UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2018

or

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

Commission File Number 001-37428

RITTER PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**26-3474527**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1880 Century Park East, Suite 1000 Los Angeles, California	
(Address of principal executive offices)	**90067 (Zip Code)**

Registrant's telephone number, including area code: (310) 203-1000

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 $0.001 per share	**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 [ ] No [X]

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

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 [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

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

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[ ] (Do not check if a smaller reporting company)	Smaller reporting company	[X]
		Emerging growth company	[X]

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

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

As of June 29, 2018 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the registrant's common stock held by non-affiliates was approximately $5.2 million based upon the closing price for shares of the registrant's common stock of $2.57 as reported by the NASDAQ Capital Market on that date.

As of March 10, 2019, there were 9,042,332 shares outstanding of the registrant's common stock, par value $0.001 per share.

DOCUMENTS INCORPORATED BY REFERENCE

None.

RITTER PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
For the Year Ended December 31, 2018
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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. The words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. 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.

Some of the factors that we believe could cause actual results to differ from those anticipated or predicted include:

- our ability to obtain additional financing on acceptable terms;
- the accuracy of our estimates regarding expenses, future revenues and capital requirements;
- the success and timing of our preclinical studies and clinical trials;
- our ability to obtain and maintain regulatory approval of RP-G28 and any other product candidates we may develop, and the labeling under any approval we may obtain;
- regulatory developments in the United States and other countries;
- the performance of third-party manufacturers;
- our ability to develop and commercialize RP-G28 and any other product candidates we may develop;
- our ability to obtain and maintain intellectual property protection for RP-G28 and any other product candidates that we may develop in the future;
- the successful development of our sales and marketing capabilities;
- the potential markets for RP-G28 and any other product candidates we may develop in the future and our ability to serve those markets;
- the rate and degree of market acceptance of our products, if approved;
- the success of competing drugs that are or become available; and
- the loss of key scientific or management personnel.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Annual Report. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Annual Report, they may not be predictive of results or developments in future periods.

Any forward-looking statement that we make in this Annual Report speaks only as of the date of this report, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Annual Report. You should also read carefully the factors described in the "Risk Factors" section of our 2018 Annual Report to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements.

This Annual Report includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third-parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

PART I

Item 1. Business

Overview

Ritter Pharmaceuticals, Inc. develops novel therapeutic products that modulate the gut microbiome to treat digestive disorders and gastrointestinal diseases. Our lead product candidate, RP-G28, is an orally administered, high purity galacto-oligosaccharide ("GOS"), currently in Phase 3 clinical development for the treatment of lactose intolerance ("LI"), a condition that affects millions of people worldwide. RP-G28 is designed to selectively stimulate the growth of lactose-metabolizing bacteria in the colon, thereby effectively adapting the gut microbiome to assist in digesting lactose (the sugar found in milk) that reaches the large intestine. RP-G28 has the potential to become the first drug approved by the Food and Drug Administration ("FDA") for the treatment of LI. We are further exploring the functionality and discovering the therapeutic potential that gut microbiome changes may have on treating/preventing a variety of conditions including gastrointestinal diseases, cancer, metabolic, and liver diseases. We intend to expand our product pipeline and create added value in the future by evaluating RP-G28 in other indications, including orphan indications, developing additional products based on our underlying microbiome-modulating technology, and/or in-licensing complementary products to treat these, or other, conditions.

In November 2011, we completed a Phase 2a clinical trial of our leading product candidate, RP-G28. Positive trends were seen when the entire per protocol study population was analyzed, including some statistically significant subgroup. The combined data demonstrated proof of concept and suggested that RP-G28 administration produced a positive therapeutic effect. RP-G28 was also well tolerated with no significant study-drug related adverse effects.

In October 2016, we completed a Phase 2b multi-center, randomized, double-blind, placebo-controlled, parallel group trial of RP-G28. Topline results of the trial were announced in March 2017. Results showed a clinically meaningful benefit to subjects in the reduction of LI symptoms across a variety of outcome measures. The majority of analyses showed positive outcome measures and the robustness of the data point to a clear drug effect. Treatment patients not only reported meaningful reduced symptoms, but also 30 days after taking the treatment, patients reported adequate relief from LI symptoms and satisfaction with the results of the treatment, with RP-G28 preventing or treating their LI symptoms. Greater milk and dairy product consumption was also reported by patients.

In August 2017, we held an End-of-Phase 2 meeting with the FDA's Division of Gastroenterology and Inborn Errors Products. The purpose of the meeting was to obtain the FDA's feedback on our Phase 3 program. We reached general consensus with the FDA on certain elements of our current Phase 3 program and have received clear guidance and recommendations on many necessary components of our Phase 3 program; including the clinical, non-clinical, and chemistry, manufacturing and controls (CMC) requirements needed to support an NDA submission.

In June 2018, we initiated the first pivotal Phase 3 clinical trial of RP-G28. Called "Liberatus", this study is to determine the efficacy, safety and tolerability of RP-G28 to treat LI when compared to placebo. The study is a multicenter, randomized, double-blind, placebo-controlled, parallel-group study conducted in the United States. The estimated enrollment of the trial will be 525 participants conducted at approximately 28 sites. The protocol design includes a 2-week screening period that includes one week of study drug administration, a randomized 30-day study drug treatment period and a 90-day "real world experience" period to assess study drug response and durability of effect after treatment as patients consume their normal diets including dairy products. The primary endpoint of the study is the mean change in LI symptom composite score 30-days post-treatment compared to baseline. Secondary endpoints are to examine the safety, tolerability and meaningfulness of treatment benefit with RP-G28 and the durability of effect of treatment with RP-G28 on reduction of LI symptoms after real-world lactose exposure. The study will utilize the prior validated symptom assessment measure and patient questionnaires to capture relevant outcomes. In addition, risk-based data review will be used to monitor and assess potential protocol deviations and site quality indicators.

In March 2019, we announced that we had completed enrollment in our Liberatus Phase 3 clinical trial and that data is expected to be publicly released in early fourth quarter of 2019. We expect our Phase 3 clinical program will include two confirmatory clinical trials of similar trial design.

We have devoted substantially all of our resources to development efforts relating to RP-G28, including conducting clinical trials of RP-G28, providing general and administrative support for these operations and protecting our intellectual property. We currently do not have any products approved for sale and we have not generated any revenue from product sales since our inception.

The Gut Microbiome

The human gut is a relatively under-explored ecosystem providing an opportunity for using dietary intervention strategies such as RP-G28 to reduce the impact of digestive disorders and gastrointestinal disease. The human body carries about 100 trillion microorganisms in the intestines, which is 10 times greater than the number of cells in the human body. This microbial population is responsible for a number of beneficial activities such as fermentation, strengthening the immune system, preventing growth of pathogenic bacteria, providing nutrients, and providing hormones. The increasing knowledge of how these microbial populations impact human health provides opportunities for novel therapies such as RP-G28 to treat an assortment of diseases such as neurological disease, cardiovascular disease, obesity, irritable bowel syndrome, inflammatory bowel disease, colon cancer, allergies, autism and depression.

Lactose Intolerance (LI)

LI is a common condition attributed to the absence or insufficient levels of the naturally-occurring enzyme lactase in the body. Lactase is needed to properly digest lactose, a complex sugar found in milk, milk-containing foods and other dairy products.

Studies have suggested that LI is a widespread condition affecting over one billion people worldwide and over 40 million people in the United States (or 15% of the U.S. population), with an estimated nine million of those individuals demonstrating moderate to severe symptoms.

Current annual spending on over-the-counter LI aids in the United States has been estimated at approximately $2.45 billion However, these options are limited and there is no long-term treatment available.

Unlike many common gastrointestinal conditions, such as irritable bowel syndrome, inflammatory bowel diseases, gastroesophageal reflux disease, or dyspepsia (among many others), LI symptoms can be completely abated by avoiding dietary lactose. In this regard, LI is an avoidance condition, similar to celiac sprue, food intolerances, or various environmental allergies. However, dairy avoidance may lead to inadequate calcium and vitamin D intake, which can predispose individuals to decreased bone accrual, osteoporosis, hypertension, rickets, osteomalacia, and possibly certain cancers. Although supplements and calcium-rich foods are available, the 2010 National Institutes of Health conference on LI highlighted the long-term consequences of dairy avoidance demonstrating both the importance of treating the condition and the need to find improved solutions for patients.

Diagnosis

LI is often diagnosed by evaluating an individual's clinical history, which reveals a relationship between lactose ingestion and onset of symptoms. Hydrogen breath tests, milk challenges and short-term dairy avoidance dieting may also be utilized to diagnose LI. Further tests can be conducted to rule out other digestive diseases or conditions, including stool examination to document the presence of a parasite, blood tests to determine the presence of celiac disease, and intestinal biopsies to determine mucosal problems leading to malabsorption, such as inflammatory bowel disease or ulcerative colitis.

Health Consequences

Substantial evidence indicates that LI is a major factor in limiting calcium intake in the diet of individuals who are lactose intolerant. Several studies have shown that LI patients had an average calcium intake of only 300-388 mg/day, significantly less than the 1000-1200 mg/day adult dietary recommended levels.

At the 2010 National Institute of Health ("NIH") Consensus Development Conference: LI and Health, the NIH highlighted numerous health risks tied to reduced calcium intake in those suffering from LI such as: osteoporosis; hypertension; and low bone density. Adequate calcium intake is essential to reducing the risks of osteoporosis and hypertension. In addition, chronic calcium depletion has been linked to increased arterial blood pressure, thereby establishing a relationship between hypertension and low calcium intake. Moreover, there is evidence of a correlation between calcium intake and both colon and breast cancer

Our History

We were formed as a Nevada limited liability company on March 29, 2004 under the name Ritter Natural Sciences, LLC. Our first prototype LI product, Lactagen™, was an alternative LI treatment method with a mechanism of action similar to RP-G28. In 2004, clinical testing was conducted with Lactagen, which included a 61-subject double-blind placebo controlled clinical trial. The results were published in the Federation of American Societies for Experimental Biology in May 2005 and demonstrated Lactagen to be an effective and safe product for reducing symptoms for nearly 80% of the clinical participants who were on Lactagen.

In early 2008, we initiated a prescription drug development program by developing RP-G28, an improved, second-generation version of Lactagen. We believe that if we are successful in gaining FDA approval of RP-G28 we will be able to make stronger claims of both efficacy and safety, garner more medical community support and reach a wider market in the effort to treat LI.

In September 2008, we converted into a Delaware corporation under the name Ritter Pharmaceuticals, Inc.

In November 2010, we were awarded a grant from the United States government's Health Care Bill program, the Qualifying Therapeutic Discovery Project to help fund the development of RP-G28. This grant program provides support for innovative projects that are determined by the U.S. Department of Health and Human Services to have reasonable potential to result in new therapies that treat areas of unmet medical need and/or prevent, detect or treat chronic or acute diseases and conditions.

We completed our initial public offering in June 2015. Our common stock is traded on the Nasdaq Capital Market under the trading symbol "RTTR".

Our Leading Product Candidate — RP-G28

Overview

RP-G28 is a novel, highly-purified GOS, which is synthesized enzymatically. The product is being developed for the treatment of LI and is taken orally (a powder solution mixed in water) for 30 consecutive days. The proposed mechanism of action of RP-G28 is to selectively increase the intestinal growth and colonization of strains of bacteria that preferentially metabolize lactose to compensate for a patient's intrinsic inability to digest lactose. Once this colonization of beneficial bacteria has occurred, it is hypothesized that patients will continue to tolerate lactose so long as they maintain their beneficial microflora balance. RP-G28 has the potential to become the first FDA-approved drug for the reduction of symptoms associated with LI.

Galacto-oligosaccharides (GOS)

RP-G28 is a >95% purified GOS product derived from a commercially available GOS food ingredient, which is designated as "generally recognized as safe" ("GRAS") by the FDA. GOS refers to a group of compounds containing β-linkages of 1 to 6 galactose units with a single glucose on the compound's terminal end and are found at low levels in human milk. GOS is purified to a pharmaceutical grade by minimizing residual glucose, lactose, galactose and other impurities. Further processing includes ultra-filtration, nano-filtration, decolorization, deionization, and concentration to yield GOS 95 syrup, which is the starting material for RP-G28.

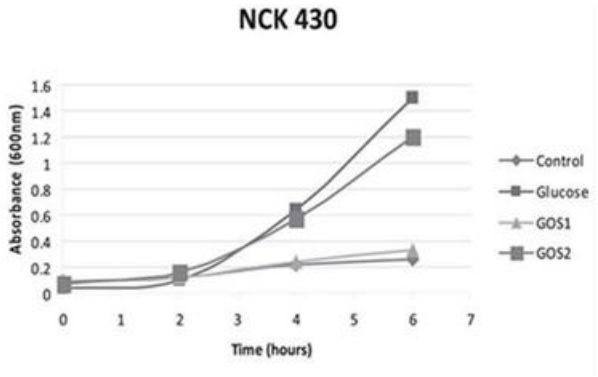
GOS products resist hydrolysis, or chemical breakdown, by salivary and intestinal enzymes of the upper digestive system because of the configuration of their glycosidic bonds and thus reach the colon virtually intact. The undigested GOS enhances the growth of beneficial, lactose-metabolizing colonic bacteria that already exist in the subject's digestive track, including multiple species and strains of bifidobacteria and lactobacilli. Once colonies of these bacteria have increased, continued lactose exposure should maintain tolerability of lactose without further exposure to RP-G28 so long as the beneficial microflora balance is maintained.

While formal nonclinical studies evaluating the safety of RP-G28 have not been performed, other commercially available GOS products have been successfully evaluated in acute and repeat-dose general toxicology studies, reproductive toxicology studies, juvenile toxicology studies, genetic toxicology studies and in long-term safety studies.

Clinical studies of GOS products were reviewed as part of the safety evaluation to support the Investigational New Drug Application ("IND") for RP-G28. These include studies in adults (including pregnant women and geriatrics), children, infants and newborns (preterm and full term). The safety of GOS products in humans has been evaluated in 1,316 adults at doses of 2.5 to 20 g/day for up to 12 months, and in 1,125 children > 1 year of age at doses of 2.0 to 12 g/day for up to 1 year. Overall, no safety concerns attributable to the consumption of GOS were reported. Where side effects were observed, they were typically mild and limited to increased flatulence, abdominal discomfort, and changes in stool consistency and frequency; however, effects were not consistently observed in all studies. Similar observations of increased flatulence have been reported following the consumption fructo-oligosaccharies (FOS) (15 g/day) over a 7-day period (Alles, 1996), and this symptom represents a localized effect that is expected in association with the consumption of indigestible fiber in large quantities. There were no reports of events in other System Organ Class (SOC) suggestive of systemic toxicity.

The significance of a higher purity GOS, namely RP-G28, was highlighted in a 2010 study by Klaenhammer. The in-vitro study concluded that RP-G28 promoted growth of lactobacilli and bifidobacteria but did not promote multiple strains of E. coli. In contrast, lower purity GOS stimulated both bifidobacteria as well as the strains of E. coli evaluated. As seen below in Figure 1, NCK 430 (E. coli) grew in the presence of low purity GOS (GOS 2). Alternatively, the higher purity GOS (RP-G28/GOS 1) did not promote the growth of E. coli.

Figure 1



Mechanism of Action

RP-G28 is understood to resist hydrolysis, or chemical breakdown, by salivary and intestinal enzymes of the upper digestive system because of the configuration of their glycosidic bonds and thus reach the colon virtually intact. The product is then broken down intracellularly by galactosidases, and eventually β-galactosidase hydrolyzes the terminal lactose generating a new nutrition supply for lactose digesting bacteria strains. This leads to selective alterations in the composition and activity of the microbiome favoring the growth of lactose-metabolizing bacteria, including species of Bifidobacteria and Lactobacilli (30). In our Phase 2a Clinical Trial (G28-001), shifts in the fecal microbiome in 82% of participants on treatment and increases in relative abundance of both Bifidobacteria and Lactobacilli were reported. RP-G28 had a bifidogenic effect in 90% of responders, which included species Bifidobacterium longum, Bifidobacterium adolenscentis, Bifidobacterium catenulatum, Bifidobacterium breve, and Bifidobacterium dentium (30). The understood mechanism of action is that by increasing lactose-metabolizing bacteria, less undigested lactose is fermented, and thus reduces gas production and related LI symptoms. Data correlating bacterial taxa and symptom metadata support this proposed hypothesis. In the Phase 2a study, microbiome changes correlated with clinical outcomes of improved lactose tolerance in which an increase in Bifidobacterium was associated with decreased pain and cramping outcomes.

Our Market Opportunity

Unmet Medical Needs

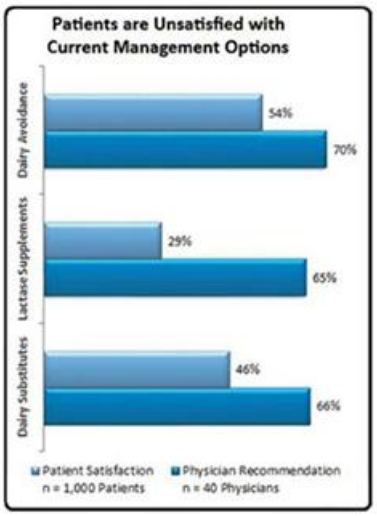
LI is a challenging condition to manage. According to a market research study conducted by Objective Insights in April 2012, approximately 60% of lactose intolerant sufferers reported experiencing symptoms daily, or bi-weekly. Not only can symptoms be painful and embarrassing, they can also dramatically affect one's quality of life, social activities, and health. Currently there are few reliable, or effective, treatments available that provide consistent or satisfactory relief.

Currently, there is no approved prescription treatment for LI. Most persons with LI attempt to avoid ingestion of milk and dairy products while others substitute non-lactose-containing foods in their diet. However, complete avoidance of lactose-containing foods is difficult to achieve (especially for those with moderate to severe symptoms) and can lead to significant long-term morbidity (*i.e.*, dietary deficiencies of calcium and vitamin D).

Treatment Options

Doctors generally recommend the following treatments for the management of LI: (1) dairy avoidance; (2) lactase supplements; (3) probiotics/dietary supplements; and (4) dairy substitutes/lactose free products. Despite educating their patients on all viable treatment options, physicians generally tend to advise their patients to refrain from consuming any dairy products whatsoever. However, in a 2008 survey conducted by Engage Health, 47% of LI sufferers reported that this method was not effective (largely due to hidden dairy products in ingredients), and only 30% of LI sufferers reported lactase supplements as being effective in managing their LI. A 2019 survey conducted by Cadence Communications and Research found that while these treatment options can be effective for mildly symptomatic patients, up to 50% of moderate to severe patients continue to experience symptoms after treatment, according to physicians. Further, while probiotics/dietary supplements have been demonstrated to aid and support one's digestive system, helping break down general foods consumed, they don't directly help with LI. The 2008 survey by Engage Health suggests that the majority of LI patients are dissatisfied with current treatment options.

Patients Unsatisfied with Current Management Options



Growing Prevalence and Awareness

LI prevalence continues to increase in both the developed and developing world. It has been estimated that gastroenterologists see approximately 15 new patients with LI each month. Education and awareness have increased, and diets in both the developed and developing world have changed greatly over the past decade to include more dairy-based goods. As the populace is growing older, the prevalence of LI also increases because more people tend to develop LI later in life. Increased education and diagnosis is making more people aware of their allergies and digestive conditions. Physicians may compound the growth of LI prevalence and its associated disorders by recommending individuals avoid dairy products, a practice which, in and of itself, may increase severity of the intolerance.

Our Competitive Strengths

Market Opportunity

RP-G28 has the potential to become the first approved drug in the United States and Europe for the treatment of LI.

Renowned Scientific Team and Management Team

Our leadership team has extensive biotechnology/pharmaceutical expertise in discovering, developing, licensing and commercializing therapeutic products. We have attracted a scientific team comprised of innovative researchers who are renowned in their knowledge and understanding of the host-microbiome in the field of LI and gastroenterology.

Patent Portfolio

We have issued patents in the United States, in select countries in Europe (Germany, the United Kingdom, France, Spain, the Netherlands, Spain), and in other jurisdictions, directed to pharmaceutical compositions, methods of making such compositions, and methods of using such compositions for the treatment of LI and certain of its symptoms. Additional worldwide patent applications are pending. The patent applications include claims covering pharmaceutical compositions, methods of making, methods of use, formulations and packaging.

In addition, in July 2015 we acquired the rights, title and interest to certain patents and related patent applications with claims covering a process for producing ultra-high purity galacto-oligosaccharide active pharmaceutical ingredients, including RP-G28 from our supplier. See "Manufacturing" for additional details regarding the second amendment to the exclusive supply agreement and our exercise of the exclusive option.

See "Intellectual Property" for additional information regarding our patent portfolio.

Our Growth Strategy

In order to achieve our objective of developing safe and effective applications to treat conditions associated with microbiome disfunctions, our near-term and long-term strategies include the following:

- complete remaining Phase 3 activities needed for a New Drug Application ("NDA");
- develop and commercialize RP-G28 either by ourselves or in collaboration with others throughout the world;
- Expand our product pipeline by exploring the use of RP-G28 for additional potential therapeutic indications, including orphan indications, develop other products based on our underlying microbiome-modulating technology, and/or via in-licensing complementary products;
- establish ourselves as a leader in developing therapeutics that modulates the human gut microbiome;
- continue to develop a robust and defensible patent portfolio, including those we own and those we plan to in-license in the future; and
- continue to optimize our product development and manufacturing capabilities both internally and externally through outside manufacturers.

Clinical and Regulatory

Type C Meeting with the FDA

In February 2013, we held a Type C meeting with the FDA's Division of Gastroenterology and Inborn Errors Products. The purpose of the meeting was to obtain the FDA's feedback on the planned Phase 2 program and Phase 3 programs, inform the FDA of our ongoing development plans, gain feedback on relevant clinical trial design and end points related to patient meaningful benefits, and to inform the FDA of the status of our product characterization

Initial New Drug ("IND") Application/Phase 1

The IND for RP-G28 was activated initially to support a Phase 2a safety, tolerability and efficacy study in lactose intolerant patients. Standard Phase 1 single and repeat dose safety and tolerability studies in healthy volunteers were not needed because other GOS products that contain similar GOS constituents are generally regarded as safe and therefore supported the safety of RP-G28 in humans.

In 2018, a Phase 1 study was conducted to understand the potential for systemic absorption of RP-G28 and any impact the presence of food may have on the pharmacokinetic profile of RP-G28. Additional Phase 1 studies may be required prior to filing our NDA based on the results of future in-vitro studies and discussions with the FDA.

Phase 2a Clinical Trial

In November 2011, we completed a double-blinded, randomized, multi-center, placebo-controlled Phase 2a clinical trial to validate the efficacy, safety and tolerability of RP-G28 compared to placebo. We evaluated RP-G28 in 62 patients with LI over a treatment period of 35 consecutive days. Post-treatment, subjects reintroduced dairy into their diets and were followed for an additional 30 days to evaluate lactose digestion, as measured by hydrogen production and symptom improvements. The primary endpoints included tracking patients' gastrointestinal symptoms via a patient-reported symptom assessment instrument (a Likert Scale, measuring individual symptoms of flatulence, bloating, cramping, abdominal pain and diarrhea, on a scale of 0 (none) to 10 (worst)) at baseline, day 36 and day 66; as well as the measurement of hydrogen gas levels in their breath following a 25-gram lactose challenge.

Positive trends were seen when the entire per protocol study population was analyzed, including some statistically significant subgroup analyses. Although there were few primary and secondary efficacy endpoints with statistically significant results, which we believe was due to the small cohort size, the combined data suggest that RP-G28 administration produced a positive therapeutic effect. RP-G28 was also well tolerated with no significant study-drug related adverse effects.

The clinical results of our Phase 2a study were published in Nutrition Journal in a manuscript entitled *"Improving lactose digestion and symptoms of LI with a novel galacto-oligosaccharide (RP-G28): a randomized, double-blind clinical trial*." The microbiome results were published in the Proceedings of the National Academy of Science in a manuscript entitled *"Impact of short-chain galacto-oligosaccharides on the gut microbiome of lactose-intolerant individuals."*

Phase 2b Clinical Trial

In March 2016, we began enrollment in a multi-center, randomized, double-blind, placebo-controlled, parallel-group Phase 2b clinical trial to validate the efficacy, safety and tolerability of two dosing regimens of RP-G28 compared to a placebo in 368 patients with moderate to severe LI.

Two hundred and forty-seven (247) patients received RP-G28 while 121 patients received placebo. Twenty-four (24) patients were discontinued prematurely from the study and 344 (91.2%) completed the study.

The trial assessed patients with LI symptoms as measured on a Likert scale after a lactose challenge. Entry criteria in the Phase 2b trial included a hydrogen breath test to validate lactase deficiency. The Phase 2b trial design included a screening period, a 30-day course treatment period, and a 30-day post-treatment "real world" observation period during which subjects were followed while lactose containing food products were re-introduced into their diets. The study was designed to escalate the dose beyond the 15 gm/day dose level evaluated in the Phase 2a study. Study subjects abstained from lactose containing food products and were then randomized evenly (1:1:1) to receive one of two doses of RP-G28 or placebo for 30 days.

The primary endpoint for the Phase 2b clinical trial was a LI symptom composite score response at day 31. A response was based on change from baseline (Day -7, visit 1) to end of treatment period at day 31 (visit 5), combined average of four maximum symptom scores taken over 0.5, 1, 2, 3, 4, and 5 hours for each symptom (abdominal pain, cramping, bloating, and gas movement) after a lactose challenge test. A response was defined as a 4-point or greater decrease from baseline or a composite score of zero at day 31. The Phase 2b trial further required the collection of fecal samples from patients enrolled to evaluate the baseline and changes to the patient's microbiome that correlate to symptom reduction and lactose tolerance.

We held a Type C meeting with the FDA in March 2017, to discuss our development plans and Phase 2b clinical trial. The focus of the meeting was to obtain the FDA's feedback on our Phase 2b clinical trial, including our Statistical Analysis Plan ("SAP"), prior to unblinding any data.

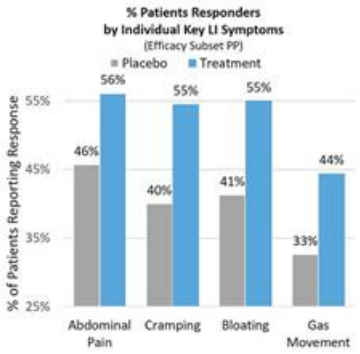
Topline results of the Phase 2b clinical trial were announced in March 2017. Due to inconsistent data results from one study site, the data from this site was excluded from the primary analysis population (Efficacy Subset mITT, n=296). After excluding the data from the one anomalous study site, results showed a clinically meaningful benefit to subjects in the reduction of LI symptoms across a variety of outcome measures. The majority of analyses showed positive outcome measures and the robustness of the data point to a clear drug effect. Treatment patients not only reported meaningful reduced symptoms, but also 30-days after taking the treatment, patients reported adequate relief from LI symptoms and satisfaction with the results of the treatment, with RP-G28 preventing or treating their LI symptoms. Greater milk and dairy product consumption was also reported by patients.

In the Efficacy Subset mITT Analysis group, the primary endpoint met statistical significance, (39.7% of the pooled dosing group compared to 25.8% of the placebo group responded (p=0.0159)). Because the primary analysis was statistically significant, the primary endpoint comparison between the high dose group and the placebo group was then tested and also met statistical significance (38.1% of the high dose group, compared to 25.8% of the placebo group responded (p=0.0294)). The comparison between the low dose group and the placebo group further met statistical significance (p=0.0434).

In the entire study population (mITT population), including patients from the excluded study site, taking at least one dose of drug (n=368), the comparison between the pooled treatment groups and the placebo group narrowly missed statistical significance (p=0.0618), (40.1% of the pooled treatment group responded compared to 31.4% of the placebo group). Both low dose and high dose group arms demonstrated a higher proportion of responders than the placebo group.

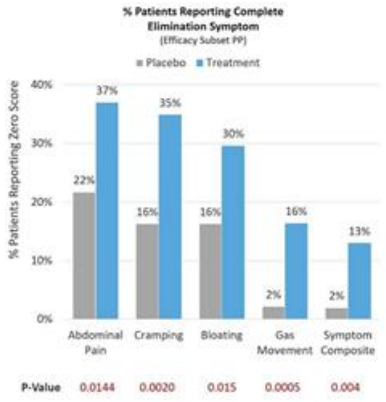
In the Efficacy Subset Per-protocol population (Efficacy Subset PP), significant and meaningful symptom improvement was consistently seen across key individual LI symptoms by patients reporting a ≥4-point improvement from baseline (proportion of subjects on treatment that reported improvement in severity of each symptom). Of the treatment patients, 56.1% reported significant improvement in abdominal pain compared to 45.7% in the placebo group (p=0.1046). Of the treatment patients, 54.5% reported statistically significant improvement in cramping compared to 40.2% in the placebo group (p=0.0257). Of the treatment patients, 55% reported statistically significant improvement in bloating compared to 41.3% in the placebo group (p=0.0282). Finally, 44.4% of treatment patients reported significant improvement in gas movement compared to 32.6% in the placebo group (p=0.0599). See Figure 4 below.

Figure 4



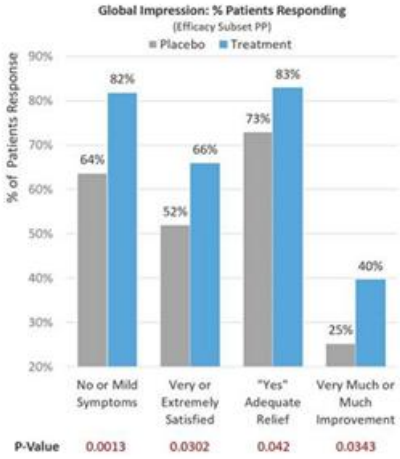
In a more stringent assessment, many patients reported that they experienced complete elimination of LI symptoms, scoring a 0 out of 10 on a Likert pain scale post-treatment (Efficacy Subset PP). Of the treatment patients, 37.0% reported complete elimination of abdominal pain compared to 21.7% in the placebo group (p=0.0144). Of the treatment patients, 34.9% reported complete elimination of cramping compared to 16.3% in the placebo group (p=0.0020). Of the treatment patients, 29.6% reported complete elimination of bloating compared to 16.3% in the placebo group (p=0.015). Of the treatment patients, 16.4% reported complete elimination of gas movement compared to 2.2% in the placebo group (p=0.0005). Symptoms of abdominal pain, cramping, bloating and gas movement were then combined into a composite endpoint representing the key symptoms of LI. Of the treatment patients, 13% experienced complete elimination of LI symptoms compared to 2% in the placebo group (p=0.004). See Figure 5 below.

Figure 5



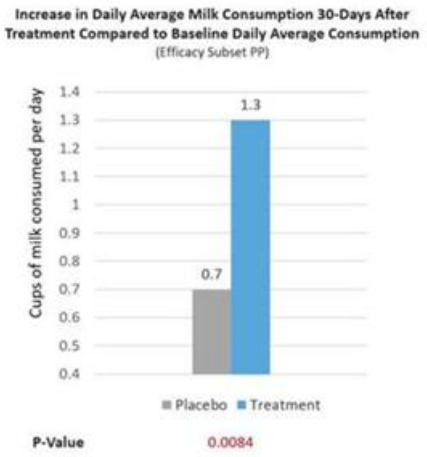
Observing global patient-reported assessments (Efficacy Subset PP) on multiple aspects of their symptom severity and treatment benefit experience 30 days after treatment and adding dairy and milk products back into their diets, 81.9% of treatment patients reported no or mild LI symptoms compared to 63.7% in the placebo group (p=0.0013). Of the treatment patients, 66.3% reported being very or extremely satisfied with RP-G28 preventing or treating their LI symptoms compared to 51.6% in the placebo group (p=0.0302). Of the treatment patients, 83.2% reported adequate relief from LI symptoms compared to 72.5% in the placebo group (p=0.042). Of the treatment patients, 39.7% reported much or very much improvement in their LI symptoms compared to 25.3% in the placebo group (p=0.0343). See Figure 6 below.

Figure 6



Further, a real-world milk intake assessment was conducted on treatment and placebo group patients (Efficacy Subset PP). At baseline, LI patients reported consuming 0.2 cups/d of milk. After RP-G28, treatment patients increased their milk consumption to 1.5 cups/d of milk, consuming 1.3 cups/d more of milk (p=0.0084), 39% more milk consumed per day than placebo patients reported consuming (See Figure 7 below). We believe this is significant because the USDA recommends healthy individuals to consume 1.5 cups/d of milk. Overall, 62% of treatment patients consumed ≥1 cups/d of milk after being treated (p=0.0095). The increase in milk consumption is meaningful for dairy avoiders because it reflects increased lactose tolerance and may lead to more dietary calcium intake post-treatment as milk contains a higher percentage of one's daily intake of calcium.

Figure 7



No serious adverse events related to treatment were reported and the number of adverse events reported was similar between treatment and placebo groups.

End-of-Phase 2 Meeting with the FDA

In August 2017, we held an End-of-Phase 2 meeting with the FDA's Division of Gastroenterology and Inborn Errors Products. The purpose of the meeting was to obtain the FDA's feedback on our planned Phase 3 program. We reached general consensus with the FDA on certain elements of our Phase 3 program and received clear guidance and recommendations on many necessary components of our Phase 3 program; including the clinical, non-clinical, and chemistry, manufacturing and controls ("CMC") requirements needed to support an NDA. We have incorporated much of this guidance into our Phase 3 program.

Phase 3 Clinical Trial ("Liberatus")

In June 2018, we began enrollment in the first pivotal Phase 3 clinical trial of RP-G28, known as Liberatus. The purpose of this study is to determine the efficacy, safety and tolerability of RP-G28 to treat LI when compared to placebo. The study is a multicenter, randomized, double-blind, placebo-controlled, parallel-group study conducted in the United States. The estimated enrollment of the trial was 525 participants conducted at approximately 28 sites. The protocol design includes a two-week screening period that includes one week of study drug administration, a randomized 30-day study drug treatment period and a 90-day "real world experience" period to assess study drug response and durability of effect after treatment, as patients consume their normal diets including dairy products. There will be a second randomized, 30-day, study drug treatment period to assess safety and efficacy of a repeat round of therapy. The primary endpoint of the study will be the mean change in LI symptom composite score 30-days post-treatment compared to baseline. Secondary endpoints are to examine the safety, tolerability and meaningfulness of treatment benefit with RP-G28 and the durability of effect of treatment with RP-G28 on reduction of LI symptoms after real-world lactose exposure. The study will utilize the prior validated symptom assessment measure and patient questionnaires to capture relevant outcomes. In addition, risk-based data review will be used to monitor and assess potential protocol deviations and site quality indicators.

In March 2019, we announced that we had completed, ahead of schedule, enrollment in Liberatus and expect top-line data release early in the fourth quarter of 2019. Trial enrollment has exceeded expectations, concluding with approximately 557 subjects randomized. More than 30 U.S. sites participated in the study. No single site enrolled more than 10.2% of the total population, and 43% of sites enrolled at least 15 subjects. Demographics, even though blinded, indicate a broad population distribution with gender balance and ethnic diversity. No safety signals have been reported to date which is consistent with the well-tolerated safety and tolerability profile seen in earlier clinical studies.

Nonclinical Safety Plans

Given the established safety profile of GOS in humans and the lack of significant safety concerns with RP-G28 administered to subjects in the Phase 2a and Phase 2b clinical trials, it was agreed with the FDA (August 2017 End-of-Phase 2 meeting) that no additional non-clinical safety studies are required to support continued evaluation of RP-G28 in the Phase 3 program. The FDA also agreed that no rat fertility, rat peri-post natal reproductive toxicity, genotoxicity or, importantly, rodent carcinogenicity studies are needed for the NDA submission.

As recommended by the FDA, we will continue to evaluate females of child-bearing potential who are willing to use appropriate contraception throughout the duration of any study. ICH-compliant embryo-fetal development toxicology studies of RP-G28 in the rat and rabbit will be conducted to support the NDA submission. Additional general toxicity studies may also need to be conducted for the NDA submission.

The requirement for additional in-vitro fertility, peri-post natal reproductive toxicity, genotoxicity or carcinogenicity studies may be reassessed by the FDA in the future based on subsequent events or changes in the agency's NDA submission requirements.

Manufacturing

We do not own or operate manufacturing facilities, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We have an exclusive worldwide agreement (the "Supply Agreement") to manufacture a higher purity form of GOS (referred to as "Improved GOS") with Ricerche Sperimentali Montaleor ("RSM") in connection with our clinical and nonclinical studies we will need to conduct prior to receiving regulatory approval for RPG-28. RSM has also agreed that it will not, except as necessary for RSM to perform its obligations under the Supply Agreement, market or sell Improved GOS, or any galacto-oligosaccharides that are of greater purity to any third party.

Pursuant to the terms of the Supply Agreement, as amended on July 24, 2015, we purchased the exclusive worldwide assignment of all right, title and interest to the Improved GOS (the "Improved GOS IP") on July 30, 2015 for $800,000. We also issued 100,000 shares of our common stock to RSM pursuant to a stock purchase agreement.

Under the terms of the Supply Agreement, as amended, if we fail to make any future option payment required under the terms of the Supply Agreement, we may be required to return the Improved GOS IP to RSM. The terms of the Supply Agreement, as amended, require us to pay RSM $400,000 within 10 days following FDA approval of a new drug application for the first product owned or controlled by us using Improved GOS as its active pharmaceutical ingredient.

Commercialization

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. RP-G28, if approved, is intended to be prescribed to patients suffering from LI. These patients are normally under the care of a gastroenterologist and/or a primary care physician. Our current plan is to evaluate a possible partnership to commercialize RP-G28 for the treatment of LI in patients in the United States and Europe if it is approved. We may also build our own commercial infrastructure or utilize contract reimbursement specialists sales people and medical education specialists, and take other steps to establish the necessary commercial infrastructure at such time as we believe that RP-G28 is approaching marketing approval. Outside of the United States and Europe, subject to obtaining necessary marketing approvals, we will likely seek to commercialize RP-G28 through distribution or other collaboration arrangements for patients suffering from LI.

Competition

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Although we know of no drug candidate, other than RP-G28, in advanced clinical trials for treating LI, other biopharmaceutical companies may be able to develop compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Some of the pharmaceutical and biotechnology companies we expect to compete with include publicly-traded microbiome-based development companies such as Synlogic, Inc., Seres Therapeutics, Inc., Evelo Biosciences, Inc. and Synthetic Biologics, Inc. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. We will also compete with providers of a wide variety of lactase supplements (the most widely used supplement in the United States being Lactaid®), probiotic/dietary supplements, and lactose-free and dairy-free products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, price and reimbursement.

Intellectual Property

The proprietary nature of, and protection for, our product candidates and our discovery programs, processes and know-how are important to our business. We have sought patent protection in the United States and internationally for uses of RP-G28 and our discovery programs, and any other inventions to which we have rights, where available and when appropriate. Our policy is to pursue, maintain and defend patent rights, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets that may be important to the development of our business. We do not have composition of matter patent protection in the United States for RP-G28, which may result in competitors being able to offer and sell products so long as these competitors do not infringe any other patents that we hold, including patents directed to oral dosage forms containing RP-G28, methods of manufacturing purified RP-G28, or methods of using RP-G28.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection relating to RP-G28 and any future product candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes from commercial competition. Furthermore, we cannot be sure that issued patents will not be challenged in court as invalid or in the Patent Office as unpatentable. For this and more comprehensive risks related to our intellectual property, please see "Risk Factors — Risks Relating to Our Intellectual Property."

Patents and Proprietary Rights Covering Our Drug Candidates

We strive to protect our product candidates and exclusivity rights, as well as both maintain and fortify our position in the field of reduction of symptoms associated with LI. We believe our intellectual property portfolio consists of early and broad filings in the area. We have focused on patents and patent applications directed to use of our products in disease treatment. We have sought and continue to seek the strongest possible intellectual property protection available to us in order to prevent others from directly competing with us, as well as to exclude competition around our products, their manufacture, and methods for use of the products in disease treatment. Our intellectual property portfolio directed to RP-G28 contains more than 15 issued patents relating to RP-G28 dosage forms, or to uses of RP-G28. That portfolio also includes at least ten other related, pending patent applications in the United States and worldwide. We also own a patent family, including claims generally directed to processes for producing an improved form of galacto-oligosaccharides (GOS) mixtures (higher purity); this family includes issued patents in United States (not expiring until 2030), Europe (validated in Germany, France, the Netherlands, Great Britain, Ireland, and Switzerland, not expiring until 2030), Italy (not expiring until 2029), and China, India, Japan, and Korea (not expiring until 2030), as well as applications pending in the United States and other jurisdictions.

This portfolio includes patents and proprietary rights related to:

- U.S. Patent No. 8,486,668, which has a current expiry date of February 17, 2030 (subject to payment of maintenance fees), includes claims generally directed to methods for treating LI comprising administering, for a predetermined number of days, a high purity galacto-oligosaccharides (GOS) pharmaceutical composition, and wherein the administration leads to a persistent decrease in at least one symptom of LI;

- U.S. Patent No. 8,492,124, which has a current expiry date of February 17, 2030 (subject to payment of maintenance fees), includes claims generally directed to methods for treating LI comprising administering, for a predetermined number of days, a controlled release pharmaceutical composition that contains galacto-oligosaccharides (GOS), but does not contain a probiotic;

- U.S. Patent No. 8,785,160, which has a current expiry date of February 17, 2030 (subject to payment of maintenance fees), includes claims generally directed to methods for treating LI comprising administering a hydrogen breath test, diagnosing LI based upon the hydrogen breath test, and administering a high purity galacto-oligosaccharides (GOS) pharmaceutical composition;

- U.S. Patent No. 9,200,303, which has a current expiry date of August 6, 2030 (subject to the payment of maintenance fees), includes claims generally directed to the processes for producing ultra-pure galacto-oligosaccharides (GOS) pharmaceutical compositions by utilizing sequential microbiological purifications;

- U.S. Patent No. 9,370,532, which has a current expiry date of February 17, 2030 (subject to payment of maintenance fees), includes claims generally directed to methods for preventing or reducing diarrhea associated with LI, and methods for the reduction of severity of diarrhea associated with LI, comprising administering a high purity galacto-oligosaccharides (GOS) having 1-10% by weight pentasaccharides and at least a 45% by weight trisaccharides;

- U.S. Patent No. 9,579,340, which has a current expiry date of February 17, 2030 (subject to payment of maintenance fees), includes claims generally directed to an oral dosage form comprising a GOS composition having 95% or more galacto-oligosaccharides (GOS) by weight and less than 5% digestible saccharides by weight, and having 45% by weight trisaccharides;

- U.S. Patent No. 9,775,860, which has a current expiry date of February 17, 2030 (subject to payment of maintenance fees), includes claims generally directed to methods of improving gastrointestinal health, including heartburn, stomach upset, bloating, diarrhea, constipation, or gas by administering a composition having 95% or more GOS by weight and less than 5% digestible saccharides by weight, and having at least 45% by weight trisaccharides;

- U.S. Patent No. 9,592,248, which has a current expiry date of February 17, 2030 (subject to payment of maintenance fees), includes claims generally directed to an oral dosage form having one or more dosing units, each having 0.1 to 10 g of a liquid GOS composition in a gelatin capsule, where the GOS composition has at least about 95% GOS by weight, less than about 5% digestible saccharides by weight, and at least 45% by weight trisaccharides;

- U.S. Patent No. 9,808,481, which has a current expiry date of February 17, 2030 (subject to payment of maintenance fees), includes claims generally directed to a GOS composition having at least 95% by weight GOS and 5% or less by weight digestible saccharides, and having about 5-25% pentasaccharides;

- European Patent No. 2400839, validated in six European countries (Germany, Spain, the Netherlands, Great Britain, Italy, and France, which has a current expiry date of August 6, 2030 (subject to payment of annuities), includes claims generally directed to the use of a high purity galacto-oligosaccharides (GOS) to treat LI;

- United Kingdom Patent No. GB2480042, which has a current expiry date of February 16, 2030 (subject to payment of annuities), includes claims generally directed to a solid oral unit-dosage form of a high purity galacto-oligosaccharides (GOS);

- Australian Patent No. 2010218439, which has a current expiry date of February 16, 2030 (subject to payment of annuities), includes claims generally directed to a solid oral unit-dosage form of a high purity galacto-oligosaccharides (GOS);

- Israel Patent No. 214806, which has a current expiry date of February 16, 2030 (subject to payment of annuities), includes claims generally directed to the use of a high purity galacto-oligosaccharides (GOS) to treat LI;

- Philippines Patent No. 1-2011-501682, which has a current expiry date of February 16, 2030 (subject to payment of annuities), includes claims generally directed to a solid oral unit-dosage form of a high purity galacto-oligosaccharides (GOS);

- Canadian Patent No. CA2752800, which has a current expiry date of February 16, 2030 (subject to payment of annuities), includes claims generally directed to the daily use of GOS compositions to increase lactose tolerance or to treat LI;

- Japanese Patent No. JP6105680, which has a current expiry date of August 6, 2030 (subject to payment of annuities), includes claims generally directed to the production of ultra-pure galacto-oligosaccharides (GOS) pharmaceutical compositions by utilizing sequential microbiological purifications;

- European Patent No. EP 2,462,234, validated in six European countries, including Germany, Great Britain, and France, which has a current expiry date of August 6, 2030 (subject to payment of annuities), includes claims generally directed to the processes for producing preparing ultra-pure galacto-oligosaccharides (GOS) pharmaceutical compositions by utilizing sequential microbiological purifications;

- Italian Patent No. IT 1,395,068, which has a current expiry date of August 7, 2029 (subject to the payment of annuities), includes claims generally directed to the production of ultra-pure galacto-oligosaccharides (GOS) pharmaceutical compositions by utilizing sequential microbiological purifications;

- Chinese Patent No. ZL 201080035013.2, which has a current expiry date of August 6, 2030 (subject to payment of annuities), includes claims generally directed to the production of ultra-pure galacto-oligosaccharides (GOS) pharmaceutical compositions by utilizing sequential microbiological purifications;

- Indian Patent No. 303745, which has a current expiry date of August 6, 2030 (subject to payment of annuities), includes claims generally directed to the production of ultra-pure galacto-oligosaccharides (GOS) pharmaceutical compositions by utilizing sequential microbiological purifications; and

- Korean Patent No. 10-1776164, which has a current expiry date of August 6, 2030 (subject to payment of annuities), includes claims generally directed to the production of ultra-pure galacto-oligosaccharides (GOS) pharmaceutical compositions by utilizing sequential microbiological purifications.

We also are pursuing patent applications. These applications are pending in the United States, Europe, Japan and other jurisdictions, and, if they issue as patents, will not expire until at least 2030, and include claims generally directed to (i) oral dosage forms of a higher purity galacto-ologosaccharides (GOS), (ii) use of galacto-ologosaccharides (GOS) for treating LI, (iii) methods of preventing or reducing certain symptoms of LI using galacto-ologosaccharides (GOS) dosage forms, (iv) methods of improving gastrointestinal health using galacto-ologosaccharides (GOS) dosage forms and (v) methods for assessing efficacy of an oligosaccharide mixture in improving gastrointestinal health by measuring a change in at least one abdominal symptom.

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Government Regulation and Product Approval

Governmental authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, packaging, promotion, storage, advertising, distribution, marketing and export and import of products such as those we are developing. Our product candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States and by the European Medicines Agency (the "EMA") through the Marketing Authorization Application ("MAA") process before they may be legally marketed in Europe. Our product candidates will be subject to similar requirements in other countries prior to marketing in those countries. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

United States Government Regulation

NDA Approval Processes

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the "FDCA") and implemented regulations. Failure to comply with the applicable FDA requirements at any time during the product development process or approval process, or after approval, may subject an applicant to administrative or judicial sanctions, any of which could have a material adverse effect on us. These sanctions could include:

- refusal to approve pending applications;

- withdrawal of an approval;

- imposition of a clinical hold;

- warning letters;
- product seizures and/or condemnation and destruction;
- total or partial suspension of production or distribution; or
- injunctions, fines, disgorgement, or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests, animal studies and formulation studies conducted according to Good Laboratory Practices ("GLPs") or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices ("GCPs"), to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of a marketing application such as an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current Good Manufacturing Practices ("cGMPs") to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the marketing application.

Once a pharmaceutical candidate is identified for development, it enters the preclinical or nonclinical testing stage. Nonclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. A sponsor of an IND must submit the results of the nonclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. Some nonclinical testing may continue even after the IND is submitted. In addition to including the results of the nonclinical studies, the IND will also include a clinical protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase lends itself to an efficacy determination. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, notifies the sponsor of a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. A clinical hold may occur at any time during the life of an IND, and may affect one or more specific studies or all studies conducted under the IND.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCPs. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as an amendment to the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually in the IND Annual Report. Sponsors must also report to the FDA, within required timelines, serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigation brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug. An institutional review board ("IRB") at each institution participating in the clinical trial must review and approve the protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each research subject or the subject's legal representative, monitor the study until completed and otherwise comply with IRB regulations.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1*. The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and elimination. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be inherently too toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2*. Clinical trials are performed on a limited patient population intended to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Although there are no statutory or regulatory definitions for Phase 2a and Phase 2b, Phase 2a is commonly used to describe a Phase 2 clinical trial designed to evaluate efficacy, adverse effects and safety risks and Phase 2b is commonly used to describe a subsequent Phase 2 clinical trial that also evaluates dosage tolerance and optimal dosage.
- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide an adequate basis for product labeling.

Human clinical trials are inherently uncertain and Phase 1, Phase 2 and Phase 3 testing may not be successfully completed. The FDA or the sponsor may suspend a clinical trial at any time for a variety of reasons, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to the submission of an IND, at the end of Phase 2 and before an NDA is submitted. Meetings with the FDA may be granted at other times during the development program when requested. For instance, we held a Type C meeting with the FDA's Division of Gastroenterology and Inborn Errors Products in February 2013. The purpose of the meeting was to obtain the FDA's feedback on the planned clinical development program and future necessary clinical studies, inform the FDA of our ongoing development plans, gain feedback on relevant clinical trial design and end points related to patient meaningful benefits, and to inform the FDA of the status of our product characterization. In August 2017, we held an End-of-Phase 2 meeting with the FDA's Division of Gastroenterology and Inborn Errors Products. The purpose of the meeting was to obtain the FDA's feedback on our planned Phase 3 program. We reached general consensus with the FDA on certain elements of our Phase 3 program and received clear guidance and recommendations on many necessary components of our Phase 3 program; including the clinical, non-clinical, and chemistry, manufacturing and controls ("CMC") requirements needed to support an NDA. We have incorporated much of this guidance into our Phase 3 program.

Concurrent with clinical trials, sponsors usually complete additional animal safety studies and also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing commercial quantities of the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug and the manufacturer must develop methods for testing the identity, strength, quality, purity and potency of the drug. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its proposed shelf-life.

The results of product development, nonclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests and other control mechanisms, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of user fees, but a waiver of such fees may be obtained under specified circumstances. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination of whether it is sufficiently complete to permit substantive review. It may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

Once the submission is accepted for filing, the FDA begins an in-depth review. NDAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. The FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant. The FDA may refer the NDA to an advisory committee for review and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured and tested.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA marketing approval of RP-G28, one of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for extension must be made prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA"), or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an approved NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric Exclusivity and Pediatric Use

Under the Best Pharmaceuticals for Children Act ("BPCA"), certain drugs may obtain an additional six months of exclusivity, if the sponsor submits information requested in writing by the FDA (a Written Request) relating to the use of the active moiety of the drug in children. The FDA may not issue a Written Request for studies on unapproved or approved indications or where it determines that information relating to the use of a drug in a pediatric population, or part of the pediatric population, may not produce health benefits in that population.

We have not received a Written Request for such pediatric studies, although we may ask the FDA to issue a Written Request for such studies in the future. To receive the six-month pediatric market exclusivity, we would have to receive a Written Request from the FDA, conduct the requested studies in accordance with a written agreement with the FDA or, if there is no written agreement, in accordance with commonly accepted scientific principles, and submit reports of the studies. A Written Request may include studies for indications that are not currently in the labeling if the FDA determines that such information will benefit the public health. The FDA will accept the reports upon its determination that the studies were conducted in accordance with and are responsive to the original Written Request or commonly accepted scientific principles, as appropriate, and that the reports comply with the FDA's filing requirements.

In addition, the Pediatric Research Equity Act ("PREA") requires all applications (or supplements to an application) submitted under section 505 of the FDCA (21 U.S.C. §355) for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration to contain a pediatric assessment unless the applicant has obtained a waiver or deferral. It also authorizes the FDA to require holders of approved NDAs for marketed drugs to conduct pediatric studies under certain circumstances. In general, PREA applies only to those drugs developed for diseases and/or conditions that occur in both the adult and pediatric populations. Products intended for pediatric-specific indications will be subject to the requirements of PREA only if they are initially developed for a subset of the relevant pediatric population.

As part of the Food and Drug Administration Safety and Innovation Act, Congress reauthorized both BPCA and PREA, which were slated to expire on September 30, 2012, and made both laws permanent.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Orphan drug exclusive marketing rights in the United States also may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

We intend to explore orphan drug designation for RP-G28 for any orphan indication in which there is a medically plausible basis for treatment of the indication through colonic adaptation of gut bacteria.

Post-approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things:

- compliance with cGMPs;
- record-keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;
- drug sampling and distribution requirements;
- notifying the FDA and gaining its approval of specified manufacturing or labeling changes; and
- complying with FDA promotion and advertising requirements.

Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with cGMP and other laws.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution or require substantial resources to correct.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to regulations of other countries governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials in such countries and approval of the regulators of such countries or economic areas, such as the European Union, before we may market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders or diabetes and optional for those medicines which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessments report, each member state must decide whether to recognize approval. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

Reimbursement

Sales of our products will depend, in part, on the extent to which the costs of our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products after approved as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA") imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for our products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the "ACA"), enacted in March 2010, substantially changed the way healthcare is financed by both government health plans and private insurers. The ACA was designed to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare Part D program.

The broader paradigm shift caused by the ACA towards performance-based reimbursement, and the launch of several value-based purchasing initiatives, have also placed demands on the pharmaceutical industry to offer products with proven real-world outcomes data and a favorable economic profile. We cannot predict the full impact of the ACA on pharmaceutical companies, as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions, which has not yet occurred. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Congress may consider other legislation to repeal or replace elements of the ACA, all of which adds to the uncertainty of the legislative changes enacted as part of the ACA. While it is too early to predict all the specific effects the ACA or any future healthcare reform legislation will have on our business, they could have a material adverse effect on our business and financial condition.

In addition, in some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Employees

As of the date of this Annual Report, we had seven employees, all of whom were full time employees. None of our employees are represented by a labor union, and we consider our relationship with our employees to be good.

Available Information

We file with the Securities and Exchange Commission ("SEC") annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy and information statements and amendments to reports filed or furnished pursuant to Sections 13(a), 14 and 15(d) of the Securities Exchange Act of 1934, as amended. The public may obtain these filings at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549 or by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website at http://www.sec.gov that contains reports, proxy and information statements and other information regarding Ritter Pharmaceuticals, Inc. and other companies that file materials with the SEC electronically. As soon as practicable after filing with the SEC, we make copies of our reports on Form 10-K, Forms 10-Q and Forms 8-K available to the public, free of charge, through the investor relations tab on our web site, http://www.ritterpharmaceuticals.com/investors.

Item 1A. Risk Factors

We operate in a dynamic and rapidly changing business environment that involves multiple risks and substantial uncertainty. The following discussion addresses risks and uncertainties that could cause, or contribute to causing, actual results to differ from expectations in material ways. In evaluating our business, investors should pay particular attention to the risks and uncertainties described below and in other sections of this Annual Report and in our subsequent filings with the SEC. These risks and uncertainties, or other events that we do not currently anticipate or that we currently deem immaterial also may affect our results of operations, cash flows and financial condition. The trading price of our common stock could also decline due to any of these risks, and you could lose all or part of your investment. 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 financial statements and related notes included in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report.

Risks Relating to Our Financial Position and Need for Additional Capital

We have incurred net losses in each year since our inception. Currently, we have no products approved for commercial sale. As a result, our ability to reduce our losses and reach profitability is unknown, and we may never achieve or sustain profitability.

We have incurred net losses in each year since our inception. The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business.

To date, we have devoted most of our financial resources to our corporate overhead and research and development, including our drug discovery research, preclinical development activities and clinical trials. We currently have no products that are approved for commercial sale. We expect to continue to incur net losses and negative operating cash flow for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, RP-G28, prepare for and begin the commercialization of RP-G28, and add infrastructure and personnel to support our product development efforts and operations. We anticipate that any such losses could be significant for the next several years as we continue to conduct Phase 3 clinical trials for RP-G28 and related activities required for regulatory approval of RP-G28. If RP-G28 does not gain regulatory approval, or does not achieve market acceptance, we may never become profitable, unless we are able to develop and market some other product. Our net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA or the EMA, to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of RP-G28, or any other product candidates we may develop in the future. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. To complete the work necessary to file an NDA in the United States and a MAA in the European Union for RP-G28, we will require substantial additional funding. If the FDA or EMA requires that we perform additional nonclinical studies or clinical trials, our expenses would further increase beyond what we currently expect and the anticipated timing of any potential NDA or MAA would likely be delayed.

We will need to secure additional financing in order to complete clinical development of and commercialize RP-G28, if approved, and generally fund our operations. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail our research and development program. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to RP-G28 or otherwise agree to terms unfavorable to us.

We may sell additional equity or debt securities to fund our operations, which would result in dilution to our stockholders and imposed restrictions on our business.

We may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. Additional funding may not be available to us on acceptable terms or at all. To the extent that we raise additional funds by issuing equity securities (including any common stock issued to Aspire Capital Fund, LLC ("Aspire Capital") pursuant to our financing arrangement with Aspire Capital), our stockholders may experience significant dilution. See "Management's Discussion and Analysis of Financial Condition and Results of Operations — Aspire Capital Common Stock Purchase Agreement." Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct business. If we are not able to raise additional capital when required or on acceptable terms, we may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of RP-G28; (ii) seek collaborators for RP-G28 and possibly on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights related to RP-G28. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline.

Risks Relating to Regulatory Review and Approval of RP-G28

We cannot be certain that RP-G28 will receive regulatory approval, and without regulatory approval we will not be able to market RP-G28.

The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the United States, the EMA in Europe, and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States or Europe until we receive approval of an NDA from the FDA or a MAA from the EMA, respectively. We have not submitted any marketing applications for RP-G28.

NDAs and MAAs must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. NDAs and MAAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA or a MAA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA and the EMA review processes can take years to complete and approval is never guaranteed. If we submit an NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA. Regulators of other jurisdictions, such as the EMA, have their own procedures for approval of product candidates. Even if a product is approved, the FDA or the EMA, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and Europe also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States, Europe or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidates or other products. Also, regulatory approval for any of our product candidates may be withdrawn.

We have completed a Phase 2a clinical trial and a Phase 2b clinical trial for RP-G28. We held an End-of-Phase 2 meeting with the FDA's Division of Gastroenterology and Inborn Errors Products in August 2017, regarding the path forward for RP-G28. We reached general consensus with the FDA on many elements of our Phase 3 program and received clear guidance and recommendations on many other necessary components of our Phase 3 program; including the clinical, non-clinical, and chemistry, manufacturing and controls (CMC) requirements needed to support an NDA submission. However, not all clinical, non-clinical, and CMC items have been agreed to with the FDA, and remaining items will need to be reviewed by the agency and agreed to by us.

Additional non-clinical development may be required to be conducted based on future FDA feedback and guidance. We cannot predict whether our future trials and studies will be successful or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date.

If we are unable to obtain approval from the FDA, the EMA or other regulatory agencies for RP-G28, we will not be able to market RP-G28. If we are unable to market RP-G28, we may not be able to ever become profitable.

The FDA and other regulatory agencies outside the United States, such as the EMA, may not agree to our proposed endpoint for approval of RP-G28 for the treatment of LI in patients, in which case we would need to complete additional clinical trials before seeking market approval.

We do not know if the FDA, the EMA or regulatory authorities in other countries will agree with our final primary endpoint for approval of RP-G28. The FDA, the EMA and regulatory authorities in other countries in which we may seek approval for and market RP-G28, may require additional nonclinical studies and/or clinical trials prior to granting approval, if at all. It may be expensive and time consuming to conduct and complete additional nonclinical studies and clinical trials that the EMA and other regulatory authorities may require us to perform. As such, any requirement by the EMA or other regulatory authorities that we conduct additional nonclinical studies or clinical trials could materially and adversely affect our business, financial condition and results of operations. Furthermore, even if we receive regulatory approval of RP-G28 for the treatment of LI in patients, the labeling for RP-G28 in the United States, Europe or other countries in which we seek approval may include limitations that could impact the commercial success of RP-G28.

Delays in the commencement, enrollment and completion of clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for RP-G28.

Delays in the commencement, enrollment and completion of clinical trials could increase our product development costs or limit the regulatory approval of RP-G28. The commencement, enrollment and completion of clinical trials may be delayed or suspended for a variety of reasons, including:

- inability to obtain sufficient funds required to conduct a clinical trial;
- inability to reach agreements on acceptable terms with prospective clinical research organizations ("CROs") and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- discussions with the FDA or non-U.S. regulators regarding the scope or design of our clinical trials;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indications targeted by RP-G28;
- inability to obtain approval from institutional review boards ("IRBs"), to conduct a clinical trial at their respective sites;
- severe or unexpected drug-related adverse effects experienced by patients;
- inability to timely manufacture sufficient quantities of RP-G28 required for a clinical trial;
- difficulty recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indications as RP-G28;
- the FDA's rejection of our end points as indicators of efficacy; and
- inability to retain enrolled patients after a clinical trial is underway.

Changes in regulatory requirements and guidance may also occur and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. In addition, a clinical trial may be suspended or terminated at any time by us, our future collaborators, the FDA or other regulatory authorities due to a number of factors, including:

- our failure or the failure of our potential future collaborators to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

- unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks;
- lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions; and
- a breach of the terms of any agreement with, or for any other reason by, future collaborators who have responsibility for the clinical development of RP-G28.

In addition, if we or any of our potential future collaborators are required to conduct additional clinical trials or other nonclinical studies of RP-G28 beyond those contemplated, our ability to obtain regulatory approval of RP-G28 and to generate revenue from its sales would be similarly harmed.

Clinical failure can occur at any stage of clinical development and may prevent us from receiving regulatory approval. The results of earlier clinical trials related to RP-G28 are not necessarily predictive of future results.

Clinical failure can occur at any stage of our clinical development. Clinical trials may produce negative or inconclusive results, and we or our collaborators may decide, or regulators may require us, to conduct additional clinical trials or nonclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Successful results from preclinical studies and early clinical trials do not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in later clinical trials, even after seeing promising results in earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced. We may be unable to design and execute a clinical trial to support regulatory approval. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether the clinical trials that we or any of our potential future collaborators may conduct will demonstrate the consistent or adequate efficacy and safety that would be required to obtain regulatory approval and market RP-G28. Our Phase 3 clinical trials for RP-G28 may not provide sufficient support for NDA approval.

The FDA may require us to conduct one or more additional clinical trials, possibly involving a larger sample size or a different clinical trial design or may require longer follow-up periods. If we are unable to bring RP-G28 to market, our ability to create long-term stockholder value will be limited.

RP-G28 may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

There were no notable differences observed between placebo-treated subjects and RP-G28-treated subjects in the Phase 2b trial. However, unforeseen side effects from RP-G28, could arise at any time during clinical development or, if approved, after the approved product has been marketed. Any undesirable or unacceptable side effects associated with RP-G28 could interrupt, delay or halt clinical trials, and results in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities.

In addition:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;

- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our products, it is less likely that they will be widely used.

Market acceptance and sales of RP-G28, or any other product candidates we develop in the future, will depend on reimbursement policies and may be affected by, among other things, future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. We cannot be certain that reimbursement will be available for RP-G28 or any other product candidates that we may develop in the future. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize RP-G28, or other product candidates that we develop in the future.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), changed the way Medicare covers and pays for pharmaceutical products. The legislation established Medicare Part D, which expanded Medicare coverage for outpatient prescription drug purchases by the elderly but provided authority for limiting the number of drugs that will be covered in any therapeutic class. The MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. Any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain in the United States. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of RP-G28, and any other product candidates that we develop in the future, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the "ACA"), enacted in March 2010, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on health industry and impose additional health policy reforms. With regard to pharmaceutical products, among other things, the ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under Medicare Part D program. The ACA will likely continue to put pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. Houses of Congress and President Trump have, at times, expressed their intentions to repeal and replace the ACA. President Trump issued an Executive Order and both chambers of Congress passed bills, all with the goal of fulfilling their intensions. However, to date, the Executive Order has had limited effect and the Congressional activities have not resulted in the passage of a law. If a law is enacted, many if not all of the provisions of the ACA may no longer apply to prescription drugs.

If we do not obtain protection under the Hatch-Waxman Act and similar legislation outside of the United States by extending the patent terms and obtaining data exclusivity for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of RP-G28, one of our U.S. patents may be eligible for a limited Patent Term Extension under the Drug Price Competition and Patent Term Restoration Act of 1984, which is sometimes referred to as the Hatch-Waxman Act, provided our U.S. patent claims a method of treating LI that is approved by the FDA. The Hatch-Waxman Act, 35 U.S.C. §156, permits a patent extension of up to five years as compensation for patent term lost during the FDA regulatory review process. The scope of protection afforded by the patent during the extended term is not commensurate with the scope of the unextended portion of the patent; for example, the "rights derived" from a method of use patent during the extended period are "limited to any use claimed by the patent and approved for the product." 35 U.S.C. §156(b)(2). We may not be granted an extension because of, for example, failing to apply for the extension within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable statutory and/or regulatory requirements including, for example, the requirement that the patent to be extended "claim" the approved product or a method of using the approved product. Moreover, the applicable period of extension could be less than we request. If we are unable to obtain patent term extension or if the term of any such extension is shorter than we request, the period during which we will be able to exclude others from marketing their versions of our product will be shortened and our competitors may obtain approval of generic products following our patent expiration, and our revenue could be reduced, possibly materially. Similar concerns are associated with obtaining Supplemental Protection Certificates of certain patents issued in Europe and owned by Inalco SpA, to which we have an exclusive options of assignment, based upon patent terms lost during European regulatory review processes. In the event that we are unable to obtain any patent term extension, the issued patents for RP-G28 are expected to expire in 2030, assuming they withstand any challenge to their validity and/or patentability.

If we market products in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws, commonly referred to as "fraud and abuse" laws, have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. Other jurisdictions such as Europe have similar laws. These laws include false claims and anti-kickback statutes. If we market our products and our products are paid for by governmental programs, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service covered by Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers or formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Most states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the payor. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates.

Any delay or disruption in the manufacture and supply of RP-G28 may negatively impact our operations.

We do not intend to manufacture RP-G28. We have an agreement with RSM, our contract manufacturer, for the production of Improved GOS, the active pharmaceutical ingredient in RP-G28, and the formulation of sufficient quantities of Improved GOS for the clinical and nonclinical studies that we believe we will need to conduct prior to seeking regulatory approval for RP-G28. However, we do not have agreements for commercial supplies of RP-G28 and we may not be able to reach agreement with RSM or any other contract manufacturer for sufficient supplies to commercialize RP-G28 if it is approved.

Reliance on third-party manufacturers entails risks, to which we would not be subject if we manufactured the products ourselves, including:

- the possibility that we are unable to enter into a manufacturing agreement with third parties to manufacture RP-G28;

- the possible breach of the manufacturing agreements by third parties because of factors beyond our control; and
- the possible termination or nonrenewal of manufacturing agreements by the third parties before we are able to arrange for qualified replacement third-party manufacturers.

Any of these factors could cause the delay of approval or commercialization of RP-G28 or cause us to incur higher costs. Furthermore, if RP-G28 is approved and contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our product and could lose potential revenue. It may take several years to establish an alternative source of supply for RP-G28 and to have any such new source approved by the government agencies that regulate our products. In the event we do need to identify alternative manufacturing partners, we may have to secure licenses to manufacturing and/or purification technologies, including third-party patent licenses, to allow us to manufacture RP-G28 that is suitable for the late-stage regulatory review process and/or adequate to manufacture commercial quantities of RP-G28.

If the FDA and EMA and other regulatory agencies do not approve the manufacturing facilities of our future contract manufacturers for commercial production, we may not be able to commercialize RP-G28.

The facilities used by any contract manufacturer to manufacture RP-G28 must be the subject of a satisfactory inspection before the FDA or the regulators in other jurisdictions approve the product candidate manufactured at that facility. We are completely dependent on these third-party manufacturers for compliance with the requirements of U.S. and non-U.S. regulators for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material that conform to our specifications and cGMP requirements of any governmental agency whose jurisdiction to which we are subject, our product candidates will not be approved or, if already approved, may be subject to recalls.

Even if RP-G28 receives regulatory approval, we may still face future development and regulatory difficulties.

RP-G28, and any other product candidates we develop in the future, if approved, will be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA and EMA requirements and requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMPs. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA and EMA and other similar agencies and to comply with certain requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. Accordingly, we may not promote our approved products, if any, for indications or uses for which they are not approved.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If RP-G28 fails to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or our potential future collaborators to enter into a consent decree or permanent injunction, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other administrative or judicial civil or criminal penalties;
- withdraw regulatory approval;

- refuse to approve pending applications or supplements to approved applications filed by us or our potential future collaborators;
- impose restrictions on operations, including costly new manufacturing requirements; or
- detain, seize and/or condemn and destroy products.

Risks Relating to the Potential Commercialization of RP-G28

Even if approved, RP-G28 may not achieve broad market acceptance among physicians, patients and healthcare payors, and as a result our revenues generated from its sales may be limited.

The commercial success of RP-G28, if approved, will depend upon its acceptance among the medical community, including physicians, health care payors and patients. The degree of market acceptance of RP-G28 will depend on a number of factors, including:

- limitations or warnings contained in our product candidates' FDA-approved labeling;
- changes in the standard of care or availability of alternative therapies at similar or lower costs for the targeted indications for such product candidates;
- limitations in the approved clinical indications for RP-G28;
- demonstrated clinical safety and efficacy compared to other products;
- lack of significant adverse side effects;
- sales, marketing and distribution support;
- availability of reimbursement from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- the degree of cost-effectiveness;
- availability of alternative therapies at similar or lower cost, including generics and over-the-counter products;
- enforcement by the FDA and EMA of laws and rulings that prohibit the illegal sale of RP-G28 as a dietary supplement;
- the extent to which RP-G28 is approved for inclusion on formularies of hospitals and managed care organizations;
- whether RP-G28 is designated under physician treatment guidelines for the treatment of or reduction of symptoms associated with the indications for which we have received regulatory approval;
- adverse publicity about RP-G28 or favorable publicity about competitive products;
- convenience and ease of administration of RP-G28; and
- potential product liability claims.

If RP-G28 is approved but does not achieve an adequate level of acceptance by physicians, patients, the medical community and healthcare payors, sufficient revenue may not be generated from its sales and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of RP-G28 may require significant resources and may never be successful.

We have no internal sales, distribution and/or marketing capabilities at this time and we will have to invest significant resources to develop those capabilities or enter into acceptable third-party sales and marketing arrangements.

We have no internal sales, distribution and/or marketing capabilities at this time. To develop these capabilities, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that RP-G28 will be approved. We could also face a number of additional risks, including:

- we or our third-party sales collaborators may not be able to attract and build an effective marketing or sales force;
- the cost of securing or establishing a marketing or sales force may exceed the revenues generated by RP-G28; and
- our direct sales and marketing efforts may not be successful.

We may have limited or no control over the sales, marketing and distribution activities of third parties. Our future revenues could depend heavily on the success of the efforts of third parties.

We may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect our ability to develop RP-G28.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we may seek to enter into collaborations with companies that have more experience and that can provide sources of funding for these efforts. Additionally, if RP-G28 receives marketing approval, we may enter into sales and marketing arrangements with third parties with respect to our unlicensed territories. If we are unable to enter into arrangements on acceptable terms, we may be unable to effectively market and sell RP-G28 in our target markets. We expect to face competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements for the development of RP-G28.

If we collaborate with a third party for the development and commercialization of RP-G28, we can expect to relinquish some or all of the control over the future success of RP-G28. For example, we may relinquish rights to RP-G28 in jurisdictions outside of the United States. Our collaboration partner may not devote sufficient resources to the commercialization of RP-G28 or may otherwise fail in its commercialization. The terms of any collaboration or other arrangement that we establish may not be favorable to us. In addition, any collaboration that we enter into may be unsuccessful in the development and commercialization of RP-G28. In some cases, we may be responsible for continuing preclinical and initial clinical development of RP-G28 or other research programs under a collaboration arrangement, and the payments we receive from our collaboration partner may be insufficient to cover the cost of this development. If we are unable to reach agreements with suitable collaborators, we would face increased costs and we may be forced to limit the territories in which we commercialize RP-G28. If we fail to achieve successful collaborations, our operating and financial condition will be materially and adversely affected.

Risks Relating to Our Business and Strategy

We may face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

Although we know of no other drug candidates in advanced clinical trials for treating LI, the biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have potential competitors in the United States, Europe and other jurisdictions, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies and universities and other research institutions. Many of these potential competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of all of these factors, these potential competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing drugs for the diseases that we are targeting before we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Some of the pharmaceutical and biotechnology companies we expect to compete with include publicly-traded microbiome-based development companies: Synlogic, Inc., Seres Therapeutics, Inc., Evelo Biosciences, Inc. and Synthetic Biologics, Inc. In addition, many universities and private and public research institutes may become active in our target disease areas. These potential competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and drug products that are more effective or less costly than RP-G28, which could render RP-G28 obsolete and noncompetitive.

We believe that our ability to successfully compete will depend on, among other things:

- our ability to commercialize and market RP-G28;
- the efficacy, safety and reliability of RP-G28;
- the price of RP-G28;
- adequate levels of reimbursement under private and governmental health insurance plans, including Medicare;
- our ability to protect intellectual property rights related to RP-G28;
- our ability to manufacture and sell commercial quantities of RP-G28 to the market; and
- acceptance of RP-G28 by physicians and other health care providers.

If our competitors market products that are more effective, safer or less expensive than RP-G28, or that reach the market sooner than RP-G28, we may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

We depend on third-party contractors for a substantial portion of our operations and may not be able to control their work as effectively as if we performed these functions ourselves.

We outsource substantial portions of our operations to third-party service providers, including the conduct of preclinical studies and clinical trials, collection and analysis of data, and manufacturing. Our agreements with third-party service providers and CROs are on a study-by-study and project-by-project basis. Typically, we may terminate the agreements with notice and are responsible for the supplier's previously incurred costs. In addition, any CRO that we retain will be subject to the FDA's and EMA's regulatory requirements and similar standards outside of the United States and Europe and we do not have control over compliance with these regulations by these providers. Consequently, if these providers do not adhere to applicable governing practices and standards, the development and commercialization of our product candidates could be delayed or stopped, which could severely harm our business and financial condition.

Because we have relied on third parties, our internal capacity to perform these functions is limited to management oversight. Outsourcing these functions involves the risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. Although we have not experienced any significant difficulties with our third-party contractors, it is possible that we could experience difficulties in the future. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. There are a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor third-party service providers. To the extent we are unable to identify, retain and successfully manage the performance of third-party service providers in the future, our business may be adversely affected, and we may be subject to the imposition of civil or criminal penalties if their conduct of clinical trials violates applicable law.

A variety of risks associated with our possible international business relationships could materially adversely affect our business.

We may enter into agreements with other third parties for the development and commercialization of RP-G28, or other product candidates we develop in the future, in international markets. International business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- differing regulatory requirements for drug approvals internationally;

- potentially reduced protection for intellectual property rights;
- potential third-party patent rights in the United States and/or in countries outside of the United States;
- the potential for so-called "parallel importing," which is what occurs when a local seller, faced with relatively high local prices, opts to import goods from another jurisdiction with relatively low prices, rather than buying them locally;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability, particularly in non-U.S. economies and markets, including several countries in Europe;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- taxes in other countries;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

We will need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth.

As we advance RP-G28 through clinical trials to commercialization and increase the number of ongoing product development programs, we will need to increase our product development, scientific and administrative headcount to manage these programs. In addition, to meet our obligations as a public company, we will need to increase our general and administrative capabilities. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- successfully attract and recruit new employees or consultants with the expertise and experience we will require;
- manage our clinical programs effectively, which we anticipate being conducted at numerous clinical sites;
- develop a marketing and sales infrastructure; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

We may not be able to attract or retain qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We are highly dependent on the development, regulatory, commercialization and business development expertise of Andrew J. Ritter, our Chief Executive Officer, John W. Beck, our Chief Financial Officer and Ira E. Ritter, our Executive Chairman and Chief Strategic Officer. If we were to lose one or more of these key employees, our ability to implement our business strategy successfully could be seriously harmed. Any of our executive officers may terminate their employment at any time. Replacing any of these persons would be difficult and could take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully.

There is also a risk that other obligations could distract our officers and employees from our business, which could have negative impact on our ability to effectuate our business plans.

In addition, we have scientific and clinical advisors and consultants who assist us in formulating our research, development and clinical strategies. Competition to hire and retain consultants from a limited pool is intense. Further, because these advisors are not our employees, they may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, and typically they will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. We are required, under Section 404 of the Sarbanes-Oxley Act, to furnish with our annual report on Form 10-K a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we remain an emerging growth company, as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm's requirement to attest to the effectiveness of our internal controls over financial reporting.

Our compliance with Section 404 requires that we incur substantial accounting expense and expend significant management efforts. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the NASDAQ stock market, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosure due to error or fraud may occur and not be detected.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could significantly harm our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with health care fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted an employee handbook, Code of Business Conduct and Ethics and Insider Trading Policy and all employees are required to read, acknowledge and sign each. However, it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit its commercialization.

The use of our product candidates in clinical trials and the sale of any products for which we may obtain marketing approval expose us to the risk of product liability claims. Product liability claims may be brought against us or our potential future collaborators by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against any such claims, we would incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- decreased demand for our product candidates and loss of revenues;
- impairment of our business reputation;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

We have product liability insurance coverage for our clinical trials in the United States and in selected other jurisdictions where we intend to conduct clinical trials at levels we believe are sufficient and consistent with industry standards for companies at our stage of development. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to product liability. We intend to expand our insurance coverage for products to include the sale of any commercial products for which we obtain marketing approval, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim, or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash resources and adversely affect our business.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, workers' compensation, and directors' and officers' insurance at levels we believe are typical for a company in our industry and at our stage of development. We currently carry clinical trial liability insurance for our clinical trials at levels we believe are sufficient and consistent with industry standards for companies at our stage of development. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

If we engage in an acquisition, reorganization or business combination, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

From time to time we have considered, and we will continue to consider in the future, strategic business initiatives intended to further the expansion and development of our business. These initiatives may include acquiring businesses, technologies or products or entering into a business combination with another company. If we pursue such a strategy, we could, among other things:

- issue equity securities that would dilute our current stockholders' percentage ownership;
- incur substantial debt that may place strains on our operations;
- spend substantial operational, financial and management resources to integrate new businesses, technologies and products;
- assume substantial actual or contingent liabilities;
- reprioritize our development programs and even cease development and commercialization of our product candidates; or
- merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash and/or shares of the other company on terms that certain of our stockholders may not deem desirable.

Although we intend to evaluate and consider acquisitions, reorganizations and business combinations in the future, we have no agreements or understandings with respect to any acquisition, reorganization or business combination at this time.

Risks Relating to Our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position does not adequately protect our product candidates, others could compete against us more directly, which would harm our business, possibly materially.

Our commercial success will depend in part on obtaining, maintaining and enforcing patent protection and on developing, preserving and enforcing current trade secret protection. In particular, it will depend in part on our ability to obtain, maintain and enforce patents, especially those directed to methods of using our current product, RP-G28, and other future drug candidates, and those directed to the methods used to develop and manufacture our products, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents (and/or trade secrets) that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will withstand subsequent challenges to their validity, enforceability, and/or patentability, or if they will be commercially useful in protecting our product candidates, discovery programs and processes. Furthermore, we cannot be sure that our existing patents and patent applications will embrace (or "claim") the particular uses for RP-G28 that will be approved by the FDA.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved.

No consistent policy regarding the patentability and/or validity of patent claims related to pharmaceutical patents has emerged, to date, in the United States or in most jurisdictions outside of the United States. Changes in either the patent laws (be they substantive or procedural) or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of any claims that will issue or will be enforceable in the patents that have or may be issued from the patents and applications we currently own or may in the future own or license from third parties. Further, if any patents we obtain, or to which we obtain licenses, are deemed invalid, unpatentable and unenforceable, our ability to commercialize or license our technology could be adversely affected.

In the future others may file patent applications directed to products, uses for products, and manufacturing techniques and related technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent or patent application owned by a third party will not have priority over patent applications filed or in-licensed by us in the future, or that we or our licensors will not be involved in interference, opposition, inter partes review or invalidity proceedings before U.S. or non-U.S. patent offices or courts.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to develop a platform similar to, or better than, ours in a way that does not infringe our patents;
- others may be able to make compounds that are similar to our product candidates but that do not infringe our patents;
- others may be able to manufacture compounds that are similar or identical to our product candidates using processes that do not infringe our method of making patents;
- others may obtain regulatory approval for uses of compounds, similar or identical to our product, that do not infringe our pharmaceutical composition patents or our method of use patents;
- we may not be able to obtain licenses for patents that are essential to the process of making the product;
- we might not have been the first to make the inventions claimed in our issued patents and pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents that we obtain may not provide us with any competitive advantages;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

Patents directed to pharmaceutical compositions containing RP-G28 or methods of using RP-G28 expire in 2030 if the appropriate maintenance fee renewal, annuity, or other government fees are paid, unless a patent term extension based on regulatory delay is obtained. We expect that expiration in 2030 of some of our pharmaceutical composition and method-of-use patents directed to RP-G28 and its use in treating LI will have a limited impact on our ability to protect our intellectual property in the United States, where we have additional issued patents directed to such compositions and uses that extend until 2030. In other countries, our issued patents and pending patent applications directed to compositions containing or methods of using RP-G28 for treating other indications, if issued, would expire in 2030. We will attempt to mitigate the effect of patent expiration by seeking data exclusivity, or the foreign equivalent thereof, in conjunction with product approval, as well as by filing additional patent applications covering improvements in our intellectual property.

We expect that the other patent applications for the RP-G28 portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, would expire in 2030. We own pending applications in the United States, Europe, and certain other countries directed to uses of RP-G28 to treat a variety of disorders, including LI. Patent protection, to the extent these patents issue, would be expected to extend to 2030, unless a patent term extension based on regulatory delay is obtained.

Due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patents directed to all of our product candidates or methods involving these candidates in the parent patent application. We plan to pursue divisional patent applications or continuation patent applications in the United States and other countries to obtain claims directed to inventions that were disclosed but not claimed in the parent patent application.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or feasible. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our patents are not directed to RP-G28 as a composition of matter.

Although we own certain patents and patent applications with claims directed to specific pharmaceutical compositions and methods of using RP-G28 to treat LI, we do not have patents directed to RP-G28 as a composition of matter in the United States or elsewhere. As a result, we may be limited in our ability to list our patents in the FDA's Orange Book if our product or the use of our product, consistent with its FDA-approved label, would not fall within the scope of our patent claims. Also, our competitors may be able to offer and sell products so long as these competitors do not infringe any other patents that we (or third parties) hold, including patents with claims directed to the manufacture of RP-G28, pharmaceutical compositions containing RP-G28, and/or method of using RP-G28. In general, pharmaceutical composition patents and method of use patents are more difficult to enforce than composition of matter patents because, for example, of the risks that FDA may approve alternative uses of the subject compounds not covered by the method of use patents, and others may engage in off-label sale or use of the subject compounds. Physicians are permitted to prescribe an approved product for uses that are not described in the product's labeling. Although off-label prescriptions may infringe our method of use patents, the practice is common across medical specialties and such infringement is difficult to prevent or prosecute. FDA approval of uses that are not covered by our patents would limit our ability to generate revenue from the sale of RP-G28, if approved for commercial sale. Off-label sales would limit our ability to generate revenue from the sale of RP-G28, if approved for commercial sale.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company may seek a post grant review (including inter partes review) of our patents, and has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party. These lawsuits and administrative proceedings are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. In addition, there is a risk that the court or administrative body will decide that such patents are not valid or unpatentable and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity/patentability of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our patents. In addition, the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have articulated and/or modified certain tests used by the U.S. Patent and Trademark Office (the "USPTO"), in assessing patentability and by the courts in assessing validity and claim scope, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood that others may succeed in challenging any patents we obtain or license.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We cannot guarantee that our products, our methods of manufacture, or our uses of RP-G28 (or our other product candidates), will not infringe third-party patents. Furthermore, a third party may claim that we or our manufacturing or commercialization collaborators are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. There is a risk that a court would decide that we or our commercialization collaborators are infringing the third party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our commercialization collaborators may not have a viable way around the patent and may need to halt commercialization of the relevant product. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages for having violated the other party's patents. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The scope of coverage of a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, the patentee would need to demonstrate, by a preponderance of the evidence that our products or methods infringe the patent claims of the relevant patent, and we would need to demonstrate either that we do not infringe or, by clear and convincing evidence, that the patent claims are invalid; we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity or enforceability of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, otherwise fail to defend an infringement action successfully or have a court hold that any patent we infringe is invalid or unenforceable, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and we may be precluded from manufacturing or selling our product candidates.

We cannot be certain that others have not filed patent applications for technology claimed in our pending applications, or that we were the first to invent the technology, because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued;
- patent applications in the United States are typically not published until at least 18 months after the earliest asserted priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Our competitors may have filed, and may in the future file, patent applications directed to technology similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents directed to such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications, and other parties may be entitled to priority over our applications in such jurisdictions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We employ an outside firm to pay fees due to non-U.S. patent agencies and this outside firm has systems in place to ensure compliance on payment of fees. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, 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. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Failure to secure trademark registrations could adversely affect our business.

We have not developed a trademark for our RP-G28 product. Hence, we do not currently own any actual or potential trademark rights associated with our RP-G28 product. If we seek to register additional trademarks, including trademarks associated with our RP-G28 product, our trademark applications may not be allowed for registration or our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many other jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

Risks Relating to Our Capital Stock

An active trading market for our common stock may not develop or be sustained.

Prior to our initial public offering, there was no public market for our common stock. Since our initial public offering in June 2015, there has been, and we expect that there will continue to be, only a limited volume of trading in our common stock. An active trading market in our common stock may not develop or, if developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

Our share price may be volatile, which could subject us to securities class action litigation and prevent you from being able to sell your shares at or above your purchase price.

The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- results of our clinical trials;
- results of clinical trials of our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated fluctuations in our financial condition and operating results;

- actual or anticipated changes in our growth rate relative to our competitors;
- actual or anticipated fluctuations in our competitors' operating results or changes in their growth rate;
- competition from existing products or new products that may emerge;
- announcements by us, our potential future collaborators or our competitors of significant acquisitions, strategic collaborations, joint ventures, or capital commitments;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- inconsistent trading volume levels of our shares;
- additions or departures of key management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- market conditions for biopharmaceutical stocks in general; and
- general economic and market conditions.

Furthermore, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of shares of our common stock. In addition, such fluctuations could subject us to securities class action litigation, which could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common stock will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

There is no active, public market for our Series A, Series B and Series C preferred stock.

There is no established public trading market for our Series A, Series B or Series C preferred stock. We do not intend to apply to list our preferred stock on a securities exchange. Without an active trading market, the liquidity of the preferred stock will be limited.

Holders of Series A, Series B and Series C preferred have no voting rights.

Except with respect to certain material changes in the terms of the Series A, Series B and Series C preferred stock and certain other matters and except as may be required by Delaware law, holders of preferred stock have no voting rights and therefore the holders of preferred stock will not be able to influence the implementation of actions requiring a shareholder vote.

Future sales of our common stock, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.

Sales by our stockholders of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

We may sell up to $6.5 million of our shares of common stock to Aspire Capital pursuant to our financing arrangement with Aspire Capital. The sale of a substantial number of shares of our common stock by Aspire Capital, or anticipation of such sales, could cause the trading price of our common stock to decline or make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise desire. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and we may terminate the financing arrangement at any time at our discretion without any penalty or cost to us.

Exercise of options or warrants or conversion of convertible securities may have a dilutive effect on your percentage ownership and may result in a dilution of your voting power and an increase in the number of shares of common stock eligible for future resale in the public market, which may negatively impact the trading price of our shares of common stock.

The exercise or conversion of some or all of our outstanding options, warrants, or convertible securities could result in significant dilution in the percentage ownership interest of investors in this offering and in the percentage ownership interest of our existing common stockholders and in a significant dilution of voting rights and earnings per share.

Additionally, the issuance of shares of our common stock upon exercise of stock options outstanding under our stock incentive plans will further dilute our stockholders' voting interests. To the extent options and/or warrants and/or conversion rights are exercised, additional shares of common stock will be issued, and such issuance will dilute stockholders.

Our executive officers, directors and principal stockholders maintain the ability to exert substantial influence over all matters submitted to stockholders for approval.

Our executive officers, directors and principal stockholders beneficially own shares representing approximately 15.8% of our outstanding capital stock. As a result, if these stockholders were to choose to act together, they would be able to exert substantial influence over all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would exert substantial influence over the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our Company on terms that other stockholders may desire.

We are an "emerging growth company" and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. 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 be more volatile.

We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the date we completed our initial public offering, which was June 29, 2015, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded $700.0 million as of the prior June 30th, or (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Our failure to meet the continued listing requirements of Nasdaq could result in a de-listing of our common stock.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to de-list our common stock. Such a de-listing 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 de-listing, 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.

On December 26, 2018, we received a notice from Nasdaq that, because the closing bid price of our common stock had been below $1.00 per share for 30 consecutive business days, we no longer complied with the minimum bid price requirement for continued listing on The Nasdaq Capital Market. Nasdaq Listing Rule 550(a)(2) requires listed securities to maintain a minimum bid price of $1.00 per share, and Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days.

The Notice has no immediate effect on the listing of our common stock on The Nasdaq Capital Market. Pursuant to Nasdaq Marketplace Rule 5810(c)(3)(A), we have been provided an initial compliance period of 180 calendar days, or until June 24, 2019, to regain compliance with the minimum bid price requirement. During the compliance period, our shares of common stock will continue to be listed and traded on The Nasdaq Capital Market. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for a minimum of 10 consecutive business days during the 180 calendar day grace period.

In the event we are not in compliance with the minimum bid price requirement by June 24, 2019, we may be afforded a second 180 calendar day grace period. To qualify, we would be required to meet the continued listing requirements for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the minimum bid price requirement. In addition, we would be required to provide written notice of our intention to cure the minimum bid price deficiency during this second 180 day compliance period by effecting a reverse stock split, if necessary.

We intend to actively monitor the bid price for our common stock between now and June 24, 2019 and will consider available options to regain compliance with the minimum bid price requirement.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions provide that:

- the authorized number of directors can be changed only by resolution of our board of directors;
- our bylaws may be amended or repealed by our board of directors or our stockholders;
- stockholders may not call special meetings of the stockholders or fill vacancies on the board of directors;
- our board of directors is authorized to issue, without stockholder approval, preferred stock, the rights of which will be determined at the discretion of the board of directors and that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our board of directors does not approve;
- our stockholders do not have cumulative voting rights, and therefore our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors; and
- our stockholders must comply with advance notice provisions to bring business before or nominate directors for election at a stockholder meeting.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful stockholder claims against us and may reduce the amount of money available to us.

As permitted by Section 102(b)(7) of the DGCL, our amended and restated certificate of incorporation limits the liability of our directors to the fullest extent permitted by law. In addition, as permitted by Section 145 of the DGCL, our amended and restated certificate of incorporation and our amended and restated bylaws provide that we shall indemnify, to the fullest extent authorized by the DGCL, each person who is involved in any litigation or other proceeding because such person is or was a director or officer of our company or is or was serving as an officer or director of another entity at our request, against all expense, loss or liability reasonably incurred or suffered in connection therewith. Our amended and restated certificate of incorporation provides that the right to indemnification includes the right to be paid expenses incurred in defending any proceeding in advance of its final disposition, provided, however, that such advance payment will only be made upon delivery to us of an undertaking, by or on behalf of the director or officer, to repay all amounts so advanced if it is ultimately determined that such director is not entitled to indemnification. If we do not pay a proper claim for indemnification in full within 60 days after we receive a written claim for such indemnification, except in the case of a claim for an advancement of expenses, in which case such period is 20 days, our restated certificate of incorporation and our restated bylaws authorize the claimant to bring an action against us and prescribe what constitutes a defense to such action.

Section 145 of the DGCL permits a corporation to indemnify any director or officer of the corporation against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person acted in good faith and in a manner that he reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, if he or she had no reason to believe his or her conduct was unlawful. In a derivative action, (*i.e.*, one brought by or on behalf of the corporation), indemnification may be provided only for expenses actually and reasonably incurred by any director or officer in connection with the defense or settlement of such an action or suit if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be provided if such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the court in which the action or suit was brought shall determine that the defendant is fairly and reasonably entitled to indemnity for such expenses despite such adjudication of liability.

The rights conferred in the restated certificate of incorporation and the restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons. We have entered into indemnification agreements with each of our officers and directors.

The above limitations on liability and our indemnification obligations limit the personal liability of our directors and officers for monetary damages for breach of their fiduciary duty as directors by shifting the burden of such losses and expenses to us. Although we plan to increase the coverage under our directors' and officers' liability insurance, certain liabilities or expenses covered by our indemnification obligations may not be covered by such insurance or the coverage limitation amounts may be exceeded. As a result, we may need to use a significant amount of our funds to satisfy our indemnification obligations, which could severely harm our business and financial condition and limit the funds available to stockholders who may choose to bring a claim against our company.

We have never paid dividends on our common stock and do not anticipate paying dividends for the foreseeable future, and accordingly, stockholders must rely on stock appreciation for any return on their investment.

We have never paid dividends on our common stock and we do not anticipate paying dividends on our common stock for the foreseeable future. Accordingly, any return on an investment in our common stock will be realized, if at all, only when stockholders sell their shares. In addition, our failure to pay dividends may make our stock less attractive to investors, adversely impacting trading volume and price.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2018, we had federal net operating loss carryforwards ("NOLs") of approximately $54 million which begin to expire in 2028. Our ability to utilize our NOLs may be limited under Section 382 and 383 of the Internal Revenue Code. The limitations apply if an ownership change, as defined by Section 382, occurs. Generally, an ownership change occurs when certain stockholders increase their aggregate ownership by more than 50 percentage points over their lowest ownership percentage in a testing period (typically three years). Although we have not undergone a Section 382 analysis, it is possible that the utilization of the NOLs, could be substantially limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes. Future changes in stock ownership may also trigger an ownership change and, consequently, a Section 382 limitation.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

On July 9, 2015, we entered into a new lease with Century Park, pursuant to which we are leasing approximately 2,780 square feet of office space in Los Angeles, California for our headquarters. The lease provides for a term of sixty-one (61) months, which commenced October 1, 2015. We paid $9,733 per month in base rent with normal escalations until November 2018, after which our monthly payment increased to $10,023 per month and will increase to $10,325 per month from November 2019 to October 2020. We have the option to extend the term of the lease for one five-year term, provided that the rent would be subject to market adjustment at the beginning of the renewal term. We believe that our facility is suitable and adequate for our current needs.

Item 3. Legal Proceedings

From time to time, we have been and may again become involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any material litigation.

Item 4. Mine Safety Disclosures

Not Applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our shares of common stock have been listed and traded on The NASDAQ Capital Market under the symbol "RTTR" since June 24, 2015. Prior to that date, there was no public market for our common stock.

Holders

As of March 10, 2019, there were approximately 35 registered holders of record of our common stock. These figures do not reflect the beneficial ownership or shares held in nominee name.

Securities Authorized for Issuance Under Equity Compensation Plans

See Part III, Item 12. "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" for information relating to our equity compensation plans.

Recent Sales of Unregistered Securities

In November 2018, we sold 6,000 shares of Series B convertible preferred stock and warrants to purchase 2,307,692 shares of common stock in a private placement to certain accredited investors, including two current institutional holders of our Series A convertible preferred stock, a key vendor and a member of the Company's board of directors. Certain investors in the private placement who held an aggregate of 1,880 shares of Series A convertible preferred stock exchanged their shares of Series A convertible preferred stock for 1,880 shares of Series C convertible preferred stock. We received gross proceeds of approximately $6.0 million, before deducting placement agent fees and other offering expenses payable by us. The securities issued and sold in the private placement were not registered under the Securities Act of 1933, as amended (the "Securities Act"), or any state securities laws, and were restricted from being offered or sold in the United States absent registration under the Securities Act or an applicable exemption from the registration requirements of the Securities Act. Pursuant to the terms of the securities purchase agreement we entered into with the investors, we filed a registration statement with the Securities and Exchange Commission to register the resale of the shares of common stock issuable upon conversion of the Series B preferred shares and the Series C preferred shares and upon exercise of the warrants described above, which registration statement became effective in December 2018.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

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 Annual Report. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements and Industry Data" for a discussion of the uncertainties, risks and assumptions associated with these statements. Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report.

Overview

Ritter Pharmaceuticals, Inc. develops novel therapeutic products that modulate the gut microbiome to treat digestive disorders and gastrointestinal diseases. Our lead product candidate, RP-G28, is an orally administered, high purity galacto-oligosaccharide, currently in Phase 3 clinical development for the treatment of LI, a condition that affects millions worldwide. RP-G28 is designed to selectively stimulate the growth of lactose-metabolizing bacteria in the colon, thereby effectively adapting the gut microbiome to assist in digesting lactose (the sugar found in milk) that reaches the large intestine. RP-G28 has the potential to become the first drug approved by the FDA for the treatment of LI. We are further exploring the functionality and discovering the therapeutic potential that gut microbiome changes may have on treating/preventing a variety of conditions including gastrointestinal diseases, cancer, metabolic, and liver diseases. We intend to expand our product pipeline and create added value in the future by evaluating RP-G28 in other indications, including orphan indications, developing additional products based on our underlying microbiome-modulating technology, and/or in-licensing complementary products to treat these, or other, conditions.

In March 2019, we announced that we had completed enrollment in our Phase 3 clinical trial and that data is expected to be publicly released in early fourth quarter of 2019. We expect our Phase 3 clinical program will include two confirmatory clinical trials of similar trial design.

We have devoted substantially all of our resources to development efforts relating to RP-G28, including conducting clinical trials of RP-G28, providing general and administrative support for these operations and protecting our intellectual property. We currently do not have any products approved for sale and we have not generated any revenue from product sales since our inception.

We have incurred net losses in each year since our inception, including net losses of approximately $16.9 million for the year ended December 31, 2018. We had an accumulated deficit of approximately $70.2 million as of December 31, 2018. Substantially all our net losses resulted from costs incurred in connection with our research and development programs, stock-based compensation, and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

- complete the development of our lead product candidate, RP-G28, for the reduction of symptoms associated with LI in patients;
- seek to obtain regulatory approvals for RP-G28;
- outsource the commercial manufacturing of RP-G28 for any indications for which we receive regulatory approval;
- contract with third parties for the sales, marketing and distribution of RP-G28 for any indications for which we receive regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- continue our research and development efforts; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. Accordingly, we anticipate that we will need to raise additional capital prior to the commercialization of RP-G28. Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our operating activities through a combination of equity offerings (including shares sold to Aspire Capital pursuant to our common stock purchase agreement with Aspire Capital (the "2017 Aspire Purchase Agreement")), debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our product candidates.

Financial Overview

Revenue

We have not generated any revenue since our inception. Our ability to generate revenue in the future will depend almost entirely on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize RP-G28 in the United States. In the event we choose to pursue a partnering arrangement to commercialize RP-G28 or other products either within or outside the United States, we may generate revenue from upfront license fees, milestones, research and development funding, including reimbursable research and development costs and sponsored research, in connection with these partnering arrangements.

Research and Development Expenses

Since our inception, we have focused our resources on our research and development activities, including conducting nonclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for RP-G28. Our research and development expenses consist primarily of:

- fees paid to consultants and CROs, including in connection with our nonclinical and clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis;
- costs related to acquiring and manufacturing clinical trial materials;
- depreciation of equipment, computers and furniture and fixtures;
- costs related to compliance with regulatory requirements; and
- overhead expenses for personnel in research and development functions.

From inception through December 31, 2018, we have incurred approximately $33.5 million in research and development expenses. We plan to increase our research and development expenses for the foreseeable future as we continue the development of RP-G28 for the reduction of symptoms associated with LI in patients and other indications, subject to the availability of additional funding.

The successful development of RP-G28 is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the development of RP-G28 or when, if ever, net cash inflows from RP-G28 may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- future clinical trial results; and
- the timing and receipt of any regulatory approvals.

For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of the clinical development of RP-G28 or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

Patent Costs

Patent costs consist primarily of professional fees for legal services to prosecute patents and maintain patent rights.

General and Administrative Expenses

General and administrative expenses include allocation of facilities costs, salaries, benefits, and stock-based compensation for employees, professional fees for directors, fees for independent contractors and accounting and legal services.

We expect that our general and administrative expenses will increase if RP-G28 is approved for commercialization. We believe that these increases will likely include increased costs for director and officer liability insurance, and increased fees for outside consultants, lawyers and accountants, among other expenses.

Interest Income and Interest Expense

Interest income consists of interest earned on our cash, cash equivalents and short-term investments in marketable debt securities.

Critical Accounting Policies and Estimates

This discussion and analysis is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to fair value of financial instruments, research and development costs, accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 3 to our financial statements appearing in "Item 8. Financial Statements and Supplementary Data," we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

Fair Value of Financial Instruments

Fair value measurement guidelines are prescribed by GAAP to value financial instruments. The guidance includes a definition of fair value, prescribes methods for measuring fair value, establishes a fair value hierarchy based on the inputs used to measure fair value and expands disclosures about the use of fair value measurements.

The valuation techniques utilized are based upon observable and unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect internal market assumptions. Assets are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

These two types of inputs create the following fair value hierarchy:

Level 1 — Quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.

Level 2 — Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 includes financial instruments that are valued using models or other valuation methodologies. These models consider various assumptions, including volatility factors, current market prices and contractual prices for the underlying financial instruments. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.

Level 3 — Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable

The carrying amounts reported in the balance sheet for cash and cash equivalents, accrued interest receivable, investment in marketable debt securities, prepaid expenses, accounts payable, accrued expenses, and the notes payable approximate the fair values due to the short-term nature of the instruments.

Research and Development Costs

We expense the cost of research and development as incurred. Research and development expenses comprise costs incurred in performing research and development activities, including clinical study costs, contracted services, and other external costs. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity is performed or when the goods have been received, rather than when payment is made, in accordance with ASC 730, *Research and Development*.

Accrued Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses include fees due to service providers.

We base our expenses on our estimates of the services received and efforts expended pursuant to quotes and contracts with our service providers that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, 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 accrual accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period.

Stock-Based Compensation

Stock-based compensation cost for equity awards granted to employees and nonemployees is measured at the grant date based on the calculated fair value of the award using the Black-Scholes option-pricing model, and is recognized as an expense, under the straight-line method, over the requisite service period (generally the vesting period of the equity grant). If we determine that other methods are more reasonable, or other methods for calculating these assumptions are prescribed by regulators, the fair value calculated for our stock options could change significantly. Higher volatility and longer expected lives would result in an increase to stock-based compensation expense to non-employees determined at the date of grant.

In addition to the assumptions used in the Black-Scholes option-pricing model, we also estimate a forfeiture rate to calculate the stock-based compensation for our equity awards. We will continue to use judgment in evaluating the expected volatility, expected terms and forfeiture rates utilized for our stock-based compensation calculations on a prospective basis.

Emerging Growth Company Status

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012 ("JOBS Act") was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended (the Securities Act), for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

As an "emerging growth company," we are entitled to rely on certain of exemptions and reduced reporting requirements, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the date we completed our initial public offering, which was June 29, 2015, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Results of Operations

Comparison of the years ended December 31, 2018 and 2017

The following table summarizes the results of our operations for the years ended December 31, 2018 and 2017, together with the changes in those items in dollars and as a percentage:

	For the Years Ended December 31,		Dollar	Percentage
	2018	2017	Change	Change
Statements of Operations Data:				
Operating costs and expenses				
Research and development	$ 11,366,117	$ 2,874,184	$ 8,491,933	295%
Patent costs	204,396	250,372	(45,976)	(18)%
General and administrative	5,425,033	4,777,902	647,131	14%
Total operating costs and expenses	16,995,546	7,902,458	9,093,088	115%
Loss from operations	(16,995,546)	(7,902,458)	(9,093,088)	115%
Other income (expense):				
Interest income	126,835	40,227	86,608	215%
Other expense	—	(1,627)	1,627	(100)%
Total other income	126,835	38,600	88,235	229%
Net loss	**$ (16,868,711)**	**$ (7,863,858)**	**$ (9,004,853)**	**115%**

Research and Development Expenses

Research and development expenses increased by approximately $8.5 million, or 295%, for the year ended December 31, 2018 as compared to the year ended December 31, 2017. The primary reason for the increase is the initiation of our much larger scale Phase 3 clinical trial in June 2018, as compared to our Phase 2b clinical trial that was completed in March 2017. This increase included an increase of approximately $6.9 million attributable to fees paid to our third-party CRO and an increase of approximately $1.2 million attributable to fees paid related to drug product and drug supply manufacturers for the year ended December 31, 2018 as part of our Phase 3 clinical trial.

Patent Costs

Patent costs were approximately $204,000 and $250,000 for the years ended December 31, 2018 and 2017, respectively, representing a decrease of approximately $46,000, or (18%). The primary reason for the decrease is that our costs and expenses related to the maintenance of patent rights, the prosecution of patents, the application for the issuance of patents, as well as the preparation to file national Phase applications in certain foreign countries was higher in 2017 than 2018.

General and Administrative Expenses

General and administrative expenses increased by approximately $0.6 million, or 14%, for the year ended December 31, 2018 as compared to the year ended December 31, 2017. The increase in general and administrative expenses was mainly due to an increase in payroll expenses of approximately $0.4 million, an increase of approximately $0.2 million in state taxes resulting from our 1-for-10 reverse stock split, and an increase of approximately $0.1 million each for insurance expense and board compensation expense, partially offset by a decrease in stock-based compensation expense of approximately $0.3 million during the year ended December 31, 2018.

Other Income

Interest income increased by approximately $87,000, or 215%, during the year ended December 31, 2018 as compared to the year ended December 31, 2017, primarily due to greater weighted-average cash and short-term investment balances and our investing in higher-yielding short-term marketable debt securities in 2018.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred net losses and negative cash flows from operations, and, as of December 31, 2018, we had an accumulated deficit of approximately $70.2 million. Substantially all our net losses resulted from costs incurred in connection with our research and development programs, stock-based compensation, and from general and administrative costs associated with our operations.

At December 31, 2018, we had investments in marketable debt securities of approximately $7.0 million, working capital of approximately $9.3 million and cash and cash equivalents of approximately $7.8 million. We have not generated any product revenues and have not achieved profitable operations.

Aspire Capital Common Stock Purchase Agreement

On May 4, 2017, we entered into a common stock purchase agreement with Aspire Capital Fund, LLC ("Aspire Capital"), which we amended and restated on March 29, 2019 (as amended and restated, the "Aspire Purchase Agreement"). We were not required to pay a commitment fee to Aspire Capital to affect the amendment to the Aspire Purchase Agreement. We have not made any sales to Aspire under the Aspire Purchase Agreement as of March 29, 2019. The Aspire Purchase Agreement provides access to us of up to an aggregate of $6.5 million in proceeds through the sale of shares of our common stock through March 31, 2021.

Under the Aspire Purchase Agreement, on any trading day we select, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice (each, a "Purchase Notice"), directing Aspire Capital (as principal) to purchase up to 100,000 shares of our common stock per trading day (which could be increased by as much as an additional 2,000,000 shares per trading day by mutual agreement), up to an aggregate of $6,500,000 of our common stock, at a per share price (the "Purchase Price") equal to the lesser of:

- the lowest sale price of our common stock on the sale date; or
- the arithmetic average of the three lowest closing sale prices for our common stock during the ten (10) consecutive trading days ending on the trading day immediately preceding the sale date.

The aggregate purchase price payable by Aspire Capital on any one purchase date cannot exceed $500,000, unless otherwise mutually agreed.

In addition, on any date on which we submit a Purchase Notice to Aspire Capital in an amount of at least 100,000 shares and our stock price is not less than $0.25 per share, we can also, in our sole discretion, present Aspire Capital with a volume-weighted average price purchase notice (each, a "VWAP Purchase Notice") directing Aspire Capital to purchase an amount of our common stock equal to up to 30% of the aggregate shares of our common stock traded on its principal market on the next trading day (the "VWAP Purchase Date"), as determined by us. The purchase price per share pursuant to such VWAP Purchase Notice was generally 97% of the volume-weighted average price for our common stock traded on its principal market on the VWAP Purchase Date.

We have the right to deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the agreement, so long as the most recent purchase had been completed.

We are prohibited from affecting any sales under the Aspire Purchase Agreement on any date where the closing sale price of our common stock is less than $0.25. There are no trading volume requirements or restrictions under the Aspire Purchase Agreement, and we control the timing and amount of sales of our common stock to Aspire Capital.

Under the terms of the Aspire Purchase Agreement, the number of shares that can be sold to Aspire Capital is limited to 1,807,562 (the "Exchange Cap"), which represented 19.99% of our outstanding shares of common stock as of March 29, 2019, the date the agreement was amended and restated, unless stockholder approval or an exception pursuant to the rules of the NASDAQ Capital Market was obtained to issue more than 19.99%. This limitation would not apply if, at any time the Exchange Cap was reached and at all times thereafter, the average price paid for all shares issued under the Aspire Purchase Agreement was equal to or greater than $0.86 (the "Minimum Price"), which was the closing price of our common stock immediately preceding the signing of the agreement. We are not required or permitted to issue any shares of common stock under the Aspire Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the NASDAQ Capital Market.

We expect to use the Aspire facility to complement, rather than replace, other financing that may be required during the next twelve months to continue our operations and support our capital needs.

October 2017 Public Offering

In October 2017, we closed a public offering of (i) 3,455,000 Class A Units consisting of 3,455,000 shares of our common stock and warrants to purchase 3,455,000 shares of our common stock with a five-year term and an exercise price of $4.40 per share , at a public offering price of $4.00 per unit, and (ii) 9,180 Class B Units consisting of 9,180 shares of our Series A Convertible Preferred stock, with a stated value of $1,000, and convertible into an aggregate of 2,295,000 shares of our common stock, and warrants to purchase 2,295,000 shares of our common stock with a five-year term and an exercise price of $4.40 per share, at a public offering price of $1,000 per unit. We received approximately $21.0 million in net proceeds from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. The offering was made pursuant to a shelf registration statement on Form S-3 (Registration Number 333-219147).

November 2018 Private Placement Financing

On November 5, 2018, we closed a private placement ("PIPE financing") with certain institutional investors, a key vendor and a member of our board of directors. Net proceeds from the PIPE financing were approximately $5.5 million, after deducting placement agent fees and other offering expenses. The securities that we sold consisted of 6,000 shares of our newly designated class of Series B convertible preferred stock, with a stated value of $1,000 per share and an initial conversion price per share of $1.30 (subject to customary adjustment for stock dividends and stock splits). In addition, each investor received a warrant to purchase a number of shares of common stock equal to one-half of the number of shares of common stock into which their Series B convertible preferred stock is initially convertible. The warrants are exercisable immediately for a five-year period and have an exercise price of $1.30 per share (subject to customary adjustment for stock dividends and stock splits). Certain investors in the PIPE financing who at the time of closing of the PIPE financing owned shares of our Series A convertible preferred stock, exchanged, on a 1-for-1 basis, their shares of Series A convertible preferred stock for shares of our newly designated class of Series C convertible preferred stock, with a stated value of $1,000 per share and convertible into shares of our common stock at an initial conversion price per share of $1.64 (subject to customary adjustment for stock dividends and stock splits).

Cash Flows

The following table sets forth the significant sources and uses of cash for the periods set forth below:

	For the Year Ended December 31,	
	2018	**2017**
Net cash (used in) provided by:		
Operating activities	$ (13,332,927)	$ (7,397,912)
Investing activities	(6,970,999)	(7,678)
Financing activities	5,484,214	22,991,279
Net (decrease) increase in cash	**$ (14,819,712)**	**$ 15,585,689**

Operating Activities

The use of cash in both periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. Net cash used in operating activities was approximately $13.3 million during the year ended December 31, 2018 compared to $7.4 million during the year ended December 31, 2017. The increase in cash used in operating activities was driven primarily by the initiation of our much larger scale Phase 3 clinical trial in June 2018, as compared to our Phase 2b clinical trial that was completed in March 2017.

Investing Activities

Net cash used in investing activities of was approximately $7.0 million and $8,000 during the years ended December 31, 2018 and 2017. These expenditures were mostly related to our investment in marketable debt securities and for furniture and equipment used in our business.

Financing Activities

Net cash provided by financing activities was approximately $5.5 million during the year ended December 31, 2018 compared to $23.0 million during the year ended December 31, 2017. Cash provided by financing activities in 2018 came from proceeds from the November 2018 private placement financing and cash provided by financing activities in 2017 came from proceeds from the October 2017 public offering.

Future Funding Requirements

To date, we have not generated any revenue. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize RP-G28 or any of our other product candidates. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, RP-G28. In addition, subject to obtaining regulatory approval of RP-G28, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Based upon our current operating plan, we believe that our existing cash and cash equivalents, together with interest and any proceeds received from our sale of shares of common stock to Aspire Capital in the future pursuant to the Amended Aspire Agreement, will enable us to fund our operating expenses and capital expenditure requirements through 2019.

Our future capital requirements will depend on many factors, including:

- the ability of RP-G28 and any other product candidate that we may develop in the future to progress through clinical development successfully;
- the outcome, costs and timing of seeking and obtaining FDA approval;
- the willingness of the EMA or other regulatory agencies outside the United States to accept our Phase 3 trials of RP-G28, as well as our other completed and planned clinical and nonclinical studies and other work, as the basis for review and approval of RP-G28 in the European Union for the reduction of symptoms associated with LI in patients;
- our need to expand our research and development activities;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- market acceptance of RP-G28 and any other product candidate that we may develop in the future;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing technological and market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future; and
- the costs of operating as a public company.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, commercialization, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

Contractual Obligations and Commitments

Master Services Agreement

In May 2018, we entered into an Amended and Restated Master Services Agreement ("Service Agreement") with a CRO, pursuant to which the CRO will perform certain services related to the management and execution of certain clinical trials involving our lead product candidate, RP-G28. The Services Agreement supersedes the Master Service Agreement, dated August 30, 2016, that we entered into with the CRO. The precise services to be performed by the CRO under the Services Agreement will be mutually agreed upon by the parties in writing and set forth in one or more task orders. We are not obligated to purchase any minimum or specific volume or dollar amount of services under the Services Agreement.

The term of the Services Agreement is four years from the effective date of the Service Agreement unless earlier terminated. We may terminate the Services Agreement or any task without cause immediately upon giving the CRO notice of such termination. The CRO may, with advance notice to us, terminate a task order if we have materially defaulted on our obligations under the Services Agreement or any task order and have not cured such material default, as described in the Services Agreement.

Clinical Supply and Cooperation Agreement with Ricerche Sperimentali Montale ("Ricerche") and Inalco SpA ("Inalco")

Under the terms of the Supply Agreement with RSM, we are required to pay RSM $400,000 within 10 days following FDA approval of an NDA for the first product owned or controlled by us using Improved GOS as its active pharmaceutical ingredient.

Lease Agreement

We lease office space for our headquarters in California. The lease provides for a term of sixty-one (61) months, commencing on October 1, 2015. We paid $9,733 per month in base rent with normal escalations until November 2018, after which our monthly payment increased to $10,023 per month and will increase to $10,325 per month from November 2019 to October 2020. The base rent payments do not include our proportionate share of any operating expenses, including real estate taxes. We have the option to extend the term of the lease for one five-year term, provided that the rent would be subject to market adjustment at the beginning of the renewal term. We will recognize rent expense on a straight-line basis over the lease term.

Rent expense, recognized on a straight-line basis, was approximately $118,000 and $115,000 for the years ended December 31, 2018 and 2017, respectively, and is recorded in general and administrative expenses in the accompanying statements of operations.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined under SEC rules.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)*. Under this guidance, an entity is required to recognize right-of-use ("ROU") assets and corresponding lease liabilities on its balance sheets and disclose key information about leasing arrangements. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842) Targeted Improvements*, which provides for an alternative transition method by allowing companies to continue to use the legacy guidance in Topic 840, Leases, including its disclosure requirements, in the comparative periods presented in the year of adoption of the new leases standard and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption rather than the earliest period presented.

We will elect the available package of practical expedients, but not the hindsight practical expedient, and implemented internal controls to enable the preparation of financial information on adoption as of January 1, 2019.

The standard will have a material impact on our balance sheets but will not have an impact on our statements of operations. The most significant impact will be the recognition of an ROU asset and lease liability for our sole operating lease—we have no finance leases. Adoption of the standard will not require us to restate previously reported results as we will elect to apply a modified retrospective approach at the beginning of the period of adoption rather than at the beginning of the earliest comparative period presented.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"), an amendment that modifies the measurement recognition of credit losses for most financial assets and certain other instruments. The amendment updates the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the "incurred loss" model with an "expected loss" model. Accordingly, these financial assets will be presented at the net amount expected to be collected. The amendment also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. The guidance is effective for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. Early adoption is permitted for annual periods after December 15, 2018. We do not expect the adoption of this guidance will have a material impact on our financial statements.

In February 2018, the FASB issued ASU No. 2018-02, Income Statement—Reporting Comprehensive Income (Topic 220), which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the passing of H.R. 1/Public Law No. 115-97, commonly known as the Tax Cuts and Jobs Act (the "Act") and requires certain disclosures about stranded tax effects. The amendments in ASU No. 2018-02 are effective beginning in 2019, with early adoption permitted, and may be applied either in the period of adoption or retrospectively to each period in which the effect of the change in the U.S. Federal corporate tax rate in the Act is recognized. We do not expect the adoption of this guidance will have an impact on our financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of Topic 718 *Compensation—Stock Compensation*, to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. ASU No. 2018-07 supersedes Subtopic 505-50 *Equity—Equity-Based Payments to Non-Employees*. The amendments in ASU No. 2018-07 are effective for us beginning in 2020, with early adoption permitted, but no earlier than a company's adoption date of Topic 606 *Revenue from Contracts with Customers*. We are currently assessing the impact and timing of adopting this guidance on our financial statements.

In August 2018, the FASB issued ASU No. 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement", an amendment to the accounting guidance on fair value measurements. The guidance modifies the disclosure requirements on fair value measurements, including the removal of disclosures of the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, the policy for timing of transfers between levels, and the valuation processes for Level 3 fair value measurements. The guidance also adds certain disclosure requirements related to Level 3 fair value measurements. The guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. We do not expect the adoption of this guidance will have a material impact on our financial statements.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheets must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective on November 5, 2018. However, as provided for by the SEC in Q&A 105.09, we will defer presenting our analysis of stockholders' equity in our quarterly report on Form 10-Q until the fiscal quarter ended March 31, 2019. We do not expect the adoption of SEC Release No. 33-10532 to have a material impact on our financial position, results of operations or cash flows.

Recently Adopted Accounting Pronouncements

In January 2016, the FASB issued ASU No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-01"). The amendments in ASU 2016-01 address certain aspects of recognition, measurement, presentation and disclosure of financial instruments. We adopted ASU 2016-01 in the first quarter of 2018. The adoption of this new standard did not have a material impact on our financial statements.

On August 26, 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230),* a consensus of the FASB's Emerging Issues Task Force ("ASU 2016-15"). The new guidance amends Accounting Standards Codification No. 230 ("ASC 230") to add or clarify guidance on the classification of certain cash receipts and payments in the statement of cash flows. ASC 230 lacks consistent principles for evaluating the classification of cash payments and receipts in the statement of cash flows. This has led to diversity in practice and, in certain circumstances, financial statement restatements. Therefore, the FASB issued ASU 2016-15 with the intent of reducing diversity in practice with respect to eight types of cash flows. ASU 2016-15 is effective for annual and interim periods in fiscal years beginning after December 15, 2017 and is effective for us for the year ending December 31, 2018. We adopted ASU 2016-15 on January 1, 2018 and it did not have a material impact on our financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception.* The ASU allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be accounted classified as liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, such as warrants, an entity will treat the value of the effect of the down round, when triggered, as a dividend and a reduction of income available to common stockholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. The guidance in ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted, and the guidance is to be applied using a full or modified retrospective approach. We adopted this guidance in the current quarter, effective October 1, 2017. As a result, the warrants issued on October 3, 2017, in connection with the October 2017 Public Offering, were equity-classified.

In January 2017, the FASB issued ASU No. 2017-04 *"Intangibles – Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment*," or ASU 2017-04. ASU 2017-04 allows companies to apply a one-step quantitative test and record the amount of goodwill impairment as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The amendments of the ASU are effective for annual or interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. We adopted this guidance as of October 1, 2018 and there was no impact on our financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *"Stock Compensation – Scope of Modification Accounting"* or ASU 2017-09. ASU 2017-09 provides guidance on which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The new standard was effective for fiscal years beginning after December 15, 2017. We adopted the guidance effective January 1, 2018. There was no impact upon adoption.

In March 2018, the FASB issued ASU No. 2018-05, *Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118*, which amended various SEC paragraphs pursuant to the issuance of SEC Staff Accounting Bulletin No. 118 ("SAB 118"). SAB 118 was issued by the SEC in December 2017 to provide immediate guidance for accounting implications of U.S. tax reform under the Act, which became effective for us on January 1, 2018. We have evaluated the potential impacts of SAB 118 and have applied this guidance to our financial statements and related disclosures in 2018. For additional information on SAB 118 and the impacts of the Act on our condensed financial statements and related disclosures, see *Note 7. Income Taxes* in the notes to the financial statements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data.

The financial statements and the reports of our independent registered accounting firm required pursuant to this item are included in Item 15 of this report and are presented beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

There has been no change of accountants nor any disagreements with accountants on any matter of accounting principles or practices or financial disclosure required to be reported under this Item.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer (our principal executive officer) and chief financial officer (our principal financial officer), evaluated the effectiveness of our disclosures controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, as amended (the "Exchange Act"), as of December 31, 2018. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2018, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our chief executive officer and chief financial officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that: (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide a reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitation. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgement and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Management has used the framework set forth in the report entitled "Internal Control – Integrated Framework" published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting. Based on its evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2018, the end of our most recent fiscal year.

Changes in Internal Control over Financial Reporting

We regularly review our system of internal control over financial reporting and make changes to our processes and systems to improve controls and increase efficiency, while ensuring that we maintain an effective internal control environment. Changes may include such activities as implementing new, more efficient systems, consolidating activities, and migrating processes. There were no changes in our internal control over financial reporting that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

On May 4, 2017, we entered into a common stock purchase agreement with Aspire Capital, which we amended and restated on March 29, 2019 (as amended and restated, the "Aspire Purchase Agreement"). We were not required to pay a commitment fee to Aspire Capital to affect the amendment to the Aspire Purchase Agreement. We have not made any sales to Aspire under the Aspire Purchase Agreement as of March 29, 2019. The Aspire Purchase Agreement provides access to us of up to an aggregate of $6.5 million in proceeds through the sale of shares of our common stock through March 31, 2021.

See "Aspire Capital Common Stock Purchase Agreement" in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report for additional information regarding the terms of the Amended Aspire Agreement.

The foregoing description of the Aspire Purchase Agreement is qualified in its entirety by reference to the full text of the Aspire Purchase Agreement, which is filed as Exhibit 10.44 to this Annual Report and is incorporated by reference herein.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

Information required by this item will be contained in our Definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2018. Such information is incorporated herein by reference.

Item 11. Executive Compensation

Information required by this item will be contained in our Definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2018. Such information is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required by this item will be contained in our Definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2018. Such information is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required by this item will be contained in our Definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2018. Such information is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

Information required by this item will be contained in our Definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2018. Such information is incorporated herein by reference.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements.

The following financial statements of Ritter Pharmaceuticals, Inc., together with the report thereon of Mayer Hoffman McCann P.C., an independent registered public accounting firm, are included in this Annual Report on Form 10-K:

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Report of Independent Registered Public Accounting Firm	F-1
Financial Statements:	
Balance Sheets as of December 31, 2018 and 2017	F-2
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Statements of Changes in Stockholders' Equity for the years ended December 31, 2018 and 2017	F-4
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(a)(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the Financial Statements or Notes thereto set forth under Item 8 above.

(a)(3) Exhibits.

		Incorporated by Reference			
Exhibit No.	**Description**	**Form**	**File No.**	**Exhibit**	**Filing Date**
3.1	Amended and Restated Certificate of Incorporation of Ritter Pharmaceuticals, Inc.	8-K	001-37428	3.1	7/1/2015
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation	8-K	001-37428	3.1	9/15/2017
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation	8-K	001-37428	3.1	3/22/2018
3.4	Amended and Restated Bylaws of Ritter Pharmaceuticals, Inc.	8-K	001-37428	3.2	7/1/2015
3.5	Certificate of Designation of Series A Convertible Preferred Stock	8-K	001-37428	3.1	10/4/2017
3.6	Certificate of Designation of Series B Convertible Preferred Stock	10-Q	001-37428	3.1	11/9/2018
3.7	Certificate of Designation of Series C Convertible Preferred Stock	10-Q	001-37428	3.2	11/9/2018
4.1	Form of Common Stock Certificate of Ritter Pharmaceuticals, Inc.	8-K	001-37428	4.1	3/22/2018

4.2	Amended and Restated Investors' Rights Agreement, dated as of November 17, 2010, by and among Ritter Pharmaceuticals, Inc. and the persons and entities named therein	S-1	333-202924	4.2	3/23/2015
4.3	Amendment No. 1 to the Amended and Restated Investors' Rights Agreement, dated as of January 13, 2011, by and among Ritter Pharmaceuticals, Inc. and the persons and entities named therein	S-1	333-202924	4.3	3/23/2015
4.4	Amendment No. 2 to the Amended and Restated Investors' Rights Agreement, dated as of February 6, 2012, by and among Ritter Pharmaceuticals, Inc. and the persons and entities named therein	S-1	333-202924	4.4	3/23/2015
4.5	Amendment No. 3 to the Amended and Restated Investors' Rights Agreement, dated as of December 4, 2014, by and among Ritter Pharmaceuticals, Inc. and the persons and entities named therein	S-1	333-202924	4.5	3/23/2015
4.6	Amendment No. 4 to the Amended and Restated Investors' Rights Agreement, by and among Ritter Pharmaceuticals, Inc. and the persons and entities named therein	S-1	333-208818	4.6	12/31/2015
4.7	Form of Common Stock Purchase Warrant	S-1	333-208818	4.7	12/31/2015
4.8	Form of Representative's Warrant Agreement	S-1/A	333-202924	4.7	5/8/2015
4.9	Registration Rights Agreement, dated May 4, 2017, by and between Ritter Pharmaceuticals, Inc. and Aspire Capital Fund, LLC	8-K	001-37428	4.1	5/9/2017
4.10	Warrant Agency Agreement by and between Ritter Pharmaceuticals, Inc. and Corporate Stock Transfer, Inc. and Form of Warrant Certificate	8-K	001-37428	4.1	10/4/2017
4.11	First Amendment to Warrant Agency Agreement by and between Ritter Pharmaceuticals, Inc. and Corporate Stock Transfer, Inc.	8-K	001-37428	4.1	5/7/2018
4.12	Registration Rights Agreement, by and among Ritter Pharmaceuticals, Inc. and the Purchasers signatory thereto, dated October 30, 2018	10-Q	001-37428	10.5	11/9/2018
10.1	Offer Letter, dated December 2, 2014, by and between Michael D. Step and Ritter Pharmaceuticals, Inc.	S-1	333-202924	10.2	5/8/2015
10.2+	Executive Compensation Plan	S-1	333-202924	10.3	5/8/2015
10.3+	Executive Severance & Change in Control Agreement, dated October 1, 2014, by and between Ritter Pharmaceuticals, Inc. and Michael D. Step	S-1	333-202924	10.4	5/8/2015
10.4+	2015 Equity Incentive Plan	S-8	333-207709	99.3	10/30/15

10.5+	Amendment to 2015 Equity Incentive Plan	8-K	001-37428	10.1	6/6/2016
10.6+	Second Amendment to 2015 Equity Incentive Plan	8-K	001-37428	10.1	6/6/2017
10.7+	Third Amendment to 2015 Equity Incentive Plan	8-K	001-37428	10.1	9/15/2017
10.8+	Form of Notice of Grant of Stock Option under the 2015 Equity Incentive Plan	S-8	333-207709	99.4	10/30/15
10.9+	Stock Option Agreement, dated December 2, 2014, by and between Ritter Pharmaceuticals, Inc. and Michael D. Step	S-1	333-202924	10.8	5/8/2015
10.10*+	Form of Performance Restricted Stock Unit Award Agreement				
10.11+	Stock Option Agreement, dated December 2, 2014, by and between Ritter Pharmaceuticals, Inc. and Michael D. Step	S-1	333-202924	10.9	5/8/2015
10.12+	Stock Option Agreement, dated December 2, 2014, by and between Ritter Pharmaceuticals, Inc. and Michael D. Step	S-1	333-202924	10.10	5/8/2015
10.13+	Stock Option Agreement, dated September 25, 2013, by and between Ritter Pharmaceuticals, Inc. and Andrew J. Ritter	S-1	333-202924	10.11	5/8/2015
10.14+	Stock Option Agreement, dated December 2, 2014, by and between Ritter Pharmaceuticals, Inc. and Andrew J. Ritter	S-1	333-202924	10.12	5/8/2015
10.15+	Stock Option Agreement, dated December 2, 2014, by and between Ritter Pharmaceuticals, Inc. and Andrew J. Ritter	S-1	333-202924	10.13	5/8/2015
10.16+	Stock Option Agreement, dated September 25, 2013, by and between Ritter Pharmaceuticals, Inc. and Ira E. Ritter	S-1	333-202924	10.14	5/8/2015
10.17+	Stock Option Agreement, dated December 2, 2014, by and between Ritter Pharmaceuticals, Inc. and Ira E. Ritter	S-1	333-202924	10.15	5/8/2015
10.18+	Stock Option Agreement, dated December 2, 2014, by and between Ritter Pharmaceuticals, Inc. and Ira E. Ritter	S-1	333-202924	10.16	5/8/2015
10.19	Research and Development Agreement & License, dated November 30, 2010, by and among Kolu Pohaku Technologies, LLC, Kolu Pohaku Management, LLC and Ritter Pharmaceuticals, Inc.	S-1	333-202924	10.17	5/8/2015
10.20	Amendment No. 1 to Research and Development Agreement & License, dated July 6, 2011, by and among Kolu Pohaku Technologies, LLC, Kolu Pohaku Management, LLC and Ritter Pharmaceuticals, Inc.	S-1	333-202924	10.18	5/8/2015

10.21	Amendment No. 2 to Research and Development Agreement & License, dated September 30, 2011, by and among Kolu Pohaku Technologies, LLC, Kolu Pohaku Management, LLC and Ritter Pharmaceuticals, Inc.	S-1	333-202924	10.19	5/8/2015
10.22	Amendment No. 3 to Research and Development Agreement & License, dated February 6, 2012, by and among Kolu Pohaku Technologies, LLC, Kolu Pohaku Management, LLC and Ritter Pharmaceuticals, Inc.	S-1	333-202924	10.20	5/8/2015
10.23	Amendment No. 4 to Research and Development Agreement & License, dated November 4, 2013, by and among Kolu Pohaku Technologies, LLC, Kolu Pohaku Management, LLC and Ritter Pharmaceuticals, Inc.	S-1	333-202924	10.21	5/8/2015
10.24	Put and Call Option Agreement, dated November 30, 2010, by and between Kolu Pohaku Technologies, LLC and Ritter Pharmaceuticals, Inc.	S-1	333-202924	10.22	5/8/2015
10.25+	Form of Indemnification Agreement between Ritter Pharmaceuticals, Inc. and each of its directors and executive officers	S-1/A	333-202924	10.29	4/24/2015
10.26	Clinical Supply and Operation Agreement, dated December 16, 2009, by and among Ritter Pharmaceuticals, Inc. and Ricerche Sperimentali Montale SpA and Inalco SpA	S-1/A	333-202924	10.30	4/24/2015
10.27	Amendment 1 to the Clinical Supply and Cooperation Agreement, dated September 25, 2010, by and among Ritter Pharmaceuticals, Inc. and Ricerche Sperimentali Montale SpA and Inalco SpA	S-1/A	333-202924	10.31	4/24/2015
10.28+	Amended and Restated Offer Letter, by and between Ritter Pharmaceuticals, Inc. and Andrew J. Ritter	10-Q	001-37428	10.5	8/14/2018
10.29+	Offer Letter, by and between Ritter Pharmaceuticals, Inc. and Ira E. Ritter	10-Q	001-37428	10.2	8/12/2015
10.30+	Executive Severance & Change in Control Agreement, by and between Ritter Pharmaceuticals, Inc. and Andrew J. Ritter	10-Q	001-37428	10.3	8/12/2015
10.31+	Executive Severance & Change in Control Agreement, by and between Ritter Pharmaceuticals, Inc. and Ira E. Ritter	10-Q	001-37428	10.4	8/12/2015
10.32	Lease Agreement, dated July 9, 2015, between the Company and Century Park	10-Q	001-37428	10.1	11/10/2015
10.33	Amendment No. 2 to Clinical Supply and Cooperation Agreement, effective July 24, 2015, between Ritter Pharmaceuticals, Inc., Ricerche Sperimentali Montale SpA, and Inalco SpA	10-Q	001-37428	10.2	11/10/2015

10.34+	Letter of Agreement, dated October 20, 2015 between Ritter Pharmaceuticals, Inc. and Chord Advisors, LLC	10-Q	001-37428	10.4	11/10/2015
10.35	Common Stock Purchase Agreement, dated May 4, 2017, by and between Ritter Pharmaceuticals, Inc. and Aspire Capital Fund, LLC	8-K	001-37428	10.1	5/9/2017
10.36	Amended and Restated Master Services Agreement, dated May 1, 2018, by and between Ritter Pharmaceuticals, Inc. and Medpace, Inc.	8-K	001-37428	10.1	5/7/2018
10.37	Offer Letter with John W. Beck, dated May 23, 2018	8-K	001-37428	10.1	5/29/2018
10.38	Executive Severance and Change in Control Agreement, by and between Ritter Pharmaceuticals, Inc. and John W. Beck, effective May 24, 2018	8-K	001-37428	10.2	5/29/2018
10.39	Agreement and General Release, dated June 26, 2018, by and between Ritter Pharmaceuticals, Inc. and Michael D. Step	8-K	001-37428	10.1	7/2/2018
10.40	Consulting Agreement, effective June 27, 2018, by and between Ritter Pharmaceuticals, Inc. and Michael D. Step	8-K	001-37428	10.2	7/2/2018
10.41	Securities Purchase Agreement, by and among Ritter Pharmaceuticals, Inc. and the Purchasers signatory thereto, dated October 30, 2018	10-Q	001-37428	10.3	11/9/2018
10.42	Form of Common Stock Purchase Warrant	10-Q	001-37428	10.4	11/9/2018
10.43	Placement Agency Agreement, by and between Ritter Pharmaceuticals, Inc. and A.G.P./Alliance Global Partners, dated October 30, 2018	10-Q	001-37428	10.6	11/9/2018
10.44*	Amended and Restated Common Stock Purchase Agreement, by and between Ritter Pharmaceuticals, Inc. and Aspire Capital Fund, LLC, dated March 29, 2019				
23.1*	Consent of Mayer Hoffman McCann P.C., independent registered public accounting firm				
24.1*	Power of Attorney (included on signature page)				
31.1*	Certificate of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certificate of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*	Certificate of principal executive officer and principal financial officer pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				

101.INS#	XBRL Instance Document.
101.SCH#	XBRL Taxonomy Extension Schema Document.
101.CAL#	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF#	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB#	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE#	XBRL Taxonomy Extension Presentation Linkbase Document.

***** Filed herewith.
+ Indicates management contract or compensatory plan or arrangement.
# XBRL (Extensible Business Reporting Language) information is furnished and not filed herewith, is not a part of a registration statement or Prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.

Item 16. Form 10-K Summary

None.

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.

RITTER PHARMACEUTICALS, INC.

By: */s/ John W. Beck*
Name: John W. Beck
Title: Principal Financial Officer and Principal Accounting Officer

Date: April 1, 2019

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Andrew J. Ritter, Ira E. Ritter and John W. Beck, jointly and severally, his attorneys-in-fact, each with the power of substitution, for him in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

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 on April 1, 2019 in the capacities indicated.

Signature	Title	Date
/s/ Andrew J. Ritter Andrew J. Ritter	Chief Executive Officer and Director (Principal Executive Officer)	April 1, 2019
/s/ John W. Beck John W. Beck	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	April 1, 2019
/s/ Ira E. Ritter Ira E. Ritter	Executive Chairman, Chief Strategic Officer and Director	April 1, 2019
/s/ Michael D. Step Michael D. Step	Director	April 1, 2019
/s/ Noah Doyle Noah Doyle	Director	April 1, 2019
/s/ Matthew W. Foehr Matthew W. Foehr	Director	April 1, 2019
/s/ Paul V. Maier Paul V. Maier	Director	April 1, 2019
/s/ William M. Merino William M. Merino	Director	April 1, 2019

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

RITTER PHARMACEUTICALS, INC.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Ritter Pharmaceuticals ("Company") as of December 31, 2018 and 2017, and the related statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred recurring operating losses and is dependent on additional financing to fund operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 1 to the financial statements. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Basis for Opinion

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 are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Mayer Hoffman McCann P.C.

We have served as the Company's auditor since 2014.

Orange County, CA
March 29, 2019

RITTER PHARMACEUTICALS, INC.
BALANCE SHEETS

	December 31, 2018	December 31, 2017
ASSETS		
Current assets		
Cash and cash equivalents	$ 7,812,259	$ 22,631,971
Accrued interest receivable	54,456	—
Investment in marketable securities	6,988,780	—
Prepaid expenses	421,522	167,400
Total current assets	15,277,017	22,799,371
Other assets	22,725	10,326
Property and equipment, net	20,160	23,873
Total Assets	**$ 15,319,902**	**$ 22,833,570**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 4,512,316	$ 2,237,579
Accrued expenses	1,407,843	454,252
Other liabilities	13,359	15,757
Total current liabilities	5,933,518	2,707,588
Stockholders' equity		
Series A preferred stock, $0.001 par value; 15,000,000 shares authorized; 4,080 and 9,140 shares issued and outstanding as of December 31, 2018 and 2017, respectively	2,289,324	5,128,536
Series B preferred stock, $0.001 par value; 6,000 shares authorized; 5,608 and 0 shares issued and outstanding as of December 31, 2018 and 2017, respectively	3,906,931	—
Series C preferred stock, $0.001 par value; 1,880 shares authorized; 1,880 and 0 shares issued and outstanding as of December 31, 2018 and 2017, respectively	1,880,000	—
Common stock, $0.001 par value; 225,000,000 and 25,000,000 shares authorized; 6,036,562 and 4,940,652 shares issued and outstanding as of December 31, 2018 and 2017, respectively	6,037	4,940
Additional paid-in capital	71,505,160	68,323,940
Accumulated other comprehensive loss	(923)	—
Accumulated deficit	(70,200,145)	(53,331,434)
Total stockholders' equity	9,386,384	20,125,982
Total Liabilities and Stockholders' Equity	**$ 15,319,902**	**$ 22,833,570**

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

RITTER PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Year Ended December 31,	
	2018	**2017**
Operating costs and expenses:		
Research and development	$ 11,366,117	$ 2,874,184
Patent costs	204,396	250,372
General and administrative	5,425,033	4,777,902
Total operating costs and expenses	16,995,546	7,902,458
Operating loss	$ (16,995,546)	$ (7,902,458)
Other income (expense):		
Interest income	126,835	40,227
Other expense	—	(1,627)
Total other income	126,835	38,600
Net loss	**$ (16,868,711)**	**$ (7,863,858)**
Other comprehensive loss:		
Unrealized loss on debt securities	(923)	—
Comprehensive loss	$ (16,869,634)	$ (7,863,858)
Net Loss	(16,868,711)	(7,863,858)
Deemed dividend of preferred stock	(2,537,844)	(3,111,020)
Net loss applicable to common stockholders	$ (19,406,555)	$ (10,974,878)
Net loss per common share – basic and diluted	$ (3.66)	$ (4.95)
Weighted average common shares outstanding – basic and diluted	5,304,667	2,214,951

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

RITTER PHARMACEUTICALS, INC.
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Series A Preferred Stock		Series B Preferred Stock		Series C Preferred Stock		Common Stock		Paid-in	Accumulated	Other Comprehensive	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at December 31, 2016	—	$ —	—	$ —	—	$ —	1,161,920	$ 1,162	$ 49,603,487	$ (45,467,576)	$ —	$ 4,137,073
Issuance of shares upon follow-on offering	9,180	5,150,980	—	—	—	—	3,453,987	3,454	17,844,220	—	—	22,998,654
Commissions and offering costs of follow-on offering	—	—	—	—	—	—	—	—	(2,038,471)	—	—	(2,038,471)
Issuance of shares under common stock purchase agreement	—	—	—	—	—	—	313,732	314	1,996,862	—	—	1,997,176
Stock-based compensation	—	—	—	—	—	—	—	—	895,498	—	—	895,498
Conversion of series A preferred shares	(40)	(22,444)	—	—	—	—	10,000	10	22,344	—	—	(90)
Net loss	—	—	—	—	—	—	—	—	—	(7,863,858)	—	(7,863,858)
Balance at December 31, 2017	9,140	$ 5,128,536	—	$ —	—	$ —	4,939,639	$ 4,940	$ 68,323,940	$ (53,331,434)	$ —	$ 20,125,982
Payout to shareholders for fractional shares	—	—	—	—	—	—	—	—	(3,256)	—	—	(3,256)
Issuance of Series B preferred shares upon closing of private placement	—	—	6,000	4,570,848	—	—	—	—	792,037	—	—	5,362,885
Commissions and offering costs of private placement	—	—	—	(390,449)	—	—	—	—	(122,081)	—	—	(512,530)
Deemed dividend of preferred stock	(1,880)	(1,054,886)	—	—	1,880	1,880,000	—	—	(188,000)	—	—	637,114
Stock-based compensation	—	—	—	—	—	—	—	—	645,823	—	—	645,823
Conversion of Series A preferred shares into common stock	(3,180)	(1,784,326)	—	—	—	—	795,000	795	1,783,531	—	—	—
Conversion of Series B preferred shares into common stock	—	—	(392)	(273,468)	—	—	301,923	302	273,166	—	—	—
Unrealized loss on investment in marketable debt securities	—	—	—	—	—	—	—	—	—	—	(923)	(923)
Net loss	—	—	—	—	—	—	—	—	—	(16,868,711)	—	(16,868,711)
Balance at December 31, 2018	4,080	$ 2,289,324	5,608	$ 3,906,931	1,880	$ 1,880,000	6,036,562	$ 6,037	$ 71,505,160	$ (70,200,145)	$ (923)	$ 9,386,384

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

RITTER PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,	
	2018	**2017**
Cash flows from operating activities		
Net loss	$ (16,868,711)	$ (7,863,858)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	5,721	5,720
Stock-based compensation	645,823	895,498
Loss on disposal of equipment	—	1,627
Settlement of accounts payable	(893,823)	—
Amortization of discount on available-for-sale debt securities	(19,789)	—
Unrealized loss on investment in marketable debt securities	(923)	—
Changes in operating assets and liabilities:		
Accrued interest receivable	(54,456)	—
Prepaid expenses and other assets	(254,122)	(10,648)
Other assets	(12,399)	—
Accounts payable	3,168,559	341,211
Accrued expenses	953,591	(768,483)
Other liabilities	(2,398)	1,021
Net cash used in operating activities	**(13,332,927)**	**(7,397,912)**
Cash flows from investing activities		
Purchase of property and equipment	(2,008)	(7,678)
Purchase of investment in marketable securities	(6,968,991)	—
Net cash used in investing activities	**(6,970,999)**	**(7,678)**
Cash flows from financing activities		
Proceeds from the issuance of preferred shares upon closing of private placement	6,000,000	—
Commission and issuance costs of private placement	(512,530)	—
Proceeds from the issuance of shares upon closing of follow-on offering	—	23,029,750
Commission and issuance costs of follow-on offering	—	(2,038,471)
Proceeds from the issuance of shares from common stock purchase agreement	—	2,000,000
Payout to shareholders for fractional shares	(3,256)	—
Net cash provided by financing activities	**5,484,214**	**22,991,279**
Net (decrease) increase in cash and cash equivalents	**(14,819,712)**	**15,585,689**
Cash and cash equivalents at beginning of period	**22,631,971**	**7,046,282**
	$ 7,812,259	**$ 22,631,971**
Supplemental disclosure of cash flow activities:		
Cash paid for taxes	$ 2,233	$ 800
Supplemental disclosure of non-cash financing activities:		
Deemed dividend on preferred stock	$ 2,537,844	$ 3,111,020
Conversion of Series A and Series B preferred stock to common stock	$ 2,057,794	$ —
Conversion of Series A preferred stock to Series C preferred stock	$ 1,880,000	$ —

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

NOTE 1 — ORGANIZATION AND PRINCIPAL ACTIVITIES

Ritter Pharmaceuticals, Inc. ("Ritter" or the "Company") is a Delaware corporation headquartered in Los Angeles, California. The Company was formed as a Nevada limited liability company in March 2004, under the name Ritter Natural Sciences, LLC, and converted into a Delaware corporation in September 2008.

Ritter Pharmaceuticals, Inc. develops novel therapeutic products that modulate the gut microbiome to treat digestive disorders and gastrointestinal diseases. The Company's lead product candidate, RP-G28, is an orally administered, high purity galacto-oligosaccharide, currently in Phase 3 clinical development for the treatment of lactose intolerance ("LI"), a condition that affects millions of people worldwide. RP-G28 is designed to selectively stimulate the growth of lactose-metabolizing bacteria in the colon, thereby effectively adapting the gut microbiome to assist in digesting lactose (the sugar found in milk) that reaches the large intestine. RP-G28 has the potential to become the first drug approved by the Food and Drug Administration ("FDA") for the treatment of LI. The Company is further exploring the functionality and discovering the therapeutic potential that gut microbiome changes may have on treating/preventing a variety of conditions including gastrointestinal diseases, cancer, metabolic, and liver diseases. The Company intends to expand its product pipeline and create added value in the future by evaluating RP-G28 in other indications, developing additional products based on its underlying, microbiome-modulating technology or in-licensing complementary products to treat these, or other, conditions.

The Company currently operates in one business segment focusing on the development and commercialization of RP-G28. The Company is not organized by market and is managed and operated as one business. A single management team reports to the chief operating decision maker, the Chief Executive Officer. The Company does not currently operate any separate lines of business or separate business entities.

NOTE 2 — BASIS OF PRESENTATION

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented.

Going Concern and Liquidity

The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. The Company has not generated any product revenue and has not achieved profitable operations. The Company had net losses of approximately $16.9 million and $7.9 million for the years ended December 31, 2018 and 2017, respectively, and had net cash used in operating activities of approximately $13.3 million and $7.4 million, for the years ended December 31, 2018 and 2017, respectively. At December 31, 2018, the Company had working capital of approximately $9.3 million, an accumulated deficit of approximately $70.2 million, cash and cash equivalents of approximately $7.8 million and investment in short-term marketable debt securities of $7.0 million. There is no assurance that profitable operations will ever be achieved, and, if achieved, could be sustained on a continuing basis. In addition, development activities, clinical and pre-clinical testing, and commercialization of the Company's products will require significant financing. These matters, among others, raise substantial doubt about the Company's ability to continue as a going concern.

Since inception, the operations of the Company have been funded through the sale of common shares, preferred shares, warrants and convertible debt. Management cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that the Company raises additional funds by issuing equity securities, the Company's stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that could impact the Company's ability to conduct business. If the Company is not able to raise additional capital when required or on acceptable terms, the Company may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that the Company would otherwise seek to develop or commercialize.

The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

NOTE 3 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates and such differences may be material to the financial statements. The more significant estimates and assumptions by management include among others; the valuation allowance of deferred tax assets resulting from net operating losses and the valuation of options on the Company's common stock.

Cash and Cash Equivalents

Cash consists of amounts held in financial institutions and consists of immediately available fund balances. The funds are maintained at stable financial institutions, generally at amounts in excess of federally insured limits. Cash equivalents include money market funds and held-to-maturity securities with a maturity date of 90 days or less. As of December 31, 2018, cash and cash equivalents consisted of bank deposits, cash and investments in money market funds and held-to-maturity securities. The Company has not realized any losses.

Investment in Marketable Securities

Investment in Marketable Securities is held in a custodial account at a financial institution and managed by the Company's capital advisors based on the Company's investment guidelines. All of the Company's investments in marketable securities are classified as available-for-sale debt securities and are carried at fair value. Interest on these securities, as well as the amortization of discounts and premiums, is included in interest income in the Statements of Operations. The unrealized gains and losses on these securities are excluded from earnings and reported in other comprehensive income until realized, except when it considers declines in value to be other than temporary. Other than temporary impairment losses related to credit losses are considered to be realized losses. When available-for-sale debt securities are sold, the cost of the securities is specifically identified and is used to determine the realized gain or loss. Securities classified as current assets have maturity dates of less than or equal to one year from the balance sheet date.

Property and Equipment

Property and equipment are recorded at cost and depreciated over their estimated useful lives using the straight-line method (see Note 4). Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to income. Maintenance and repairs are charged to expense as incurred while expenditures for refurbishments and improvements that significantly add to the productive capacity or extend the useful life of an asset are capitalized.

Impairment of Long-Lived Assets

The Company periodically assesses the impairment of long-lived assets in accordance with Accounting Standards Codification ("ASC") Topic 360,*Property Plant and Equipment.* When indicators of impairment are present, the Company evaluates the carrying value of these assets in relation to the operating performance of the business and future undiscounted cash flows expected to result from the use of these assets. No such impairments have been recognized during the years ended December 31, 2018 or 2017.

Clinical Trial and Pre-Clinical Study Accruals

The Company makes estimates of accrued expenses as of each balance sheet date in its financial statements based on the facts and circumstances known to it at that time. Accrued expenses for pre-clinical studies and clinical trials are based on estimates of costs incurred and fees that may be associated with services provided by contract research organizations, clinical trial investigational sites, and other related vendors. Payments under certain contracts with such parties depend on factors such as successful enrollment of patients, site initiation and the completion of milestones. In accruing service fees, management estimates the time period over which services will be performed and the level of effort to be expended in each period. If possible, the Company obtains information regarding unbilled services directly from these service providers. However, the Company may be required to estimate these services based on other information available to it. If the Company underestimates or overestimates the activity or fees associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, estimated accrued liabilities have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in the Company's accruals.

Research and Development

The Company expenses the cost of research and development as incurred. Research and development expenses comprise costs incurred in performing research and development activities, including clinical trial costs, manufacturing costs for both clinical and pre-clinical materials as well as other contracted services, license fees, and other external costs. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity is performed or when the goods have been received, rather than when payment is made, in accordance with ASC Topic 730, *Research and Development*.

Patent Costs

The Company has no historical data to support a probable future economic benefit for the arising patent applications, filing and prosecution costs. Therefore, patent costs are expensed as incurred. Should the Company experience a legal cost to defend a patent in the future, that cost would be capitalized only when it is part of the cost of retaining and obtaining the future economic benefit of the patent. Costs related to an unsuccessful outcome would be expensed.

Stock-based Compensation

Stock-based compensation cost for stock awards issued to employees, members of the Company's board of directors and non-employees, is measured at the grant date based on the fair value of the award and is recognized as expense over the required service period, which is generally equal to the vesting period. Stock-based compensation is recognized only for those awards that are ultimately expected to vest. Common stock, stock options or warrants issued to non-employees, including consultants and members of the Company's Scientific Advisory Board as consideration for goods or services received by the Company, are accounted for based on the fair value of the equity instruments issued unless the fair value consideration received can be more reliably measured. The fair value of stock options is determined using the Black-Scholes option-pricing model. The fair value of any options issued to non-employees is recorded as expense over the vesting period. See Note 8 for further information.

Fair Value Measurements

The fair value of the Company's financial instruments reflects the amounts that it estimates it would receive in connection with the sale of an asset or pay in connection with the transfer of a liability in an orderly transaction between market participants at the measurement date (exit price). The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). The guidance establishes three levels of the fair value hierarchy as follows:

Level 1 - Inputs that reflect unadjusted quoted prices in active markets for identical assets or liabilities that we have the ability to access at the measurement date;

Level 2 - Inputs other than quoted prices that are observable for the assets or liability either directly or indirectly, including inputs in markets that are not considered to be active;

Level 3 - Inputs that are unobservable.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the year ended December 31, 2018.

A summary of the assets and liabilities carried at fair value in accordance with the hierarchy defined above is as follows:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
December 31, 2018				
Assets:				
Cash and money market fund	$ 2,353,825	$ —	$ —	$ 2,353,825
Corporate debt securities	—	6,908,710	—	6,908,710
Commercial paper	—	2,979,213	—	2,979,213
Total assets	$ 2,353,825	$ 9,887,923	$ —	$ 12,241,748

The Company uses a market approach for determining the fair value of all its Level 1 and Level 2 money market funds and marketable securities. To value its money market funds, the Company values the funds at $1 stable net asset value, which is the market pricing convention for identical assets that the Company has the ability to access.

The investments are classified as available-for-sale debt securities. At December 31, 2018, the balance in the Company's accumulated other comprehensive loss was comprised primarily of activity related to the Company's available-for-sale debt securities and some activity related to held-to-maturity debt securities. There were no realized gains or losses recognized on the sale or maturity of available-for-sale debt securities for the years ended December 31, 2018 and as a result, the Company did not reclassify any amounts out of accumulated other comprehensive loss for the year. The Company has a limited number of available-for-sale debt securities in insignificant loss positions as of December 31, 2018, which the Company does not intend to sell and has concluded it will not be required to sell before recovery of the amortized cost for the investment at maturity.

The following table summarizes the available-for-sale debt securities at December 31, 2018:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	$ 4,010,003	$ 27	$ (463)	$ 4,009,567
Commercial paper	2,979,583	72	(442)	2,979,213
Total available-for-sale debt securities	$ 6,989,586	$ 99	$ (905)	$ 6,988,780

Convertible Preferred Stock

The Company follows authoritative accounting guidance to distinguish liabilities from equity when assessing the classification and measurement of preferred stock. Preferred shares subject to mandatory redemptions are considered liabilities and measured at fair value. Conditionally redeemable preferred shares are considered temporary equity. All other preferred shares are considered as stockholders' equity.

Derivative Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. Management evaluates all of the Company's financial instruments, including warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. The Company generally uses either the Black-Scholes option-pricing model or a Monte Carlo simulation, as applicable, to value the derivative instruments at inception and subsequent valuation dates when needed. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period.

Accounting for Income Taxes

Deferred tax assets and liabilities are recognized for the expected future consequences of events that have been reflected in the financial statements. Deferred tax assets and liabilities are determined based on the differences between the book and tax basis of assets and liabilities and operating loss carryforwards, using tax rates expected to be in effect for the years in which the differences are expected to reverse. Such differences arise primarily from stock-based compensation and net operating loss carryforwards. The Company records a valuation allowance to reduce deferred income tax assets when it is more likely than not that some portion or all of the deferred tax asset will not be realized. Prior to September 15, 2008, the Company was a limited liability company and the Company's tax losses and credits generally flowed directly to the members.

Net Loss Per Share

The Company determines basic net loss per share and diluted net loss per share in accordance with the provisions of ASC 260, "Earnings per Share." Basic net loss per share was calculated by dividing net loss by the weighted-average common shares outstanding during the period. Diluted net loss per share was calculated by dividing net loss by the weighted-average common shares outstanding during the period using the treasury stock method or the two-class method, whichever is more dilutive. The potentially dilutive stock options issued under the 2015 Stock Plan (described in Note 8), Series A, Series B and Series C Convertible Preferred Stock (described in Note 6) and warrants on the Company's common stock (described in Notes 6 and 7) were not considered in the computation of diluted net loss per share because they would be anti-dilutive.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company is required to record all components of comprehensive loss in the financial statements in the period in which they are recognized. Net income (loss) and other comprehensive loss, including foreign currency translation adjustments and unrealized gains and losses on investments are reported, net of their related tax effect, to arrive at a comprehensive loss. For the years ended December 31, 2018 and 2017, comprehensive loss comprised of unrealized losses on investments in available-for-sale debt securities and held-to-maturity debt securities.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)*. Under this guidance, an entity is required to recognize ROU assets and corresponding lease liabilities on its balance sheets and disclose key information about leasing arrangements. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842) Targeted Improvements*, which provides for an alternative transition method by allowing companies to continue to use the legacy guidance in Topic 840, Leases, including its disclosure requirements, in the comparative periods presented in the year of adoption of the new leases standard and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption rather than the earliest period presented.

The Company will elect the available package of practical expedients, but not the hindsight practical expedient, and implemented internal controls to enable the preparation of financial information on adoption as of January 1, 2019.

The standard will have a material impact on the Company's balance sheets but will not have an impact on its statements of operations. The most significant impact will be the recognition of a ROU asset and lease liability for the Company's sole operating lease—the Company has no finance leases. Adoption of the standard will not require the Company to restate previously reported results as it will elect to apply a modified retrospective approach at the beginning of the period of adoption rather than at the beginning of the earliest comparative period presented.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"), an amendment which modifies the measurement recognition of credit losses for most financial assets and certain other instruments. The amendment updates the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the "incurred loss" model with an "expected loss" model. Accordingly, these financial assets will be presented at the net amount expected to be collected. The amendment also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. The guidance is effective for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. Early adoption is permitted for annual periods after December 15, 2018. The Company does not expect the adoption of this guidance will have a material impact on its financial statements.

In February 2018, the FASB issued ASU No. 2018-02, Income Statement—Reporting Comprehensive Income (Topic 220), which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the passing of H.R. 1/Public Law No. 115-97, commonly known as the Tax Cuts and Jobs Act (the "Act") and requires certain disclosures about stranded tax effects. The amendments in ASU No. 2018-02 are effective beginning in 2019, with early adoption permitted, and may be applied either in the period of adoption or retrospectively to each period in which the effect of the change in the U.S. Federal corporate tax rate in the Act is recognized. The Company does not expect the adoption of this guidance will have an impact on its financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of Topic 718 *Compensation—Stock Compensation*, to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. ASU No. 2018-07 supersedes Subtopic 505-50 *Equity—Equity-Based Payments to Non-Employees*. The amendments in ASU No. 2018-07 are effective for the Company beginning in 2020, with early adoption permitted, but no earlier than a company's adoption date of Topic 606 *Revenue from Contracts with Customers*. The Company is currently assessing the impact and timing of adopting this guidance on its financial statements.

In August 2018, the FASB issued ASU No. 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement", an amendment to the accounting guidance on fair value measurements. The guidance modifies the disclosure requirements on fair value measurements, including the removal of disclosures of the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, the policy for timing of transfers between levels, and the valuation processes for Level 3 fair value measurements. The guidance also adds certain disclosure requirements related to Level 3 fair value measurements. The guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The Company does not expect the adoption of this guidance will have a material impact on its financial statements.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheets must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective on November 5, 2018. However, as provided for by the SEC in Q&A 105.09, the Company will defer presenting its analysis of stockholders' equity in its quarterly report in Form 10-Q until its quarter ended March 31, 2019. The Company does not expect the adoption of SEC Release No. 33-10532 to have a material impact on its financial position, results of operations or cash flows.

Recently Adopted Accounting Pronouncements

In January 2016, the FASB issued ASU No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-01"). The amendments in ASU 2016-01 address certain aspects of recognition, measurement, presentation and disclosure of financial instruments. The Company adopted ASU 2016-01 in the first quarter of 2018. The adoption of this new standard did not have a material impact on the Company's financial statements.

On August 26, 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230),* a consensus of the FASB's Emerging Issues Task Force ("ASU 2016-15"). The new guidance amends Accounting Standards Codification No. 230 ("ASC 230") to add or clarify guidance on the classification of certain cash receipts and payments in the statement of cash flows. ASC 230 lacks consistent principles for evaluating the classification of cash payments and receipts in the statement of cash flows. This has led to diversity in practice and, in certain circumstances, financial statement restatements. Therefore, the FASB issued ASU 2016-15 with the intent of reducing diversity in practice with respect to eight types of cash flows. ASU 2016-15 is effective for annual and interim periods in fiscal years beginning after December 15, 2017 and is effective for the Company for the year ending December 31, 2018. The Company adopted ASU 2016-15 on January 1, 2018 and it did not have a material impact on the Company's financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception.* The ASU allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be accounted classified as liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, such as warrants, an entity will treat the value of the effect of the down round, when triggered, as a dividend and a reduction of income available to common stockholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. The guidance in ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted, and the guidance is to be applied using a full or modified retrospective approach. The Company adopted this guidance in the current quarter, effective October 1, 2017. As a result, the warrants issued on October 3, in connection with the October 2017 Public Offering, were equity-classified.

In January 2017, the FASB issued ASU No. 2017-04 "*Intangibles – Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment*," or ASU 2017-04. ASU 2017-04 allows companies to apply a one-step quantitative test and record the amount of goodwill impairment as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The amendments of the ASU are effective for annual or interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company adopted this guidance as of October 1, 2018 and there was no impact on its financial statements.

In May 2017, the FASB issued ASU No. 2017-09, "*Stock Compensation – Scope of Modification Accounting"* or ASU 2017-09. ASU 2017-09 provides guidance on which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The new standard was effective for fiscal years beginning after December 15, 2017. The Company adopted the guidance effective January 1, 2018. There was no impact upon adoption.

In March 2018, the FASB issued ASU No. 2018-05, *Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118*, which amended various SEC paragraphs pursuant to the issuance of SEC Staff Accounting Bulletin No. 118 ("SAB 118"). SAB 118 was issued by the SEC in December 2017 to provide immediate guidance for accounting implications of U.S. tax reform under the Act, which became effective for the Company on January 1, 2018. The Company has evaluated the potential impacts of SAB 118 and has applied this guidance to its financial statements and related disclosures in 2018. For additional information on SAB 118 and the impacts of the Act on the Company's condensed financial statements and related disclosures, see *Note 7. Income Taxes* in the notes to the financial statements.

NOTE 4 — PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	Estimated Life	December 31, 2018	December 31, 2017
Computer equipment	5 years	$ 15,589	$ 13,582
Furniture and fixtures	7 years	19,158	19,158
Total property and equipment		34,747	32,740
Accumulated depreciation		(14,587)	(8,867)
Property and equipment, net		$ 20,160	$ 23,873

Depreciation expense of approximately $5,700 was recognized for each of the years ended December 31, 2018 and 2017, and is classified in general and administrative expense in the accompanying Statements of Operations.

NOTE 5 — COMMITMENTS AND CONTINGENCIES

Master Services Agreement

In May 2018, the Company entered into an Amended and Restated Master Services Agreement ("Service Agreement") with a clinical research organization ("CRO"), pursuant to which the CRO will perform certain services related to the management and execution of certain clinical trials involving the Company's lead product candidate, RP-G28. The Services Agreement supersedes the Master Service Agreement, dated August 30, 2016, by and between the Company and the CRO. The precise services to be performed by the CRO under the Services Agreement will be mutually agreed upon by the parties in writing and set forth in one or more task orders. The Company is not obligated to purchase any minimum or specific volume or dollar amount of services under the Services Agreement.

The term of the Services Agreement is four years from the effective date of the Service Agreement unless earlier terminated. The Company may terminate the Services Agreement or any task without cause immediately upon giving the CRO notice of such termination. The CRO may terminate a task order if the Company has materially defaulted on its obligations under the Services Agreement or any task order and has not cured such material default with advance notice to the Company, as described in the Services Agreement.

Lease Agreement

In July 2015, the Company entered into a lease with Century Park, a California limited partnership, pursuant to which we are leasing approximately 2,780 square feet of office space in Los Angeles, California for our headquarters. The lease provides for a term of sixty-one (61) months, commencing on October 1, 2015. We paid no rent for the first month of the term and will pay base rent of $9,174 per month for months 2 through 13 of the term, with increasing base rent for each twelve-month period thereafter under the term of the lease to a maximum of $10,325 per month for months 50 through 61. The base rent payments do not include our proportionate share of any operating expenses, including real estate taxes. We have the option to extend the term of the lease for one five-year term, provided that the rent would be subject to market adjustment at the beginning of the renewal term. We will recognize rent expense on a straight-line basis over the lease term.

Rent expense, recognized on a straight-line basis, was approximately $118,000 and $115,000 for the years ended December 31, 2018 and 2017, respectively, and is recorded in general and administrative expenses in the accompanying statements of operations.

The following table summarizes our lease obligations at December 31, 2018:

	LEASE COMMITMENTS
Years ended December 31,	**Operating Lease**
2019	$ 120,898
2020	103,254
Total minimum lease payments	$ 224,152

Legal

From time to time, we are party to legal claims and proceedings that arise in the ordinary course of business, which may relate to our operations or assets. These may include disputes and lawsuits related to intellectual property, licensing, contract law and employee relations matters. Periodically, the Company reviews the status of significant matters, if any exist, and assesses its potential financial exposure. If the potential loss from any claim or legal claim is considered probable and the amount can be estimated, the Company accrues a liability for the estimated loss. Legal proceedings are subject to uncertainties, and the outcomes are difficult to predict. Because of such uncertainties, accruals are based on the best information available at the time. As additional information becomes available, the Company reassesses the potential liability related to pending claims and litigation. We do not believe that any individual legal claim or proceeding that is currently pending is material to the Company or that these claims and proceedings in the aggregate are material to the Company.

NOTE 6— STOCKHOLDERS' EQUITY

Authorized Shares

In September 2017, the Company amended its Amended and Restated Certificate of Incorporation to authorize the issuance of up to 225,000,000 shares of common stock, $0.001 par value per share, and 15,000,000 shares of preferred stock, $0.001 par value per share.

All common share amounts and per share amounts were retroactively restated to reflect a 1-for-10 reverse stock split that was effective March 23, 2018.

As of December 31, 2018, the Company had 6,036,562 shares of common stock, 4,080 shares of Series A convertible preferred stock, 5,608 shares of Series B convertible preferred stock and 1,880 shares of Series C convertible preferred stock issued and outstanding. Each share of the Company's common stock is entitled to one vote, and all shares rank equally as to voting and other matters. Each share of Series A preferred stock is convertible by the holder at $4.00 per share; subject to adjustment for stock splits, stock dividends, subsequent rights offerings, pro rata distributions, and fundamental transactions. Each share of Series B preferred stock is convertible by the holder at $1.30 per share; subject to customary adjustment in the event of future stock dividends and stock splits. Each share of Series C preferred stock is convertible by the holder at $1.64 per share; subject to customary adjustment in the event of future stock dividends and stock splits. Holders are entitled to receive, and the Company shall pay, dividends on outstanding shares of Series A preferred stock, on an as-if-converted-to-common-stock basis, equal to and in the same form as dividends actually paid on outstanding common shares when, as and if such dividends are paid on outstanding common shares. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders of Series A, Series B and Series C preferred stock shall be entitled to receive out of the assets, whether capital or surplus, of the Company the same amount that a holder of common stock would receive if the Series A, Series B and Series C preferred stock were fully converted to common stock, which amounts shall be paid pari passu with all common stockholders. Holders of Series A, Series B and Series C preferred stock have no voting rights. However, as long as any shares of Series A, Series B and Series C preferred stock are outstanding, the Company shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of Series A, Series B and Series C preferred stock, (a) alter or change adversely the powers, preferences or rights given to the Series A, Series B and Series C preferred stock or alter or amend the applicable Certificate of Designation, (b) amend the Company's certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series A, Series B and Series C preferred stock, (c) increase the number of authorized shares of Series A, Series B and Series C preferred stock, or (d) enter into any agreement with respect to any of the foregoing.

Aspire Capital Common Stock Purchase Agreement

On May 4, 2017, the Company entered into a common stock purchase agreement with Aspire Capital Fund, LLC ("Aspire Capital"), which the Company and Aspire amended and restated on March 29, 2019 (as amended and restated, the "Aspire Purchase Agreement"). The Aspire Purchase Agreement was amended and restated to adjust certain provisions to improve the Company's access to funding under the agreement. The Company was not required to pay a commitment fee to Aspire Capital to affect the amendment to the Aspire Purchase Agreement. The Company has not made any sales to Aspire under the Aspire Purchase Agreement as of March 29, 2019. The Aspire Purchase Agreement provides access to the Company of up to an aggregate of $6.5 million in proceeds through the sale of shares of its common stock through March 31, 2021.

Under the Aspire Purchase Agreement, as amended, on any trading day the Company selects,it has the right, in its sole discretion, to present Aspire Capital with a purchase notice (each, a "Purchase Notice"), directing Aspire Capital (as principal) to purchase up to 100,000 shares of its common stock per trading day (which could be increased by as much as an additional 2,000,000 shares per trading day by mutual agreement), up to an aggregate of $6,500,000 of its common stock, at a per share price (the "Purchase Price") equal to the lesser of: (i) the lowest sale price of the Company's common stock on the sale date, or (ii) the arithmetic average of the three lowest closing sale prices for the Company's common stock during the ten (10) consecutive trading days ending on the trading day immediately preceding the sale date. The aggregate purchase price payable by Aspire Capital on any one purchase date cannot exceed $500,000, unless otherwise mutually agreed. In addition, on any date on which the Company submits a Purchase Notice to Aspire Capital in an amount of at least 100,000 shares and its stock price is not less than $0.25 per share, the Company can also, in its sole discretion, present Aspire Capital with a volume-weighted average price purchase notice (each, a "VWAP Purchase Notice") directing Aspire Capital to purchase an amount of its common stock equal to up to 30% of the aggregate shares of the Company's common stock traded on its principal market on the next trading day (the "VWAP Purchase Date"), as determined by the Company. Under the terms of the Aspire Purchase Agreement, the number of shares that can be sold pursuant to Aspire Capital is limited to 1,807,562 (the "Exchange Cap"), which represented 19.99% of the Company's outstanding shares of common stock as of March 29, 2019, the date the agreement was amended and restated, unless stockholder approval or an exception pursuant to the rules of the NASDAQ Capital Market was obtained to issue more than 19.99%. This limitation would not apply if, at any time the Exchange Cap was reached and at all times thereafter, the average price paid for all shares issued under the Aspire Purchase Agreement was equal to or greater than $0.86 (the "Minimum Price"), which was the closing price of eth Company's common stock immediately preceding the signing of the agreement. As of March 29, 2019, no shares of common stock have been sold or issued to Aspire Capital under the Aspire Purchase Agreement since May 5, 2017.

October 2017 Public Offering

On October 3, 2017, the Company closed a public offering, selling an aggregate of (i) 3,455,000 Class A Units consisting of 3,455,000 shares of the Company's common stock and warrants to purchase 3,455,000 shares of the Company's common stock at a public offering price of $4.00 per unit, and (ii) 9,180 Class B Units consisting of 9,180 shares of Series A convertible preferred stock, with a stated value of $1,000 per unit, and convertible into an aggregate of 2,295,000 shares of the Company's common stock, and warrants to purchase an aggregate of 2,295,000 shares of the Company's common stock. The securities were offered by the Company pursuant to a registration statement filed with the SEC that was declared effective on September 28, 2017. The final prospectus relating to the offering was filed with the SEC on October 2, 2017.

The warrants initially had an exercise price of $4.40, were exercisable upon issuance and expire five years from the date of issuance. The warrant agreements provide for an adjustment to the number of common shares issuable under the warrants and/or adjustment to the exercise price, including but not limited to, if: (a) the Company issues shares of common stock as a dividend or distribution to holders of its common stock; (b) the Company subdivides or combines its common stock; or (c) the Company issues new securities at a price less than the exercise price of the warrants. In November 2018, the Company closed a private placement ("PIPE financing") at a price per share below the exercise price of the warrants resulting in an adjustment of their exercise price from $4.40 to $1.30. In accordance with ASC 2017-11, the Company treated the value of the effect of this down round as a deemed dividend of $1.6 million recognized on the closing date and recorded as a reduction of income available to common stockholders in computing basic and diluted loss per share.

The Company granted the underwriters a 45-day option to purchase an additional 862,500 shares of the Company's common stock and/or warrants to purchase an additional 862,500 shares of the Company's common stock. At the closing of the offering, the underwriters exercised their over-allotment option for warrants to purchase 297,500 shares of the Company's common stock.

Aggregate gross proceeds to the Company from the public offering were approximately $23.0 million. The Company paid underwriting discounts and commissions of approximately $1.6 million in connection with the offering, and approximately $0.4 million of other expenses in connection with the offering.

The Company early adopted the provisions of ASU 2017-11 in recognizing the warrants. As a result, the exercise price reset provisions were excluded from the assessment of whether the warrants are considered indexed to the Company's own stock. The warrants otherwise meet the requirements for equity classification, and as such were initially classified in Stockholders' Equity. The Company will recognize the value of the exercise price reset provision if and when it becomes triggered, by recognizing the value of the effect of the exercise price reset as a deemed dividend and a reduction of income available to common stockholders in computing basic earnings per share.

The proceeds received in the October 2017 Public Offering were allocated to each instrument on a relative fair value basis. Total proceeds of $23.0 million were allocated as follows: $10.1 million to warrants issued, $7.8 million to Common Stock, and $5.1 million to Series A convertible preferred stock. The allocation resulted in an effective conversion price for the Series A preferred stock that was below the quoted market price of the Company's common stock on the closing date. As such, the Company recognized a beneficial conversion feature equal to the intrinsic value of the conversion feature on the closing date, resulting in a deemed dividend for the Series A convertible preferred stock of approximately $3.1 million recognized on the closing date.

In the nine-month period ended September 30, 2018, holders of 3,180 shares of Series A convertible preferred stock converted their shares of preferred stock into an aggregate of 795,000 shares of common stock at the stated conversion price of $4.00 per share

November 2018 Private Placement Financing

On November 5, 2018, the Company closed a PIPE financing with certain institutional investors, a key vendor and a member of its board of directors. Net proceeds from the PIPE financing were approximately $5.5 million, after deducting placement agent fees and other offering expenses. The securities sold by the Company consisted of 6,000 shares of a newly designated class of Series B convertible preferred stock of the Company, with a stated value of $1,000 per share and an initial conversion price per share of $1.30 (subject to customary adjustment for stock dividends and stock splits) and warrants to purchase an aggregate of 2,307,685 shares of the Company's common stock. Each investor received a warrant to purchase a number of shares of common stock equal to one half the number of shares of common stock into which their Series B convertible preferred stock is initially convertible. The warrants are exercisable immediately for a five-year period and have an exercise price of $1.30 per share (subject to customary adjustment for stock dividends and stock splits but without the down-round protective provisions of previously issued warrants). The proceeds received in the PIPE financing were allocated to each instrument on a relative fair value basis. Total proceeds of $6.0 million were allocated as follows: $1.4 million to warrants issued and $4.6 million to Series B convertible preferred stock. The allocation resulted in an effective conversion price for the Series B preferred stock that was below the quoted market price of the Company's common stock on the closing date. As such, the issuance was considered a beneficial conversion feature equal to the intrinsic value of the conversion feature on the closing date, resulting in a deemed dividend for the Series B convertible preferred stock of approximately $0.7 million, recognized on the closing date and recorded as a reduction of income available to common stockholders in computing basic and diluted loss per share.

Certain investors in the PIPE financing who at the time of closing of the PIPE financing owned shares of the Company's Series A convertible preferred stock, exchanged, on a 1 for 1 share basis, their shares of Series A convertible preferred stock for shares of a newly designated class of Series C convertible preferred stock of the Company, with a stated value of $1,000 per share and convertible into shares of the Company's common stock at an initial conversion price per share of $1.64 (subject to customary adjustment for stock dividends and stock splits), ("the Exchange"). As the Series A convertible preferred stock contained a beneficial conversion feature, the Exchange was considered an extinguishment equal to the excess of (a) the fair value of the consideration transferred to the holders of the Series A convertible preferred stock over (b) the carrying amount of the Series A convertible preferred stock on the Company's balance sheet plus (c) the amount previously recognized for the beneficial conversion feature, or approximately $0.2 million, which was recognized on the closing date and recorded as a reduction of income available to common stockholders in computing basic and diluted loss per share.

NOTE 7 — WARRANTS

Warrants to purchase an aggregate of 8,413,017 shares of the Company's common stock were outstanding at December 31, 2018. These warrants are all vested and exercisable, have exercise prices ranging from $1.30 to $93.00 per share, with a weighted average exercise price of $1.78, and expire at various dates through November 2023.

NOTE 8 — STOCK-BASED COMPENSATION

Equity Incentive Plans

The Company has issued equity awards pursuant to its 2015 Equity Incentive Plan (the "2015 Plan"), 2009 Stock Plan and 2008 Stock Plan (collectively the "Plans"). The Plans permit the Company to grant non-statutory stock options, incentive stock options and other equity awards to the Company's employees, outside directors and consultants; however, incentive stock options may only be granted to the Company's employees. Beginning June 29, 2015, no further awards may be granted under the 2009 Stock Plan or 2008 Stock Plan. However, to the extent awards under the 2008 Plan or 2009 Plan are forfeited or lapse unexercised or are settled in cash, the common stock subject to such awards will be available for future issuance under the 2015 Plan.

In June 2017, the stockholders of the Company approved an amendment to the 2015 Plan at the 2017 annual meeting of stockholders, which among other things, increased the number of shares that may be issued pursuant to awards under the 2015 Plan by 83,800 shares of common stock.

In September 2017, the stockholders of the Company approved an amendment to the 2015 Plan at a special meeting of stockholders, which among other things, increased the number of shares that may be issued pursuant to awards under the 2015 Plan by 2,585,871 shares of common stock. As of December 31, 2018, the aggregate number of shares of common stock authorized for issuance under the 2015 Plan, as amended, was 2,750,000, and 2,263,374 shares were available for issuance as of December 31, 2018.

The following represents a summary of the options granted to employees and non-employees that are outstanding at December 31, 2018 and changes during the period then ended:

	Number of Shares	Weighted- Average Exercise Price	Aggregate Intrinsic Value	Weighted- Average Remaining Contractual Life (in years)
Outstanding at December 31, 2017	254,171	$ 47.43	$ —	7.3
Options granted	456,718	3.16	—	8.6
Options forfeited	(37,004)	3.90	—	—
Outstanding at December 31, 2018	673,885	19.82	—	8.2
Exercisable at December 31, 2018	290,818	$ 50.19	$ —	6.9

The exercise price for an option issued under the Plans is determined by the Board of Directors, but will be (i) in the case of an incentive stock option (A) granted to an employee who, at the time of grant of such option, is a 10% stockholder, no less than 110% of the fair market value per share on the date of grant; or (B) granted to any other employee, no less than 100% of the fair market value per share on the date of grant; and (ii) in the case of a non-statutory stock option, no less than 100% of the fair market value per share on the date of grant. The options awarded under the Plans will vest as determined by the Board of Directors but will not exceed a ten-year period. The weighted average grant date fair value per share of options granted during the year ended December 31, 2018 was $0.90.

Fair Value of Equity Awards

The Company utilizes the Black-Scholes option pricing model to value awards under its Plans. Key valuation assumptions include:

- *Expected dividend yield.* The expected dividend is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on the Company's common stock.

- *Expected stock-price volatility.* As the Company's common stock only recently became publicly traded, the expected volatility is derived from the average historical volatilities of publicly traded companies within the Company's industry that the Company considers to be comparable to the Company's business over a period approximately equal to the expected term.

- *Risk-free interest rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities approximately equal to the expected term.

- *Expected term*. The expected term represents the period that the stock-based awards are expected to be outstanding. The Company's historical share option exercise experience does not provide a reasonable basis upon which to estimate an expected term because of a lack of sufficient data. Therefore, the Company estimates the expected term by using the simplified method provided by the SEC. The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of the options.

The material factors incorporated in the Black-Scholes model in estimating the fair value of the options granted for the periods presented were as follows (adjusted for 1-for-10 reverse stock split):

	For the year ended December 31,	
	2018	**2017**
Expected dividend yield	0.00%	0.00%
Expected stock-price volatility	46.47% - 53.11%	53.08% - 54.08%
Risk-free interest rate	2.46% - 3.07%	1.89% - 2.58%
Term of options	5 - 10	10
Stock price	$ 1.85 - $3.40	$ 0.30 - $3.48

Stock-Based Compensation

The Company recognized stock-based compensation expense for services within general and administrative expense in the accompanying statements of operations of approximately $646,000 and $895,000 for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, there was approximately $469,000 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. This cost is expected to be recognized over a weighted average period of 1.6 years.

No stock options were exercised during the year ended December 31, 2018 and 2017.

NOTE 10 — RELATED PARTY TRANSACTIONS

A director of the Company is a managing director of Javelin Venture Partners GP, LLC, the general partner of Javelin Venture Partners GP, L.P., which holds a significant investment in the Company's common stock and warrants. Two directors of the Company have acted as a managing director of Stonehenge Partners, LLC, which holds significant investment in the Company's common stock.

Other than disclosed, the Company has not entered into or been a participant in any transaction in which a related party had or will have a direct or indirect material interest.

NOTE 11 — INCOME TAXES

As of December 31, 2018, the Company has net operating loss carryforwards of approximately $54 million available to reduce future taxable income, if any, for Federal and state income tax purposes. The U.S. federal and state net operating loss carryforwards will begin to expire in 2028.

As of December 31, 2018, the Company has Federal and state research and development credit carryforwards of approximately $2.8 million and $2.3 million, respectively, available to reduce future taxable income, if any, for Federal and state income tax purposes. The Federal credit carryforwards begin to expire in 2029. California credits have no expiration date.

Under the Internal Revenue Code ("IRC") Sections 382 and 383, annual use of the Company's net operating loss and research tax credit carryforwards to offset taxable income may be limited based on cumulative changes in ownership. The Company has not completed an analysis to determine whether any such limitations have been triggered as of December 31, 2018. The Company has no income tax affect due to the recognition of a full valuation allowance on the expected tax benefits of future loss carry forwards based on uncertainty surrounding realization of such assets.

A reconciliation of the statutory income tax rates and the Company's effective tax rate is as follows:

	December 31,	
	2018	2017
Statutory U.S. federal rate	21.0%	34.0%
State income tax, net of federal benefit	7.0%	5.8%
Meals & entertainment	(0.1)%	(0.2)%
Valuation allowance	(27.96)%	(39.76)%
Provision for income taxes	0.0%	0.0%

The tax effects of the temporary differences and carry forwards that give rise to deferred tax assets consist of the following:

	As of December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carry forwards	$ 15,108,073	$ 10,853,800
Patent costs	382,812	325,615
Accrued Vacation	11,516	21,019
Research and development credit	4,314,813	3,047,985
Stock-based compensation	1,903,104	1,722,380
Other	8,495	6,894
Gross deferred tax assets	21,728,813	15,977,693
Valuation allowance	(21,728,813)	(15,977,693)
Net deferred tax assets	$ —	$ —

The Company did not record any accruals for income tax accounting uncertainties for the years ended December 31, 2018 and 201'.'

Authoritative guidance requires companies to accrue interest and related penalties, if applicable, on all tax positions for which reserves have been established consistent with jurisdictional tax laws. The Company's policy is to recognize interest and penalties that would be assessed in relation to the settlement value of unrecognized tax benefits as a component of income tax expense. The Company did not accrue either interest or penalties from inception through December 31, 2018.

The Company does not have any unrecognized tax benefits that will significantly decrease or increase within 12 months of December 31, 2018.

The Company's major tax jurisdictions are the United States and California. All of the Company's tax years will remain open three and four years for examination by the Federal and state tax authorities, respectively, from the date of utilization of the net operating loss. The Company does not have any tax audits pending.

Regarding 2018 federal tax reform, the Company re-measured certain deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%. For certain deferred tax assets, the Company has recorded a decrease of approximately $5.5 million, with a corresponding adjustment to valuation allowance for the year ended December 31, 2018. There is no impact on the tax expense.

NOTE 12 — SUBSEQUENT EVENT

On May 4, 2017, the Company entered into a common stock purchase agreement with Aspire Capital, which the Company and Aspire amended and restated on March 29, 2019 (as amended and restated, the "Aspire Purchase Agreement"). The Aspire Purchase Agreement was amended and restated to adjust certain provisions to improve the Company's access to funding under the agreement (see footnote 6).

Exhibit 10.10

RITTER PHARMACEUTICALS, INC.
2015 EQUITY INCENTIVE PLAN

NOTICE OF GRANT OF RESTRICTED STOCK UNITS
PERFORMANCE AWARD

The Grantee has been granted the number of Restricted Stock Units set forth below (the *"**RSUs**"*) pursuant to the Ritter Pharmaceuticals, Inc. 2015 Equity Incentive Plan (the *"**Plan**"*), as follows:

Grantee: _____

Date of Grant: _____

Maximum Number of Restricted Stock Units: _____

Vested Shares: Subject to your continued status as a service provider through each of the applicable vesting dates, the RSUs shall become vested, in whole or in part, in accordance with the terms of the Plan, the Restricted Stock Unit Agreement, this Notice of Grant and schedule set forth on Exhibit A to this Notice of Grant.

Capitalized terms not defined herein shall have the meaning as set forth in the Plan.

By signing below, the Grantee agrees that the Company, its directors, officers and shareholders shall not be held liable for any tax, penalty, interest or cost incurred by the Grantee as a result of such determination by the IRS. The Grantee is urged to consult with his or her own tax advisor regarding the tax consequences of the RSUs, including the application of Section 409A of the Code.

By their signatures below, the Company and the Grantee agree that the RSUs are governed by this Notice of Grant and by the provisions of the Plan and the Restricted Stock Unit Agreement, both of which are made a part of this document. The Grantee acknowledges receipt of copies of the Plan and the Restricted Stock Unit Agreement, represents that the Grantee has read and is familiar with their provisions, and hereby accepts the RSUs subject to all of their terms and conditions.

RITTER PHARMACEUTICALS, INC.	GRANTEE
By: _____	_____
	Signature
Its: _____	_____
	Date
	_____
	Address
	_____

ATTACHMENTS: Restricted Stock Unit Agreement

EXHIBIT A

Performance Criteria for Vesting of RSUs

Performance Goal and Performance Period	Number of RSUs Subject to Performance Goal (Target RSUs)	Maximum Number of RSUs to be Issued if Performance Goals are Achieved by Dates Set Forth Herein

Vesting Conditions:

RITTER PHARMACEUTICALS, INC.
2015 EQUITY INCENTIVE PLAN

RESTRICTED STOCK UNIT AGREEMENT
PERFORMANCE AWARD

Ritter Pharmaceuticals, Inc. has granted to the Grantee named in the *Notice of Grant of Restricted Stock Units* (the "***Notice of Grant***") to which this Restricted Stock Unit Agreement (the "***Award Agreement***") is attached a number of Restricted Stock Units (the "***RSUs***") pursuant to the terms and conditions set forth in the Notice of Grant and this Award Agreement. The RSUs have been granted pursuant to and shall in all respects be subject to the terms and conditions of the Ritter Pharmaceuticals, Inc. 2015 Equity Incentive Plan (the "***Plan***"), as amended to the Date of Grant, the provisions of which are incorporated herein by reference. By signing the Notice of Grant, the Grantee: (a) acknowledges receipt of, and represents that the Grantee has read and is familiar with the terms and conditions of, the Notice of Grant, this Award Agreement and the Plan, (b) accepts the RSUs subject to all of the terms and conditions of the Notice of Grant, this Award Agreement and the Plan, and (c) agrees to accept as binding, conclusive and final all decisions or interpretations of the Board or the Administrator upon any questions arising under the Notice of Grant, this Award Agreement or the Plan.

1. **Definitions and Construction.**

1.1 ***Definitions.*** Unless otherwise defined herein, capitalized terms shall have the meanings assigned to such terms in the Notice of Grant or the Plan.

1.2 ***Construction.*** Captions and titles contained herein are for convenience only and shall not affect the meaning or interpretation of any provision of this Award Agreement. Except when otherwise indicated by the context, the singular shall include the plural and the plural shall include the singular. Use of the term "or" is not intended to be exclusive, unless the context clearly requires otherwise.

2. **Administration.**

All questions of interpretation concerning the Notice of Grant, this Award Agreement, the Plan or any other form of agreement or other document employed by the Company in the administration of the Plan or the RSUs shall be determined by the Board or the Administrator. All such determinations by the Board or the Administrator shall be final, binding and conclusive upon all persons having an interest in the RSUs, unless fraudulent or made in bad faith. Any and all actions, decisions and determinations taken or made by the Board or the Administrator in the exercise of its discretion pursuant to the Plan or the RSUs or other agreement thereunder (other than determining questions of interpretation pursuant to the preceding sentence) shall be final, binding and conclusive upon all persons having an interest in the RSUs.

3. **Vesting.**

Subject to the limitations contained herein, the RSUs shall vest as provided in the Notice of Grant, provided that vesting shall cease upon the Grantee's Termination of Service. Any RSUs that have not vested shall be forfeited upon Grantee's Termination of Service.

4. **Dividends.**

The Grantee shall not receive any payment or other adjustment in the number of RSUs for dividends or other distributions that may be made in respect of the Shares to which the RSUs relate.

5. **Distribution of Shares.**

The Company will deliver to the Grantee a number of Shares equal to the number of vested Shares subject to the RSUs on the vesting date or dates provided in the Notice of Grant; *provided, however*, that the Shares subject to the RSUs that vest on or prior to the execution of the Notice of Grant shall be delivered as soon as practicable following the date of execution of the Notice of Grant; and *provided further, however*, that in the event that the Company determines that the Grantee is subject to its policy regarding insider trading of the Company's Shares, where the Shares are scheduled to be delivered on a day (the "***Original Distribution Date***") that does not occur during an applicable "window period," as determined by the Company in accordance with such policy, then such Shares shall not be delivered on such Original Distribution Date and shall instead be delivered as soon as practicable within the next applicable "window period" pursuant to such policy.

6. **Number of Shares.**

The number of RSUs may be adjusted from time to time for capitalization adjustments, as provided in Section 13.2 of the Plan.

7. **Securities Law Compliance.**

The Grantee may not be issued any Shares pursuant to the RSUs unless the Shares are either (i) then registered under the Securities Act or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. The RSUs must also comply with other applicable laws and regulations governing the RSUs, and the Grantee shall not receive such Shares if the Company determines that such receipt would not be in material compliance with such laws and regulations.

8. **Unsecured Obligation.**

The RSUs are unfunded, and as a holder of vested RSUs, the Grantee shall be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue Shares pursuant to Section 5 of this Award Agreement.

9. **Tax Withholding.**

9.1 ***In General.*** At the time this Award Agreement is executed, or at any time thereafter as requested by the Company, the Grantee hereby authorizes withholding from payroll and any other amounts payable to the Grantee, and otherwise agrees to make adequate provision for, any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company, if any, which arise in connection with the grant or vesting of the RSUs or the issuance of Shares in settlement thereof. The Company shall have no obligation to deliver Shares until the tax obligations of the Company have been satisfied by the Grantee.

9.2 ***Withholding in Securities.*** The Company may, in its discretion, permit or require the Grantee to satisfy all or any portion of the tax obligations by deducting from the Shares otherwise deliverable to the Grantee in settlement of the RSUs a number of Shares having a fair market value, as determined by the Company as of the date on which the tax obligations arise, not in excess of the amount of such tax obligations determined by the applicable withholding rates. In the event that the Company determines that the tax obligations will not be satisfied by the method described above, the Grantee authorizes the designated plan administrator or any successor plan administrator, to sell a number of Shares otherwise deliverable to the Grantee in settlement of the RSUs, which the Company determines is sufficient to generate an amount that meets the tax obligations plus additional Shares, as necessary to account for rounding and market fluctuation, and to pay such tax withholding amounts to the Company. The Shares may be sold as part of a block trade with Shares from other Grantees under the Plan for which all Grantees receive an average price. Any adverse consequences to the Grantee resulting from the procedure permitted under this Section 9.2, including, without limitation, tax consequences, shall be the sole responsibility of the Grantee.

9.3 ***Consultation*****.** The Grantee hereby acknowledges that he or she understands that the Grantee may suffer adverse tax consequences as a result of participation in the Plan. The Grantee hereby represents that the Grantee has consulted with tax advisors in connection with the Award and that the Grantee is not relying on the Company for any tax advice.

10. **Nontransferability of the RSUs.**

The RSUs and the rights and privileges conferred hereby shall not be subject in any manner to anticipation, alienation, sale, exchange, transfer, assignment, pledge, encumbrance, or garnishment by creditors of the Grantee or the Grantee's beneficiary, except transfer by will or by the laws of descent and distribution. The terms of the Plan and the Award Agreement shall be binding upon the executors, administrators, heirs, successors and assigns of the Grantee.

11. **Rights as a Shareholder, Director, Employee or Advisor.**

The Grantee shall have no rights as a shareholder with respect to any Shares covered by the RSUs until the date of the issuance of the Shares (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). No adjustment shall be made for dividends, distributions or other rights for which the record date is prior to the date the Shares are issued, except as provided in the Plan. If the Grantee is an Employee, the Grantee understands and acknowledges that, except as otherwise provided in a separate, written employment agreement between the Company Group and the Grantee, the Grantee's employment is "at will" and is for no specified term. Nothing in this Award Agreement shall confer upon the Grantee any right to continue in the service of the Company or Company Group or interfere in any way with any right of the Company or Company Group to terminate the Grantee's service as a Director, an Employee or Advisor, as the case may be, at any time. Furthermore, RSUs are not part of Grantee's employment contract (if any) with the Company or Company Group, Grantee's salary, Grantee's normal or expected compensation, or other remuneration for any purposes, including for purposes of computing severance pay or other termination compensation or indemnity.

12. **Miscellaneous Provisions.**

12.1 ***Termination or Amendment.*** The Board or the Administrator may terminate or amend the Plan or the RSUs at any time; provided, however, that except as provided in the Plan in connection with a Change in Control, no such termination or amendment may adversely affect the RSUs without the consent of the Grantee unless such termination or amendment is necessary to comply with any applicable law or government regulation, including, but not limited to Section 409A of the Code. No amendment or addition to this Award Agreement shall be effective unless in writing.

12.2 ***Compliance with Section 409A.*** The Company intends that income realized by the Grantee pursuant to the Plan and this Award Agreement will not be subject to taxation under Section 409A of the Code. The provisions of the Plan and this Award Agreement shall be interpreted and construed in favor of satisfying any applicable requirements of Section 409A of the Code. The Company, in its reasonable discretion, may amend (including retroactively) the Plan and this Award Agreement in order to conform to the applicable requirements of Section 409A of the Code, including amendments to facilitate the Grantee's ability to avoid taxation under Section 409A of the Code. However, the preceding provisions shall not be construed as a guarantee by the Company of any particular tax result for income realized by the Grantee pursuant to the Plan or this Award Agreement. In any event, and except for the responsibilities of the Company set forth in Section 9, neither the Company nor the Company Group shall be responsible for the payment of any applicable taxes on income realized by the Grantee pursuant to the Plan or this Award Agreement.

12.3 ***Fractional Shares.*** The Company shall not be required to issue fractional Shares upon the settlement of the RSUs.

12.4 ***Further Instruments.*** The parties hereto agree to execute such further instruments and to take such further action as may reasonably be necessary to carry out the intent of this Award Agreement.

12.5 ***Beneficial Ownership of Shares; Certificate Registration.*** The Grantee hereby authorizes the Company, in its sole discretion, to deposit for the benefit of the Grantee with any broker with which the Grantee has an account relationship of which the Company has notice any or all Shares acquired by the Grantee pursuant to the settlement of the RSUs. Except as provided by the preceding sentence, a certificate for the Shares pursuant to the RSUs shall be registered in the name of the Grantee, or, if applicable, in the names of the heirs of the Grantee.

12.6 ***Binding Effect.*** Subject to the restrictions on transfer set forth herein, this Award Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective heirs, executors, administrators, successors and assigns.

12.7 ***Electronic Delivery and Acceptance.*** The Company may, in its sole discretion, decide to deliver any documents related to current or future participation in the Plan by electronic means. Grantee hereby consents to receive such documents by electronic delivery and agrees to participate in the Plan through an on-line or electronic system established and maintained by the Company or a third party designated by the Company.

12.8 ***Integrated Agreement.*** The Notice of Grant, this Award Agreement and the Plan shall constitute the entire understanding and agreement of the Grantee and the Company Group with respect to the subject matter contained herein or therein and supersede any prior agreements, understandings, restrictions, representations, or warranties among the Grantee and the Company Group with respect to such subject matter. To the extent contemplated herein or therein, the provisions of the Notice of Grant, this Award Agreement and the Plan shall survive any vesting of the RSUs and shall remain in full force and effect.

12.9 ***Applicable Law.*** This Award Agreement shall be governed by the laws of the State of Delaware as such laws are applied to agreements between Delaware residents entered into and to be performed entirely within the State of Delaware.

12.10 ***Counterparts.*** The Notice of Grant may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

Exhibit 10.44

AMENDED AND RESTATED COMMON STOCK PURCHASE AGREEMENT

This **AMENDED AND RESTATED COMMON STOCK PURCHASE AGREEMENT** is entered into as of March 29, 2019, by and between **RITTER PHARMACEUTICALS, INC.**, a Delaware corporation (the "**Company**"), and **ASPIRE CAPITAL FUND, LLC**, an Illinois limited liability company (the "**Buyer**"). This Agreement hereby amends and restates the Common Stock Purchase Agreement entered into between the parties as of May 4, 2017. Any references to the "Agreement" herein mean the Common Stock Purchase Agreement as originally entered into between the parties on May 4, 2017, as amended and restated hereby, as of the date hereof. Capitalized terms used herein and not otherwise defined herein are defined in Section 10 hereof.

WHEREAS:

Subject to the terms and conditions set forth in this Agreement, the Company wishes to sell to the Buyer, and the Buyer wishes to buy from the Company, up to Six Million Five Hundred Thousand Dollars ($6,500,000) of the Company's common stock, par value $0.001 per share (the "**Common Stock**"). The shares of Common Stock to be purchased hereunder are referred to herein as the "**Purchase Shares**."

Beginning on May 5, 2017, (the "**Commencement Date**"), the Company has had the right to commence (the "Commencement") sales to the Buyer of Purchase Shares hereunder. As of the date hereof, the Company has not made any such sales of Purchase Shares to the Buyer.

NOW THEREFORE, the Company and the Buyer hereby agree as follows:

1. PURCHASE OF COMMON STOCK.

Subject to the terms and conditions set forth in this Agreement, the Company has the right to sell to the Buyer, and the Buyer has the obligation to purchase from the Company, Purchase Shares as follows:

(a) Purchases of Common Stock. The purchase and sale of Purchase Shares hereunder shall occur from time to time upon written notices by the Company to the Buyer on the terms and conditions as set forth herein

(b) The Company's Right to Require Regular Purchases. Subject to the terms and conditions of this Agreement, on any given Business Day, the Company shall have the right but not the obligation to direct the Buyer by its delivery to the Buyer of a Purchase Notice from time to time, and the Buyer thereupon shall have the obligation, to buy the number of Purchase Shares specified in such notice, up to 100,000 Purchase Shares, on such Business Day (as long as such notice is delivered on or before 5:00 p.m. Eastern time on such Business Day) (each such purchase, a "**Regular Purchase**") at the Purchase Price on the Purchase Date; however, in no event shall the Purchase Amount of a Regular Purchase exceed Five Hundred Thousand Dollars ($500,000) per Business Day, unless the Buyer and the Company mutually agree. The Company and the Buyer may mutually agree to increase the number of Purchase Shares that may be sold per Regular Purchase to as much as an additional 2,000,000 Purchase Shares per Business Day. The Company may deliver additional Purchase Notices to the Buyer from time to time so long as the most recent purchase has been completed. The share amounts in this Section 1(b) shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction.

(c) VWAP Purchases. Subject to the terms and conditions of this Agreement, in addition to purchases of Purchase Shares as described in Section 1(b) above, on any given Business Day with one Business Day's prior written notice, the Company shall also have the right but not the obligation to direct the Buyer by the Company's delivery to the Buyer of a VWAP Purchase Notice from time to time, and the Buyer thereupon shall have the obligation, to buy the VWAP Purchase Share Percentage of the trading volume of the Common Stock on the VWAP Purchase Date up to the VWAP Purchase Share Volume Maximum on the VWAP Purchase Date (each such purchase, a " **VWAP Purchase**") at the VWAP Purchase Price. The Company may deliver a VWAP Purchase Notice to the Buyer on or before 5:00 p.m. Eastern time on a date on which the Company also submitted a Purchase Notice for a Regular Purchase of at least 100,000 Purchase Shares to the Buyer. The share amount in the prior sentence shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split, or other similar transaction. A VWAP Purchase shall automatically be deemed completed at such time on the VWAP Purchase Date that the Sale Price falls below the VWAP Minimum Price Threshold; in such circumstance, the VWAP Purchase Amount shall be calculated using (i) the VWAP Purchase Share Percentage of the aggregate shares traded on the Principal Market for such portion of the VWAP Purchase Date prior to the time that the Sale Price fell below the VWAP Minimum Price Threshold and (ii) a VWAP Purchase Price calculated using the volume weighted average price of Common Stock sold during such portion of the VWAP Purchase Date prior to the time that the Sale Price fell below the VWAP Minimum Price Threshold. Each VWAP Purchase Notice must be accompanied by instructions to the Company's Transfer Agent to immediately issue to the Buyer an amount of Common Stock equal to the VWAP Purchase Share Estimate, a good faith estimate by the Company of the number of Purchase Shares that the Buyer shall have the obligation to buy pursuant to the VWAP Purchase Notice. In no event shall the Buyer, pursuant to any VWAP Purchase, purchase a number of Purchase Shares that exceeds the VWAP Purchase Share Estimate issued on the VWAP Purchase Date in connection with such VWAP Purchase Notice; however, the Buyer will immediately return to the Company any amount of Common Stock issued pursuant to the VWAP Purchase Share Estimate that exceeds the number of Purchase Shares the Buyer actually purchases in connection with such VWAP Purchase. Upon completion of each VWAP Purchase Date, the Buyer shall submit to the Company a confirmation of the VWAP Purchase in form and substance reasonably acceptable to the Company. The Company may deliver additional VWAP Purchase Notices to the Buyer from time to time so long as the most recent purchase has been completed.

(d) Payment for Purchase Shares. For each Regular Purchase, the Buyer shall pay to the Company an amount equal to the Purchase Amount as full payment for such Purchase Shares via wire transfer of immediately available funds on the same Business Day that the Buyer receives such Purchase Shares. For each VWAP Purchase, the Buyer shall pay to the Company an amount equal to the VWAP Purchase Amount as full payment for such Purchase Shares via wire transfer of immediately available funds on the third Business Day following the VWAP Purchase Date. All payments made under this Agreement shall be made in lawful money of the United States of America via wire transfer of immediately available funds to such account as the Company may from time to time designate by written notice in accordance with the provisions of this Agreement. Whenever any amount expressed to be due by the terms of this Agreement is due on any day that is not a Business Day, the same shall instead be due on the next succeeding day that is a Business Day.

(e) Purchase Price Floor. The Company and the Buyer shall not effect any sales under this Agreement on any Purchase Date where the Closing Sale Price is less than the Floor Price. "**Floor Price**" means $0.25 per share of Common Stock, which shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction.

(f) Records of Purchases. The Buyer and the Company shall each maintain records showing the remaining Available Amount at any given time and the dates and Purchase Amounts for each purchase, or shall use such other method reasonably satisfactory to the Buyer and the Company to reconcile the remaining Available Amount.

(g) Taxes. The Company shall pay any and all transfer, stamp or similar taxes that may be payable with respect to the issuance and delivery of any shares of Common Stock to the Buyer made under this Agreement.

(h) Compliance with Principal Market Rules. Notwithstanding anything in this Agreement to the contrary, and in addition to the limitations set forth in Section 1(e), the total number of shares of Common Stock that may be issued under this Agreement, including the Commitment Shares (as defined in Section 4(e) hereof), shall be limited to 1,807,562 shares of Common Stock (the "**Exchange Cap**"), which equals 19.99% of the Company's outstanding shares of Common Stock as of the date hereof, unless stockholder approval is obtained to issue more than such 19.99%. The Exchange Cap shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. The foregoing limitation shall not apply if stockholder approval has not been obtained and at any time the Exchange Cap is reached and at all times thereafter the average price paid for all shares issued under this Agreement is equal to or greater than $0.86 (the "**Minimum Price**"), a price equal to the lower of (1) the Closing Sale Price immediately preceding the execution of this Agreement or (2) the arithmetic average of the five (5) Closing Sale Prices for the Common Stock immediately preceding the execution of this Agreement (in such circumstance, for purposes of the Principal Market, the transaction contemplated hereby would not be "below market" and the Exchange Cap would not apply). The Minimum Price shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. Notwithstanding anything to the contrary in this Agreement or otherwise, the Company shall not be required or permitted to issue, and the Buyer shall not be required to purchase, any shares of Common Stock under this Agreement if such issuance would breach the Company's obligations under the rules or regulations of the Principal Market. The Company may, in its sole discretion, determine whether to obtain stockholder approval to issue more than 19.99% of its outstanding shares of Common Stock hereunder if such issuance would require stockholder approval under the rules or regulations of the Principal Market.

(i) Beneficial Ownership Limitation. The Company shall not issue, and the Buyer shall not purchase any shares of Common Stock under this Agreement, if such shares proposed to be issued and sold, when aggregated with all other shares of Common Stock then owned beneficially (as calculated pursuant to Section 13(d) of the Securities Exchange Act of 1934, as amended (the "**1934 Act**") and Rule 13d-3 promulgated thereunder) by the Buyer and its affiliates would result in the beneficial ownership by the Buyer and its affiliates of more than 19.99% of the then issued and outstanding shares of Common Stock of the Company.

2. BUYER'S REPRESENTATIONS AND WARRANTIES.

The Buyer represents and warrants to the Company that as of the date hereof:

(a) Investment Purpose. The Buyer is entering into this Agreement and acquiring the Commitment Shares and the Purchase Shares (the Purchase Shares and the Commitment Shares are collectively referred to herein as the "**Securities**"), for its own account for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof; provided however, by making the representations herein, the Buyer does not agree to hold any of the Securities for any minimum or other specific term.

(b) Accredited Investor Status. The Buyer is an "accredited investor" as that term is defined in Rule 501(a)(3) of Regulation D under the 1933 Act.

(c) [Intentionally Omitted.]

(d) Information. The Buyer has been furnished with all materials relating to the business, finances and operations of the Company and materials relating to the offer and sale of the Securities that have been reasonably requested by the Buyer, including, without limitation, the SEC Documents (as defined in Section 3(f) hereof). The Buyer understands that its investment in the Securities involves a high degree of risk. The Buyer (i) is able to bear the economic risk of an investment in the Securities including a total loss, (ii) has such knowledge and experience in financial and business matters that it is capable of evaluating the merits and risks of the proposed investment in the Securities and (iii) has had an opportunity to ask questions of and receive answers from the officers of the Company concerning the financial condition and business of the Company and other matters related to an investment in the Securities. Neither such inquiries nor any other due diligence investigations conducted by the Buyer or its representatives shall modify, amend or affect the Buyer's right to rely on the Company's representations and warranties contained in Section 3 below. The Buyer has sought such accounting, legal and tax advice as it has considered necessary to make an informed investment decision with respect to its acquisition of the Securities.

(e) No Governmental Review. The Buyer understands that no United States federal or state agency or any other government or governmental agency has passed on or made any recommendation or endorsement of the Securities or the fairness or suitability of the investment in the Securities nor have such authorities passed upon or endorsed the merits of the offering of the Securities.

(f) [Intentionally Omitted.]

(g) Organization. The Buyer is a limited liability company duly organized and validly existing in good standing under the laws of the jurisdiction in which it is organized, and has the requisite organizational power and authority to own its properties and to carry on its business as now being conducted.

(h) Validity; Enforcement. This Agreement has been duly and validly authorized, executed and delivered on behalf of the Buyer and is a valid and binding agreement of the Buyer enforceable against the Buyer in accordance with its terms, subject as to enforceability to (i) general principles of equity and to applicable bankruptcy, insolvency, reorganization, moratorium, liquidation and other similar laws relating to, or affecting generally, the enforcement of applicable creditors' rights and remedies and (ii) public policy underlying any law, rule or regulation (including any federal or state securities law, rule or regulation) with regards to indemnification, contribution or exculpation. The execution and delivery of the Transaction Documents (as defined in Section 3(b) hereof) by the Buyer and the consummation by it of the transactions contemplated hereby and thereby do not conflict with the Buyer's certificate of organization or operating agreement or similar documents, and do not require further consent or authorization by the Buyer, its managers or its members.

(i) Residency. The Buyer is a resident of the State of Illinois.

(j) No Prior Short Selling. The Buyer represents and warrants to the Company that at no time prior to the date of this Agreement has any of the Buyer, its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any (i) "short sale" (as such term is defined in Section 242.200 of Regulation SHO of the 1934 Act of the Common Stock or (ii) hedging transaction, which establishes a net short position with respect to the Common Stock.

3. REPRESENTATIONS AND WARRANTIES OF THE COMPANY.

The Company represents and warrants to the Buyer that as of the date hereof:

(a) Organization and Qualification. The Company and its "Subsidiaries" (which for purposes of this Agreement means any entity in which the Company, directly or indirectly, owns more than 50% of the voting stock or capital stock or other similar equity interests) are corporations or limited liability companies duly organized and validly existing in good standing under the laws of the jurisdiction in which they are incorporated or organized, and have the requisite corporate or organizational power and authority to own their properties and to carry on their business as now being conducted. Each of the Company and its Subsidiaries is duly qualified as a foreign corporation or limited liability company to do business and is in good standing in every jurisdiction in which its ownership of property or the nature of the business conducted by it makes such qualification necessary, except to the extent that the failure to be so qualified or be in good standing could not reasonably be expected to have a Material Adverse Effect. As used in this Agreement, "Material Adverse Effect" means any material adverse effect on any of: (i) the business, properties, assets, operations, results of operations or financial condition of the Company and its Subsidiaries, if any, taken as a whole, or (ii) the authority or ability of the Company to perform its obligations under the Transaction Documents. The Company has no material Subsidiaries except as set forth on Schedule 3(a).

(b) Authorization; Enforcement; Validity. (i) The Company has the requisite corporate power and authority to enter into and perform its obligations under this Agreement, the Registration Rights Agreement and each of the other agreements entered into by the parties on the Commencement Date (collectively, the "**Transaction Documents**"), and to issue the Securities in accordance with the terms hereof and thereof, (ii) the execution and delivery of the Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby, including without limitation, the issuance of the Commitment Shares on the Commencement Date and the reservation for issuance and the issuance of the Purchase Shares issuable under this Agreement, have been duly authorized by the Company's Board of Directors or duly authorized committee thereof, do not conflict with the Company's Certificate of Incorporation or Bylaws (as defined below), and do not, except as set forth in this Agreement, require further consent or authorization by the Company, its Board of Directors, or its stockholders, (iii) this Agreement has been, and each other Transaction Document shall have been on the Commencement Date and as of the date hereof, duly executed and delivered by the Company and (iv) this Agreement and each other Transaction Document constitutes the valid and binding obligations of the Company enforceable against the Company in accordance with their terms, except as such enforceability may be limited by (y) general principles of equity or applicable bankruptcy, insolvency, reorganization, moratorium, liquidation or similar laws relating to, or affecting generally, the enforcement of creditors' rights and remedies and (z) public policy underlying any law, rule or regulation (including any federal or state securities law, rule or regulation) with regards to indemnification, contribution or exculpation. The Board of Directors of the Company or duly authorized committee thereof has previously approved resolutions to authorize this Agreement and the transactions contemplated hereby. Such resolutions are valid, in full force and effect and have not been modified or supplemented in any material respect.

(c) Capitalization. As of the date hereof, the authorized capital stock of the Company consists of (i) 225,000,000 shares of Common Stock, par value $0.001, of which as of the date hereof, 9,042,332 shares are issued and outstanding, zero shares are held as treasury shares, 2,750,000 shares are reserved for future issuance pursuant to the Company's equity incentive plans, of which approximately 2,263,374 shares remain available for future option grants or stock awards, and 11,887,051 shares are issuable and reserved for issuance pursuant to securities (other than stock options or equity based awards issued pursuant to the Company's stock incentive plans) exercisable or exchangeable for, or convertible into, shares of Common Stock, and (ii) 15,000,000 shares of preferred stock, with per share liquidation preferences set forth on Schedule 3(c), of which (A) 9,500 shares have been designated as Series A Convertible Preferred Stock, of which 4,080 shares are issued and outstanding as of the date hereof, (B) 6,000 shares have been designated as Series B Convertible Preferred Stock, of which 3,000 shares are issued and outstanding as of the date hereof, and (C) 1,880 shares have been designated as Series C Convertible Preferred Stock, of which 240 shares are issued and outstanding as of the date hereof. All of such outstanding shares have been, or upon issuance will be, validly issued and are fully paid and non-assessable. Except as disclosed in Schedule 3(c), (i) no shares of the Company's capital stock are subject to preemptive rights or any other similar rights or any liens or encumbrances suffered or permitted by the Company, (ii) there are no outstanding debt securities of the Company or any of its Subsidiaries, (iii) there are no outstanding options, warrants, scrip, rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities or rights convertible into, any shares of capital stock of the Company or any of its Subsidiaries, or contracts, commitments, understandings or arrangements by which the Company or any of its Subsidiaries is or may become bound to issue additional shares of capital stock of the Company or any of its Subsidiaries or options, warrants, scrip, rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities or rights convertible into, any shares of capital stock of the Company or any of its Subsidiaries, (iv) there are no material agreements or arrangements under which the Company or any of its Subsidiaries is obligated to register the sale of any of their securities under the 1933 Act (except the Registration Rights Agreement), (v) there are no outstanding securities or instruments of the Company or any of its Subsidiaries which contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any of its Subsidiaries is or may become bound to redeem a security of the Company or any of its Subsidiaries, (vi) there are no securities or instruments containing anti-dilution or similar provisions that will be triggered by the issuance of the Securities as described in this Agreement and (vii) the Company does not have any stock appreciation rights or "phantom stock" plans or agreements or any similar plan or agreement. The Company has furnished or made available to the Buyer true and correct copies of the Company's Certificate of Incorporation, as amended and as in effect on the date hereof (the "**Certificate of Incorporation**"), and the Company's Bylaws, as amended and as in effect on the date hereof (the "**Bylaws**").

(d) Issuance of Securities. The Commitment Shares that were issued to the Buyer on the Commencement Date have been duly authorized and are (i) validly issued, fully paid and non-assessable and (ii) free from all taxes, liens and charges with respect to the issuance thereof. Upon issuance and payment therefore in accordance with the terms and conditions of this Agreement, the Purchase Shares shall be validly issued, fully paid and non-assessable and free from all taxes, liens and charges with respect to the issue thereof, with the holders being entitled to all rights accorded to a holder of Common Stock.

(e) No Conflicts. Except as disclosed in Schedule 3(e), the execution, delivery and performance of the Transaction Documents by the Company and the consummation by the Company of the transactions contemplated hereby and thereby (including, without limitation, the reservation for issuance and issuance of the Purchase Shares) will not (i) result in a violation of the Certificate of Incorporation, any Certificate of Designations, Preferences and Rights of any outstanding series of preferred stock of the Company or the Bylaws or (ii) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any agreement, indenture or instrument to which the Company or any of its Subsidiaries is a party, or result, to the Company's knowledge, in a violation of any law, rule, regulation, order, judgment or decree (including federal and state securities laws and regulations and the rules and regulations of the Principal Market applicable to the Company or any of its Subsidiaries) or by which any property or asset of the Company or any of its Subsidiaries is bound or affected, except in the case of conflicts, defaults, terminations, amendments, accelerations, cancellations and violations under clause (ii), which could not reasonably be expected to result in a Material Adverse Effect. Except as disclosed in Schedule 3(e), neither the Company nor its Subsidiaries is in violation of any term of or in default under its Certificate of Incorporation , any Certificate of Designation, Preferences and Rights of any outstanding series of preferred stock of the Company or Bylaws or their organizational charter or bylaws, respectively. Except as disclosed in Schedule 3(e), neither the Company nor any of its Subsidiaries is in violation of any term of or is in default under any material contract, agreement, mortgage, indebtedness, indenture, instrument, judgment, decree or order or any statute, rule or regulation applicable to the Company or its Subsidiaries, except for possible violations, defaults, terminations or amendments that could not reasonably be expected to have a Material Adverse Effect. The business of the Company and its Subsidiaries is not being conducted, and shall not be conducted, in violation of any law, ordinance, or regulation of any governmental entity, except for possible violations, the sanctions for which either individually or in the aggregate could not reasonably be expected to have a Material Adverse Effect. Except as specifically contemplated by this Agreement, reporting obligations under the 1934 Act, or as required under the 1933 Act or applicable state securities laws or the filing of a Listing of Additional Shares Notification Form with the Principal Market, the Company is not required to obtain any consent, authorization or order of, or make any filing or registration with, any court or governmental agency or any regulatory or self-regulatory agency in order for it to execute, deliver or perform any of its obligations under or contemplated by the Transaction Documents in accordance with the terms hereof or thereof. Except as disclosed in Schedule 3(e) and for reporting obligations under the 1934 Act, all consents, authorizations, orders, filings and registrations which the Company is required to obtain pursuant to the preceding sentence have been obtained or effected on or prior to the Commencement Date. Except as disclosed in Schedule 3(e), the Company is not subject to any notices or actions from or to the Principal Market other than routine matters incident to listing on the Principal Market and not involving a violation of the rules of the Principal Market. Except as disclosed in Schedule 3(e), to the Company's knowledge, the Principal Market has not commenced any delisting proceedings against the Company.

(f) SEC Documents; Financial Statements. Except as disclosed in Schedule 3(f), since September 30, 2017, the Company has filed all reports, schedules, forms, statements and other documents required to be filed by it with the SEC pursuant to the reporting requirements of the 1934 Act (all of the foregoing filed prior to the date hereof and all exhibits included therein and financial statements and schedules thereto and documents incorporated by reference therein being hereinafter referred to as the "**SEC Documents**"). As of their respective dates (except as they have been correctly amended), the SEC Documents complied in all material respects with the requirements of the 1934 Act and the rules and regulations of the SEC promulgated thereunder applicable to the SEC Documents, and none of the SEC Documents, at the time they were filed with the SEC (except as they may have been properly amended), contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. As of their respective dates (except as they have been properly amended), the financial statements of the Company included in the SEC Documents complied as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto. Such financial statements have been prepared in accordance with generally accepted accounting principles, consistently applied, during the periods involved (except (i) as may be otherwise indicated in such financial statements or the notes thereto or (ii) in the case of unaudited interim statements, to the extent they may exclude footnotes or may be condensed or summary statements) and fairly present in all material respects the financial position of the Company as of the dates thereof and the results of its operations and cash flows for the periods then ended (subject, in the case of unaudited statements, to normal year-end audit adjustments). Except as disclosed in Schedule 3(f) or routine correspondence, such as comment letters and notices of effectiveness in connection with previously filed registration statements or periodic reports publicly available on EDGAR, to the Company's knowledge, the Company or any of its Subsidiaries are not presently the subject of any inquiry, investigation or action by the SEC.

(g) Absence of Certain Changes. Except as disclosed in Schedule 3(g), since September 30, 2018, there has been no material adverse change in the business, properties, operations, financial condition or results of operations of the Company or its Subsidiaries taken as a whole. For purposes of this Agreement, neither a decrease in cash or cash equivalents or in the market price of the Common Stock nor losses incurred in the ordinary course of the Company's business shall be deemed or considered a material adverse change. The Company has not taken any steps, and does not currently expect to take any steps, to seek protection pursuant to any Bankruptcy Law nor does the Company or any of its Subsidiaries have any knowledge or reason to believe that its creditors intend to initiate involuntary bankruptcy or insolvency proceedings. The Company is financially solvent and is generally able to pay its debts as they become due**.**

(h) Absence of Litigation. Except as disclosed in Schedule 3(h), to the Company's knowledge, there is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of the Company or any of its Subsidiaries, threatened against the Company, the Common Stock or any of the Company's Subsidiaries or any of the Company's or the Company's Subsidiaries' officers or directors in their capacities as such, which could reasonably be expected to have a Material Adverse Effect (each, an "**Action**"). A description of each such Action, if any, is set forth in Schedule 3(h).

(i) Acknowledgment Regarding Buyer's Status. The Company acknowledges and agrees that the Buyer is acting solely in the capacity of arm's length purchaser with respect to the Transaction Documents and the transactions contemplated hereby and thereby. The Company further acknowledges that the Buyer is not acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to the Transaction Documents and the transactions contemplated hereby and thereby and any advice given by the Buyer or any of its representatives or agents in connection with the Transaction Documents and the transactions contemplated hereby and thereby is merely incidental to the Buyer's purchase of the Securities. The Company further represents to the Buyer that the Company's decision to enter into the Transaction Documents has been based solely on the independent evaluation by the Company and its representatives and advisors.

(j) Intellectual Property Rights. To the Company's knowledge, the Company and its Subsidiaries own or possess adequate rights or licenses to use all material trademarks, trade names, service marks, service mark registrations, service names, patents, patent rights, copyrights, inventions, licenses, approvals, governmental authorizations, trade secrets and other intellectual property rights (collectively, "**Intellectual Property**") necessary to conduct their respective businesses as now conducted, except as set forth in Schedule 3(j) or to the extent that the failure to own, possess, license or otherwise hold adequate rights to use Intellectual Property would not, individually or in the aggregate, have a Material Adverse Effect. Except as disclosed in Schedule 3(j), to the Company's knowledge, none of the Company's active and registered Intellectual Property have expired or terminated, or, by the terms and conditions thereof, will expire or terminate within two years from the date of this Agreement, except as would not reasonably be expected to have a Material Adverse Effect. The Company and its Subsidiaries do not have any knowledge of any infringement by the Company or its Subsidiaries of any Intellectual Property of others and, except as set forth on Schedule 3(j), there is no claim, action or proceeding being made or brought against, or to the Company's knowledge, being threatened against, the Company or its Subsidiaries regarding Intellectual Property, which could reasonably be expected to have a Material Adverse Effect.

(k) Environmental Laws. To the Company's knowledge, the Company and its Subsidiaries (i) are in material compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety or the environment and with respect to hazardous or toxic substances or wastes, pollutants or contaminants ("**Environmental Laws**"), (ii) have received all material permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses and (iii) are in material compliance with all terms and conditions of any such permit, license or approval, except where, in each of the three foregoing clauses, the failure to so comply or receive such approvals could not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

(l) Title. The Company and its Subsidiaries have good and marketable title to all personal property owned by them that is material to the business of the Company and its Subsidiaries, in each case free and clear of all liens, encumbrances and defects except such as are described in Schedule 3(l) or such as do not materially affect the value of such property and do not interfere with the use made and proposed to be made of such property by the Company and any of its Subsidiaries or could not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect. Any real property and facilities held under lease by the Company and any of its Subsidiaries, to the Company's knowledge, are held by them under valid, subsisting and enforceable leases with such exceptions as are not material and do not interfere with the use made and proposed to be made of such property and buildings by the Company and its Subsidiaries.

(m) Insurance. The Company and each of its Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as management of the Company believes to be reasonable and customary in the businesses in which the Company and its Subsidiaries are engaged. To the Company's knowledge, since January 1, 2015, neither the Company nor any such Subsidiary has been refused any insurance coverage sought or applied for and neither the Company nor any such Subsidiary, to the Company's knowledge, will be unable to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not reasonably be expected to have a Material Adverse Effect.

(n) Regulatory Permits. The Company and its Subsidiaries possess all material certificates, authorizations and permits issued by the appropriate federal, state or foreign regulatory authorities necessary to conduct their respective businesses as currently conducted, and neither the Company nor any such Subsidiary has received any written notice of proceedings relating to the revocation or modification of any such material certificate, authorization or permit.

(o) Tax Status. The Company and each of its Subsidiaries has made or filed all federal and state income and all other material tax returns, reports and declarations required by any jurisdiction to which it is subject (unless and only to the extent that the Company and each of its Subsidiaries has set aside on its books reserves reasonably adequate for the payment of all unpaid and unreported taxes or filed valid extensions) and has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations, except those being contested in good faith and has set aside on its books reserves reasonably adequate for the payment of all taxes for periods subsequent to the periods to which such returns, reports or declarations apply. To the Company's knowledge, there are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction.

(p) Transactions With Affiliates. Except as set forth on Schedule 3(p) and other than the grant or exercise of stock options or any other equity securities offered pursuant to duly adopted stock or incentive compensation plans as disclosed on Schedule 3(c), none of the officers, directors or employees of the Company is presently a party to any transaction with the Company or any of its Subsidiaries (other than for services as employees, officers and directors and reimbursement for expenses incurred on behalf of the Company), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any corporation, partnership, trust or other entity in which any officer, director, or any such employee has a material interest or is an officer, director, trustee or general partner.

(q) Application of Takeover Protections. The Company and its board of directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Certificate of Incorporation or the laws of the state of its incorporation, other than Section 203 of the Delaware General Corporation Law, which is or could become applicable to the Buyer as a result of the transactions contemplated by this Agreement, including, without limitation, the Company's issuance of the Securities and the Buyer's ownership of the Securities.

(r) Registration Statement. The Shelf Registration Statement (as defined in Section 4(a) hereof) has been declared effective by the SEC, and no stop order has been issued or is pending or, to the knowledge of the Company, threatened by the SEC with respect thereto. As of the date hereof, the Company has a dollar amount of securities registered and unsold under the Shelf Registration Statement, which is not less than the Available Amount on the date hereof.

4. COVENANTS.

(a) **Disclosure under the 1934 Act**. The Company agrees that it shall, within the time required under the 1934 Act, file a Current Report on Form 8-K disclosing this Agreement unless such disclosure is made by the Company in the Company's Annual Report on Form 10-K. The Company has filed prior to the Commencement Date a prospectus supplement to the Company's existing shelf registration statement on Form S-3 (File No. 333-213087, the "**Shelf Registration Statement**") covering the sale of the Commitment Shares and Purchase Shares (the "**Prospectus Supplement**") in accordance with the terms of the Registration Rights Agreement between the Company and the Buyer, dated as of May 4, 2017 (the "**Registration Rights Agreement**"). The Company shall use its reasonable best efforts to keep the Shelf Registration Statement and any New Registration Statement (as defined in the Registration Rights Agreement) effective pursuant to Rule 415 promulgated under the 1933 Act and available for sales of all Securities to the Buyer until such time as (i) it no longer qualifies to make sales under the Shelf Registration Statement (which shall be understood to include the inability of the Company to immediately register sales of Securities to the Buyer under the Shelf Registration Statement or any New Registration Statement pursuant to General Instruction I.B.6 of Form S-3), (ii) the date on which all the Securities have been sold under this Agreement and no Available Amount remains thereunder, or (iii) the Agreement has been terminated. The Shelf Registration Statement (including any amendments or supplements thereto and prospectuses or prospectus supplements, including the Prospectus Supplement, contained therein) shall not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein, or necessary to make the statements therein, in light of the circumstances in which they were made, not misleading.

(b) Blue Sky. The Company shall take such action, if any, as is reasonably necessary in order to obtain an exemption for or to qualify (i) the initial sale of the Securities to the Buyer under this Agreement and (ii) any subsequent sale of the Securities by the Buyer, in each case, under applicable securities or "Blue Sky" laws of the states of the United States in such states as is reasonably requested by the Buyer from time to time, and shall provide evidence of any such action so taken to the Buyer.

(c) Listing. The Company shall promptly secure the listing of all of the Securities upon each national securities exchange and automated quotation system that requires an application by the Company for listing, if any, upon which shares of Common Stock are then listed (subject to official notice of issuance) and shall maintain such listing, so long as any other shares of Common Stock shall be so listed. The Company shall use its reasonable best efforts to maintain the Common Stock's listing on the Principal Market. Neither the Company nor any of its Subsidiaries shall take any action that would be reasonably expected to result in the delisting or suspension of the Common Stock on the Principal Market, unless the Common Stock is immediately thereafter traded on the New York Stock Exchange, the NYSE MKT, the NASDAQ Global Select Market, or the NASDAQ Capital. The Company shall pay all fees and expenses in connection with satisfying its obligations under this Section.

(d) Limitation on Short Sales and Hedging Transactions. The Buyer agrees that beginning on the date of this Agreement and ending on the date of termination of this Agreement as provided in Section 11(k), the Buyer and its agents, representatives and affiliates shall not in any manner whatsoever enter into or effect, directly or indirectly, any (i) "short sale" (as such term is defined in Section 242.200 of Regulation SHO of the 1934 Act) of the Common Stock or (ii) hedging transaction, which establishes a net short position with respect to the Common Stock.

(e) Issuance of Commitment Shares. In connection with the Commencement, the Company previously issued to the Buyer as consideration for the Buyer entering into this Agreement shares of Common Stock (the "**Commitment Shares**") with an aggregate dollar value equal to $97,500, calculated based on the Closing Sale Price on the Business Day prior to the date the Commitment Shares are issued.

(f) Due Diligence. The Buyer shall have the right, from time to time as the Buyer may reasonably deem appropriate, to perform reasonable due diligence on the Company during normal business hours and subject to reasonable prior notice to the Company. The Company and its officers and employees shall provide information and reasonably cooperate with the Buyer in connection with any reasonable request by the Buyer related to the Buyer's due diligence of the Company; provided, however, that at no time is the Company required to disclose material nonpublic information to the Buyer or breach any obligation of confidentiality or non-disclosure to a third party or make any disclosure that could cause a waiver of attorney-client privilege. Each party hereto agrees not to disclose any Confidential Information of the other party to any third party and shall not use the Confidential Information of such other party for any purpose other than in connection with, or in furtherance of, the transactions contemplated hereby. Each party hereto acknowledges that the Confidential Information shall remain the property of the disclosing party and agrees that it shall take all reasonable measures to protect the secrecy of any Confidential Information disclosed by the other party.

5. TRANSFER AGENT INSTRUCTIONS.

All of the Purchase Shares to be issued under this Agreement shall be issued without any restrictive legend unless the Buyer expressly consents otherwise. The Company has issued irrevocable instructions to the Transfer Agent, and shall issue irrevocable instructions to any subsequent transfer agent, to issue Common Stock in the name of the Buyer for the Purchase Shares (the "**Irrevocable Transfer Agent Instructions"**). The Company warrants to the Buyer that no instruction other than the Irrevocable Transfer Agent Instructions referred to in this Section 5, will be given by the Company to the Transfer Agent with respect to the Purchase Shares and that the Purchase Shares shall otherwise be freely transferable on the books and records of the Company as and to the extent provided in this Agreement and the Registration Rights Agreement.

6. [Intentionally Omitted.]

7. [Intentionally Omitted.]

8. INDEMNIFICATION.

In consideration of the Buyer's execution and delivery of the Transaction Documents and acquiring the Securities hereunder and in addition to all of the Company's other obligations under the Transaction Documents, the Company shall defend, protect, indemnify and hold harmless the Buyer and all of its affiliates, members, officers, directors, and employees, and any of the foregoing person's agents or other representatives (including, without limitation, those retained in connection with the transactions contemplated by this Agreement) (collectively, the "**Indemnitees**") from and against any and all actions, causes of action, suits, claims, losses, costs, penalties, fees, liabilities and damages, and expenses in connection therewith (irrespective of whether any such Indemnitee is a party to the action for which indemnification hereunder is sought), and including reasonable attorneys' fees and disbursements (the "**Indemnified Liabilities**"), incurred by any Indemnitee as a result of, or arising out of, or relating to (a) any misrepresentation or breach of any representation or warranty made by the Company in the Transaction Documents or any other certificate, instrument or document contemplated hereby or thereby, (b) any breach of any covenant, agreement or obligation of the Company contained in the Transaction Documents or any other certificate, instrument or document contemplated hereby or thereby, or (c) any cause of action, suit or claim brought or made against such Indemnitee and arising out of or resulting from the execution, delivery, performance or enforcement of the Transaction Documents or any other certificate, instrument or document contemplated hereby or thereby, other than with respect to Indemnified Liabilities which directly and primarily result from (A) a breach of any of the Buyer's representations and warranties, covenants or agreements contained in this Agreement, or (B) the gross negligence, bad faith or willful misconduct of the Buyer or any other Indemnitee. To the extent that the foregoing undertaking by the Company may be unenforceable for any reason, the Company shall make the maximum contribution to the payment and satisfaction of each of the Indemnified Liabilities which is permissible under applicable law.

9. EVENTS OF DEFAULT.

An "**Event of Default**" shall be deemed to have occurred at any time as any of the following events occurs:

(a) during any period in which the effectiveness of any registration statement is required to be maintained pursuant to the terms of the Registration Rights Agreement, the effectiveness of such registration statement lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to the Company for sale of all of the Registrable Securities (as defined in the Registration Rights Agreement) to the Buyer in accordance with the terms of the Registration Rights Agreement, and such lapse or unavailability continues for a period of ten (10) consecutive Business Days or for more than an aggregate of thirty (30) Business Days in any 365-day period, which is not in connection with a post-effective amendment to any such registration statement or the filing of a new registration statement; provided, however, that in connection with any post-effective amendment to such registration statement or filing of a new registration statement that is required to be declared effective by the SEC, such lapse or unavailability may continue for a period of no more than thirty (30) consecutive Business Days, which such period shall be extended for an additional thirty (30) Business Days if the Company receives a comment letter from the SEC in connection therewith;

(b) the suspension from trading or failure of the Common Stock to be listed on a Principal Market for a period of three (3) consecutive Business Days;

(c) the delisting of the Common Stock from the Principal Market, and the Common Stock is not immediately thereafter trading on the New York Stock Exchange, the NYSE MKT, the NASDAQ Global Select Market, the NASDAQ Global Market, or the NASDAQ Capital Market;

(d) the failure for any reason by the Transfer Agent to issue Purchase Shares to the Buyer within five (5) Business Days after the applicable Purchase Date that the Buyer is entitled to receive;

(e) the breach of any representation or warranty (as of the dates made), covenant or other term or condition under any Transaction Document if such breach could reasonably be expected to have a Material Adverse Effect and except, in the case of a breach of a covenant which is reasonably curable, only if such breach continues uncured for a period of at least five (5) Business Days;

(f) if any Person commences a proceeding against the Company pursuant to or within the meaning of any Bankruptcy Law;

(g) if the Company pursuant to or within the meaning of any Bankruptcy Law; (A) commences a voluntary case, (B) consents to the entry of an order for relief against it in an involuntary case, (C) consents to the appointment of a Custodian of it or for all or substantially all of its property, (D) makes a general assignment for the benefit of its creditors or (E) becomes insolvent;

(h) a court of competent jurisdiction enters an order or decree under any Bankruptcy Law that (A) is for relief against the Company in an involuntary case, (B) appoints a Custodian of the Company or for all or substantially all of its property, or (C) orders the liquidation of the Company or any Subsidiary; or

(i) if at any time, the Exchange Cap is reached unless and until stockholder approval is obtained pursuant to Section 1(h) hereof. The Exchange Cap shall be deemed to be reached at such time if, upon submission of a Purchase Notice or VWAP Purchase Notice under this Agreement, the issuance of such shares of Common Stock would exceed the number of shares of Common Stock which the Company may issue under this Agreement without breaching the Company's obligations under the rules or regulations of the Principal Market.

In addition to any other rights and remedies under applicable law and this Agreement, including the Buyer termination rights under Section 11(k) hereof, so long as an Event of Default has occurred and is continuing, or if any event which, after notice and/or lapse of time, would become an Event of Default, has occurred and is continuing, or so long as the Closing Sale Price is below the Floor Price, the Company may not require and the Buyer shall not be obligated to purchase any shares of Common Stock under this Agreement. If pursuant to or within the meaning of any Bankruptcy Law, the Company commences a voluntary case or any Person commences a proceeding against the Company, a Custodian is appointed for the Company or for all or substantially all of its property, or the Company makes a general assignment for the benefit of its creditors, (any of which would be an Event of Default as described in Sections 9(f), 9(g) and 9(h) hereof) this Agreement shall automatically terminate without any liability or payment to the Company without further action or notice by any Person. No such termination of this Agreement under Section 11(k)(i) shall affect the Company's or the Buyer's obligations under this Agreement with respect to pending purchases and the Company and the Buyer shall complete their respective obligations with respect to any pending purchases under this Agreement.

10. CERTAIN DEFINED TERMS.

For purposes of this Agreement, the following terms shall have the following meanings:

(a) "**1933 Act**" means the Securities Act of 1933, as amended.

(b) "**Available Amount**" means initially Six Million Five Hundred Thousand Dollars ($6,500,000) in the aggregate which amount shall be reduced by the Purchase Amount each time the Buyer purchases shares of Common Stock pursuant to Section 1 hereof.

(c) "**Bankruptcy Law**" means Title 11, U.S. Code, or any similar federal or state law for the relief of debtors.

(d) "**Business Day**" means any day on which the Principal Market is open for trading during normal trading hours (i.e., 9:30 a.m. to 4:00 p.m. Eastern Time), including any day on which the Principal Market is open for trading for a period of time less than the customary time.

(e) "**Closing Sale Price**" means the last closing trade price for the Common Stock on the Principal Market as reported by the Principal Market.

(f) "**Confidential Information**" means any information disclosed by either party to the other party, either directly or indirectly, in writing, orally or by inspection of tangible objects (including, without limitation, documents, prototypes, samples, plant and equipment), which is designated as "Confidential," "Proprietary" or some similar designation. Information communicated orally shall be considered Confidential Information if such information is expressly identified as Confidential Information at the time of such initial disclosure and confirmed in writing as being Confidential Information within ten (10) Business Days after the initial disclosure. Confidential Information may also include information disclosed to a disclosing party by third parties. Confidential Information shall not, however, include any information which (i) was publicly known and made generally available in the public domain prior to the time of disclosure by the disclosing party; (ii) becomes publicly known and made generally available after disclosure by the disclosing party to the receiving party through no action or inaction of the receiving party; (iii) is already in the possession of the receiving party at the time of disclosure by the disclosing party as shown by the receiving party's files and records immediately prior to the time of disclosure; (iv) is obtained by the receiving party from a third party without a breach of such third party's obligations of confidentiality; (v) is independently developed by the receiving party without use of or reference to the disclosing party's Confidential Information, as shown by documents and other competent evidence in the receiving party's possession; or (vi) is required by law to be disclosed by the receiving party, provided that the receiving party gives the disclosing party prompt written notice of such requirement prior to such disclosure and assistance in obtaining an order protecting the information from public disclosure.

(g) "**Custodian**" means any receiver, trustee, assignee, liquidator or similar official under any Bankruptcy Law.

(h) "**Maturity Date**" means March 31, 2021.

(i) "**Person**" means an individual or entity including any limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization and a government or any department or agency thereof.

(j) "**Principal Market**" means the NASDAQ Capital Market; provided however, that in the event the Company's Common Stock is ever listed or traded on the New York Stock Exchange, the NYSE MKT, the NASDAQ Global Select Market, the Nasdaq Global Market, or the NASDAQ Capital Market, then the "Principal Market" shall mean such other market or exchange on which the Company's Common Stock is then listed or traded.

(k) "**Purchase Amount**" means, with respect to any particular purchase made hereunder, the portion of the Available Amount to be purchased by the Buyer pursuant to Section 1 hereof as set forth in a valid Purchase Notice or VWAP Purchase Notice which the Company delivers to the Buyer.

(l) "**Purchase Date**" means, with respect to any Regular Purchase made hereunder, the Business Day of receipt by the Buyer of a valid Purchase Notice that the Buyer is to buy Purchase Shares pursuant to Section 1(b) hereof.

(m) "**Purchase Notice**" shall mean an irrevocable written notice from the Company to the Buyer directing the Buyer to buy Purchase Shares pursuant to Section 1(b) hereof as specified by the Company therein at the applicable Purchase Price on the Purchase Date.

(n) "**Purchase Price**" means the lesser of (i) the lowest Sale Price of the Common Stock on the Purchase Date or (ii) the arithmetic average of the three (3) lowest Closing Sale Prices for the Common Stock during the ten (10) consecutive Business Days ending on the Business Day immediately preceding such Purchase Date (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction).

(o) "**Sale Price**" means any trade price for the shares of Common Stock on the Principal Market during normal trading hours, as reported by the Principal Market.

(p) "**SEC**" means the United States Securities and Exchange Commission.

(q) "**Transfer Agent**" means the transfer agent of the Company as set forth in Section 11(f) hereof or such other person who is then serving as the transfer agent for the Company in respect of the Common Stock.

(r) "**VWAP Minimum Price Threshold**" means, with respect to any particular VWAP Purchase Notice, the Sale Price on the VWAP Purchase Date equal to the greater of (i) 80% of the Closing Sale Price on the Business Day immediately preceding the VWAP Purchase Date or (ii) such higher price as set forth by the Company in the VWAP Purchase Notice.

(s) "**VWAP Purchase Amount**" means, with respect to any particular VWAP Purchase Notice, the portion of the Available Amount to be purchased by the Buyer pursuant to Section 1(c) hereof pursuant to a valid VWAP Purchase Notice which requires the Buyer to buy the VWAP Purchase Share Percentage of the aggregate shares traded on the Principal Market during normal trading hours on the VWAP Purchase Date up to the VWAP Purchase Share Volume Maximum, subject to the VWAP Minimum Price Threshold.

(t) "**VWAP Purchase Date**" means, with respect to any VWAP Purchase made hereunder, the Business Day following the receipt by the Buyer of a valid VWAP Purchase Notice that the Buyer is to buy Purchase Shares pursuant to Section 1(c) hereof.

(u) "**VWAP Purchase Notice**" shall mean an irrevocable written notice from the Company to the Buyer directing the Buyer to buy Purchase Shares on the VWAP Purchase Date pursuant to Section 1(c) hereof as specified by the Company therein at the applicable VWAP Purchase Price with the applicable VWAP Purchase Share Percentage specified therein.

(v) "**VWAP Purchase Share Percentage**" means, with respect to any particular VWAP Purchase Notice pursuant to Section 1(c) hereof, the percentage set forth in the VWAP Purchase Notice which the Buyer will be required to buy as a specified percentage of the aggregate shares traded on the Principal Market during normal trading hours up to the VWAP Purchase Share Volume Maximum on the VWAP Purchase Date subject to Section 1(c) hereof but in no event shall this percentage exceed thirty percent (30%) of such VWAP Purchase Date's share trading volume of the Common Stock on the Principal Market during normal trading hours.

(w) "**VWAP Purchase Price**" means the lesser of (i) the Closing Sale Price on the VWAP Purchase Date; or (ii) ninety-seven percent (97%) of volume weighted average price for the Common Stock traded on the Principal Market during normal trading hours on (A) the VWAP Purchase Date if the aggregate shares traded on the Principal Market on the VWAP Purchase Date have not exceeded the VWAP Purchase Share Volume Maximum and the Sale Price of Common Stock has not fallen below the VWAP Minimum Price Threshold (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction), or (B) the portion of the VWAP Purchase Date until such time as the sooner to occur of (1) the time at which the aggregate shares traded on the Principal Market has exceeded the VWAP Purchase Share Volume Maximum, or (2) the time at which the Sale Price of Common Stock falls below the VWAP Minimum Price Threshold (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction).

(x) "**VWAP Purchase Share Estimate**" means the number of shares of Common Stock that the Company has in its sole discretion irrevocably instructed its Transfer Agent to issue to the Buyer via the Depository Trust Company ("**DTC**") Fast Automated Securities Transfer Program in connection with a VWAP Purchase Notice pursuant to Section 1(c) hereof and issued to the Buyer's or its designee's balance account with DTC through its Deposit Withdrawal At Custodian (DWAC) system on the VWAP Purchase Date (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction).

(y) "**VWAP Purchase Share Volume Maximum**" means a number of shares of Common Stock traded on the Principal Market during normal trading hours on the VWAP Purchase Date equal to: (i) the VWAP Purchase Share Estimate, divided by (ii) the VWAP Purchase Share Percentage (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction).

11. MISCELLANEOUS.

(a) Governing Law; Jurisdiction; Jury Trial. The corporate laws of the State of Delaware shall govern all issues concerning the relative rights of the Company and its stockholders. All other questions concerning the construction, validity, enforcement and interpretation of this Agreement and the other Transaction Documents shall be governed by the internal laws of the State of Illinois, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of Illinois or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of Illinois. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of Chicago, for the adjudication of any dispute hereunder or under the other Transaction Documents or in connection herewith or therewith, or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof to such party at the address for such notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. **EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT IT MAY HAVE, AND AGREES NOT TO REQUEST, A JURY TRIAL FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION HEREWITH OR ARISING OUT OF THIS AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREBY.**

(b) Counterparts. This Agreement may be executed in two or more identical counterparts, all of which shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to the other party; provided that a facsimile or pdf (or other electronic reproduction) signature shall be considered due execution and shall be binding upon the signatory thereto with the same force and effect as if the signature were an original, not a facsimile or pdf (or other electronic reproduction) signature.

(c) Headings. The headings of this Agreement are for convenience of reference and shall not form part of, or affect the interpretation of, this Agreement.

(d) Severability. If any provision of this Agreement shall be invalid or unenforceable in any jurisdiction, such invalidity or unenforceability shall not affect the validity or enforceability of the remainder of this Agreement in that jurisdiction or the validity or enforceability of any provision of this Agreement in any other jurisdiction.

(e) Entire Agreement. This Agreement and the Registration Rights Agreement supersede all other prior oral or written agreements between the Buyer, the Company, their affiliates and persons acting on their behalf with respect to the matters discussed herein, and this Agreement, the other Transaction Documents and the instruments referenced herein contain the entire understanding of the parties with respect to the matters covered herein and therein and, except as specifically set forth herein or therein, neither the Company nor the Buyer makes any representation, warranty, covenant or undertaking with respect to such matters. Each of the Company and the Buyer acknowledge and agree that it has not relied on, in any manner whatsoever, any representations or statements, written or oral, other than as expressly set forth in this Agreement. The Buyer and the Company agree that that certain Common Stock Purchase Agreement, dated as of December 18, 2015 by and between the Company and the Buyer is hereby terminated as of the date hereof.

(f) Notices. Any notices, consents or other communications required or permitted to be given under the terms of this Agreement must be in writing and will be deemed to have been delivered: (i) upon receipt, when delivered personally; (ii) upon receipt, when sent by facsimile (provided confirmation of transmission is mechanically or electronically generated and kept on file by the sending party); (iii) upon receipt, when sent by electronic message (provided the recipient responds to the message and confirmation of both electronic messages are kept on file by the sending party); or (iv) one (1) Business Day after timely deposit with a nationally recognized overnight delivery service, in each case properly addressed to the party to receive the same. The addresses and facsimile numbers for such communications shall be:

If to the Company:

Ritter Pharmaceuticals, Inc.
1880 Century Park East, #1000
Los Angeles, CA 90067
Telephone: 310-203-1000
Facsimile: 310-919-1600
Attention: John Beck
Email: john@ritterpharm.com

With a copy (which shall not constitute notice) to:

Reed Smith LLP
1901 Avenue of the Stars
Suite 700
Los Angeles, CA 90067
Telephone: 310-734-5232
Facsimile: 310-734-5299
Attention: Michael Sanders, Esq.
Email: msanders@reedsmith.com

If to the Buyer:

Aspire Capital Fund, LLC
155 North Wacker Drive, Suite 1600
Chicago, IL 60606
Telephone: 312-658-0400
Facsimile: 312-658-4005
Attention: Steven G. Martin
Email: smartin@aspirecapital.com

With a copy to (which shall not constitute delivery to the Buyer):

Morrison & Foerster LLP
2000 Pennsylvania Avenue, NW, Suite 6000
Washington, DC 20006
Telephone: 202-778-1611
Facsimile: 202-887-0763
Attention: Martin P. Dunn, Esq.
Email: mdunn@mofo.com

If to the Transfer Agent:

Corporate Stock Transfer, Inc.
3200 Cherry Creek South Drive, Suite 430
Denver, CO 80209
Telephone: 303-282-4800
Facsimile: 303-282-5800
Attention: H. Daniel Bell
Email: dbell@corporatestock.com

or at such other address and/or facsimile number and/or to the attention of such other person as the recipient party has specified by written notice given to each other party at least one (1) Business Day prior to the effectiveness of such change. Written confirmation of receipt (A) given by the recipient of such notice, consent or other communication, (B) mechanically or electronically generated by the sender's facsimile machine containing the time, date, and recipient facsimile number, (C) electronically generated by the sender's electronic mail containing the time, date and recipient email address or (D) provided by a nationally recognized overnight delivery service, shall be rebuttable evidence of receipt in accordance with clause (i), (ii), (iii) or (iv) above, respectively.

(g) Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their respective successors and assigns. The Company shall not assign this Agreement or any rights or obligations hereunder without the prior written consent of the Buyer, including by merger or consolidation; provided, however, that any transaction, whether by merger, reorganization, restructuring, consolidation, financing or otherwise, whereby the Company remains the surviving entity immediately after such transaction shall not be deemed a succession or assignment. The Buyer may not assign its rights or obligations under this Agreement.

(h) No Third Party Beneficiaries. This Agreement is intended for the benefit of the parties hereto and their respective permitted successors and assigns, and is not for the benefit of, nor may any provision hereof be enforced by, any other person.

(i) Publicity. The Buyer shall have the right to approve before issuance any press release, SEC filing or any other public disclosure made by or on behalf of the Company whatsoever with respect to, in any manner, the Buyer, its purchases hereunder or any aspect of this Agreement or the transactions contemplated hereby; provided, however, that the Company shall be entitled, without the prior approval of the Buyer, to make any press release or other public disclosure (including any filings with the SEC) with respect to such transactions as is required by applicable law and regulations so long as the Company and its counsel consult with the Buyer in connection with any such press release or other public disclosure at least one (1) Business Day prior to its release. The Buyer must be provided with a copy thereof at least one (1) Business Day prior to any release or use by the Company thereof.

(j) Further Assurances. Each party shall do and perform, or cause to be done and performed, all such further acts and things, and shall execute and deliver all such other agreements, certificates, instruments and documents, as the other party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and the consummation of the transactions contemplated hereby.

(k) Termination. This Agreement may be terminated only as follows:

(i) By the Buyer any time an Event of Default exists without any liability or payment to the Company. However, if pursuant to or within the meaning of any Bankruptcy Law, the Company commences a voluntary case or any Person commences a proceeding against the Company, a Custodian is appointed for the Company or for all or substantially all of its property, or the Company makes a general assignment for the benefit of its creditors, (any of which would be an Event of Default as described in Sections 9(f), 9(g) and 9(h) hereof) this Agreement shall automatically terminate without any liability or payment to the Company without further action or notice by any Person. No such termination of this Agreement under this Section 11(k)(i) shall affect the Company's or the Buyer's obligations under this Agreement with respect to pending purchases and the Company and the Buyer shall complete their respective obligations with respect to any pending purchases under this Agreement.

(ii) [Intentionally Omitted.]

(iii) [Intentionally Omitted.]

(iv) At any time, the Company shall have the option to terminate this Agreement for any reason or for no reason by delivering notice (a "**Company Termination Notice**") to the Buyer electing to terminate this Agreement without any liability whatsoever of either party to the other party under this Agreement. The Company Termination Notice shall not be effective until one (1) Business Day after it has been received by the Buyer.

(v) This Agreement shall automatically terminate on the date that the Company sells and the Buyer purchases the full Available Amount as provided herein, without any action or notice on the part of any party and without any liability whatsoever of any party to any other party under this Agreement.

(vi) If by the Maturity Date for any reason or for no reason the full Available Amount under this Agreement has not been purchased as provided for in Section 1 of this Agreement, this Agreement shall automatically terminate on the Maturity Date, without any action or notice on the part of any party and without any liability whatsoever of any party to any other party under this Agreement.

Except as set forth in Sections 11(k)(i) (in respect of an Event of Default under Sections 9(f), 9(g) and 9(h)), 11(k)(v) and 11(k)(vi), any termination of this Agreement pursuant to this Section 11(k) shall be effected by written notice from the Company to the Buyer, or the Buyer to the Company, as the case may be, setting forth the basis for the termination hereof. The representations and warranties of the Company and the Buyer contained in Sections 2, 3 and 5 hereof, the indemnification provisions set forth in Section 8 hereof and the agreements and covenants set forth in Sections 4(e) and 11, shall survive the Commencement and any termination of this Agreement. No termination of this Agreement shall affect the Company's or the Buyer's rights or obligations (i) under the Registration Rights Agreement which shall survive any such termination in accordance with its terms or (ii) under this Agreement with respect to pending purchases and the Company and the Buyer shall complete their respective obligations with respect to any pending purchases under this Agreement.

(l) No Financial Advisor, Placement Agent, Broker or Finder. The Company represents and warrants to the Buyer that it has not engaged any financial advisor, placement agent, broker or finder in connection with the transactions contemplated hereby. The Buyer represents and warrants to the Company that it has not engaged any financial advisor, placement agent, broker or finder in connection with the transactions contemplated hereby. Each party shall be responsible for the payment of any fees or commissions, if any, of any financial advisor, placement agent, broker or finder engaged by such party relating to or arising out of the transactions contemplated hereby. Each party shall pay, and hold the other party harmless against, any liability, loss or expense (including, without limitation, attorneys' fees and out of pocket expenses) arising in connection with any such claim.

(m) No Strict Construction. The language used in this Agreement will be deemed to be the language chosen by the parties to express their mutual intent, and no rules of strict construction will be applied against any party.

(n) Failure or Indulgence Not Waiver. No failure or delay in the exercise of any power, right or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such power, right or privilege preclude other or further exercise thereof or of any other right, power or privilege.

* * * * *

IN WITNESS WHEREOF, the Buyer and the Company have caused this Amended and Restated Common Stock Purchase Agreement to be duly executed as of the date first written above.

THE COMPANY:

RITTER PHARMACEUTICALS, INC.

By: */s/ Andrew J. Ritter*
Name: Andrew J. Ritter
Title: President

BUYER:

ASPIRE CAPITAL FUND, LLC
BY: ASPIRE CAPITAL PARTNERS, LLC
BY: SGM HOLDINGS CORP

By: */s/ Steven G. Martin*
Name: Steven G. Martin
Title: President

SCHEDULES

Schedule 3(a)	Subsidiaries
Schedule 3(c)	Capitalization
Schedule 3(e)	Conflicts
Schedule 3(f)	1934 Act Filings
Schedule 3(g)	Material Changes
Schedule 3(h)	Litigation
Schedule 3(j)	Intellectual Property
Schedule 3(l)	Title
Schedule 3(p)	Transactions with Affiliates

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

As independent registered public accountants, we hereby consent to the incorporation by reference in Registration Statement Nos. 333-213087 and 333-228501 on Form S-3 and Registration Statement Nos. 333-212062, 333-207709, 333-218636, and 333-220907 on Form S-8 pertaining to the 2008 Stock Plan, 2009 Stock Plan, and 2015 Equity Incentive Plan of Ritter Pharmaceuticals, Inc. of our report dated March 29, 2019, with respect to the financial statements of Ritter Pharmaceuticals, Inc. (which report includes an explanatory paragraph relating to the uncertainty of the Company's ability to continue as a going concern) for each of the years in the two year period ended December 31, 2018, included in this annual report on Form 10-K of Ritter Pharmaceuticals, Inc. for the year ended December 31, 2018.

/s/ Mayer Hoffman McCann P.C.

Orange County, California
March 29, 2019

Exhibit 31.1

CERTIFICATIONS

I, Andrew J. Ritter, certify that:

1. I have reviewed this Annual Report on Form 10-K of Ritter Pharmaceuticals, Inc.;

2. Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Annual Report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Annual Report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this Annual Report is being prepared;

b) Designed such control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes with generally accepted accounting principles;

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

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

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

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

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

Date: April 1, 2019

By: */s/ Andrew J. Ritter*
Andrew J. Ritter
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, John W. Beck, certify that:

1. I have reviewed this Annual Report on Form 10-K of Ritter Pharmaceuticals, Inc.;

2. Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Annual Report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Annual Report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this Annual Report is being prepared;

b) Designed such control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes with generally accepted accounting principles;

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

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

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

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

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

Date: April 1, 2019

By: */s/ John W. Beck*
John W. Beck
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS PURSUANT TO 18 U.S.C. 1350

Pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 Andrew J. Ritter, the Chief Executive Officer (principal executive officer) of Ritter Pharmaceuticals, Inc. (the "Company"), and John W. Beck, the Chief Financial Officer (principal financial officer) of the Company, each hereby certifies that, to his/her knowledge on the date hereof:

(a) The Annual Report on Form 10-K of the Company for the period ended December 31, 2018 filed on the date hereof with the Securities and Exchange Commission (the "Annual Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(b) The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period covered by the Annual Report.

These certifications accompanying the Annual Report to which they relate, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Annual Report), irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained and furnished to the Securities and Exchange Commission or its staff upon request.

By: */s/ Andrew J. Ritter*
Andrew J. Ritter
Chief Executive Officer
(Principal Executive Officer)
April 1, 2019

By: */s/ John W. Beck*
John W. Beck
Chief Financial Officer
(Principal Financial Officer)
April 1, 2019