements with veterinarians, who may prescribe or recommend our products. 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.

Employees

As of March 1, 2016, we had 24 employees. Of our employees, seven hold D.V.M. or Ph.D. degrees and ten of our employees are engaged in research and development activities. None of our employees are represented by labor unions or covered by collective bargaining agreements.

Description of Properties

Our corporate headquarters are located in San Francisco, California, where we sublease 6,008 rentable square feet of office space from SeeChange Health Management Company, Inc. Our sublease agreement expires on August 31, 2018. We believe that our existing facilities are adequate for our near-term needs. We believe that suitable additional or alternative space would be available if required in the future on commercially reasonable terms if we are not able to convert our current sublease to a lease by August 31, 2018 on commercially reasonable terms.

Table of Contents

ITEM 1A. RISK FACTORS

The business, financial condition and operating results of the Company may be affected by a number of factors, whether currently known or unknown, including but not limited to those described below. Any one or more of such factors could directly or indirectly cause the Company's actual results of operations and financial condition to vary materially from past or anticipated future results of operations and financial condition. Any of these factors, in whole or in part, could materially and adversely affect the Company's business, financial condition, results of operations and stock price. The following information should be read in conjunction with Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and related notes in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report.

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, 2015 was $16,291,550. As of December 31, 2015, we had total stockholders' equity of $4,399,097. We expect to continue to incur losses for the foreseeable future, which will increase significantly from historical levels as we expand our product development activities, seek necessary approvals for our product candidates, conduct species-specific formulation studies for our non-prescription products and begin commercialization activities. Even if we succeed in developing and 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 independent registered public accounting firm has included an explanatory paragraph in its audit report on our financial statements for the year ended December 31, 2015, regarding our assessment of substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. 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 and horses. Since inception 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

Table of Contents

regulatory agencies in various jurisdictions. We have not yet received any regulatory approvals for our prescription drug product candidates. In addition, certain of our non-prescription products, such as Neonorm, may be subject to regulatory approval outside the United States prior to commercialization. Accordingly, until and unless we receive any necessary regulatory approvals, we cannot market or sell our products. Moreover, even if we receive the necessary approvals, we may not be successful in generating revenue from sales of our products as we do not have any 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 commenced sales of Neonorm for preweaned dairy calves in the United States under the brand name Neonorm Calf at the end of 2014. 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.

Table of Contents

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 are forecasting continued losses and negative cash flows as we continue to fund our operating and marketing activities and research and development programs, and we will not have sufficient cash on hand to fund our operating plan through December 2016 and to complete the development of all the current products in our pipeline, or any additional products we may identify. We will need to seek additional funds sooner than planned through public or private equity or debt financings or other sources such as strategic collaborations. Other than the loan and security agreement (which provided for an initial loan commitment of $6.0 million), we have no current agreements or arrangements with respect to any such financings or collaborations, and any such financings or collaborations may result in dilution to our stockholders, the imposition of debt covenants and repayment obligations or other restrictions that may harm our business or the value of our common stock. We may also seek from time to time to raise additional capital based upon favorable market conditions or strategic considerations such as potential acquisitions.

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 product revenue, obtain any new financing if needed to fund our business and operations or enter into

Table of Contents

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;

Table of Contents

- 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.

Table of Contents

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

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

Although there are currently no FDA-approved anti-secretory products to treat 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 safety and efficacy data from pivotal trials that adequately demonstrate that our prescription drug product candidates are safe and effective in the target species (*e.g.* dogs, cats or horses) for the intended indications. In addition, we must provide manufacturing data evidencing that we can produce our product candidates in accordance with cGMP. For the FDA, we must also provide data from toxicology studies, also called target animal safety studies, and in some cases environmental impact data. In addition to our internal activities, we will partially rely on contract research organizations, 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

Table of Contents

our studies and other development activities are completed as planned, the results may not be sufficient to obtain a required regulatory approval for a product candidate.

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

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

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

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

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

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

37

Table of Contents

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

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

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

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

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

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

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;

Table of Contents

- the potential and perceived advantages over alternative treatments or products, including generic medicines and competing products currently prescribed by veterinarians, and products approved for use in humans that are used extra-label in animals;

- the acceptance by veterinarians, companion animal owners and production animal owners, including in the dairy industry, of our products as safe and effective;

- the cost in relation to alternative treatments and willingness on the part of veterinarians and animal owners to pay for our products;

- the prevalence and severity of any adverse side effects of our products;

- the relative convenience and ease of administration of our products; and

- the effectiveness of our sales, marketing and distribution efforts.

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

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

The demand for production animal health products, such as Neonorm 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

Table of Contents

non-economic damages such as pain and suffering and emotional distress for harm to their companion animals based on theories applicable to personal injuries to humans. If new legislation is passed to allow recovery for such non-economic damages, or if precedents are set allowing for such recovery, we could be exposed to increased product liability claims that could result in substantial losses to us if successful. In addition, some horses can be worth millions of dollars or more, and product liability for horses may be very high. While we currently have product liability insurance, such insurance may not be sufficient to cover any future product liability claims against us.

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

Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We are highly dependent upon our senior management, particularly Lisa A. Conte, our President and Chief Executive Officer. The loss of services of any of our key personnel would cause a disruption in our ability to develop our current or future product pipeline and commercialize our products and product candidates. Although we have offer letters with these key members of senior management, such agreements do not prohibit them from resigning at any time. For example, the resignation of our former Chief Financial Officer, Charles O. Thompson, in September 2014, and the mutually agreed departure of our former Chief Veterinary Officer, Serge Martinod, D.V.M., Ph.D. in February 2015, caused us to incur additional expenses and expend resources to ensure a smooth transition with their respective successors, which diverted management attention away from executing our operational plan during this period. We currently do not maintain "key man" life insurance on any of our senior management team. The loss of Ms. Conte or other members of our current senior management could adversely affect the timing or outcomes of our current and planned studies, as well as the prospects for commercializing our products.

In addition, competition for qualified personnel in the 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.

Table of Contents

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 four-year manufacturing and supply agreement with Glenmark for the supply of the API in Canalevia. Glenmark is the current manufacturer of crofelemer, the active API in Canalevia, for the FDA-approved human anti-secretory product, and the manufacturer on file for the NADA to which we have a right of reference. We have contracted with a third-party manufacturer for formulation development and manufacturing, whereby the manufacturer will provide enteric-coated tablets to us for use in animals. We also may contract with additional third parties for the formulation and supply of finished products, which we will use in our planned studies and commercialization efforts.

We will be dependent upon our contract manufacturers for the supply of the API in 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

Table of Contents

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 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 15, 2016, we had 24 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

Table of Contents

other industries continues to be the subject of controversy and adverse publicity. Some organizations and individuals have sought to ban animal testing or encourage the adoption of additional regulations applicable to animal testing. To the extent that such bans or regulations are imposed, our research and development activities, and by extension our operating results and financial condition, could be harmed. In addition, negative publicity about animal practices by us or in our industry could harm our reputation among potential customers.

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

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

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

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

Table of Contents

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.

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.

As of March 15, 2016, Napo owned in the aggregate 26.3% 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

Table of Contents

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. Further, Jaguar and Napo are engaged in preliminary exploratory discussions to review a potential merger and/or other ways to cooperate with their respective business endeavors; however, there is no assurance that any agreement will be reached to merge or further cooperate with their respective business endeavors.

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

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

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

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

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

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

Table of Contents

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 except humans. 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.

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.

Table of Contents

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 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 that cover enteric protected formulations of proanthocyanidin polymers isolated from *Croton spp*. and methods of treating watery diarrhea using the enteric protected formulations 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 and have currently pending three applications under the Patent Cooperation Treaty, or PCT, one U.S. non-provisional patent application and eight 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

Table of Contents

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.

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

Table of Contents

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 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.

Table of Contents

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.

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.

Table of Contents

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 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.

Table of Contents

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

As is the case with other 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 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

Table of Contents

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.

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, clinical development, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product may be subject to extensive and ongoing regulatory requirements. These requirements could include, but are not limited to, submissions of efficacy and safety and other post-marketing information and reports, establishment registration, and product listing, compliance with new rules promulgated under the FSMA, as well as continued compliance with cGMP, GLP and GCP for any studies that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our contract manufacturers or manufacturing processes, or failure to comply with regulatory requirements, are reportable events to the FDA and may result in, among other things:

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

Table of Contents

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 issuance by the FDA of protocol concurrences for our pivotal studies does not guarantee ultimate approval of our NADA.

We intend to seek protocol concurrences from the FDA for the pivotal trial of Canalevia that we 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 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 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, 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, facility inspections, removal of our products from the market, recalls of certain lots or batches, or cause a delay in approval or clearance of future products.

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

From time to time, legislation is drafted and introduced in the U.S. Congress or other jurisdictions in which we intend to operate that could significantly change the statutory provisions governing the testing, regulatory clearance or approval, manufacture, and marketing of regulated products. In addition, the FDA's regulations and guidance are often revised or reinterpreted by the FDA and such other regulators in ways that may significantly affect our business and our products and product candidates. Similar changes in

Table of Contents

laws or regulations can occur in other countries. Any new regulations or revisions or reinterpretations of existing regulations in the United States or in other countries may impose additional costs or lengthen review times of any of our current or future products and product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;
- additional clinical trials or testing;
- new requirements related to approval to enter the market;
- recall, replacement, or discontinuance of certain products; and
- additional record keeping or the development of certain regulatory required hazard identification plans.

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

We believe that our non-prescription products are not subject to regulation by regulatory agencies in the United States, but there is a risk that regulatory bodies may disagree with our interpretation, or may redefine the scope of 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 animal prescription drug products however, in many instances, the Federal Trade Commission will exercise primary or concurrent jurisdiction with FDA on non-prescription products as to post marketing claims made regarding the product. On April 22, 1996, the FDA published a statement in the Federal Register, 61 FR 17706, that it believes that the Dietary Supplement and Health Education Act, or DSHEA, does not apply to animal health supplement products, such as our non-prescription products. Accordingly, the FDA's Center for Veterinary Medicine only regulates those animal supplements that fall within the FDA's definition of an animal drug, animal food or animal feed additive. The Federal Food Drug and Cosmetic Act defines food as "articles used for food or drink for man or other animals and articles used as components of any such article." Animal foods are not subject to pre-market approval and are designed to provide a nutritive purpose to the animals that receive them. Feed additives are defined as those articles that are added to an animal's feed or water as illustrated by the guidance documents. Our non-prescription products are not added to food, are not ingredients in food nor are they added to any animal's drinking water. Therefore, our non-prescription products do not fall within the definition of a food or feed additive. In light of the pronouncement by the FDA that the DSHEA was not intended to apply to animals, the FDA seeks to regulate such supplements as food or food additives depending on 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

Table of Contents

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 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 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.

The trading price of our common stock could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed previously in this "Risk Factors" section of this report and others, such as:

- delays in the commercialization of 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;

Table of Contents

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.

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 public offering price.

Prior to our initial public offering in May 2015, there was no public market for shares of our common stock. The listing of our common stock on The NASDAQ Capital Market does not assure that a meaningful, consistent and liquid trading market exists. Although our common stock is listed on The NASDAQ Capital Market, trading volume in our common stock has been limited and an active trading market for our shares my never develop or be sustained. If an active market for our common stock does not develop, you may be unable to sell your shares when you wish to sell them or at a price that you consider attractive or satisfactory. The lack of an active market may also adversely affect our ability to raise capital by selling securities in the future, or impair our ability to license or acquire other product candidates, businesses or technologies using our shares as consideration.

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.

The trading market for our common stock depends in part on the research and reports that industry or financial analysts publish about us or our business. We do not influence or control the reporting of these analysts. If one or more of the analysts who do cover us downgrade or provide a negative outlook on our company or our industry, or the stock of any of our competitors, the price of our common stock could decline. If one or more of these analysts ceases coverage of our company, we could lose visibility in the market, which in turn could cause the price of our common stock to decline.

Table of Contents

You may be diluted by exercises of outstanding options and warrants.

As of December 31, 2015, we had outstanding options to purchase an aggregate of 919,506 shares of our common stock at a weighted average exercise price of $3.87 per share and warrants to purchase an aggregate of 748,872 shares of our common stock at a weighted-average exercise price of $5.37 per share. The exercise of such outstanding options and warrants will result in further dilution of your investment. In addition, you may experience additional dilution if we issue common stock in the future. As a result of this dilution, you may receive significantly less in net tangible book value than the full purchase price you paid for the shares in the event of liquidation.

Our failure to meet the continued listing requirements of The NASDAQ Capital Market could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of The NASDAQ Capital Market, such as the minimum closing bid price requirement, NASDAQ may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we would take actions to restore our compliance with NASDAQ's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the NASDAQ minimum bid price requirement or prevent future non-compliance with NASDAQ's listing requirements. Further, if we were to be delisted from The NASDAQ Capital Market, our common stock would cease to be recognized as covered securities and we would be subject to regulation in each state in which we offer our securities.

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 contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions to include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could adversely affect the rights of our common stockholders or be used to deter a possible acquisition of our company;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of the holders of at least 75% of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our 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;

Table of Contents

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

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

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

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

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

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, (iv) any action asserting a claim that is governed by the internal affairs doctrine or (v) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws. Any person purchasing or otherwise acquiring any interest in any shares of our capital stock shall be deemed to have notice of and to have consented to this provision of our amended and restated bylaws. This choice-of-forum provision may limit our stockholders' ability to bring a claim in a judicial forum that 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, 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 report, 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.

As of March 15, 2016, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned in the aggregate approximately 75.7% 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

Table of Contents

requiring stockholder approval such as elections of directors, amendments of our organizational documents or approvals of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

The requirements of being a public company, including compliance with the reporting requirements of the Exchange Act and the requirements of the Sarbanes-Oxley Act, may strain our resources, increase our costs and distract management, and we may be unable to comply with these requirements in a timely or cost-effective manner.

Our initial public offering had a significant, transformative effect on us. Prior to our initial public offering, our business operated as a privately-held company, and we were not required to comply with public reporting, corporate governance and financial accounting practices and policies required of a publicly-traded company. As a publicly-traded company, we incur significant 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. These rules and regulations have substantially increased our legal and financial compliance costs and diverted management time and attention from our product development and other business activities.

The Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of 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 have needed to expend time and resources on documenting our internal control over financial reporting so that we are in a position to perform such evaluation when required. As an "emerging growth company," we expect to avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail 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 control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 requires that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not "emerging growth companies." In particular, while we are an "emerging growth company" (i) we will not be required to comply with the

Table of Contents

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

We may remain an "emerging growth company" until as late as December 31, 2020 (the fiscal year-end following the fifth anniversary of the closing of our initial public offering, which occurred on May 18, 2015), although we may cease to be an "emerging growth company" earlier under certain circumstances, including (i) if the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of any June 30, in which case we would cease to be an "emerging growth company" as of December 31 of such year, (ii) if our gross revenue exceeds $1.0 billion in any fiscal year or (iii) if we issue more than $1.0 billion of non-convertible debt over a three-year period.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters are located in San Francisco, California, where we sublease 6,008 rentable square feet of office space from SeeChange Health Management Company, Inc. Our sublease agreement expires on August 31, 2018. We believe that our existing facilities are adequate for our near-term needs. We believe that suitable additional or alternative space would be available if required in the future on commercially reasonable terms if we are not able to convert our current sublease to a lease by August 31, 2018 on commercially reasonable terms. We believe that our existing facilities are adequate to meet our business requirements for at least the next 12 months and that additional space will be available on commercially reasonable terms, if required.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. There are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations, financial condition or cash flows.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

Table of Contents

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our shares of common stock have been listed and traded on The NASDAQ Capital Market under the symbol "JAGX" since May 13, 2015. Prior to that date, there was no public market for our common stock.

The following table sets forth, for the periods indicated, the high and low intra-day sale prices in dollars on The NASDAQ Capital Market for our common stock.

Quarter Ended	High	Low
June 30, 2015 (from May 13, 2015)	$ 7.06	$ 4.56
September 30, 2015	$ 5.48	$ 1.90
December 31, 2015	$ 4.70	$ 1.69

Holders

As of March 15, 2016, there were approximately 21 stockholders of record of our common stock. These figures do not reflect the beneficial ownership or shares held in nominee name, nor do they include holders of any RSUs.

Dividend Policy

We have never paid any cash dividends on our common stock to date. We currently anticipate that we will retain all future earnings, if any, to fund the development and growth of our business and do not anticipate paying any cash dividends for at least the next five years, if ever.

Table of Contents

ITEM 6. SELECTED FINANCIAL DATA

Not Applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read together with our financial statements and the related notes appearing elsewhere in this report.

Overview

We are an animal health company focused on developing and commercializing first-in-class gastrointestinal products for companion and production animals, and horses. Canalevia is our lead prescription drug product candidate, intended for the treatment of various forms of 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 completed submission of all required major technical sections for the conditional approval application for Canalevia for chemotherapy-induced diarrhea, or CID, in dogs, to the FDA for phased review. Canalevia is a canine-specific formulation of crofelemer, an active pharmaceutical ingredient isolated and purified from the *Croton lechleri* tree, which is sustainably harvested. A human-specific formulation of crofelemer, 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 while at Napo Pharmaceuticals, Inc., which was Jaguar's parent company until May 13, 2015. SB-300 is Jaguar's prescription drug product candidate for the treatment of gastrointestinal ulcers in horses. SB-300 contain ingredients isolated and purified from the *Croton lechleri* tree. Neonorm Calf and Neonorm Foal are our lead non-prescription products. Neonorm is a standardized botanical extract derived from the *Croton lechleri* tree. Neonorm is our lead non-prescription product to improve gut health and normalize fecal 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 in 2015 we launched Neonorm in the United States for foals under the brand name Neonorm Foal. As of March 1, 2016, we have shipped $638,000 of Neonorm Calf to distributors. 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, and Canalevia for both cats and dogs.

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

In May 2015, we completed the initial public offering of our common stock. In connection with our initial public offering, we issued 2,860,000 shares of our common stock at a price to the public of $7.00 per share. Our shares of common stock began trading on The NASDAQ Capital Market on May 13, 2015. As a result of the initial public offering, we received approximately $15.9 million in net proceeds, after deducting underwriting discounts and commissions of $1.2 million and offering expenses of $3.3 million, including a $0.4 million non-cash expense.

Table of Contents

In September 2015, we entered into a four year manufacture and supply agreement, or Supply Agreement, with a contract manufacturer in India for the manufacture and supply of active pharmaceutical ingredient, or API. For each calendar year, we and the manufacturer will agree to a minimum annual quantity that we will purchase.

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

In December 2015, we hired a new Chief Financial Officer and entered into an employment agreement.

In December 2015, we entered into an amendment to our technology transfer and commercial manufacturing agreement with our contract manufacturer in Italy delaying a €150,000 payment which was originally due on December 31, 2015. This payment is now due on March 31, 2016.

In December 2015, we met benchmarks which reduced our restricted cash balance by $1.5 million from $4.5 million to $3.0 million as required by Hercules Technology Growth Capital, Inc., or Hercules Technology, pursuant to the Loan and Security Agreement dated August 18, 2015, between us, certain of our subsidiaries, the several banks and other financial institutions or entities from time to time party thereto as lenders and Hercules Technology.

In December 2015, we paid a license fee of $500,000 to Napo Pharmaceuticals pursuant to the Amended and Restated License Agreement, dated August 6, 2014 as amended, between Napo and us.

In February 2016, we hired a Chief Veterinary Officer and entered into an employment agreement.

In February 2016, we completed a follow-on registration offering of our common stock. In connection with the offering, we issued 2,000,000 shares of our common stock at a price to the public of $2.50 per share. As a result of the follow-on offering, we received $4.1 million in net proceeds, after deducting underwriting discounts and commissions of $373,000 and estimated offering expenses of $540,000.

Financial Operations Overview

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

We have not generated any material revenue to date and expect to continue to incur significant research and development and other expenses. Our net loss attributable to common stockholders was $16.6 million and $9.3 million for the years ended December 31, 2015 and 2014. As of December 31, 2015, we had total stockholders' equity of $4.4 million and cash and cash equivalents of $7.7 million. We expect to continue to incur losses for the foreseeable future as we expand our product development activities, seek necessary approvals for our product candidates, conduct species-specific formulation studies for our non-prescription products, establish API manufacturing capabilities and begin commercialization activities. As a result, we expect to experience increased expenditures for 2016.

Revenue

We sell our primary commercial product Neonorm to distributors under agreements that may provide distributor price adjustments and rights of return under certain circumstances. Until we have sufficient sales history and pipeline visibility, we will defer revenue and costs of distributor sales until products are sold by the distributor to the distributor's customers. Revenue recognition depends on notification either

Table of Contents

directly from the distributor that product has been sold to the distributor's customer, when we have access to the data. We maintain system controls to verify that the reported distributor and third party data is accurate. Deferred revenue on shipments to distributors will reflect the estimated effects of distributor price adjustments, if any, and the estimated amount of gross margin expected to be realized when the distributor sells through product purchased from the Company. Accounts receivable from distributors will be recognized and included in deferred revenue when we ship product to the distributor. We relieve inventory and recognize revenue typically upon shipment by the distributor to their customer. While we did not have revenue in the year ended December 31, 2014, we did recognize $258,381 in revenue for the year ended December 31, 2015.

Cost of Revenue

Cost of revenue expenses consist of costs to manufacture, package and distribute Neonorm that distributors have sold through to their customers.

Research and Development Expense

Research and development expenses consist primarily of clinical and contract manufacturing expense, personnel and related benefit expense, stock-based compensation expense, employee travel expense, reforestation expenses and expenses attributable to services received from Napo under the Service Agreement. Clinical and contract manufacturing expense consists primarily of costs to conduct stability, safety and efficacy studies, and manufacturing startup expenses at an outsourced API provider in Italy.

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

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

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

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

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

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

Table of Contents

Sales and Marketing Expense

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

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

General and Administrative Expense

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

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

Interest Expense

Interest expense consists primarily of interest on convertible promissory notes, the standby bridge financing commitment and the loan and security agreement. 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

Comparison of the years ended December 31, 2015 and 2014

The following table summarizes the Company's results of operations with respect to the items set forth in such table for the years ended December 31, 2015 and 2014 together with the change in such items in dollars and as a percentage:

	Years Ended December 31,		Variance	
	2015	2014	$	%
	(In thousands of $)			
Revenue	$ 258	$	$ 258	
Operating Expenses				
Cost of revenue	124		124	
Research and development expense	6,476	4,221	2,255	53.4%
Sales and marketing expense	765		765	
General and administrative expense	5,339	4,095	1,244	30.4%
Total operating expenses	12,704	8,316	4,388	52.8%
Loss from operations	(12,446)	(8,316)	(4,130)	49.7%
Interest expense, net	(3,317)	(345)	(2,972)	861.4%
Other income	(27)		(27)	
Change in fair value of warrants	(502)	51	(553)	(1084.3)%
Net loss and comprehensive loss	$ (16,292)	$ (8,610)	$ (7,682)	89.2%

Table of Contents

Revenue and Cost of Revenue

Revenue and related cost of revenue for the years ended December 31, 2015 is for sales of Neonorm to our distributors. We defer revenue and cost of revenue until products are sold by the distributor to the distributor's end customers and recognition will depend on notification from the distributor that product has been sold to the distributor's end customer. Although we did sell Neonorm to distributors in the year ended December 31, 2014, there was no distributor sell-through and consequently we did not recognize any revenue.

Research and Development Expense

The following table presents the components of research and development expense for the years ended December 31, 2015 and 2014 together with the change in such components in dollars and as a percentage:

	Years Ended December 31,		Variance	
	2015	2014	$	%
	(In thousands of $)			
Personnel and related benefits	$ 1,892	$ 1,245	$ 647	52.0%
Materials expense and tree planting	188	1,391	(1,203)	(86.5)%
Travel, other expenses	360	344	16	4.7%
Clinical and contract manufacturing	3,093	695	2,398	345.0%
Stock-based compensation	472	71	401	564.8%
Other	471	475	(4)	(0.8)%
Total	$ 6,476	$ 4,221	$ 2,255	53.4%

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

We increased Research and development expense $2.3 million, or 53% from $4.2 million in 2014 to $6.5 million in 2015. We added headcount in 2015 to enable us to make significant progress in the development of certain drug candidates that resulted in the increase of $2.4 million in clinical and contract manufacturing expenses, $647,000 in personnel expense and $401,000 in stock-based compensation expense.

We also incurred $188,000 and $194,000 in reforestation expenses in 2015 and 2014, respectively, to replenish trees consumed in order to extract the raw material to manufacture our primary commercial product and the drug product for use in clinical trials. The remaining $1.2 million of materials expense in 2014 was API transferred to us as part of the Napo License Agreement.

Sales and Marketing Expense

Sales and marketing expense for the years ended December 31, 2015 and 2014 consisted of personnel costs, direct marketing, travel and consulting expenses.

Table of Contents

General and Administrative Expense

The following table presents the components of general and administrative expense for the years ended December 31, 2015 and 2014 together with the change in such components in dollars and as a percentage:

	Years Ended December 31,		Variance	
	2015	2014	$	%
	(In thousands of $)			
Personnel and related benefits	$ 2,025	$ 1,693	$ 332	19.6%
Accounting fees	352	190	162	85.3%
Third-party consulting fees and Napo service fees	201	463	(262)	(56.6)%
Legal fees	611	415	196	47.2%
Travel	442	638	(196)	(30.7)%
Stock-based compensation	466	93	373	401.1%
Rent and lease expense	281	152	129	84.9%
Public company expenses	234		234	
Other	727	451	276	61.2%
Total	$ 5,339	$ 4,095	$ 1,244	30.4%

We expect to incur additional general and administrative expense as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, additional insurance expenses, investor relations activities and other administrative and professional services.

Our general and administrative expenses increased $1.2 million from $4.1 million in 2014 to $5.3 million in 2015. In 2015, we became a public company, and as a result, we added headcount and incurred increases of $332,000 in personnel expense, $373,000 in stock-based compensation expense, net of a reduction of $196,000 in travel expense. We incurred direct public company expenses of $234,000 in 2015 primarily for public and investor relations expenses, NASDAQ fees, printer fees for SEC filings, and board of directors expenses, and also experienced significant increases in professional services expenses, including a $162,000 increase in audit fees and $196,000 in legal fees. Rent expense increased $129,000 as a result of our moving into new facilities to accommodate the added headcount. Other expenses all other expenses, including insurance costs also increased as a result of becoming a public company in 2015.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred net losses since our inception as we have not generated significant revenue through fiscal year 2015. Our net loss and comprehensive loss was $801,000 for the period from inception to December 31, 2013, $8.6 million for the year ended December 31, 2014 and $16.3 million for the year ended December 31, 2015. Our accumulated deficit was $25.7 million as of December 31, 2015. We expect to continue to incur additional losses through the end of fiscal year 2016 and in future years due to expected significant expenses for toxicology, safety and efficacy clinical trials of our products and product candidates, for establishing contract manufacturing capabilities, and for the commercialization of one or more of our product candidates, if approved.

We had cash and cash equivalents of $7.7 million as of December 31, 2015 compared to $845,192 as of December 31, 2014. We do not believe our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements for the next 12 months. Our independent registered public accounting firm has included an explanatory paragraph in its audit report 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.

Table of Contents

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

In 2013, we received $400 from the issuance of 2,666,666 shares of common stock to our parent Napo Pharmaceuticals, Inc. We also received $519,000 of net cash from the issuance of convertible promissory notes in an aggregate principal amount of $525,000. These notes were all converted to common stock in 2014.

In 2014, we received $6.7 million in proceeds from the issuance of convertible preferred stock. Effective as of the closing of our initial public offering, the 3,015,902 shares of outstanding convertible preferred stock were automatically converted into 2,010,596 shares of common stock. Following our initial public offering, there were no shares of preferred stock outstanding.

In 2014, we received $1.1 million from the issuance of convertible promissory notes in an aggregate principal amount of $1.1 million. These notes were converted to common stock upon the effectiveness of the initial public offering in May of 2015. In August 2014, we entered into a standby line of credit with an individual, who is an accredited investor, for up to $1.0 million. To date, we had not made any drawdowns under this facility. Also, in October of 2014, as amended and restated in December 2014, we entered into a $1.0 million standby bridge loan which was repaid in 2015.

In 2015, we received $1.25 million in exchange for $1.25 million of convertible promissory notes, of which $1.0 million was converted to common stock in 2015, and $100,000 was repaid in 2015. The remaining $150,000 remains outstanding.

In May 2015, we received net proceeds of $15.9 million upon the closing of our initial public offering, gross proceeds of $20.0 million (2,860,000 shares at $7.00 per share) net of $1.2 million of underwriting discounts and commissions and $3.3 million of offering expenses, including $0.4 million of non-cash expense. These shares began trading on The NASDAQ Capital Market on May 13, 2015.

In 2015, we received net proceeds of $5.9 million from the issuance of long-term debt. We entered into a loan and security agreement with a lender for up to $8.0 million, which provided for an initial loan commitment of $6.0 million. Under the loan agreement we are required to maintain $4.5 million of the proceeds in cash, which amount may be reduced or eliminated on the achievement of certain milestones. An additional $2.0 million is available contingent on the achievement of certain further milestones. The agreement has a term of three years, with interest only payments through February 29, 2016. Thereafter, principal and interest payments will be made with an interest rate of 9.9%. Additionally, there will be a balloon interest payment of $560,000 on August 1, 2018. This amount is being recognized over the term of the loan agreement and the effective interest rate, considering the balloon payment, is 15.0%. Our proceeds are net of a $134,433 debt discount under the terms of such agreement.

In 2014 and 2015, we received $24,000 and $531,000, respectively, in cash from sales of Neonorm to distributors.

In 2015, we received approximately $13,000 in proceeds from the exercise of stock options.

In 2016, we received net proceeds of $4.1 million upon the closing of our follow-on public offering, reflecting gross proceeds of $5.0 million (2.0 million shares at $2.50 per share) net of $373,000 of underwriting discounts and commissions and $540,500 of estimated offering expenses.

We expect our expenditures will continue to increase as we continue our efforts to develop animal health products, expand our commercially available Neonorm product and continue development of Canalevia in the near term. We have agreed to pay Indena S.p.A. fees of approximately €2.1 million under a memorandum of understanding relating to the establishment of our commercial API manufacturing arrangement in Italy. As of December 2015, we have paid €1.7 million of the €2.1 million and we will remit the remaining €400,000 in March of 2016.

69

Table of Contents

We do not believe our current capital is sufficient to fund our operating plan through December 2016. We will need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. We may also not be successful in entering into partnerships that include payment of upfront licensing fees for our products and product candidates for markets outside the United States, where appropriate. If we do not generate upfront fees from any anticipated arrangements, it would have a negative effect on our operating plan.

Cash Flows for Year Ended December 31, 2015 Compared to the Year Ended December 31, 2014

The following table shows a summary of cash flows for the years ended December 31, 2015 and 2014:

	Years Ended December 31,	
	2015	**2014**
	(in thousands of $)	
Cash used in operations	$ (14,316)	$ (5,359)
Cash flows from financing activities	(3,003)	(55)
Cash provided by financing activities	24,171	6,074
	$ 6,852	$ 660

Cash Used in Operating Activities

During the year ended December 31, 2015, cash used in operating activities resulted from our net loss of $16.3 million, offset by non-cash accretion of debt discounts of $2.5 million, non-cash revaluation of warrant liability of $502,000 and stock-based compensation of $992,000, amortization of debt issuance costs of $130,000, accretion of the balloon payment on the long-term debt of $116,000, loss on the sale of property and equipment of $35,000, depreciation expense of $5,000, net of changes in operating assets and liabilities of $2.3 million.

During the year ended December 31, 2014, cash used in operating activities resulted from our net loss of $8.6 million, offset by the non-cash expense of the write-off of certain materials received from Napo Pharmaceuticals, Inc. of $1.1 million, warrants issued in connection with transfer agreement and line of credit of $152,000, accretion of the debt discount of $177,000, amortization of the debt issuance costs of $21,000, and stock-based compensation of $164,000, offset by of the revaluation of the warrant liability of $51,000 and by changes in operating assets and liabilities of $1.7 million.

Cash Used in Investing Activities

During the year ended December 31, 2015, cash used in investing activities primarily consisted of $3.0 million in restricted cash that resulted from our issuance of long-term debt, $23,000 from the purchase of property and equipment, net of $21,000 from the sale of property and equipment. During the year ended December 31, 2014, cash used in investing activities consisted of $55,000 from the purchase of property and equipment.

Cash Provided by Financing Activities

During the year ended December 31, 2015, cash provided by financing activities primarily consisted of the gross proceeds from the issuance of $5.6 million in long-term debt, net of discounts and debt issuance costs, $1.3 million in convertible promissory notes, offset by $1.1 million in repayments thereof, and

Table of Contents

$18.4 million in net cash was provided related to our initial public offering, net of commissions and certain deferred offering costs, offset by the repayment of the $1.0 million bridge loans and $100,000 in convertible notes.

During the year ended December 31, 2014, cash provided by financing activities consisted of net proceeds of $6.7 million from the issuance of Series A preferred stock, $796,000 from the issuance of bridge loans, and $1.1 million from the issuance of convertible notes payable, offset by $2.5 million of offering costs.

Description of Indebtedness

Standby Lines of Credit, Convertible Notes and Warrant Issuances

In August 2014, we entered into a standby line of credit with an individual, who is an accredited investor, for up to $1.0 million pursuant to a Line of Credit Loan Agreement dated August 26, 2014. In connection with the entry into the standby line of credit, we issued the lender a warrant to purchase 33,333 shares of our common stock at an exercise price equal to $5.60 per share, which expires in August 2016. There were no drawdowns under the facility as of March 31, 2015 when the line of credit expired.

On October 30, 2014, we entered into a standby bridge financing agreement, or the Bridge, with two lenders, which was amended and restated on December 3, 2014. The Bridge provided a loan commitment in the aggregate principal amount of $1.0 million. Proceeds to us were net of a $100,000 debt discount under the terms of the Bridge. This debt discount was recorded as interest expense using the effective interest method, over the six month term of the Bridge. The Bridge became payable upon our initial public offering. The Bridge was paid in May 2015, including interest thereon in an amount of $321,600. In connection with the Bridge, the lenders were granted warrants to purchase that number of shares of our common stock determined by dividing $1.0 million by the exercise price of 80% of our initial public offering price, amended to $5.60 in March 2015. The fair value of the warrants, $505,348, was originally recorded as a debt discount and liability at December 3, 2014. The warrants were originally valued using the Black-Scholes model with the following assumptions: stock price of $5.01, exercise price of $5.23, term of five years, volatility of 63%, dividend yield of 0%, and risk-free interest rate of 1.61%. Based on the circumstances, the value derived using the Black-Scholes model approximated that which would be obtained using a lattice model. The debt discount was recorded as interest expense over the six month term of the Bridge. Of the aggregate debt discount of $605,348 (warrants and original $100,000 discount), $521,291 was recorded as interest expense during the year ended December 31, 2015. Additional financing costs of $104,000 were incurred related to the Bridge and deferred on closing. These are being recognized as interest expense over the six-month term of the Bridge using the effective interest method. During the year ended December 31, 2015, the remaining $86,667 of these deferred financing charges was recorded as interest expense.

On December 23, 2014, pursuant to a convertible note and warrant purchase agreement, we issued $650,000 aggregate principal amount of convertible promissory notes to three accredited investors. In February 2015, we issued an additional $250,000 aggregate principal amount of notes pursuant to this convertible note purchase agreement to two additional accredited investors. Upon consummation of our initial public offering, the noteholders converted the notes into 116,070 shares of common stock at a conversion price equal to 80% of the initial public offering price, amended to $5.60 in March 2015. We also issued these investors three-year warrants to purchase an aggregate 80,355 shares of our common stock (determined by dividing 50% of the corresponding original principal amount issued by the exercise price). The exercise price is $5.60 per share (80% of the initial public offering price).

In February 2015, we issued convertible promissory notes to two accredited investors in the aggregate principal amount of $250,000. These notes were issued pursuant to the convertible note purchase agreement dated December 23, 2014. Principal and interest of $103,912 was paid in May 2015 for $100,000 of these notes.

Table of Contents

In March 2015, we entered into a non-binding letter of intent with Dechra Pharmaceuticals PLC, or Dechra. In connection therewith, Dechra paid us $1.0 million. At March 31, 2015, we recorded this amount as a loan advance on the balance sheet. In April 2015, Dechra purchased $1.0 million of convertible promissory notes from us, the terms of which provided that such notes were to be converted into shares of our common stock upon the closing of an initial public offering at a conversion price of $5.60 per share. In connection with the purchase of the notes, we issued Dechra a warrant to purchase 89,285 shares at $5.60 per share, which expires December 31, 2017. The notes accrued simple interest of 12% per annum and, upon consummation of our initial public offering in May 2015, converted into 178,571 shares of our common stock. We analyzed the beneficial nature of the conversion terms and determined that a beneficial conversion feature, or BCF, existed because the effective conversion price was less than the fair value at the time of the issuance. We calculated the value of the BCF using the intrinsic method. A BCF of for the full face value was recorded as a discount to the notes payable and to additional paid-in capital. For the nine months ended June 30, 2015, we amortized the entire BCF of $1.0 million which has also been recorded as interest expense.

In August 2015, we entered into a loan and security agreement with a lender for up to $8.0 million, which provided for an initial loan commitment of $6.0 million. The loan agreement requires us to maintain $4.5 million of the proceeds in cash, which amount may be reduced or eliminated on the achievement of certain milestones. An additional $2.0 million is available contingent on the achievement of certain further milestones. The agreement has a term of three years, with interest only payments through February 29, 2016. Thereafter, principal and interest payments will be made with an interest rate of 9.9%. Additionally, there will be a balloon interest payment of $560,000 on August 1, 2018. This amount is being recognized over the term of the loan agreement and the effective interest rate, considering the balloon payment, is 15.0%. We received proceeds of $5.9 million, $6.0 million net of a $134,433 debt discount under the terms of the loan agreement. This debt discount is being recorded as interest expense, using the interest method, over the term of the loan agreement. Under the agreement, we are entitled to prepay principal and accrued interest upon five days prior notice to the lender. In the event of prepayment, we are obligated to pay a prepayment charge. If such prepayment is made during any of the first twelve months of the loan agreement, the prepayment charge will be (a) during such time as we are required to maintain a minimum cash balance, 2% of the minimum cash balance amount plus 3% of the difference between the amount being prepaid and the minimum cash balance, and (b) after such time as we are no longer required to maintain a minimum cash balance, 3% of the amount being prepaid. If such prepayment is made during any time after the first twelve months of the loan agreement, the prepayment charge will be 1% of the amount being prepaid.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Significant Judgments and Estimates

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

Table of Contents

other accounting policies, see Note 2 to our audited financial statements, appearing elsewhere in this report.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate accrued research and development expenses. Estimated accrued expenses include fees paid to vendors and clinical sites in connection with our clinical trials and studies. We review new and open contracts and communicate with applicable internal and vendor personnel to identify services that have been performed on our behalf and estimate the level of service performed and the associated costs incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost for accrued expenses. The majority of our service providers invoice us monthly in arrears for services performed or as milestones are achieved in relation to our contract manufacturers. We make estimates of our accrued expenses as of each reporting date.

We base our accrued expenses related to clinical trials and studies on our estimates of the services received and efforts expended pursuant to contracts with vendors, our internal resources, and payments to clinical sites based on enrollment projections. The financial terms of the vendor agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of animals and the completion of development milestones. We estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the related expense accrual accordingly on a prospective basis. If we do not identify costs that have been incurred or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. To date, we have not made any material adjustments to our estimates of accrued research and development expenses or the level of services performed in any reporting period presented.

Accounting for Stock-Based Compensation

During 2013, we did not issue any stock awards to employees, directors or consultants and did not incur any stock based compensation expense. Beginning in the second quarter of 2014, we awarded options and restricted stock units. We measure stock-based awards granted to employees and directors at fair value on the date of grant and recognize the corresponding compensation expense of the awards, net of estimated forfeitures, over the requisite service periods, which correspond to the vesting periods of the awards.

Key Assumptions. Our Black-Scholes-Merton option-pricing model requires the input of highly subjective assumptions, including the fair value of the underlying common stock, the expected volatility of the price of our common stock, the expected term of the option, risk-free interest rates and the expected dividend yield of our common stock. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future. These assumptions are estimated as follows:

Fair value of our common stock Our common stock is valued by reference to the publicly-traded price of our common stock.

Expected volatility As we do not have any trading history for our common stock, the expected stock price volatility for our common stock was estimated by taking the average historic price volatility for industry peers based on daily price observations for common stock values over a period equivalent to the expected term of our stock option grants. We did not rely on implied volatilities of traded options in our industry peers' common stock because the volume of activity was relatively low. We intend to continue to consistently apply this process using the same or similar public

Table of Contents

companies until a sufficient amount of historical information regarding the volatility of our own common stock share price becomes available.

Expected term The expected term represents the period that our stock-based awards are expected to be outstanding. It is based on the "simplified method" for developing the estimate of the expected life of a "plain vanilla" stock option. Under this approach, the expected term is presumed to be the midpoint between the average vesting date and the end of the contractual term for each vesting tranche. We intend to continue to apply this process until a sufficient amount of historical exercise activity is available to be able to reliably estimate the expected term.

Risk-free interest rate The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected term of the options for each option group.

Dividend yield We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

Forfeitures We estimate forfeitures at the time of grant and revise those estimates periodically in subsequent periods. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest.

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

the prices, rights, preferences and privileges of our Series A preferred stock relative to those of our common stock;

lack of marketability of our common stock;

our actual operating and financial performance;

current business conditions and projections;

hiring of key personnel and the experience of our management;

our stage of development;

illiquidity of share-based awards involving securities in a private company;

the U.S. capital market conditions; and

the likelihood of achieving a liquidity event, such as an offering or a merger or acquisition of our company given prevailing market conditions.

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

Table of Contents

Classification of Securities

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

Income Taxes

As of December 31, 2014, we had net operating loss carryforwards for federal and state income tax purposes of $8.8 million and $8.6 million, respectively, which will begin to expire in 2033, subject to limitations. Our management has evaluated the factors bearing upon the realizability of our deferred tax assets, which are comprised principally of net operating loss carryforwards. Our management concluded that, due to the uncertainty of realizing any tax benefits as of December 31, 2014, a valuation allowance was necessary to fully offset our deferred tax assets. We have evaluated our uncertain tax positions and determined that we have no liabilities from unrecognized tax benefits and therefore we have not incurred any penalties or interest. The Tax Reform Act of 1986, as amended, limits the use of net operating loss and tax credit carryforward in certain situations where changes occur in the stock ownership of a company. In the event we have a change in ownership in the future, as defined by the tax law, utilization of the carryforwards could be limited.

Recently Issued Accounting Pronouncements

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842),* which provides guidance for accounting for leases. Under ASU 2016-02, the Company will be required to recognize the assets and liabilities for the rights and obligations created by leased assets. ASU 2016-02 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. We are currently evaluating the impact of the adoption of ASU 2016-02 on our consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes (Topic 740),* which simplifies the presentation of deferred income taxes. Under ASU 2015-17, deferred tax assets and liabilities are required to be classified as noncurrent, eliminating the prior requirement to separate deferred tax assets and liabilities into current and noncurrent. The new guidance is effective for the Company beginning on January 1, 2017, with early adoption permitted. The standard may be adopted prospectively or retrospectively to all periods presented. The Company is currently assessing the timing of adoption of the new guidance, but does not expect it will have a material impact on the Company's Consolidated Financial Statements.

In April 2015, the FASB issued ASU No. 2015-03, *Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs,* to simplify the presentation of debt issuance costs by requiring debt issuance costs to be presented as a deduction from the corresponding debt liability. ASU 2015-03 will be effective for the Company beginning in its first quarter of 2016, however early adoption is permitted for financial statements that have not been previously issued. The guidance is to be applied retrospectively to all periods presented. We adopted ASU 2015-03 on December 31, 2015 and recognized unamortized debt issuance costs of $250,024 and $104,000 for the years ended December 31, 2015 and 2014, respectively, as a reduction to our long-term debt balance.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements Going Concern (Subtopic 205-40) Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern," which provides guidance regarding management's responsibility to assess whether substantial doubt exists regarding the ability to continue as a going concern and to provide related footnote disclosures. In connection with preparing financial statements for each annual and interim reporting

Table of Contents

period, management should evaluate whether there are condition or events, considered in the aggregate, that raise substantial doubt about the company's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). This ASU is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. We are evaluating the new guidance and have not determined the impact this standard may have on our financial statements.

In June 2014, the FASB issued authoritative guidance that requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. The performance target should not be reflected in estimating the grant-date fair value of the awarded. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. If the performance target becomes probable of being achieved before the end of the requisite service period, the remaining unrecognized compensation cost should be recognized prospectively over the remaining requisite service period. The total amount of compensation cost recognized during and after the requisite service period should reflect the number of awards that are expected to vest and should be adjusted to reflect those awards that ultimately vest. The requisite service period ends when the employee can cease rendering service and still be eligible to vest in the award if the performance target is achieved. This guidance will be effective for annual periods (and interim periods within those annual periods) beginning after December 15, 2015. We will implement this guidance for all interim and annual periods beginning after December 15, 2015. The adoption of this guidance is not expected to have an impact on our financial condition, results of operations or cash flows.

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers." The objective of ASU2014-19 is to establish a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most of the existing revenue recognition guidance, including industry-specific guidance. The core principle of the new standard is that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard is effective for annual reporting periods beginning after December 15, 2017 and allows for prospective or retrospective application. We are evaluating this pronouncement and have not yet determined the impact it will have on our financial statements.

JOBS Act

In April 2012 the JOBS Act was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Jaguar Animal Health, Inc.

Index to Financial Statements

Table of Contents

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Jaguar Animal Health, Inc.
San Francisco, CA

We have audited the accompanying balance sheets of Jaguar Animal Health, Inc. (the "Company") as of December 31, 2015 and 2014 and the related statements of comprehensive loss, changes in common stock, convertible preferred stock and stockholders' equity (deficit) and cash flows for the years ended December 31, 2015 and 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Jaguar Animal Health, Inc. as of December 31, 2015 and 2014, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP

San Francisco, California
March 29, 2016

Table of Contents

Jaguar Animal Health, Inc.

Balance Sheets

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 7,697,531	$ 845,192
Accounts receivable	55,867	
Due from former parent	3,199	
Inventory	229,871	198,029
Deferred offering costs	143,231	2,480,049
Prepaid expenses	324,083	24,170
Total current assets	8,453,782	3,547,440
Property and equipment, net	829,232	872,523
Restricted cash	3,000,000	
Other assets	122,163	
Total assets	$ 12,405,177	$ 4,419,963
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 574,462	$ 698,318
License fee payable to former parent	425,000	
Due to parent		16,581
Deferred revenue	251,936	23,802
Convertible notes payable	150,000	424,674
Notes payable		392,042
Warrant liability		601,889
Accrued expenses	798,434	1,317,991
Current portion of long-term debt	1,707,899	
Total current liabilities	3,907,731	3,475,297
Long-term debt, net of discount	4,095,028	
License fee payable to parent		1,875,000
Deferred rent	3,321	
Total liabilities	$ 8,006,080	$ 5,350,297
Commitments and Contingencies (See note 7)		
Series A redeemable convertible preferred stock; $0.0001 par value, 0 and 3,017,488 shares authorized at December 31, 2015 and December 31, 2014, respectively; 0 and 3,015,902 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively; (liquidation preferrence of $0 and $6,777,338 at December 31, 2015 and December 31, 2014, respectively).		7,304,914
Stockholders' Equity (Deficit):		
Preferred stock: $0.0001 par value, 10,000,000 and 0 shares authorized at December 31, 2015 and December 31, 2014, respectively; no shares issued and outstanding at December 31, 2015 and December 31, 2014.		
Common stock: $0.0001 par value, 50,000,000 and 15,000,000 shares authorized at December 31, 2015 and December 31, 2014, respectively; 8,124,923 and 2,874,330 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively.	812	288
Additional paid-in capital	30,100,613	1,175,242
Accumulated deficit	(25,702,328)	(9,410,778)
Total stockholders' equity (deficit)	4,399,097	(8,235,248)

Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 12,405,177	$ 4,419,963

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

Table of Contents

Jaguar Animal Health, Inc.

Statements of Operations and Comprehensive Loss

	Years Ended December 31,	
	2015	**2014**
Revenue	$ 258,381	$
Operating Expenses		
Cost of revenue	123,457	
Research and development expense	6,475,851	4,220,338
Sales and marketing expense	765,091	
General and administrative expense	5,339,351	4,095,324
Total operating expenses	12,703,750	8,315,662
Loss from operations	(12,445,369)	(8,315,662)
Interest expense, net	(3,317,287)	(345,336)
Other expense	(27,277)	
Change in fair value of warrants	(501,617)	51,423
Net loss and comprehensive loss	(16,291,550)	(8,609,575)
Accretion of redeemable convertible preferred stock	(346,374)	(646,673)
Net loss attributable to common stockholders	$ (16,637,924)	$ (9,256,248)
Net loss per share atributable to common stockholders, basic and diluted	$ (2.70)	$ (3.24)
Weighted-average common shares outstanding, basis and diluted	6,153,139	2,854,417

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

Table of Contents

Jaguar Animal Health, Inc.

Statement of Changes in Common Stock, Convertible Preferred Stock and Stockholders' Equity (Deficit)

	Series A Convertible Preferred Stock		Common Stock		Additional paid-in capital	Accumulated deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balances December 31, 2013		$	2,666,666	$ 267	$ 366,083	$ (801,203)	$ (434,853)
Stock-based compensation					164,156		164,156
Conversion of notes payable into common stock			207,664	21	524,979		525,000
Issuance of redeemable convertible preferred stock, net	3,015,902	6,658,241					
Beneficial conversion feature on issuance of convertible promissory notes					614,557		614,557
Warrants issued in connection with the line of credit					114,300		114,300
Warrants issued in connection with the transfer agreement					37,840		37,840
Deemed dividends on redeemable convertible preferred stock		610,889			(610,889)		(610,889)
Accretion of issuance costs to liquidity amount		35,784			(35,784)		(35,784)
Net and comprehensive loss						(8,609,575)	(8,609,575)
Balances December 31, 2014	3,015,902	$ 7,304,914	2,874,330	$ 288	$ 1,175,242	$ (9,410,778)	$ (8,235,248)
Issuance of common stock in initial public offering, net of discounts and commissions of $1,209,802, offering costs of $2,897,825 and offering costs in the form of common stock warrants of $400,400			2,860,000	286	15,511,974		15,512,260
Warrant, issued in conjunction with the initial public offering					400,400		400,400
Conversion of preferred stock into common stock upon initial public offering	(3,015,902)	(7,651,288)	2,010,596	201	7,651,087		7,651,288
Conversion of preferred stock warrant liability into additional paid-in capital upon initial public offering					1,150,985		1,150,985
Conversion of convertible notes into common stock upon initial public offering			374,997	37	2,099,963		2,100,000
Stock-based compensation					992,165		992,165
Beneficial conversion feature on notes payable					1,202,521		1,202,521
Deemed dividends on Series A		263,060			(263,060)		(263,060)
Accretion of issuance costs		83,314			(83,314)		(83,314)
Napo license fee abatement					250,000		250,000
Issuance of common stock upon exercise of stock options			5,000		12,650		12,650
Net and comprehensive loss						(16,291,550)	(16,291,550)
Balances December 31, 2015		$ 0	8,124,923	$ 812	$ 30,100,613	$ (25,702,328)	$ 4,399,097

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

Table of Contents

Jaguar Animal Health, Inc.

Statements of Cash Flow

	Years Ended December 31,	
	2015	**2014**
Cash Flows from Operating Activities		
Net loss	$ (16,291,550)	$ (8,609,575)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	5,155	
Gain/loss on disposal of fixed assets	34,549	
Materials cost in connection with license activity	6,287	1,082,626
Warrants issued in connection with transfer agreement		37,840
Warrants issued in connection with line of credit		114,300
Stock-based compensation	992,165	164,156
Amortization of debt issuance costs and debt discount	2,720,668	197,993
Revaluation of warrant liability	501,617	(51,423)
Changes in assets and liabilities		
Accounts receivable trade	(55,867)	
Inventory	(31,842)	(198,029)
Prepaid license fee		100,000
Prepaid expenses	(299,913)	(24,170)
Other long-term assets	(122,163)	
Due from/to former parent	(19,780)	(99,802)
Deferred revenue	228,134	23,802
Deferred rent	3,321	
License fee payable	(1,200,000)	(25,000)
Accounts payable	(240,087)	689,323
Accrued expenses	(546,557)	1,238,741
Total cash used in operations	(14,315,863)	(5,359,218)
Cash Flows from Investing Activities		
Purchase of equipment	(23,300)	(55,149)
Sale of equipment	20,600	
Change in restricted cash	(3,000,000)	
Total cash used in investing activities	(3,002,700)	(55,149)
Cash Flows from Financing Activities		
Proceeds from issuance of long-term debt	5,615,543	
Proceeds from issuance of redeemable convertible preferred stock, net		6,658,241
Proceeds from issuance of redeemable convertible notes payable, net	1,250,000	1,100,000
Proceeds from issuance of notes payable, net		796,000
Repayment of convertible notes payable	(100,000)	
Repayment of notes payable	(1,000,000)	
Proceeds from issuance of common stock in initial public offering, net of commissions and discounts	18,810,484	
Deferred offering costs	(417,775)	(2,480,049)
Proceeds from the exercise of common stock options	12,650	
Total Cash Provided by Financing Activities	24,170,902	6,074,192
Net increase in cash and cash equivalents	6,852,339	659,825
Cash and cash equivalents, beginning of period	845,192	185,367
Cash and cash equivalents, end of period	$ 7,697,531	$ 845,192

Supplemental Cash Flow information including Non-Cash Financing and Investing Activities		
Interest paid on long-term debt	$ 173,250	
Equipment received in connection with license agreement	$	$ 817,374
Note payable converted into common stock	$	$ 525,000
Warrants issued in connection with convertible notes payable	$ 47,479	$ 147,943
Warrants issued in connection with notes payable	$	$ 505,348
Warrants issued in connection with the initial public offering	$ 400,400	$
Accretion of redeemable convertible preferred stock	$ 346,374	$ 646,673
Abatement of license fee payable to Napo	$ 250,000	$
Conversion of convertible preferred stock to common stock	$ 7,651,288	$
Conversion of preferred stock warrant liability to common stock warrants	$ 1,150,985	$
Conversion of convertible notes to common stock	$ 2,100,000	$
Deferred offering costs in accounts payable	$ 116,231	$
Deferred offering costs in accrued liabilities	$ 27,000	$

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

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements

1. Organization and Business

Jaguar Animal Health, Inc. ("Jaguar" or the "Company") was incorporated on June 6, 2013 (inception) in Delaware. The Company was a majority-owned subsidiary of Napo Pharmaceuticals, Inc. ("Napo" or the "Former Parent") until the close of the Company's initial public offering on May 18, 2015. The Company was formed to develop and commercialize first-in-class gastrointestinal products for companion and production animals and horses. The Company's first commercial product, Neonorm Calf, was launched in 2014. The Company's activities are subject to significant risks and uncertainties, including failing to secure additional funding in order to timely compete the development and commercialization of products. The Company operates in one segment and is headquartered in San Francisco, California.

On June 11, 2013, Jaguar issued 2,666,666 shares of common stock to Napo in exchange for cash and services. On July 1, 2013, Jaguar entered into an employee leasing and overhead agreement (the "Service Agreement") with Napo, under which Napo agreed to provide the Company with the services of certain Napo employees for research and development and the general administrative functions of the Company. On January 27, 2014, Jaguar executed an intellectual property license agreement with Napo pursuant to which Napo transferred fixed assets and development materials, and licensed intellectual property and technology to Jaguar. On February 28, 2014, the Service Agreement terminated and the associated employees became employees of Jaguar effective March 1, 2014. See Note 10 for additional information regarding the capital contributions and Notes 4 and 5 for the Service Agreement and license agreement details, respectively.

Reverse Stock Split

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

Initial Public Offering

On May 18, 2015, the Company completed an initial public offering ("IPO") of its common stock. In connection with its IPO, the Company issued and sold 2,860,000 shares of common stock at a price to the public of $7.00 per share. As a result of the IPO, the Company received $15.9 million in net proceeds, after deducting underwriting discounts and commissions of $1.2 million and offering expenses of $2.9 million ($3.3 million including non-cash offering expenses) payable by the Company. In connection with the IPO, the Company's outstanding shares of convertible preferred stock were automatically converted into 2,010,596 shares of common stock and the Company's outstanding warrants to purchase convertible preferred stock were all converted to warrants to purchase common stock.

Liquidity

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. The Company has incurred recurring operating losses since inception and has an accumulated deficit of $25,702,328 as of December 31, 2015. The Company expects to incur substantial

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

1. Organization and Business (Continued)

losses in future periods. Further, the Company's future operations are dependent on the success of the Company's ongoing development and commercialization efforts. There is no assurance that profitable operations, if ever achieved, could be sustained on a continuing basis.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

The financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company's management to make judgments, assumptions and estimates that affect the amounts reported in its financial statements and the accompanying notes. The accounting policies that reflect the Company's more significant estimates and judgments and that the Company believes are the most critical to aid in fully understanding and evaluating its reported financial results are valuation of stock options; valuation of warrant liabilities; impairment of long lived assets; useful lives for depreciation; valuation adjustments for excess and obsolete inventory; deferred taxes and valuation allowances on deferred tax assets; and evaluation and measurement of contingencies. Those estimates could change, and as a result, actual results could differ materially from those estimates.

Deferred Offering Costs

Deferred offering costs are costs incurred in filings of registration statements with the Securities and Exchange Commission. These deferred offering costs are offset against proceeds received upon the closing of the offerings. Deferred costs of $143,231 as of December 31, 2015 include legal, accounting and filing fees associated with the follow-on registration offering as more fully described in Note 16. Deferred costs of $2,480,049 as of December 31, 2014 include legal, accounting and filing fees associated with the Company's IPO, which closed on May 18, 2015.

Concentration of Credit Risk and Cash and Cash Equivalents

The financial instrument that potentially subjects the Company to a concentration of credit risk is that is held at a financial institution of high credit standing. Cash is generally in excess of Federal Deposit Insurance Corporation ("FDIC") insurance limits. Therefore, the Company is exposed to credit risk in the

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

event that the balances exceed FDIC insurance limits. The carrying value of cash approximates fair value at December 31, 2015 and 2014.

Fair Values

The Company's financial instruments include, cash and cash equivalents, accounts payable, accrued expenses, amounts due to Napo, the former parent, warrant liabilities, and debt. Cash is reported at fair value. The recorded carrying amount of accounts payable, accrued expenses and amounts due to Napo approximates their fair value due to their short-term nature. The carrying value of the interest-bearing debt approximates fair value based upon the borrowing rates currently available to the Company for bank loans with similar terms and maturities. See Note 3 for the fair value measurements, and Note 8 for the fair value of the Company's warrant liabilities.

Restricted Cash

On August 18, 2015, the Company entered into a long-term loan and security agreement with a lender for up to $8,000,000, which provided for an initial loan commitment of $6,000,000. The loan agreement required the Company to maintain a base minimum cash balance of $4.5 million until the Company met certain milestones. On December 22, 2015, the Company achieved certain milestones and the base minimum cash balance was reduced to $3.0 million.

Inventories

Inventories are stated at the lower of cost or market. The Company calculates inventory valuation adjustments when conditions indicate that the net realizable value is less than cost due to physical deterioration, usage, obsolescence, reductions in estimated future demand or reduction in selling price. Inventory write-downs are measured as the difference between the cost of inventory and estimated net realizable value. There were no write-downs in either 2015 or 2014.

Property and Equipment

Equipment is stated at cost, less accumulated depreciation. Equipment begins to be depreciated when it is placed into service. Depreciation will be calculated using the straight-line method over the estimated useful lives of 3 to 10 years.

Expenditures for repairs and maintenance of assets are charged to expense as incurred. Costs of major additions and betterments are capitalized and depreciated on a straight-line basis over their estimated useful lives. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in income (loss) from operations.

Long-Lived Assets

The Company regularly reviews the carrying value and estimated lives of all of its long-lived assets, including property and equipment to determine whether indicators of impairment may exist that warrant adjustments to carrying values or estimated useful lives. The determinants used for this evaluation include management's estimate of the asset's ability to generate positive income from operations and positive cash flow in future periods as well as the strategic significance of the assets to the Company's business objectives.

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

Should an impairment exist, the impairment loss would be measured based on the excess of the carrying amount over the asset's fair value. The Company has not recognized any impairment losses through December 31, 2015.

Research and Development Expense

Research and development expense consists of expenses incurred in performing research and development activities including related salaries, clinical trial and related drug and non-drug product costs, contract services and other outside service expenses. Research and development expense is charged to operating expense in the period incurred.

Revenue Recognition

Sales to distributors are made under agreements that may provide distributor price adjustments and rights of return under certain circumstances. Until the Company develops sufficient sales history and pipeline visibility, revenue and costs of distributor sales will be deferred until products are sold by the distributor to the distributor's customers. Revenue recognition depends on notification either directly from the distributor that product has been sold to the distributor's customer, when the Company has access to the data. The Company will maintain controls to verify that the reported distributor and third party data is accurate. Deferred revenue on shipments to distributors will reflect the estimated effects of distributor price adjustments, if any, and the estimated amount of gross margin expected to be realized when the distributor sells through product purchased from the Company. Accounts receivable from distributors are recognized and included in deferred revenue when shipped to the distributor. Inventory is relieved and revenue recognized upon shipment by the distributor to their customer. The Company had no revenue for the year ended December 31, 2014 and $258,381 for the year ended December 31, 2015.

Stock-Based Compensation

The Company's 2013 Equity Incentive Plan and 2014 Stock Incentive Plan (see Note 11) provides for the grant of stock options, restricted stock and restricted stock unit awards.

The Company measures stock awards granted to employees and directors at fair value on the date of grant and recognizes the corresponding compensation expense of the awards, net of estimated forfeitures, over the requisite service periods, which correspond to the vesting periods of the awards. The Company issues stock awards with only service-based vesting conditions, and records compensation expense for these awards using the straight-line method.

The Company values its shares of common stock by taking into consideration its most recently available valuation of common stock performed by management and the board of directors, as well as additional factors that may have changed since the date of the most recent contemporaneous valuations through the date of grant.

Classification of Securities

The Company applies the principles of ASC 480-10 "Distinguishing Liabilities from Equity" and ASC 815-40 "Derivatives and Hedging Contracts in Entity's Own Equity" to determine whether financial instruments such as warrants, contingently issuable shares and shares subject to repurchase should be classified as liabilities or equity and whether beneficial conversion features exist.

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate, as well as the related net interest and penalties.

Comprehensive Loss

Comprehensive loss is defined as changes in stockholders' equity (deficit) exclusive of transactions with owners (such as capital contributions and distributions). For the years ending December 31, 2015 and 2014 there was no difference between net loss and comprehensive loss.

Segment Data

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

Basic and Diluted Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders for the period by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders for the period by the weighted-average number of common shares, including potential dilutive shares of common stock assuming the dilutive effect of potential dilutive securities. For periods in which the Company reports a net loss, diluted net loss per common share is the same as basic net loss per common share, because their impact would be anti-dilutive to the calculation of net loss per common share. Diluted net loss per common share is the same as basic net loss per common share for the years ended December 31, 2015 and 2014.

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842),* which provides guidance for accounting for leases. Under ASU 2016-02, the Company will be required to recognize the assets and liabilities for the rights and obligations created by leased assets. ASU 2016-02 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. We are currently evaluating the impact of the adoption of ASU 2016-02 on our consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes (Topic 740),* which simplifies the presentation of deferred income taxes. Under ASU 2015-17, deferred tax assets and liabilities are required to be classified as noncurrent, eliminating the prior requirement to separate deferred tax assets and liabilities into current and noncurrent. The new guidance is effective for the Company beginning on January 1, 2017, with early adoption permitted. The standard may be adopted prospectively or retrospectively to all periods presented. The Company is currently assessing the timing of adoption of the new guidance, but does not expect it will have a material impact on the Company's Consolidated Financial Statements.

In April 2015, the FASB issued ASU No. 2015-03, *Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs,* to simplify the presentation of debt issuance costs by requiring debt issuance costs to be presented as a deduction from the corresponding debt liability. ASU 2015-03 will be effective for the Company beginning in its first quarter of 2016, however early adoption is permitted for financial statements that have not been previously issued. The guidance is to be applied retrospectively to all periods presented. We adopted ASU 2015-03 on December 31, 2015 and recognized unamortized debt issuance costs of $250,024 and $104,000 for the years ended December 31, 2015 and 2014, respectively, as a reduction to our long-term debt balance.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements Going Concern (Subtopic 205-40) Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern", which provides guidance regarding management's responsibility to assess whether substantial doubt exists regarding the ability to continue as a going concern and to provide related footnote disclosures. In connection with preparing financial statements for each annual and interim reporting period, management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). This ASU is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. The Company is currently evaluating the new guidance and has not determined the impact this standard may have on its financial statements.

In June 2014, the FASB issued authoritative guidance which requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. The performance target should not be reflected in estimating the grant-date fair value of the award. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. If the performance target becomes probable of being achieved before the end of the requisite service period, the remaining unrecognized compensation cost should be recognized prospectively over the remaining requisite service period. The

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

total amount of compensation cost recognized during and after the requisite service period should reflect the number of awards that are expected to vest and should be adjusted to reflect those awards that ultimately vest. The requisite service period ends when the employee can cease rendering service and still be eligible to vest in the award if the performance target is achieved. This guidance will be effective for annual periods (and interim periods within those annual periods) beginning after December 15, 2015. The Company will implement this guidance for all interim and annual periods beginning after December 15, 2015. The adoption of this guidance is not expected to have an impact on the Company's financial condition, results of operations or cash flows.

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers." The objective of ASU 2014-19 is to establish a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most of the existing revenue recognition guidance, including industry-specific guidance. The core principle of the new standard is that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard is effective for annual reporting periods beginning after December 15, 2016 and allows for prospective or retrospective application. The Company is evaluating the new guidance and has not determined the impact this pronouncement will have on its financial statements.

3. Fair Value Measurements

ASC 820 "Fair Value Measurements," defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under ASC 820 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under ASC 820 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

Level 1 Quoted prices in active markets for identical assets or liabilities;

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data; and

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The following table presents information about the Company's warrant liability that was measured at fair value on a recurring basis as of December 31, 2014 and indicates the fair value hierarchy of the valuation:

	Level 1	Level 2	Level 3	Total
Fiscal Year 2014:				
Warrant Liability	$	$	$ 601,889	$ 601,889

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

3. Fair Value Measurements (Continued)

The warrant liability was converted into an equity instrument when it became convertible into common stock at the IPO. The change in the estimated fair value of the warrant liability is summarized below:

	Beginning Value of Warrant Liability	Issuance of Common Stock Warrants	Change in Fair Value of Level 3 Liability	Conversion into Additional Paid-in Capital	Ending Fair Value of Level 3 Liability
For the year ended December 31, 2015	$ 601,889	$ 47,479	$ 501,617	$ (1,150,985)	$
For the year ended December 31, 2014	$	$ 653,312	$ (51,423)	$	$ 601,889

The change in the fair value of the level 3 warrant liability is reflected in the statement of operations and comprehensive loss for the year ended December 31, 2015.

There were no assets or liabilities measured at fair value on a recurring basis at December 31, 2015.

4. Employee Leasing and Overhead Allocation Agreement

Effective July 1, 2013, the Company entered into an employee leasing and overhead allocation agreement (the "Service Agreement") with Napo. The term of the Service Agreement was from July 1, 2013 through February 28, 2014. In connection with the Service Agreement, Napo provided the Company with the services of Napo employees. The Service Agreement also stipulated that Jaguar would pay for a portion of Napo's overhead costs. The Company agreed to pay Napo $71,811 per month (consisting of $38,938 for executive compensation, $26,873 for employee services, and $6,000 for overhead costs) for the months from July 2013 through February 2014 as follows: (1) for the period from July 2013 through November 2013, in 2,666,666 shares of common stock and (2) for the period from December 2013 through February 2014, in cash. Commencing March 1, 2014, the relevant Napo employees became employees of the Company and all overhead costs related to the animal health business will be paid by the Company. The Company recognized $114,858 and $28,764 in general and administrative expense and research and development expense, respectively, in the Company's 2014 statement of operations and comprehensive loss.

5. License Agreement

On July 11, 2013, Jaguar entered into an option to license Napo's intellectual property and technology (the "Option Agreement"). Under the Option Agreement, upon the payment of $100,000 in July 2013, the Company obtained an option for a period of two years to execute an exclusive worldwide license to Napo's intellectual property and technology to use for the Company's animal health business. The option price was creditable against future license fees to be paid to Napo under the License Agreement (as defined below).

In January 2014, the Company exercised its option and entered into a license agreement (the "License Agreement") with Napo for an exclusive worldwide license to Napo's intellectual property and technology to permit the Company to develop, formulate, manufacture, market, use, offer for sale, sell, import, export, commercialize and distribute products for veterinary treatment uses and indications for all species of animals. The Company was originally obligated to pay a one-time non-refundable license fee of $2,000,000, less the option fee of $100,000. At the Company's option, the license fee could have been paid in common

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

5. License Agreement (Continued)

stock. Milestone payments aggregating $3,150,000 may also be due to Napo based on regulatory approvals of various veterinary products. In addition to the milestone payments, the Company will owe Napo an 8% royalty on annual net sales of products derived from the *Croton lechleri* tree, up to $30,000,000 and then, a royalty of 10% on annual net sales of $30,000,000 or more. Additionally, if any other products are developed, the Company will owe Napo a 2% royalty on annual net sales of pharmaceutical prescription products that are not derived from *Croton lechleri* and a 1% royalty on annual net sales of nonprescription products that are not derived from *Croton lechleri*. The royalty term expires at the longer of 10 years from the first sale of each individual product or when there is no longer a valid patent claim covering any of the products and a competitive product has entered the market. However, because an IPO of at least $10,000,000 was consummated prior to December 31, 2015, the royalty was reduced to 2% of annual net sales of its prescription products derived from *Croton lechleri* and 1% of net sales of its nonprescription products derived from *Croton lechleri* and no milestone payment will be due and no royalties will be owed on any additional products developed. The Company incurred $39,734 in royalties for the year ended December 31, 2015, and is included in general and administrative expense in the Company's statement of operations and comprehensive loss. The Company's unpaid royalties total $2,810 at December 31, 2015, which is included in accrued liabilities in the Company's balance sheet.

In addition to receiving a License Agreement to Napo's intellectual property and technology, the License also transferred to the Company certain materials and equipment. Materials transferred from Napo have been included in research and development expense on the statements of operations and comprehensive loss during the year ended December 31, 2014. Equipment of $811,087 related to the License is included in property and equipment on the Company's balance sheet at December 31, 2015 at the cost paid by Napo, which approximates fair value. As of December 31, 2015, the certain equipment has been placed into service, and the Company has booked $4,379 in depreciation expense for the year ended December 31, 2015, which is included in research and development expense in the Company's statement of operations and comprehensive loss.

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

In January 2015, the License Agreement was amended to decrease the one-time non-refundable license fee payable from $2,000,000 to $1,750,000 in exchange for acceleration of the payment of the fee. In 2015, payments totalling $1.2 million were made, with the balance of $425,000 due March 31, 2016, which is included in License Fee Payable on the Company's balance sheet. Additionally, the terms of the License Agreement were amended to require the mutual agreement of the parties for payment of the license fee to be remitted in the form of the Company's common stock. The Company may also, at its sole discretion, elect to remit any milestone payments and/or royalties in the form of the Company's common stock. Given that Napo is a significant shareholder of the Company, the abatement of the license fee amount has been recorded as a capital contribution in the accompanying condensed financial statements.

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

6. Balance Sheet Components

Property and Equipment

Property and equipment at December 31, 2015 and 2014 consisted of the following:

	December 31, 2015	December 31, 2014
Lab equipment	811,087	872,523
Clinical equipment	23,300	
Total property and equipment at cost	834,387	872,523
Accumulated depreciation	(5,155)	
Property and equipment, net	829,232	872,523

Depreciation and amortization expense was $5,155 in the year ended December 31, 2015 and was recorded in research and development expense in the statements of operations and comprehensive loss.

The Company expensed $6,287 of materials cost in connection with license activity in 2015.

Accrued Expenses

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

	December 31, 2015	December 31, 2014
Accrued compensation and related:		
Accrued vacation	187,734	140,408
Accrued payroll	80,692	53,090
Accrued payroll tax	43,702	30,744
	312,128	224,242
Accrued legal costs		738,600
Accrued printing		275,000
Accrued interest	127,149	29,292
Accrued contract manufacturing costs	110,141	
Accrued clinical	166,750	25,000
Accrued other	82,266	25,857
Total	798,434	1,317,991

7. Commitments and Contingencies

Operating Leases

Effective July 1, 2015, the Company leases its San Francisco, California headquarters under a non-cancelable sub-lease agreement that expires August 31, 2018. The Company provided cash deposits of $122,163, consisting of a security deposit of $29,539 and prepayment of the last three months of the lease of $92,623, which is identified as other assets on the Company's balance sheet.

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

7. Commitments and Contingencies (Continued)

Future minimum lease payments under non-cancelable operating leases as of December 31, 2015 are as follows:

	Amount
Years ending December 31,	
2016	357,478
2017	363,486
2018	245,327
Total minimum lease payments	966,291

The Company recognizes rent expense on a straight-line basis over the non-cancelable lease period. Rent expense under the non-cancelable operating lease was $180,557 for the year ended December 31, 2015, which was included in general and administrative expense in the Company's statement of operations and comprehensive loss.

Since March 1, 2014, the date the Service Agreement terminated (Note 4), the Company paid Napo $33,897 for rent related to the office space utilized by the Company for the months of March, April and May of 2014. Effective June 1, 2014, the Company assumed the existing sublease from Napo. The term of the assumed sublease was from June 1, 2014 through June 30, 2015. Rent expense under the sub-lease was $69,580 and $80,816 for the years ended December 31, 2015 and 2014, respectively, which was included in general and administrative expense in the Company's statement of operations and comprehensive loss.

Contract Manufacturing Commitment

Effective June 26, 2014 the Company entered into a technology transfer and commercial manufacturing agreement (the "Transfer Agreement") with a contract manufacturer in Italy (the "Manufacturer"), whereby the Company and the Manufacturer will cooperate to develop and refine the manufacturing process for the Company's prescription and non-prescription products. Pursuant to the Transfer Agreement, the Company was to make prepayments to the Manufacturer as follows: (1) a start-up fee of €500,000, €250,000 of which was to be paid at the earlier to occur of September 15, 2014 or the closing date of an initial public offering and €250,000 of which was to be paid at the time of installation and qualification of the Company's equipment at their facility, (2) related to the technology transfer, €620,000, €310,000 of which was paid subsequent to the signature of the Transfer Agreement and €310,000 of which was to be paid after the delivery of a final study report, (3) for design of a portion of the Manufacturer's facility, €100,000 was to be paid within five days of the signature of the Transfer Agreement, and (4) a €300,000 bonus fee payable in two equal installments, the first of which is due by the end of March 2015, with the remainder paid by the end of December 2015. The first €150,000 of the bonus fee payable was paid in May 2015. Additionally, the Transfer Agreement stipulated that the Company was to pay the Manufacturer an aggregate of €500,000 upon the delivery of agreed-upon levels of satisfactory product. Further, the Company issued the Manufacturer warrants to purchase 16,666 shares of common stock with an exercise price of 90% of the initial public offering price, amended to $6.30 in March 2015. (Note 8)

Effective February 12, 2015, March 25, 2015 and July 15, 2015 the Company entered into amendments delaying payments to the Manufacturer as follows: i) the €500,000 start-up fee was due by the end of April 2015 and has been paid during the year ended December 31, 2015, (ii) related to the technology transfer, of the remaining €310,000, €215,000 was due April 2015 and €95,000 was due June 30, 2015, both of which were paid during the year ended December 31, 2015, (iii) related to the design of a portion of the

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

7. Commitments and Contingencies (Continued)

Manufacturer's facility, the payment has increased to €170,000, €150,000 of which was due at the end of April 2015 and €20,000 was due on June 30, 2015, both of which have been paid during the year ended December 31, 2015 (iv) the fees linked to the deliverables are now due €250,000 on December 31, 2015 and €250,000 on March 31, 2016, 2015, (v) the bonus fee payable of €300,000, €150,000 was due at the end of April 2015 and has been paid during the year ended December 31, 2015 and €150,000 due at December 31, 2015. In May 2015, the Company entered into a Memorandum of Understanding ("MOU") with the contract manufacturer and paid the start-up fee of €500,000 and the technology transfer fee of €215,000. In accordance with the terms of the Memorandum of Understanding, the Manufacturer will supply 400Kg of the Company's API at no cost in anticipation of the future deduction by December 2015.

In December 2015, we entered into an amendment to our technology transfer and commercial manufacturing agreement with our contract manufacturer in Italy delaying a €150,000 bonus fee payment which was originally due on December 31, 2015. This payment is now due on March 31, 2016.

The Company expenses the total cost of the contract ratably over the estimated life of the contract, or the total amount paid if greater. As of December 31, 2015, the amortized costs exceeded amounts paid by $110,141 and are included in accrued manufacturing costs in accrued liabilities in the Company's balance sheet.

Debt Obligations

See Note 8 Debt and Warrants.

Contingencies

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

8. Debt and Warrants

Warrants Issued with the Preferred Stock

In February 2014, the Company closed its first equity round of financing and sold 2,224,991 shares of Series A convertible preferred stock at a price of $2.2472 per share. The pre-money valuation was in excess of $3.0 million setting the exercise price of the Warrants at 75% of the purchase price paid by the investors, or $2.5281 (as adjusted for the 1-for-1.5 reverse stock split approved in October 2014) per share. As such, the fair value of the Warrants, $6,895, was recorded as equity in February 2014. The Warrants were valued at $6,895 using the Black-Scholes model with the following assumptions: exercise price of $2.5281, term of five years, volatility of 64%, dividend yield of 0%, and risk-free interest rate of 1.82%. Based on the fair value of the Warrants, the Company used the residual value of the total proceeds from the issuance of the Notes and Warrants to record the Notes on the balance sheet as of issuance of the Notes. Thus, the amount recorded, in the aggregate, for the Notes on issuance was $518,105, net. The debt discount of $6,895 is recorded as interest expense over the five-year term of the Warrants.

Convertible Notes and Warrants

2013 Convertible Notes

From July through September 2013, the Company issued four convertible promissory notes (collectively the "Notes") for gross aggregate proceeds of $525,000 to various third-party lenders. The

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

8. Debt and Warrants (Continued)

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

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

2014 Convertible Notes

On June 2, 2014, pursuant to a convertible note purchase agreement, the Company issued convertible promissory notes in the aggregate principal amount of $300,000 to two accredited investors, including a convertible promissory note for $200,000 to a board member to which Series A preferred stock was sold. These notes accrued interest at 3% per annum and automatically were to mature on June 1, 2015. Accrued interest was to be paid in cash upon maturity. Upon the closing of the IPO, the outstanding principal amount automatically converted into 53,571 shares common stock at $5.60, as amended in March 2015. Upon issuance, the Company analyzed the beneficial nature of the conversion terms and determined that a beneficial conversion feature ("BCF") existed because the effective conversion price on issuance of the notes was less than the fair value at the time of the issuance. The Company calculated the value of the BCF using the intrinsic method and recorded a BCF of $75,000 as a discount to the notes payable and to additional paid-in capital. For the year ended December 31, 2015 and 2014, the Company amortized $31,250 and $6,250, respectively, of the discount, which has also been recorded as interest expense.

On July 16, 2014, pursuant to a convertible note purchase agreement, the Company issued a convertible promissory note in the principal amount of $150,000 to an accredited investor. This note accrued interest at 3% per annum and automatically was to mature on June 1, 2015. Accrued interest was to be paid in cash upon maturity. Upon the closing of the IPO, the outstanding principal amount automatically converted into 26,785 shares of common stock at $5.60, as amended in March 2015. Upon issuance, the Company analyzed the beneficial nature of the conversion terms and determined that a BCF existed because the effective conversion price was less than the fair value at the time of the issuance. The Company calculated the value of the BCF using the intrinsic method and recorded a BCF of $37,500 as a discount to the notes payable and to additional paid-in capital. For the year ended December 31, 2015, the Company amortized $17,857 of the discount, which has also been recorded as interest expense.

In connection with the Transfer Agreement (Note 7) the Company issued fully vested and immediately exercisable warrants to the Manufacturer to purchase 16,666 shares of common stock at 90% of the IPO price, amended to $6.30 in March 2015, for a period of five years. The fair value of the warrants, $37,840,

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

8. Debt and Warrants (Continued)

was recorded as research and development expense and additional paid-in capital in June 2014. The warrants were originally valued using the Black-Scholes model with the following assumptions: stock price of $4.83, exercise price of $4.35, term of five years, volatility of 49%, dividend yield of 0%, and risk-free interest rate of 1.64%.

On December 23, 2014, pursuant to a convertible note purchase agreement, the Company issued convertible promissory notes in the aggregate principal amount of $650,000 to three accredited investors, including a convertible promissory note for $250,000 to the same board member to which the June 2, 2014 $200,000 convertible promissory note was issued and to which Series A preferred stock was sold. These notes accrued interest at 12% per annum and became payable within thirty days following the IPO. Upon consummation of the Company's IPO, the noteholders converted the notes into 116,070 shares of common stock at a conversion price equal to 80% of the IPO price, amended to $5.60 in March 2015. In connection with these notes, the Company also issued the lenders a fully vested warrant to purchase shares of the Company's common stock at an exercise price equal to 80% of the IPO price, amended to $5.60 in March 2015. These warrants entitle the noteholders to purchase 58,035 shares of common stock. The fair value of the warrants, $147,943, was recorded as a debt discount and liability at December 23, 2014. The Company amortized the remaining $141,890 of this discount during the year ended December 31, 2015. The warrants were originally valued using the Black-Scholes model with the following assumptions: stock price of $4.59, exercise price of $4.15, term of three years, volatility of 49%, dividend yield of 0%, and risk-free interest rate of 1.10%. Based on the circumstances, the value derived using the Black-Scholes model approximated that which would be obtained using a lattice model. The debt discount was be recorded as interest expense over the one hundred ninety days from issuance of the notes through their first maturity date of July 31, 2015, beginning in January 2015. The Company analyzed the beneficial nature of the conversion terms and determined that a BCF existed because the effective conversion price was less than the fair value at the time of the issuance. The Company calculated the value of the BCF using the intrinsic method. A BCF of $502,057 has been recorded as a discount to the notes payable and to additional paid-in capital. For the year ended December 31, 2015, the Company amortized the remaining $484,326 of the BCF which has also been recorded as interest expense.

2015 Convertible Notes

In February 2015, the Company issued convertible promissory notes to two accredited investors in the aggregate principal amount of $250,000. These notes were issued pursuant to the convertible note purchase agreement dated December 23, 2014. Principal and interest of $103,912 was paid in May 2015 for $100,000 of these notes.

The Company's remaining outstanding note of $150,000 is payable to Serious Change II LP at an effective simple interest rate of 12% per annum, and is due in full on July 31, 2016. The note is included in notes payable in the Company's balance sheet. The Company has accrued interest of $15,879, which is included in accrued liabilities in the Company's balance sheet. The note remains outstanding as Serious Change II LP elected not to convert the note as per the terms of the agreement.

In March 2015, the Company entered into a non-binding letter of intent with Dechra Pharmaceuticals PLC ("Dechra"). In connection therewith, Dechra paid the Company $1.0 million. At March 31, 2015, the Company had recorded this amount as a loan advance on the balance sheet. In April 2015, Dechra purchased $1.0 million of convertible promissory notes from the Company, the terms of which provided that such notes were to be converted into shares of the Company's common stock upon the closing of an IPO at a conversion price of $5.60 per share. In connection with the purchase of the notes,

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

8. Debt and Warrants (Continued)

the Company issued Dechra a warrant to purchase 89,285 shares at $5.60 per share, which expires December 31, 2017. The notes accrued simple interest of 12% per annum and, upon consummation of the Company's IPO in May 2015, converted into 178,571 shares of the Company's common stock. The Company analyzed the beneficial nature of the conversion terms and determined that a BCF existed because the effective conversion price was less than the fair value at the time of the issuance. The Company calculated the value of the BCF using the intrinsic method. A BCF of for the full face value was recorded as a discount to the notes payable and to additional paid-in capital. For the year ended December 31, 2015, the Company amortized the entire BCF of $1.0 million which has also been recorded as interest expense.

As of December 31, 2015 and 2014, the convertible notes payable obligations were as follows:

	December 31, 2015	December 31, 2014
Notes payable	$ 150,000	$ 1,100,000
Unamortized note discount		(675,326)
Net debt obligation	$ 150,000	$ 424,674

Interest expense on the convertible notes payable was as follows:

	December 31, 2015	December 31, 2014
Nominal interest	$ 70,619	$ 9,292
Amortization of debt discount	1,925,326	87,174
	$ 1,995,945	$ 96,466

At December 31, 2015 and 2014, interest payable on convertible notes payable was $75,999 and $29,276, respectively.

Notes Payable Bridge Loans

On October 30, 2014, the Company entered into a standby bridge financing agreement with two lenders, which was amended and restated on December 3, 2014, which provided a loan commitment in the aggregate principal amount of $1.0 million (the "Bridge"). Proceeds to the Company were net of a $100,000 debt discount under the terms of the Bridge and net of $104,000 of debt issuance costs. This debt discount and debt issuance costs were recorded as interest expense using the effective interest method, over the six month term of the Bridge. The Bridge became payable upon the IPO. The Bridge was repaid in May 2015, including interest thereon in an amount of $1,321,600. In connection with the Bridge, the lenders were granted warrants to purchase that number of shares of the Company's common stock determined by dividing $1.0 million by the exercise price of 80% of the IPO price, amended to $5.60 in March 2015. The fair value of the warrants, $505,348, was originally recorded as a debt discount and liability at December 3, 2014. The warrants were originally valued using the Black-Scholes model with the following assumptions: stock price of $5.01, exercise price of $5.23, term of five years, volatility of 63%, dividend yield of 0%, and risk-free interest rate of 1.61%. Based on the circumstances, the value derived using the Black-Scholes model approximated that which would be obtained using a lattice model. The debt discount was recorded as interest expense over the six month term of the Bridge. Of the aggregate debt discount of $605,348 (warrants and original $100,000 discount), $521,291 was recorded as interest expense

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

8. Debt and Warrants (Continued)

during the year ended December 31, 2015. Additional financing costs of $104,000 were incurred related to the Bridge and deferred on closing. These are being recognized as interest expense over the six-month term of the Bridge using the effective interest method. During the year ended December, 2015, the remaining $86,667 of these deferred financing charges was recorded as interest expense.

As of December 31, 2015 and 2014, the notes payable obligation was as follows:

	December 31, 2015	December 31, 2014
Notes Payable	$	$ 1,000,000
Unamortized note discount		(521,291)
Debt issuance costs		(86,667)
Net debt obligation	$	$ 392,042

Interest expense on the notes payable-bridge loans was as follows:

	December 31, 2015	December 31, 2014
Nominal Interest	$ 100,000	$ 20,000
Amortization of debt discount	521,291	84,057
Repayment premium	201,600	
Debt issuance costs	86,667	17,333
	$ 909,558	$ 121,390

Standby Line of Credit

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

Long-term Debt

In August 2015, the Company entered into a loan and security agreement with a lender for up to $8.0 million, which provided for an initial loan commitment of $6.0 million. The loan agreement requires the Company to maintain $4.5 million of the proceeds in cash, which may be reduced or eliminated on the achievement of certain milestones. An additional $2.0 million is available contingent on the achievement of certain further milestones. The agreement has a term of three years, with interest only payments through February 29, 2016. Thereafter, principal and interest payments will be made with an interest rate of 9.9%. Additionally, there will be a balloon payment of $560,000 on August 1, 2018. This amount is being recognized over the term of the loan agreement and the effective interest rate, considering the balloon payment, is 15.0%. Proceeds to the Company were net of a $134,433 debt discount under the terms of the loan agreement. This debt discount is being recorded as interest expense, using the interest method, over

98

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

8. Debt and Warrants (Continued)

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

As of December 31, 2015 and 2014, the net long-term debt obligation was as follows:

	December 31, 2015	December 31, 2014
Debt and unpaid accrued end-of-term payment	$ 6,115,797	$
Unamortized note discount	(106,635)	
Unamortized debt issuance costs	(206,234)	
Net debt obligation	$ 5,802,927	$
Current portion of long-term debt	$ 1,707,899	$
Long-term debt, net of discount	4,095,028	
Total	$ 5,802,927	$

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

	Amount
Years ending December 31,	
2016	$ 1,832,500
2017	2,409,780
2018	1,757,720
Total principal payments	$ 6,000,000

The obligation at December 31, 2015 includes an end-of-term payment of $560,000, which accretes over the life of the loan as interest expense. As a result of the debt discount and the end-of-term payment, the effective interest rate for the loan differs from the contractual rate.

Interest expense on the long-term debt was as follows:

	December 31, 2015	December 31, 2014
Nominal interest	$ 224,400	$
Amortization of debt discount	27,798	
Accretion of end-of-term payment	115,797	

Debt issuance costs	43,789	
	$ 411,784	$

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

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

8. Debt and Warrants (Continued)

The Company's warrant activity is summarized as follows:

	December 31, 2015	December 31, 2014
Warrants outstanding at January 1	494,267	207,664
Warrants issued	254,605	286,603
Warrants outstanding at December 31	748,872	494,267

9. Redeemable Convertible Preferred Stock

In February, April and May of 2014, the Company issued 3,015,902 shares of convertible preferred stock in exchange for $6,777,338. The redemption value of the convertible preferred stock was $9.0 million. The differences between the respective redemption values/liquidation preference and carrying values are being accreted over the period from the date of issuance to the earliest possible redemption date, February 2017. The Company has recorded accretion of $263,060 and $610,889 for the years ended December 31, 2015 and 2014, respectively.

Costs incurred in connection with the issuance of Series A redeemable convertible preferred stock (the "Preferred Stock") during the year ended December 31, 2014 were $119,097 which have been recorded as a reduction to the carrying amounts of Preferred Stock and are being accreted to the carrying value of the applicable preferred stock to the redemption date. The Company has recorded accretion of $83,314 and $35,784 for the years ended December 31, 2015 and 2014, respectively.

On May 18, 2015, the Company completed its IPO. In connection with the IPO, the Company's 3,015,902 outstanding shares of convertible preferred stock were automatically converted into 2,010,596 shares of common stock.

As of December 31, 2015 and 2014, Convertible Preferred Stock balances were comprised of:

	December 31, 2015	December 31, 2014
Preferred stock, net of issuance costs	$	$ 6,658,241
Accretion of deemed dividend		610,889
Amortization of issuance costs		35,784
	$	$ 7,304,914

Convertible Preferred Stock has been classified outside of stockholders' (deficit) in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities.

The Preferred Stock was classified outside of stockholders' (deficit) in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities.

10. Stockholders' Equity

Common Stock

The Company's second amended and restated certificate of incorporation authorizes the Company to issue 50,000,000 shares of common stock $0.0001 par value. The holders of common stock are entitled to

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

10. Stockholders' Equity (Continued)

one vote for each share of common stock held at all meetings of stockholders. The number of authorized shares of common stock may be increased or decreased by the affirmative vote of the holders of shares of capital stock of the Company representing a majority of the votes represented by all shares (including Preferred Stock) entitled to vote.

As of December 31, 2015, the Company had reserved shares of common stock for issuance as follows:

	December 31, 2015	December 31, 2014
Options issued and outstanding	919,506	659,554
Options available for grant	106,833	119,077
RSUs issued and outstanding	55,536	68,902
Warrants issued and outstanding	748,872	494,267
Total	1,830,747	1,341,800

Preferred Stock

The Company's second amended and restated certificate of incorporation authorizes the Company to issue 10,000,000 shares of preferred stock $0.0001 par value. No shares of preferred stock were issued or outstanding at December 31, 2015 or 2014.

11. Stock Incentive Plans

2013 Equity Incentive Plan

Effective November 1, 2013, the Company's board of directors and sole stockholder adopted the Jaguar Animal Health, Inc. 2013 Equity Incentive Plan (the "2013 Plan"). The 2013 Plan allows the Company's board of directors to grant stock options, restricted stock awards and restricted stock unit awards to employees, officers, directors and consultants of the Company. As of December 31, 2013, the

Company had reserved 300,000 shares of its common stock for issuance under the 2013 Plan. In April 2014, the board of directors amended the 2013 Plan to increase the shares reserved for issuance to 847,533 shares. Following the effective date of the IPO and after effectiveness of any grants under the 2013 Plan that were contingent on the IPO, no additional stock awards will be granted under the 2013 Plan. Outstanding grants continue to be exercisable, however any unissued shares under the plan and any forfeitures of outstanding options do not rollover to the 2014 Stock Incentive Plan.

2014 Stock Incentive Plan

Effective May 12, 2015, the Company adopted the Jaguar Animal Health, Inc. 2014 Stock Incentive Plan ("2014 Plan"). The 2014 Plan provides for the grant of options, restricted stock and restricted stock units to eligible employees, directors and consultants to purchase the Company's common stock. The Company reserved 333,333 shares of common stock for issuance pursuant to the 2014 Plan. The share reserve automatically increases January 1 of each fiscal year in the amount of 2% of the outstanding number of shares of the Company's common stock on December 31 of the preceding calendar year. The 2014 Plan replaces the 2013 Plan except that all outstanding options under the 2013 Plan remain outstanding until exercised, cancelled or until they expire.

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

11. Stock Incentive Plans (Continued)

In July 2015, the Company amended the 2014 Plan reserving an additional 550,000 shares under the plan contingent upon approval by the Company's stockholders at the next stockholders meeting.

Stock Options and Restricted Stock Units ("RSUs")

The following table summarizes incentive plan activity for the years ended December 31, 2015 and 2014:

	Shares Available for Grant	Stock Options Outstanding	RSUs Outstanding	Weighted Average Stock Option Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
2013 Equity Incentive Plan Balance December 31, 2013	300,000					
Additional shares authorized	547,533					
Options Granted	(753,110)	753,110		$ 2.65		
Options Cancelled	93,556	(93,556)		$ 2.53		
RSUs Granted	(79,297)		79,297			
RSUs Cancelled	10,395		(10,395)			
2013 Equity Incentive Plan Balance December 31, 2014	119,077	659,554	68,902	$ 2.67		
Additional shares authorized						
Options Granted	(176,364)	176,364		$ 7.00		
Options Cancelled	95,784	(95,784)		$ 2.53		
Options available for grant cancelled upon IPO	(51,863)					
Options Cancelled post-IPO not rolled back into the 2013 Plan		(42,128)				
Options Exercised		(5,000)		$ 2.53		
RSUs Granted	(1,484)		1,484			
RSUs Cancelled	14,850		(14,850)			
2013 Equity Incentive Plan Balance December 31, 2015		693,006	55,536	$ 3.74		
2014 Stock Stock Plan Balance December 31, 2014						
Shares Authorized	333,333					
Options Granted	(241,500)	241,500		$ 4.32		
Options Cancelled	15,000	(15,000)		$ 5.09		
Combined Incentive Plan Balance December 31, 2015	106,833	919,506	55,536	$ 3.87	8.81	$
Options vested and exercisable December 31, 2015		413,063		$ 3.96	8.60	$
Options vested and expected to vest December 31, 2015		776,470		$ 3.83	8.81	$

The weighted average grant date fair value of stock options granted was $2.90 and $1.55 per share during the years ended December 31, 2015 and 2014.

The number of options vested was 413,063 at December 31, 2015. No options were vested at December 31, 2014. The grant date fair value of options vested was $893,974 at December 31, 2015.

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

11. Stock Incentive Plans (Continued)

There was no intrinsic value of options exercised in 2015 as the fair market value as of December 31, 2015 was $2.25 per share as reported by NASDAQ and the weighted average exercise price of the options exercised in 2015 was $2.53 per share. The intrinsic value is calculated as the difference between the market value as of December 31, 2015 and the weighted average exercise price of shares exercised.

The Company granted RSUs in 2014 and 2015 under the 2013 Equity Incentive Plan. The units granted vest upon the occurrence of both a liquidity event and satisfaction of the service-based requirement. The time-based vesting provides that 50% of the RSU will vest on January 1, 2016 and the remaining 50% vest on July 1, 2017. The Company began recording stock-based compensation expense relating to the RSU grants effective May 18, 2015, the date of the Company's initial public offering, and the date the liquidity condition was met. The stock-based compensation expense is based on the grant date fair value which is the equivalent to the fair market value on the date of grant, and is amortized over the vesting period using the straight-line method, net of estimated forfeitures.

Stock-Based Compensation

The following table summarizes stock-based compensation expense related to stock options and RSUs for the years ended December 31, 2015 and 2014, and are included in the statements of operations and comprehensive loss as follows:

	December 31, 2015	December 31, 2014
Research and development expense	$ 472,145	$ 70,796
Sales and marketing expense	54,115	
General and administrative expense	465,905	93,360
Total	$ 992,165	$ 164,156

As of December 31, 2015, the Company had $850,758 of unrecognized stock-based compensation expense for options outstanding, which is expected to be recognized over a weighted-average period of 1.9 years. As of December 31, 2015, the Company had $105,077 of unrecognized stock-based compensation expense for outstanding RSUs which is expected to be recognized over a weighted-average period of 1.5 years.

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

	December 31, 2015	December 31, 2014
Weighted-average volatility	55.43 - 61.51%	63%
Weighted-average expected term (years)	5.15 - 5.82	5.81
Risk-free interest rate	1.60 - 1.84%	2%
Expected dividend yield		

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

11. Stock Incentive Plans (Continued)

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

	December 31, 2015	December 31, 2014
Weighted-average volatility	76.63%	
Weighted-average expected term (years)	9.69	
Risk-free interest rate	2.25%	
Expected dividend yield		

12. Related Party Transactions

The Company is a majority-owned subsidiary of Napo. Additionally, Lisa A. Conte, Chief Executive Officer of the Company, is also the interim Chief Executive Officer of Napo Pharmaceuticals, Inc. The Company has total outstanding liabilities to Napo at December 31, 2015 and 2014 as follows:

	December 31, 2015	December 31, 2014
Due to (from) Napo	$ (6,008)	$ 16,581
Royalty payable to Napo	2,810	
License Fee payable to Napo	425,000	1,875,000
Total	$ 421,801	$ 1,891,581

A member of the board of directors of the Company purchased 148,332 shares of the Company's preferred stock during the year ended December 31, 2014. The Company also issued a convertible promissory note for $200,000 to the same board member to whom the preferred stock was sold.

13. Net Loss Per Share Attributable to Common Stockholders

The following table presents the calculation of basic and diluted net loss per common share for the years ended December 31, 2015 and 2014:

	December 31, 2015	December 31, 2014
Net loss attributable to common shareholders	$ (16,637,924)	$ (9,256,248)
Shares used to compute net loss per common share, basic and diluted	6,153,139	2,854,417
Net loss per share attributable to common shareholders, basic and diluted	$ (2.70)	$ (3.24)

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company's potentially dilutive securities which include stock options, convertible preferred stock and common stock warrants

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

13. Net Loss Per Share Attributable to Common Stockholders (Continued)

have been excluded from the computation of diluted net loss per share as they would be anti-dilutive. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares outstanding due to the Company's net loss position.

The following outstanding common stock equivalents have been excluded from diluted net loss per common share for the years ended December 31, 2015 and 2014 because their inclusion would be anti-dilutive:

	December 31, 2015	December 31, 2014
Convertible preferred stock		2,010,596
Options	919,506	659,554
Warrants to purchase common stock	748,872	494,267
Restricted stock units	55,536	68,902
Total	1,723,914	3,233,319

14. Income Taxes

The Company had net comprehensive losses of $16,291,550 and $8,609,575 for the years ended December 31, 2015 and 2014, respectively.

Due to continued losses, and a full valuation allowance, the Company has not recorded a provision for income taxes for the years ended December 31, 2015 and 2014.

The components of the provision for income taxes during the years ended December 31, 2015 and 2014 is as follows:

	December 31, 2015	December 31, 2014
Current:		
Federal	$	$
State		
Foreign		
Total Current		
Deferred:		
Federal	(4,197,007)	(2,844,539)
State	(587,696)	(511,406)
Foreign		
Total Deferred	(4,784,703)	(3,355,945)
Valuation Allowance	4,784,703	3,355,945
Total Provision for Income Taxes	$	$

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

14. Income Taxes (Continued)

The Company's effective tax during the years ended December 31, 2015 and 2014, differed from the federal statutory rate as follows:

	December 31, 2015	December 31, 2014
Statutory Rate	(34.0)%	(34.0)%
State Taxes	(3.6)%	(5.9)%
Tax Credits	5.2%	(0.8)%
Other	1.7%	2.2%
Valuation Allowance	30.7%	38.50%
Effective Tax Rate	0.0%	0.0%

Net deferred tax assets as of December 31, 2015 and 2014 consist of the following:

	December 31, 2015	December 31, 2014
Non-current Deferred Tax Assets:		
Net Operating Costs	$ 7,459,489	$ 3,610,478
Tax Credits	261,851	124,025
Other	734,611	(56,713)
	8,455,951	3,677,790
Valuation Allowance	(8,455,951)	(3,677,790)
Net Non-current Deferred Tax Assets	$	$

A valuation allowance is provided when it is more likely than not that the deferred tax assets will not be realized. The Company has established a valuation allowance to offset net deferred tax assets as of December 31, 2015 and 2014, due to the uncertainty of realizing future tax benefits from its net operating loss carryforwards and other deferred tax assets.

The valuation allowance increased by $4,784,703 during the year ended December 31, 2015.

As of December 31, 2015, the Company had federal and California net operating loss carryovers of approximately $19,131,333 and $10,643,472, respectively. The federal and California net operating losses will begin to expire in 2033.

As of December 31, 2015, the Company had federal and California research credit carryovers of approximately $196,593 and $198,062, respectively. The federal research credits will begin to expire in 2033. The California research credits carry forward indefinitely.

The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carryforward in certain situations where changes occur in the stock ownership of a company. The Company does not believe that the use of net operating loss and tax credit carryforwards were limited in prior years, nor as a consequence of the IPO. However, in the event the Company has a change in ownership in the future, as defined by the tax law, utilization of the carryforwards could be limited.

In November 2015, the FASB issued Accounting Standards Update 2015-17, which simplifies the presentation of deferred income taxes by requiring that deferred tax assets and liabilities be presented as non-current. The standard impacts presentation only. The Company elected to

early adopt the standard on a retrospective basis effective December 31, 2015 and all deferred tax assets and liabilities are classified as

Table of Contents

Jaguar Animal Health, Inc.

Notes to Financial Statements (Continued)

14. Income Taxes (Continued)

non-current on the Company's consolidated balance sheets. Adoption of this ASU had no effect on the Company's balance sheet for 2015 or 2014 as presented.

Uncertain Tax Positions

The Company has adopted the provisions of ASC 740, "Income Taxes Related to Uncertain Tax Positions." Under these principals, tax positions are evaluated in a two-step process. The Company first determines whether it is more-likely-than-not that a tax positions will be sustained upon examination. If a tax position meets the more-likely-than-not recognition threshold it is then measured to determine the amount of benefit to be recognized in the financial statements. The tax position is measured as the largest amount of benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement.

The following is a reconciliation of the beginning and ending amount of our total gross unrecognized tax benefit liabilities for the years ended December 31, 2015 and 2014:

	December 31, 2015	December 31, 2014
Gross Unrecognized Tax Benefit Beginning Balance	$ 31,006	$
Increases Related to Tax Positions from Prior Years	5,920	
Increases Related to Tax Positions Taken During the Current Year	42,004	31,006
Gross Unrecognized Tax Benefit Beginning Balance	$ 78,930	$ 31,006

There are no liabilities from unrecognized tax benefits included in the Company's balance sheet as of December 31, 2015 and 2014, and therefore the Company has not accrued for any penalties or interest. The Company does not have any tax positions that are expected to significantly increase or decrease over the next 12 months.

The Company files income tax returns in the United States and California, where the statute of limitations are 3 years and 4 years, respectively. The Company remains open for audit by the United States Internal Revenue Service and California state tax jurisdictions since inception.

The Company is not currently under examination by income tax authorities in federal or state jurisdictions.

15. 401(k) Plan

The Company sponsors a 401(k) defined contribution plan covering all employees. There were no employer contributions to the plan in the years ended December 31, 2015 and 2014.

16. Subsequent Events

The Company completed an evaluation of the impact of subsequent events through March 31, 2016, the date these financial statements were issued.

In February 2016, the Company completed an secondary public offering of its common stock. In connection with its secondary offering, the Company issued 2,000,000 shares of its common stock at a price to the public of $2.50 per share. As a result of the secondary offering, the Company received approximately $4.1 million in net proceeds, after deducting underwriting discounts and commissions of $373,000 and estimated offering expenses of $540,000.

107

Table of Contents

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Exchange Act that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

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

Internal Control Over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting during the fourth quarter of 2015.

ITEM 9B. OTHER INFORMATION

On March 18, 2016, John A. Kallassy submitted his resignation, effective immediately, as Chief Operating Officer of our company.

Table of Contents

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference from the Proxy Statement for the 2016 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2015.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information under the captions "Compensation of Directors and Executive Officers" contained in the Proxy Statement for the 2016 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2015.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference from the information under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Compensation of Directors and Executive Officers Equity Compensation "contained in the Proxy Statement for the 2016 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2015.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference from the information under the caption "Proposal 1 Election of Directors Director Independence" and "Certain Relationships and Related Transactions" contained in the Proxy Statement for the 2016 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2015.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference from the information under the caption "Proposal 2 Ratification of the Appointment of Independent Registered Public Accounting Firm Principal Accountant Fees and Services" contained in the Proxy Statement for the 2016 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2015.

Table of Contents

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)

Documents filed as part of this report

1.

Financial Statements:

Reference is made to the Index to Financial Statements of Jaguar Animal Health, Inc. included in Item 8 of Part II hereof.

2.

Financial Statement Schedules

All schedules have been omitted because they are not required, not applicable, or the required information is included in the financial statements or notes thereto.

3.

Exhibits

See Item 15(b) below. Each management contract or compensating plan or arrangement required to be filed has been identified.

(b)

Exhibits The following exhibits are included herein or incorporated herein by reference.

Exhibit No.	Description
3.1	Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K (No. 001-36714) filed with the Securities and Exchange Commission on May 18, 2015).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K (No. 001-36714) filed with the Securities and Exchange Commission on May 18, 2015).
4.1	Specimen Common Stock Certificate of Jaguar Animal Health, Inc. (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1/A (No. 333-198383) filed with the Securities and Exchange Commission on October 10, 2014).
10.1	Form of Indemnification Agreement by and between Jaguar Animal Health, Inc. and its directors and officers (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-1 (No. 333-198383) filed with the Securities and Exchange Commission on August 27, 2014).
10.2	Jaguar Animal Health, Inc. 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1/A (No. 333-198383) filed with the Securities and Exchange Commission on October 31, 2014).
10.3	Form of Notice of Grant of Stock Option and Stock Option Agreement under the 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1 (No. 333-198383) filed with the Securities and Exchange Commission on August 27, 2014).
10.4	Form of Notice of Grant of Restricted Stock and Restricted Stock Agreement under the 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1 (No. 333-198383) filed with the Securities and Exchange Commission on August 27, 2014).

Table of Contents

Exhibit No.	Description
10.5	Form of Notice of Grant of Restricted Stock Units and Restricted Stock Unit Agreement under the 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1 (No. 333-198383) filed with the Securities and Exchange Commission on August 27, 2014).
10.6	Offer Letter by and between Jaguar Animal Health, Inc. and Lisa A. Conte, dated March 1, 2014 (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1 (No. 333-198383) filed with the Securities and Exchange Commission on August 27, 2014).
10.7	Offer Letter by and between Jaguar Animal Health, Inc. and Steven R. King, Ph.D., dated February 28, 2014 (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form S-1 (No. 333-198383) filed with the Securities and Exchange Commission on August 27, 2014).
10.8	Amended and Restated License Agreement by and between Jaguar Animal Health, Inc. and Napo Pharmaceuticals, Inc., dated August 6, 2014 (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form S-1 (No. 333-198383) filed with the Securities and Exchange Commission on August 27, 2014).
10.9	Employee Leasing and Overhead Allocation Agreement by and between Jaguar Animal Health, Inc. and Napo Pharmaceuticals, Inc., dated July 1, 2013 (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1 (No. 333-198383) filed with the Securities and Exchange Commission on August 27, 2014).
10.10	Assignment of Sublease and Landlord Consent by and between Jaguar Animal Health, Inc. and Napo Pharmaceuticals, Inc., dated June 1, 2014 (incorporated by reference to Exhibit 10.15 to the Registration Statement on Form S-1 (No. 333-198383) filed with the Securities and Exchange Commission on August 27, 2014).
10.11	Form of Common Stock Warrant that expires February 5, 2019 (incorporated by reference to Exhibit 10.16 to the Registration Statement on Form S-1 (No. 333-198383) filed with the Securities and Exchange Commission on August 27, 2014).
10.12	Form of Common Stock Warrant issued to Indena S.p.A. that expires June 26, 2019 (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form S-1 (No. 333-198383) filed with the Securities and Exchange Commission on August 27, 2014).
10.13	Form of Common Stock Warrant issued to Joshua Mailman, which expires August 26, 2016 (incorporated by reference to Exhibit 10.21 to the Registration Statement on Form S-1/A (No. 333-198383) filed with the Securities and Exchange Commission on September 9, 2014).
10.14	Offer Letter by and between Jaguar Animal Health, Inc. and John A. Kallassy, dated as of September 19, 2014 (incorporated by reference to Exhibit 10.22 to the Registration Statement on Form S-1/A (No. 333-198383) filed with the Securities and Exchange Commission on October 10, 2014).
10.15	Non-Disturbance Letter Agreement by and between Napo Pharmaceuticals, Inc. and Nantucket Investments Limited, as Administrative Agent and Collateral Agent, dated October 10, 2014 (incorporated by reference to Exhibit 10.23 to the Registration Statement on Form S-1/A (No. 333-198383) filed with the Securities and Exchange Commission on October 10, 2014).

Table of Contents

Exhibit No.	Description
10.16	Form of Warrant to Purchase Common Stock issued to GPB Life Science Holdings LLC and 31 Group, LLC, which expires October 30, 2019 (incorporated by reference to Exhibit 10.25 to the Registration Statement on Form S-1/A (No. 333-198383) filed with the Securities and Exchange Commission on October 31, 2014).
10.17	Form of Exchange Warrant to Purchase Common Stock, issued to GPB Life Science Holdings LLC and 31 Group, LLC, which expires June 3, 2020, as amended (incorporated by reference to Exhibit 10.27 to the Registration Statement on Form S-1/A (No. 333-198383) filed with the Securities and Exchange Commission on April 17, 2015).
10.18	Amendment No. 1 to Amended and Restated License Agreement between Jaguar Animal Health, Inc. and Napo Pharmaceuticals, Inc., dated as of January 27, 2015 (incorporated by reference to Exhibit 10.28 to the Registration Statement on Form S-1/A (No. 333-198383) filed with the Securities and Exchange Commission on March 20, 2015).
10.19	Offer Letter by and between Jaguar Animal Health, Inc. and Michael Hauser, D.V.M., dated as of March 3, 2015 (incorporated by reference to Exhibit 10.32 to the Registration Statement on Form S-1/A (No. 333-198383) filed with the Securities and Exchange Commission on March 20, 2015).
10.20	Form of Representative's Warrant (incorporated by reference to Exhibit 10.33 to the Registration Statement on Form S-1/A (No. 333-198383) filed with the Securities and Exchange Commission on April 17, 2015).
10.21	Form of Warrant and Note Exercise Amendment pursuant to Convertible Note and Warrant Purchase Agreement dated December 23, 2014 (incorporated by reference to Exhibit 10.35 to the Registration Statement on Form S-1/A (No. 333-198383) filed with the Securities and Exchange Commission on April 17, 2015).
10.22	Convertible Note and Warrant Purchase Agreement dated March 20, 2015 by and between Jaguar Animal Health, Inc., and Dechra Pharmaceuticals PLC (incorporated by reference to Exhibit 10.37 to the Registration Statement on Form S-1/A (No. 333-198383) filed with the Securities and Exchange Commission on April 17, 2015).
10.23	Common Stock Warrant issued pursuant to the Convertible Note and Warrant Purchase Agreement dated March 20, 2015, which expires December 31, 2017 (incorporated by reference to Exhibit 10.39 to the Registration Statement on Form S-1/A (No. 333-198383) filed with the Securities and Exchange Commission on April 17, 2015).
10.24	Form of Warrant Exercise Amendment pursuant to Exchange Warrant to Purchase Common Stock dated December 3, 2014 (incorporated by reference to Exhibit 10.40 to the Registration Statement on Form S-1/A (No. 333-198383) filed with the Securities and Exchange Commission on April 17, 2015).
10.25	Form of Amended and Restated Exchange Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.41 to the Registration Statement on Form S-1/A (No. 333-198383) filed with the Securities and Exchange Commission on April 17, 2015).
10.26	Sublease Agreement by and between SeeChange Health Management LLC and Jaguar Animal Health, Inc., dated June 23, 2015 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K (No. 001-36714) filed with the Securities and Exchange Commission on June 23, 2015).

Table of Contents

Exhibit No.	Description
10.27	Consent to Sublease by and among CA-Mission Street Limited Partnership, SeeChange Health Management LLC and Jaguar Animal Health, Inc., dated June 19, 2015 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K (No. 001-36714) filed with the Securities and Exchange Commission on June 23, 2015).
10.28	Loan and Security Agreement between Jaguar Animal Health, Inc., Qualified Subsidiaries thereof, the several banks and other financial institutions or entities from time to time parties thereto as lenders and Hercules Technology Growth Capital, Inc., dated as of August 18, 2015 (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K (No. 001-36714) filed with the Securities and Exchange Commission on August 20, 2015).
10.29	Manufacture and Supply Agreement between Jaguar Animal Health, Inc. and Glenmark Pharmaceuticals Ltd., dated September 22, 2015 (incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q (No. 001-36714) filed with the Securities and Exchange Commission on November 13, 2015).
10.30	Formulation Development and Manufacturing Agreement between Jaguar Animal Health, Inc. and Patheon Pharmaceuticals Inc., dated October 8, 2015 (incorporated by reference to Exhibit 10.30 to the Registration Statement on Form S-1 (No. 333-208905) filed with the Securities and Exchange Commission on January 7, 2016).
10.31	Offer Letter by and between Jaguar Animal Health, Inc., and Karen Wright, dated as of October 11, 2015 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 18, 2015).
10.32	Form of Convertible Promissory Note issued pursuant to the Convertible Note and Warrant Purchase Agreement dated as of December 23, 2014 (incorporated by reference to Exhibit 10.30 to the Registration Statement on Form S-1/A (No. 333-198383) filed with the Securities and Exchange Commission on March 20, 2015).
23.1*	Consent of Independent Registered Public Accounting Firm.
31.1*	Principal Executive Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Principal Financial Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
32.2**	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

*

Filed herewith.

**

In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-K and

113

Table of Contents

will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933 except to the extent that the registrant specifically incorporates it by reference.

Confidential treatment granted as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

Management contract or compensatory plan or arrangement.

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

JAGUAR ANIMAL HEALTH, INC.

By: /s/ LISA A. CONTE

Lisa A. Conte
Chief Executive Officer and President

Date: March 29, 2016

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons, on behalf of the registrant in the capacities indicated.

Signatures	Titles	Date
/s/ LISA A. CONTE Lisa A. Conte	Chief Executive Officer, President and Director	March 29, 2016
/s/ KAREN S. WRIGHT Karen S. Wright	Chief Financial Officer	March 29, 2016
/s/ JAMES J. BOCHNOWSKI James J. Bochnowski	Chairman of the Board of Directors	March 29, 2016
/s/ JIAHAO QIU Jiahao Qiu	Director	March 29, 2016
/s/ ZHI YANG, PH.D. Zhi Yang, Ph.D.	Director	March 29, 2016
/s/ FOLKERT W. KAMPHUIS Folkert W. Kamphuis	Director	March 29, 2016