

Jaguar Health, Inc.  
Form 424B5  
January 08, 2019

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Registration No. 333-220236

PROSPECTUS SUPPLEMENT (TO PROSPECTUS DATED SEPTEMBER 14, 2017)

## JAGUAR HEALTH, INC.

### Up to 5,633,333 Shares of Common Stock

We are offering up to 5,633,333 shares ("Shares") of our voting common stock, par value \$0.0001 per share ("Common Stock").

The Shares represent securities that Oasis Capital, LLC ("Oasis Capital") agreed to purchase pursuant to a Common Stock Purchase Agreement dated January 7, 2018 (the "CSPA"). We have the right to "put," or sell, up to 5,333,333 shares of Common Stock (the "Purchase Shares") to Oasis Capital at a price of \$0.75 per share or such other price as mutually agreed upon the parties. We may issue Purchase Shares at any time on or after the date of the CSPA until the date on which Oasis Capital has purchased 5,333,333 Purchase Shares or the agreement is otherwise terminated. Separately, an additional 300,000 Shares (the "Commitment Shares") will be issued to Oasis Capital as an inducement to enter into the CSPA on the effective date of the CSPA. We are not paying any underwriting discounts or commissions.

This prospectus supplement covers the issuance of the Shares to Oasis Capital and the resale of the Purchase Shares on or behalf of Oasis Capital. With regard to the Purchase Shares, Oasis Capital is an "underwriter" within the meaning of the Securities Act of 1933, as amended (the "Securities Act"), in connection with the resale of the Purchase Shares. Any broker-dealers or agents that are involved in resales of Purchase Shares may be deemed "underwriters". We will not receive any proceeds from the resale of the Shares by Oasis Capital, though we will receive proceeds from the sale of the Purchase Shares directly to them pursuant to the CSPA.

Our Common Stock is listed on the Nasdaq Capital Market under the symbol "JAGX." On January 7, 2019, the last reported sale price of our common stock on the Nasdaq Capital Market was \$0.34 per share.

The aggregate market value of our outstanding voting and non-voting common stock held by non-affiliates, or public float, is approximately \$12.1 million, which was calculated based on 23,188,253 shares of outstanding voting and non-voting common stock held by non-affiliates on January 7, 2019 and on a closing price per share of \$0.52 on November 8, 2018. Following this offering, we will have sold securities with an aggregate market value of approximately \$4.0 million pursuant to General Instruction I.B.6 of Form S-3 during the prior 12 calendar month period that ends on and includes the date hereof.

**Investing in our Common Stock involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks that we have described on page S-8 of this prospectus supplement under the caption "Risk Factors" and in the documents incorporated by reference into this**

**prospectus supplement and the accompanying prospectus.**

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

The date of this prospectus supplement is January 8, 2019.

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**ABOUT THIS PROSPECTUS SUPPLEMENT**

This prospectus supplement and the accompanying prospectus dated September 14, 2017 are part of a registration statement that we filed with the Securities and Exchange Commission (the "SEC") using a "shelf" registration process. This prospectus supplement and the accompanying prospectus relate to the offer by us of shares of our common stock to certain investors. We provide information to you about this offering of shares of our common stock in two separate documents that are bound together: (1) this prospectus supplement, which describes the specific details regarding this offering; and (2) the accompanying prospectus, which provides general information, some of which may not apply to this offering. Generally, when we refer to this "prospectus," we are referring to both documents combined. If information in this prospectus supplement is inconsistent with the accompanying prospectus, you should rely on this prospectus supplement. However, if any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference in this prospectus supplement or the accompanying prospectus—the statement in the document having the later date modifies or supersedes the earlier statement as our business, financial condition, results of operations and prospects may have changed since the earlier dates. You should not assume that the information contained or incorporated by reference in this prospectus supplement, the accompanying prospectus or any free-writing prospectus is accurate as of any date other than as of the date of this prospectus supplement, the accompanying prospectus or any related free-writing prospectus, as the case may be, or in the case of the documents incorporated by reference, the date of such documents regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or any sale of our securities. You should read this prospectus supplement, the accompanying prospectus, the documents and information incorporated by reference in this prospectus supplement and the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering when making your investment decision. You should also read and consider the information in the documents to which we have referred you under the captions "Where You Can Find More Information" and "Incorporation of Information by Reference" in this prospectus supplement. We have not authorized anyone to provide you with information that is in addition to, or different from, that contained or incorporated by reference in this prospectus supplement, the accompanying prospectus or in any free writing prospectuses we have prepared. If anyone provides you with different or inconsistent information, you should not rely on it. We are not offering to sell securities in any jurisdiction where the offer or sale is not permitted.

Unless the context otherwise requires, references in this prospectus supplement to "Jaguar," the "Company," "we," "us," and "our" refer to Jaguar Health, Inc.

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

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**PROSPECTUS SUPPLEMENT SUMMARY**

*The following is a summary of what we believe to be the most important aspects of our business and the offering of our securities under this prospectus supplement and in the accompanying prospectus. We urge you to read this entire prospectus supplement, the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering, including the section entitled "Risk Factors" and the more detailed financial statements, notes to the financial statements and other information incorporated by reference from our other filings with the SEC.*

**Overview**

We are a commercial stage pharmaceutical company focused on developing novel, sustainably derived gastrointestinal products on a global basis. Our wholly-owned subsidiary, Napo Pharmaceuticals, Inc. ("Napo"), focuses on developing and commercializing proprietary human gastrointestinal pharmaceuticals for the global marketplace from plants used traditionally in rainforest areas. Our Mytesi (crofelemer) product is a first-in-class anti-secretory agent, approved by the U.S. Food and Drug Administration ("FDA") for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. The full launch of Mytesi began in April 2018 with the support of a full complement of patient and healthcare practitioner programs when Napo's direct sales force of 18 sales representatives, a national sales director and one regional sales director became fully deployed.

Jaguar was founded in San Francisco, California as a Delaware corporation on June 6, 2013. The Company was a majority-owned subsidiary of Napo until the close of the Company's initial public offering on May 18, 2015. On July 31, 2017 with the merger of Jaguar and Napo, Napo began operating as a wholly-owned subsidiary of Jaguar focused on human health and the ongoing commercialization of, and development of follow-on indications for, Mytesi.

We believe that Jaguar is poised to realize a number of value adding events including continued commercial growth of Mytesi for the current HIV-diarrhea indication, an expanded pipeline of human follow-on indications, and a second-generation anti-secretory agent, upon which to build global partnerships. As previously announced, Jaguar, through Napo, now controls commercial rights for Mytesi for all indications, territories and patient populations globally, and crofelemer manufacturing is being conducted at a new, multimillion-dollar commercial manufacturing facility that has been FDA-inspected and approved. Additionally, several of the drug product candidates in Jaguar's Mytesi pipeline are backed by Phase 2 and/or proof of concept evidence from completed human clinical trials. The current approved indication in HIV-related diarrhea is a chronic approval, with a safety package that supports chronic use of Mytesi for follow-on indications as well.

Mytesi is a novel, first-in-class anti-secretory agent which has a basic normalizing effect locally on the gut, and this mechanism of action has the potential to benefit multiple gastrointestinal disorders. Mytesi is in development for multiple possible follow-on indications, including cancer therapy-related diarrhea; orphan-drug indications for infants and children with congenital diarrheal disorders and short bowel syndrome (SBS); supportive care for inflammatory bowel disease (IBD); irritable bowel syndrome (IBS); idiopathic/functional diarrhea; and as a second-generation anti-secretory agent for use in cholera patients. Mytesi has received orphan-drug designation for SBS.

**Recent Developments**

As announced December 6, 2018, Jaguar has engaged T.R. Winston & Company, LLC ("T.R. Winston") to provide strategic advice with respect to collaboration, licensing and development activities in support of Mytesi and crofelemer. Through our engagement with T.R. Winston, we are seeking partners that share our commitment to making this important anti-secretory agent available to relieve suffering across patient populations, spanning geographies around the world. T.R. Winston possesses

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extensive industry knowledge, and the experience and expertise to assist us in identifying like-minded partners with the resources to assist us in reaching our pipeline goals.

**Risks Related to Our Business**

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

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

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

We are substantially dependent on the success of our current lead prescription drug product candidates, Mytesi and Canalevia, and cannot be certain that necessary approvals will be received for planned Mytesi follow-on indications or Canalevia or that these product candidates will be successfully commercialized, either by us or any of our partners.

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

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

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

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

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

**Corporate Information**

We were incorporated in the State of Delaware on June 6, 2013. Our principal executive offices are located at 201 Mission Street, Suite 2375, San Francisco, CA 94015 and our telephone number is (415) 371-8300. Our website address is [www.jaguar.health](http://www.jaguar.health). The information contained on, or that can be accessed through, our website is not part of this prospectus supplement. Our Common Stock is listed on the NASDAQ Capital Market and trades under the symbol "JAGX." On July 31, 2017, we completed the acquisition of Napo (the "Merger") pursuant to the Agreement and Plan of Merger, dated March 31, 2017, by and among the Company, Napo, Napo Acquisition Corporation, and Napo's representative (the "Merger Agreement").

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**Emerging Growth Company Information**

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

We may remain an "emerging growth company" until as late as December 31, 2020 (the fiscal year-end following the fifth anniversary of the closing of 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 \$1.07 billion in any fiscal year or (iii) if we issue more than \$1.0 billion of non-convertible debt over a three-year period.

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**THE OFFERING**

Common stock offered by us	Up to 5,633,333 shares, of which 5,333,333 are Purchase Shares and 300,000 are Commitment Shares
Public offering price for Purchase Shares	\$0.75 per share, or such price as mutually agreed upon between the Company and Oasis Capital from time to time
Common stock outstanding prior to this offering	27,289,853 shares
Common stock to be outstanding after this offering	32,923,186 shares
Manner of offering	"Equity line of credit" arrangement involving from time-to-time "puts" of shares of Common Stock to Oasis Capital pursuant to the terms of the CSPA. See "Plan of Distribution" beginning on page S-91
Use of proceeds	We intend to use the net proceeds from this offering for the commercialization of Mytesi and working capital and general corporate purposes. See "Use of Proceeds" on page S-45.
Plan of distribution	Oasis Capital may, from time to time, sell any or all of the Shares in any manner that is in compliance with applicable state and federal securities laws, including on the stock exchange on which our common stock is traded or in private transactions. These sales may be at fixed or negotiated prices; provided, that, short sales (as defined in Rule 200 of Regulation SHO under the Exchange Act), whether by Oasis Capital or on its behalf, are prohibited under the CSPA. See "Plan of Distribution" beginning on page S-91.
Upsize Option	We have the option to increase the equity line of credit by an additional 8,000,000 shares by notifying Oasis Capital on any Business Day after the effective date of the CSPA.
Risk factors	You should read the "Risk Factors" section of this prospectus supplement and in the documents incorporated by reference in this prospectus supplement for a discussion of factors to consider before deciding to invest in our Common Stock.
NASDAQ Capital Market symbol	"JAGX"
We have two classes of common stock: (i) voting common stock, par value \$0.0001 per share, and (ii) non-voting common stock, par value \$0.0001 per share. The shares offered by us in this offering are voting common stock.	

The number of shares of our common stock to be outstanding after this offering is based on 24,603,104 shares of our voting common stock and 2,686,749 shares of our non-voting common stock outstanding as of December 31, 2018, and excludes the following:

3,314,955 shares of common stock issuable upon conversion of outstanding preferred stock as of December 31, 2018 with a weighted-average conversion price of \$2.775 per share;

2,925,513 shares of voting common stock issuable upon exercise of outstanding options as of December 31, 2018, with a weighted average exercise price of \$5.84 per share;



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208,865 shares of common stock issuable upon exercise of outstanding inducement options as of December 31, 2018 with a weighted-average exercise price of \$1.75 per share;

181,527 shares of voting common stock reserved for future issuance under the 2014 Stock Incentive Plan;

1,160,682 shares of voting common stock issuable upon exercise of warrants outstanding as of December 31, 2018, with a weighted average exercise price of \$3.81 per share;

392,904 shares of voting common stock issuable upon vesting of outstanding restricted stock unit awards, or RSUs, as of December 31, 2018; and

Up to 720,721 shares of common stock issuable upon conversion of outstanding convertible promissory notes in the aggregate principal amount of \$10,000,000 issued as of December 31, 2018, convertible at a price of \$13.875 per share;

38,675 shares of common stock issuable pursuant to a convertible promissory note issued to Chicago Venture Partners, L.P. ("CVP"), in the aggregate principal amount of \$580,127, convertible at a price of \$15 per share of common stock as of December 31, 2018;

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**RISK FACTORS**

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information contained in or incorporated by reference in this prospectus supplement, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, as updated in our Quarterly Reports on Form 10-Q, before deciding whether to invest in our Common Stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. In such an event, the market price of our Common Stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may harm our business, financial condition, results of operations and prospects.

**Risks Related to Our Financial Position and Need for Additional Capital**

*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.*

From the date of our formation in June 2013, until the consummation of the Merger on July 31, 2017, our operations were primarily limited to the research and development of our animal prescription drug product candidate, Canalevia, to treat various forms of diarrhea in dogs, our non-prescription product, Neonorm Calf, to help dairies and calf farms proactively retain fluid in calves, the ongoing commercialization of Neonorm Foal, our antidiarrheal for newborn horses, and Equilevia, our product for total gut health in high-performance equine athletes. Since the consummation of the Merger on July 31, 2017, our operations have been primarily focused on research, development and the ongoing commercialization of our lead prescription drug product candidate, Mytesi, which is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. As a result, we have limited meaningful historical operations upon which to evaluate our business and prospects or to successfully overcome the risks and uncertainties frequently encountered by companies in emerging fields such as the gastrointestinal health industry in general. 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, 2017 was \$22.0 million. As of September 30, 2018, we had an accumulated deficit of \$81.9 million. 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 human and veterinary drug 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 beyond Mytesi, 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.

As more fully discussed in Note 1 to our consolidated financial statements for the year ended December 31, 2017 and the quarter ended September 30, 2018 incorporated by reference in this prospectus supplement, we believe there is substantial doubt about our ability to continue as a going concern as we do not currently have sufficient cash resources to fund our operations through March 31, 2019. 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.

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***We currently generate limited revenue from the sale of products and may never become profitable.***

We are a pharmaceuticals company focused on the development and commercialization of novel, sustainably derived gastrointestinal products for human prescription use primarily and also for animals on a global basis. Napo, our wholly-owned subsidiary, began the commercial pre-launch activities of our first FDA approved product, Mytesi, in February 2017. Accordingly, we have only generated limited revenue from product sales. There is no guarantee that our commercialization efforts for Neonorm Calf for preweaned dairy calves in the United States and Neonorm Foal for newborn horses in the United States will be successful or that we will be able to generate a consistent revenue stream from the sale of any of these products in the future. Further, in order to commercialize our other prescription drug product candidates, we must receive regulatory approval from the FDA in the United States and other regulatory agencies in various jurisdictions. Other than Mytesi, 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 Calf, may be subject to regulatory approval outside the United States prior to commercialization in other countries. Accordingly, until and unless we receive any necessary regulatory approvals, we cannot market or sell our products in many regions. 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.

***Raising additional capital may cause dilution to our stockholders, including purchasers of our common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.***

Unless and until we can generate a substantial amount of revenue from our products or product candidates, we expect to finance our future cash needs through public or private equity offerings, debt financings or collaborations, licensing arrangements and government funding arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, your ownership interest may be materially diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a stockholder. In addition, debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, which could adversely affect our ability to conduct our business. In addition, securing additional financing would require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us.

***Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations.***

Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as

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a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

**Risks Related to Our Business**

*We expect to incur significant additional costs as we continue commercialization efforts for current prescription drug candidates, or other product candidates, and undertake the clinical trials necessary to obtain any necessary regulatory approvals, which will increase our losses.*

Napo commenced sales of Mytesi for adults with HIV/AIDS on antiretroviral therapy in February 2017. 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 gastrointestinal health industry, including physicians, as applicable. We will also need to conduct clinical trials for Mytesi in order to broaden Mytesi to additional indications.

We are actively identifying additional products for development and commercialization, and will continue to expend substantial resources for the foreseeable future to develop Mytesi, a second generation anti-secretory agent, and Canalevia for the MUMS indication of chemotherapy-induced diarrhea in dogs. 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, including potential business development and/or strategic partnerships, to pursue our research and development efforts, we may never realize the benefit of our development efforts and our business may be harmed.



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***We will need to raise substantial additional capital in the future in the event that we conduct clinical trials for new indications and we may be unable to raise such funds when needed and on acceptable terms, which would force us to delay, limit, reduce or terminate one or more of our product development programs.***

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 March 31, 2019 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. 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 or potential license arrangements.

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 Mytesi, Neonorm, Equilevia 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 our current lead prescription drug product candidate, Mytesi, and cannot be certain that necessary approvals will be received for planned Mytesi follow-on indications or that these product candidates will be successfully commercialized, either by us or any of our partners.***

Other than Mytesi, 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 ongoing commercialization of Mytesi, and development efforts related to Mytesi and Canalevia. With regard to Mytesi, we are focused on the commercial launch of the product in the United States as well as on development efforts related to a follow-on indication for Mytesi in CTD, an important supportive care indication for patients undergoing cancer treatment. Mytesi is also in

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development for rare disease indications for infants and children with congenital diarrheal disorders and short bowel syndrome; for

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IBS (Mytesi has demonstrated benefit to IBS-D patients in published Phase 2 studies); for supportive care for IBD; for idiopathic/functional diarrhea; and as a second-generation anti-secretory agent for use in cholera patients. Mytesi has received orphan-drug designation for SBS. Accordingly, our near term prospects, including our ability to generate material product revenue, obtain any new financing if needed to fund our business and operations or enter into potential strategic transactions, will depend heavily on the success of Mytesi and potential follow-on indications.

Substantial time and capital resources have been previously devoted by third parties in the development of crofelemer, the active pharmaceutical ingredient, or API, in Mytesi and Canalevia, and the development of the botanical extract used in Equilevia and Neonorm. Both crofelemer and the botanical extract used in Equilevia and Neonorm were originally developed at Shaman Pharmaceuticals, Inc. ("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 of 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 Equilevia and 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 was the current interim chief executive officer of Napo and a member of Napo's board of directors prior to the Merger. 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 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, Jaguar entered into the Napo License Agreement pursuant to which Jaguar acquired an exclusive worldwide license to Napo's intellectual property rights and technology, including crofelemer and the botanical extract used in Equilevia and 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 Jaguar's employees. In March 2016, Napo settled with Salix for the return of all commercial rights to crofelemer. Following the merger of Jaguar and Napo in July 2017, Napo became Jaguar's wholly-owned subsidiary. If we are not successful in the development and commercialization of Mytesi, Neonorm, Equilevia and Canalevia, our business and our prospects will be harmed.

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

our ability to demonstrate to the satisfaction of the FDA and any other regulatory bodies, the safety and efficacy of Canalevia for chemotherapy-induced diarrhea in dogs;

our ability and that of our contract manufacturers to manufacture supplies of Mytesi, Neonorm, Equilevia and Canalevia

our ability to successfully continue commercial efforts associated with Mytesi, whether alone or in collaboration with others;

our ability to successfully launch Canalevia, assuming approval is obtained, and Equilevia, whether alone or in collaboration with others;



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

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

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 ("USPTO").

Many of these factors are beyond our control. Accordingly, we may not be successful in developing or commercializing Mytesi, Neonorm, Equilevia, Canalevia or any of our other potential products. If we are unsuccessful or are significantly delayed in developing and commercializing Mytesi, Neonorm, Equilevia, 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 is focused on the commercial performance of Mytesi, a key element of our strategy is to identify, develop and commercialize a portfolio of products to serve the gastrointestinal health market. Most of our potential products are based on our knowledge of medicinal plants. Our current focus is primarily on product candidates whose active pharmaceutical ingredient or botanical extract has been successfully commercialized or demonstrated to be safe and effective in human or animal 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;

an outside party may develop a cure for any disease state that is the target indication for any of our planned or approved drug products;

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 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 physicians, veterinarians, patients, animal owners, key opinion leaders and other decision-makers in the gastrointestinal health market, as applicable.

While we are developing specific formulations, including flavors, methods of administration, new patents and other strategies with respect to our current potential products, we may be unable to



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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.

***Mytesi faces significant competition from other pharmaceutical companies, both for its currently approved indication and for planned follow-on indications, and our operating results will suffer if we fail to compete effectively.***

The development and commercialization of products for human gastrointestinal health is highly competitive and our success depends on our ability to compete effectively with other products in the market. During the ongoing commercialization of Mytesi for its currently approved indication, and during the future commercialization of Mytesi for any planned follow-on indications, if such follow-on indications receive regulatory approval, we expect to compete with major pharmaceutical and biotechnology companies that operate in the gastrointestinal space, such as Sucampo AG, Takeda Pharmaceuticals, Allergan, Inc., Ironwood Pharmaceuticals, Inc., Synergy Pharmaceuticals Inc., Heron Therapeutics, Inc., Sebela Pharmaceuticals, Inc. and Salix Pharmaceuticals.

Many of our competitors and potential competitors in the human gastrointestinal space 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 human gastrointestinal health products.

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

***We may be unable to obtain, or obtain on a timely basis, regulatory approval for our existing or future human or animal 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 human and animal health products are subject to extensive regulation. We are typically not permitted to market our prescription drug product candidates in the United States until we receive approval of the product from the FDA through the filing of an NDA or NADA, as applicable. To gain approval to market a prescription drug, 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 for the intended indications. Likewise, 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) 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 ("CROs"), and other third parties to conduct our toxicology studies and for certain other product development activities. The results of toxicology studies, other initial development activities, and/or 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. 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

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sometimes fail to show a benefit even for drugs that are effective because of statistical limitations in the design of the trials or other statistical anomalies. Therefore, even if our studies and other development activities are completed as planned, the results may not be sufficient to obtain a required regulatory approval for a product candidate.

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

if they disagree with our interpretation of data from our pivotal studies or other development efforts;

if we are unable to demonstrate to their satisfaction that our product candidate is safe and effective for the target indication and, if applicable, 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 human or animal 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 Mytesi may not be predictive of the results in any future clinical trials and species-specific formulation studies, respectively, and we may not be successful in our efforts to develop or commercialize line extensions of Mytesi.***

Our product pipeline includes a number of potential indications of Mytesi, our lead prescription product. The results of our studies and other development activities and of any previous studies conducted by us or third parties may not be predictive of future results of these clinical studies and formulation studies, respectively. Failure can occur at any time during the conduct of these trials and other development activities. Even if our formulation/clinical studies and other development activities are completed as planned, the results may not be sufficient to pursue a particular line extension for Mytesi. Further, even if we obtain promising results from our clinical trials, we may not successfully commercialize any line extension. Because line extensions are developed for a particular market, we may not be able to leverage our experience from the commercial launch of Mytesi in new 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 human and animal gastrointestinal health 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;

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complete the studies due to deviations from the study protocols or the occurrence of adverse events;

add new study sites;

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

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

Further, we may not be successful in developing new indications for Mytesi and 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 human or animal 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 ("GCPs"), or good laboratory practices ("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 planned follow-on indications of Mytesi, or for Canalevia or our other product candidates, they may never achieve market acceptance. Further, even if we are successful in the ongoing commercialization of Mytesi, we may not achieve commercial success.***

If we obtain necessary regulatory approvals for planned follow-on indications of Mytesi or for Canalevia or our other product candidates, such products may still not achieve market acceptance and

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may not be commercially successful. Market acceptance of Mytesi and Canalevia, and any of our other products depends on a number of factors, including:

the safety of our products as demonstrated in our target human and animal studies;

the indications for which our products are approved or marketed;

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

the acceptance by physicians, veterinarians, companion animal owners and production animal owners, as applicable, of our products as safe and effective;

the cost in relation to alternative treatments and willingness on the part of physicians, veterinarians, patients and animal owners, as applicable, 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 Mytesi, Canalevia and Equilevia or any of our other products to achieve market acceptance or commercial success would harm our financial condition and results of operations.

***Human and animal gastrointestinal health 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 human and animal gastrointestinal 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, such as Mytesi, 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 could harm our reputation and business, regardless of whether such concerns or actions are justified.

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

Under current federal and state laws, companion and production animals are generally considered to be the personal property of their owners and, as such, the owners' recovery for product liability claims involving their companion and production animals may be limited to the replacement value of the animal. Companion animal owners and their advocates, however, have filed lawsuits from time to time seeking non-economic damages such as pain and suffering and emotional distress for harm to their companion animals based on theories applicable to personal injuries to humans. If new legislation is passed to allow recovery for such non-economic damages, or if precedents are set allowing for such recovery, we could be exposed to increased product liability claims that could result in substantial losses to us if successful. In addition, some horses can be worth millions of dollars or more, and product liability for horses may be very high. While we currently have product liability insurance, such insurance may not be sufficient to cover any future product liability claims against us.

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***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. 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 human and animal gastrointestinal health fields is intense, because there are a limited number of individuals who are trained or experienced in the field. 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 Mytesi and Canalevia and the botanical extract in Neonorm and Equilevia. 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 Mytesi, Canalevia, Neonorm and Equilevia is crude plant latex ("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 Mytesi, Canalevia, Neonorm, Equilevia and anticipated line extensions.

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

We have contracted with third parties for the formulation of API and botanical extract into finished products for our studies. We have also 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. Glenmark is the current manufacturer of crofelemer, the active API in Canalevia, for Mytesi, and the manufacturer on file for the NDA to which we have a right of reference. As announced in October of 2015, we have entered an agreement with Patheon, a provider of drug development and delivery solutions, under which Patheon provides enteric-coated tablets to us. 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.

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We will be dependent upon our contract manufacturers for the supply of the API in Mytesi and Canalevia. We currently have sufficient quantities of the botanical extract used in Neonorm and Equilevia to support initial commercialization of Neonorm and Equilevia. However, we will require additional quantities of the botanical extract if our ongoing commercialization of Neonorm or our commercial launch of Equilevia 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 human and animal 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 (the "EMA"), employ different regulatory standards than the FDA, so we may require multiple manufacturing processes and facilities for the same human or animal 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 human or animal products and product candidates, if approved, and generate product or other revenue.***

We currently have limited sales, marketing or distribution capabilities, and prior to Napo's launch of Mytesi for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy, and our launch of Neonorm for preweaned dairy calves, we had no experience in the sale, marketing and distribution of human or animal health products. There are significant risks involved in building and managing a sales organization, including our potential inability to attract, hire, retain and motivate qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively oversee a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities and entry into adequate arrangements with distributors or other partners would adversely impact the commercialization of Mytesi, Neonorm, Equilevia and, if approved, Canalevia. If we are not successful in commercializing Mytesi, Neonorm, Equilevia, 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.



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

In the United States, animal owners typically purchase their animal health prescription drugs from their local veterinarians who also prescribe such drugs. There is a trend, however, toward increased purchases of animal health 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 health 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 animal health prescription drug products.

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 health pharmaceuticals directly from veterinarians, which also could harm our business.

***Consolidation of our customers could negatively affect the pricing of our animal health products.***

Veterinarians will be our primary customers for our prescription animal health drug products. 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 animal health 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 December 31, 2018, we had 40 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 hiri