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, 2019

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 Number)

1880 Century Park East, Suite 1000
Los Angeles, CA 90067
(Address and zip code of principal executive offices)

Registrant's Telephone Number, Including Area Code: **(310) 203-1000**

Securities Registered Pursuant to Section 12(b) of the Exchange Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value $0.001	RTTR	Nasdaq Capital Market

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 whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an 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	[X]	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 28, 2019 (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 $7.1 million based upon the closing price for shares of the registrant's common stock of $1.07 as reported by the Nasdaq Capital Market on that date.

As of March 25, 2020, there were 45,713,862 shares outstanding of the registrant's common stock, par value $0.001 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2020 annual meeting of shareholders (the "2020 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2020 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

RITTER PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
For the Year Ended December 31, 2019
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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:

- the timing and anticipated completion of our merger with Qualigen, Inc. ("Qualigen");
- the expected benefits of and potential value created by the merger for our stockholders;
- our estimates regarding the sufficiency of our cash resources, expenses, including those related to the consummation of the merger, capital requirements and needs for additional financing;
- our ability to obtain additional financing to continue the development and commercialization of RP-G28 as either a prescription drug, over-the-counter ("OTC") product or dietary supplement for the consumer healthcare industry and to continue as a going concern if the merger is not completed;
- our ability to regain and maintain compliance with Nasdaq listing standards in connection with the merger;
- the success and timing of any preclinical studies and clinical trials;
- regulatory developments in the United States and other countries;
- the performance of third-party manufacturers;
- our ability to develop and commercialize any product candidate;
- our ability to obtain and maintain intellectual property protection for any product candidates that we may develop in the future;
- the rate and degree of market acceptance of our products, if approved;
- the success of competing products that are or become available in the future;
- our ability to retain key personnel; and
- our ability to maintain effective internal control over financial reporting.

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 this 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

We were formed as a Nevada limited liability company on March 29, 2004 under the name Ritter Natural Sciences, LLC. Since our inception, we have focused on the development of therapeutic products that modulate the gut microbiome to treat gastrointestinal diseases. Our only product candidate, RP-G28, is an orally administered, high purity galacto-oligosaccharide ("GOS"), 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.

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.

In early 2008, we initiated a prescription drug development program by developing RP-G28, an improved, second-generation version of Lactagen, based on the belief that if we were successful in gaining approval from the U.S. Food and Drug Administration ("FDA"), we would 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 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.

In November 2011, we completed a Phase 2a clinical trial of 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 Phase 3 program and 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 a new drug application ("NDA") submission.

In June 2018, we initiated the first pivotal Phase 3 clinical trial of RP-G28. Called "Liberatus", this study was to determine the efficacy, safety and tolerability of RP-G28 to treat LI when compared to placebo. The study was a multicenter, randomized, double-blind, placebo-controlled, parallel-group study conducted in the United States. Trial enrollment exceeded expectations, concluding with approximately 557 subjects randomized. More than 30 U.S. sites participated in the study. The protocol design included a 2-week screening period that included 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 consumed their normal diets including dairy products. The primary endpoint of the study was the mean change in LI symptom composite score 30-days post-treatment compared to baseline. Secondary endpoints were 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 utilized the prior validated symptom assessment measure and patient questionnaires to capture relevant outcomes. In addition, risk-based data review was used to monitor and assess potential protocol deviations and site quality indicators.

We completed enrollment of our Liberatus Phase 3 clinical trial of RP-G28 in March 2019 and last patient visit in July 2019. In September 2019, we announced that our Phase 3 clinical trial of RP-G28 for LI failed to demonstrate statistical significance in its pre-specified primary and secondary endpoints.

On October 7, 2019, we announced publicly that we had engaged A.G.P./Alliance Global Partners ("AGP") as a financial advisor to explore and evaluate potential strategic alternatives, as we continued to analyze the results of the trial to better understand the data and clinical outcome to assess a path forward for RP-G28. All further development efforts for RP-G28 have been suspended, until such time as we determine a path forward.

On January 15, 2020, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Qualigen, pursuant to which a wholly-owned subsidiary of Ritter (the "Merger Sub") will merge with and into Qualigen, with Qualigen surviving as a wholly-owned subsidiary of Ritter Pharmaceuticals, Inc. ("Ritter")

If the merger is consummated, the combined company does not intend to continue the clinical development of RP-G28. Pursuant to the terms of the Merger Agreement, at the Effective Time, Ritter, John Beck, as the initial CVR Holders' Representative, and Andrew Ritter, in his capacity as a consultant to Ritter, will enter into the CVR Agreement, pursuant to which, each Ritter Stockholder of record as of immediately prior to the Effective Time (after giving effect to the exercise of any outstanding Ritter stock options or warrants and the conversion of any outstanding Ritter preferred stock, but not to be adjusted for any reverse split to be effected in connection with the merger) will receive one CVR for each share of Ritter capital stock held by such stockholder, entitling the holder to receive the net proceeds, if any, from a Legacy Monetization that is entered into during the period beginning on the date the Merger Agreement was signed and ending on the third anniversary of the closing date of the Merger. Under the CVR Agreement, the combined company agreed to commit up to $350,000 (subject to reduction pursuant to the terms of the Merger Agreement) for certain expenses to be incurred by Ritter in pursuing and closing any Legacy Monetization. The CVRs will not be transferable by the CVR Holders, except in certain limited circumstances, will not be certificated or evidenced by any instrument, will not accrue interest and will not be registered with the SEC or listed for trading on any exchange. The CVRs will terminate on the CVR Termination Date. No payments with respect to the CVRs will be payable in respect of any Legacy Monetization proceeds actually received after the CVR Termination Date by Ritter. From and after the CVR Termination Date, any further proceeds received by Ritter arising from any Legacy Monetization will be retained by Ritter and will not be distributed to the CVR Holders.

We may not be successful in completing the merger. If the merger is not completed, we may seek to pursue the development and commercialization of RP-G28 as either a prescription drug, OTC product or dietary supplement for the consumer healthcare industry, which would, in any case, require significant additional funding. If we are unable to obtain funding for the development of RP-G28, whether through potential collaborative, partnering or other strategic arrangements or otherwise, we will likely be required to cease operations. See "*Risk Factors—Our business has been entirely dependent on the success of RP-G28, its only product candidate. The failure of RP-G28 to demonstrate statistical significance in its pre-specified primary and secondary endpoints in our Liberatus Phase 3 clinical trial has severely diminished our prospects to continue as a going concern. If the merger is not completed, we may seek to recommence the development and commercialization of RP-G28 as a prescription drug (which may require the filing of a new investigational new drug ("IND") or explore its potential development as an OTC product or a dietary supplement for the consumer healthcare industry, which would, in any case, require significant additional funding. If we are unable to obtain funding for and to advance the development of RP-G28, we would likely be required to cease operations. Even if we are able to obtain funding for and to advance the development of RP-G28 (as either a prescription drug, OTC product or dietary supplement), we may never receive marketing approval for, or successfully commercialize, RP-G28 for any indication."*

The Gut Microbiome

The human gut is a relatively under-explored ecosystem providing an opportunity for using dietary intervention strategies 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 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 OTC 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

RP-G28

Overview

RP-G28 is a novel, highly-purified GOS, which is synthesized enzymatically. The product was being developed for the treatment of LI, to be 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.

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.

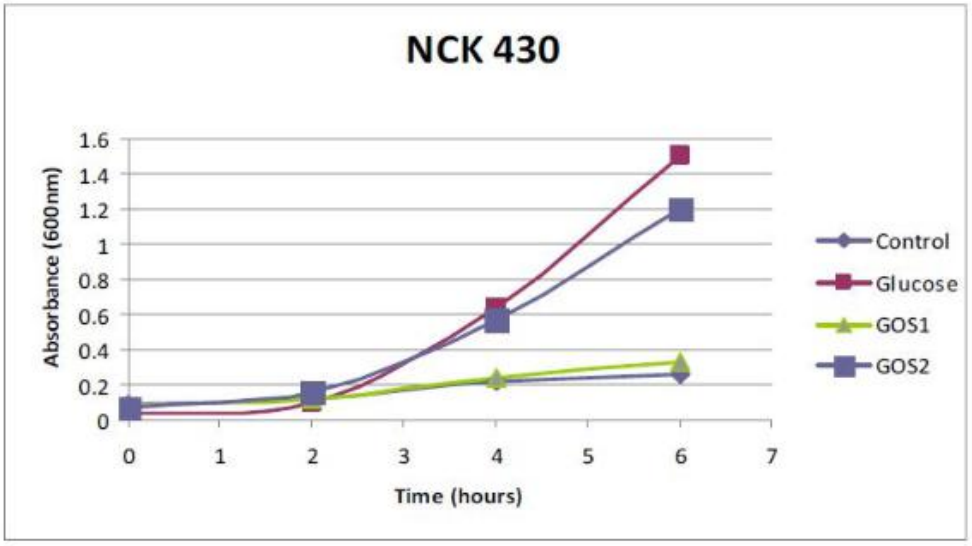
GOS products resist hydrolysis, or chemical breakdown, by salivary and intestinal enzymes of the upper digestive system because of the configuration of their glycosidic bonds and thus reach the colon virtually intact. The undigested GOS enhances the growth of beneficial, lactose-metabolizing colonic 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 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-oligosaccharides (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 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.

Market Opportunity

Unmet Medical Needs

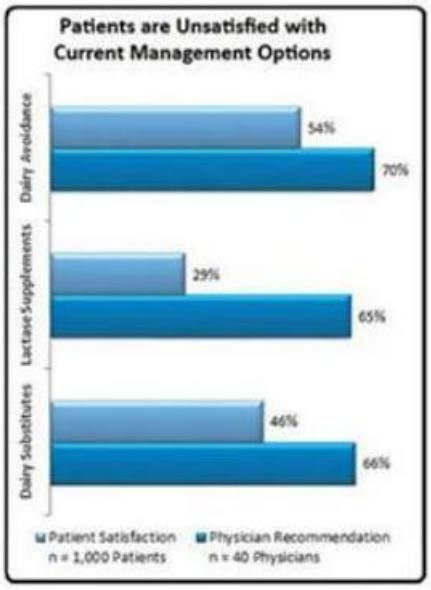
LI is a challenging condition to manage. According to a market research study conducted by Objective Insights in April 2012, approximately 60% of lactose intolerant sufferers reported experiencing symptoms daily, or bi-weekly. Not only can symptoms be painful and embarrassing, they can also dramatically 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.

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

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. The IND was inactivated on February 21, 2020, as a result of our determination not to proceed with the clinical development of RP-G28 in light of the anticipated merger.

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 any filing of an 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 were 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.

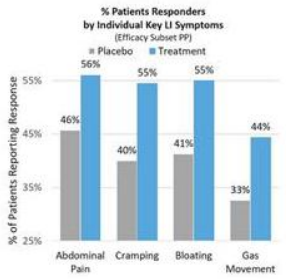
Topline results of the Phase 2b clinical trial were announced in March 2017. Due to inconsistent data results from one study site, the data from this site was excluded from the primary analysis population (Efficacy Subset mITT, n=296). After excluding the data from the one anomalous study site, results 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.

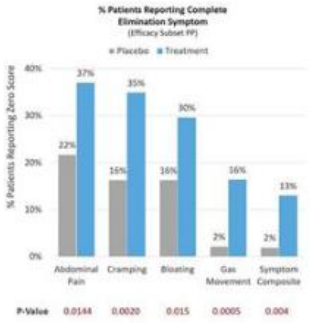
In the Efficacy Subset Per-protocol population (Efficacy Subset PP), significant and meaningful symptom improvement was consistently seen across key individual LI symptoms by patients reporting a ≥4-point improvement from baseline (proportion of subjects on treatment that reported improvement in severity 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.

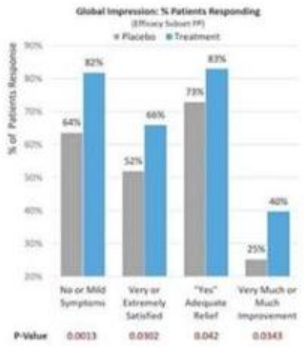
Figure 5



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).

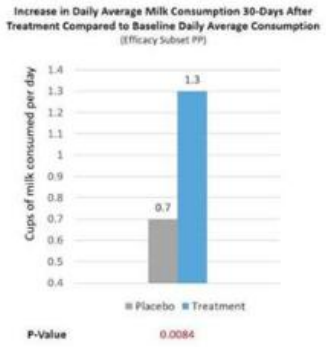
Of the treatment patients, 83.2% reported adequate relief from LI symptoms compared to 72.5% in the placebo group (p=0.042). Of the treatment patients, 39.7% reported much or very much improvement in their LI symptoms compared to 25.3% in the placebo group (p=0.0343). See Figure 6 below.

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 CMC requirements needed to support an NDA. We incorporated much of this guidance into our Phase 3 program.

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 that no additional non-clinical safety studies would be 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 would be needed for the NDA submission.

The FDA recommended that we 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 may be needed to support an NDA submission. Additional general toxicity studies may also need to be conducted for an 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.

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 was to determine the efficacy, safety and tolerability of RP-G28 to treat LI when compared to placebo. The study was a multicenter, randomized, double-blind, placebo-controlled, parallel-group study conducted in the United States. The protocol design included a two-week screening period that included 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 was 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 was the mean change in LI symptom composite score 30-days post-treatment compared to baseline. Secondary endpoints were 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 utilized the prior validated symptom assessment measure and patient questionnaires to capture relevant outcomes. In addition, risk-based data review was 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. Trial enrollment 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, indicated a broad population distribution with gender balance and ethnic diversity. No safety signals were reported, which was consistent with the well-tolerated safety and tolerability profile seen in earlier clinical studies.

On September 12, 2019, we announced publicly that its Liberatus Phase 3 clinical trial of RP-G28 in LI had failed to demonstrate statistical significance in its pre-specified primary and secondary endpoints. Top-line data from the 557-subject Phase 3 clinical trial indicated that RP-G-28 provided significant symptom improvements in patients; however, there was no, or little difference compared to the placebo. In the primary endpoint, measuring LI symptom reduction at day 61 (30 days post-treatment) compared to baseline, the treatment group reported a 3.159 mean reduction compared to a reported 3.420 mean reduction in the placebo group (p-value, one-sided = 0.106). In addition, RP-G28 missed its first secondary endpoint of responders with a meaningful treatment benefit: 36.2% of treatment group compared to 34.1% of placebo group (p-value, one-sided = 0.284). The remaining secondary endpoints also missed statistical significance with treatment and placebo groups generally reporting similar results to each other. RP-G28 was generally well-tolerated, with placebo and treatment groups reporting similar safety profiles. In light of these results, we also announced that we planned to continue in the near term to analyze the results of the trial to better understand the data and clinical outcomes to assess a path forward, and publicly announced that our board of directors was conducting a review of a range of strategic alternatives.

We inactivated the IND for RP-G28 on February 21, 2020, as a result of our determination not to proceed with the clinical development of RP-G28 in light of the anticipated merger.

Manufacturing

We do not own or operate manufacturing facilities. We have an exclusive worldwide agreement (the "Supply Agreement") with Ricerche Sperimentali Montale SpA ("RSM") pursuant to which RSM manufactures a higher purity form of GOS (referred to as "Improved GOS") in connection with our clinical and nonclinical studies. 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

We have not established a commercial organization or distribution capabilities. If the merger is not completed and RP-G28 is ultimately approved by the necessary regulatory authorities, our plan would be to evaluate a possible partnership to commercialize RP-G28 for the treatment of LI in patients in the United States and/or Europe. Outside of the United States and Europe, subject to obtaining necessary marketing approvals, we would 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 are unaware of any drug candidate, other than RP-G28, that is 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, if the merger is not completed and we elect to continue the development of RP-G28, would 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 we would 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 could also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. We would 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 that the key competitive factors that would affect the development and commercial success of any approved product candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, price and reimbursement.

Intellectual Property

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 has been 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 its business. We have also relied 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.

Patents and Proprietary Rights Covering RP-G28

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 have patent applications still 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-oligosaccharides (GOS), (ii) use of galacto-oligosaccharides (GOS) for treating LI, (iii) methods of preventing or reducing certain symptoms of LI using galacto-oligosaccharides (GOS) dosage forms, (iv) methods of improving gastrointestinal health using galacto-oligosaccharides (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 have relied on trade secrets and know-how to develop and maintain our competitive position. Trade secrets and know-how can be difficult to protect. We have sought 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 have also sought to preserve the integrity and confidentiality of its data, trade secrets and know-how by maintaining physical security of its premises and physical and electronic security of its 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. Any product candidate must be approved by the FDA through the NDA process before it may be legally marketed in the United States and by the European Medicines Agency ("EMA") through the Marketing Authorization Application ("MAA") process before it may be legally marketed in Europe. Product candidates are 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 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 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 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 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.

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 any 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. We could apply for restorations of patent term for some of its 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 could 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.

If the merger is not completed and we elect to continue the development of RP-G28, we may 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 have relied on third parties for the production of clinical and commercial quantities of our products. Future FDA and state inspections could identify compliance issues at the facilities of our contract manufacturers that could 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 a business and its 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 are subject to regulations of other countries governing clinical trials and commercial sales and distribution of its 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 EU, 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 EU 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 EU 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

If RP-G28 or any other future product candidate is approved by regulatory authorities, sales of such product will depend, in part, on the extent to which the costs of such 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 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 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 any of our products that receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan would 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 Ritter's product candidates. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover Ritter's products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow Ritter to sell its 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. Ritter 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.

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 EU 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. Historically, products launched in the EU do not follow price structures of the United States and generally tend to be significantly lower.

Employees

As of March 25, 2020, we had five employees, all of whom were full time employees. None of our employees are represented by a labor union or subject to a collective bargaining agreement.

Corporate Information

We were formed as a Nevada limited liability company on March 29, 2004 under the name Ritter Natural Sciences, LLC. In September 2008, we converted into a Delaware corporation under the name Ritter Pharmaceuticals, Inc.

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

Available Information

We file 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, with the SEC. The SEC 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, Ritter also makes copies of its 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 its web site, http://www.ritterpharmaceuticals.com/investors.

Properties

We currently lease approximately 2,780 square feet of office space located at 1880 Century Park East, Suite 1000, Los Angeles, California 90067 for our headquarters.

Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceeding that, in the opinion of its management, is likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

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 Related to the Merger

Failure to complete the merger may result in our having to paying a termination fee to Qualigen and could significantly harm the market price of our common stock and negatively affect our future business and operations of each company.

If the merger is not completed and the Merger Agreement is terminated under certain circumstances, we may be required to pay Qualigen a termination fee of $100,000. Even if a termination fee is not payable in connection with a termination of the Merger Agreement, we will have incurred significant fees and expenses, most of which must be paid whether or not the merger is completed. Further, if the merger is not completed, it could significantly harm the market price of our common stock and will likely result our being involuntarily delisted from Nasdaq. See section entitled "*Risk Factors–Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock and the termination of the Merger Agreement by Qualigen*."

In addition, if the Merger Agreement is terminated and our board of directors determines to seek another business combination, there can be no assurance that we will be able to find a partner and close an alternative transaction on terms that are as favorable or more favorable than the terms set forth in the Merger Agreement. See the section entitled "*Risk Factors—If the merger is not completed, we may be unsuccessful in completing an alternative transaction on terms that are as favorable as the terms of the merger with Qualigen, or at all, and we may otherwise be unable to continue to operate our business. Our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.*"

The issuance of our common stock to Qualigen stockholders pursuant to the Merger Agreement and the resulting change in control resulting from the merger must be approved by our stockholders (pursuant to Nasdaq rules) along with certain other matters, and the Merger Agreement and transactions contemplated thereby must be approved by the Qualigen's stockholders. Failure to obtain these approvals would prevent the closing of the merger.

Before the merger can be completed, the stockholders of each of Ritter and Qualigen must approve the merger. Failure to obtain the required stockholder approvals may result in a material delay in, or the abandonment of, the merger. Any delay in completing the merger may materially adversely affect the timing and benefits that are expected to be achieved from the merger and could result in our being involuntarily delisted from Nasdaq. See "*Risk Factors–Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock and the termination of the Merger Agreement by Qualigen*."

The merger may be completed even though certain events occur prior to the closing that materially and adversely affect Ritter or Qualigen.

The Merger Agreement provides that either Ritter or Qualigen can refuse to complete the merger if there is a material adverse change affecting the other party between January 15, 2020, the date of the Merger Agreement, and the closing. However, certain types of changes do not permit either party to refuse to complete the merger, even if such change could be said to have a material adverse effect on Ritter or Qualigen, including:

- general business or economic conditions affecting the industries in which Qualigen or Ritter, as applicable, operates, except to the extent they disproportionately affect Ritter or Qualigen, taken as a whole, relative to other similarly situated companies in the industries in which Ritter and Qualigen operate;
- any acts of war, armed hostilities or terrorism, except to the extent they disproportionately affect Ritter or Qualigen, taken as a whole, relative to other similarly situated companies in the industries in which Ritter and Qualigen operate;
- any changes in financial, banking or securities markets, except to the extent they disproportionately affect Ritter or Qualigen, taken as a whole, relative to other similarly situated companies in the industries in which Ritter and Qualigen operate;

- with respect to Ritter, any change in the stock price or trading volume of Ritter common stock (it being understood, however, that any underlying effect that may have caused or contributed to such change may be taken into account in determining whether a material adverse effect has occurred, unless such effects are otherwise excepted from causing a material adverse effect under the Merger Agreement);

- failure to meet internal or analysts' expectations or projections or the results of operations;

- with respect to Ritter, any clinical trial programs or studies, including any adverse data, event or outcome arising out of or related to any such programs or studies;

- any change in, or any compliance with or action taken for the purpose of complying with, any applicable laws or generally accepted accounting principles in the United States ("GAAP", or interpretations thereof;

- any effect resulting from the announcement or pendency of the Merger Agreement, merger or any related transactions;

- with respect to Ritter, continued losses from operations or decreases in its cash balances; and

- any effect resulting from the taking of any action by Ritter or Qualigen specifically required to be taken by the Merger Agreement;

If adverse changes occur and we still complete the merger, the market price of the combined company's common stock may suffer. This in turn may reduce the value of the merger to the stockholders of Ritter, Qualigen or both.

Some of our officers and directors have interests in the merger that are different from those of our stockholders and that may influence them to support or approve the merger without regard to the interests of our stockholders.

Certain of our officers and directors participate in arrangements that provide them with interests in the merger that are different from the interests of our stockholders.

For example, we have entered into executive severance and change of control agreements with our executive officers that will result in the receipt by such executive officers of cash severance payments, vesting of equity awards and other benefits in the event of a covered termination of employment of each executive officer's employment in connection with a change of control of Ritter.

The CVR Agreement provides that our legacy executives, if any, who assisted a particular Legacy Monetization on behalf of Parent, will be entitled to receive a cash bonus, in an amount equal in the aggregate to 30% of the net proceeds of such Legacy Monetization (a "Success Bonus") which shall be allocated among the Legacy Executives in accordance with, during the Consultant Term, the sole, good-faith discretion of the Consultant or, after expiration or termination of the Consultant Term, the sole, good-faith discretion of the CVR Holders' Representative.

These interests, among others, may influence our officers and directors to support or approve the merger.

The market price of our common stock following the merger may decline as a result of the merger.

The market price of our common stock may decline as a result of the merger for a number of reasons, including if:

- investors react negatively to the prospects of the combined company's product candidates, business and financial condition following the merger;
- the effect of the merger on the combined company's business and prospects is not consistent with the expectations of financial or industry analysts; or
- the combined company does not achieve the perceived benefits of the merger as rapidly or to the extent anticipated by financial or industry analysts.

Alpha Capital Anstalt will own a large percentage of the combined company, which may dissuade others from investing in Ritter. The Investor may also have different interests than other stockholders of the combined company following the merger.

Alpha Capital Anstalt (the "Investor') is expected to own securities representing in excess of 25% of the fully-diluted outstanding securities of Ritter as of immediately after the merger. Although the derivative securities of Ritter owned after the merger by the Investor will be subject to a 9.9% "blocker" provision (meaning that they will not be convertible or exercisable to the extent that conversion or exercise results in the Investor owning, following the conversion or exercise, more than 9.9% of Ritter common stock), the Investor's ownership may have an impact on the future willingness of other persons to invest in Ritter. The Investor may have different interests and goals than other stockholders, and its sales of our common stock could depress our stock market price.

Our securityholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the Closing as compared to their current ownership and voting interest in our company.

If the proposed merger is completed, our current securityholders will own a smaller percentage of the combined company than their current ownership in Ritter prior to the merger. Applying the current estimate of the exchange ratio, the pre-merger Ritter securityholders are expected to own approximately 7.5% of the combined company, on a fully diluted basis, Accordingly, the issuance of shares of our common stock to Qualigen stockholders in the merger will reduce significantly the relative voting power of each share of common stock held by our current stockholders. Consequently, our stockholders as a group will have less influence over the management and policies of the combined company after the merger than prior to the merger.

Our stockholders may not realize a benefit from the merger commensurate with the ownership dilution they will experience in connection with the merger.

If the combined company is unable to realize the strategic and financial benefits currently anticipated from the merger, our stockholders will have experienced substantial dilution of their ownership interests without receiving the expected commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the expected strategic and financial benefits currently anticipated from the merger.

The combined company will need to raise additional capital by issuing securities or debt or through licensing or other strategic arrangements, which may cause dilution to the combined company's stockholders or restrict the combined company's operations or impact its proprietary rights.

The combined company may be required to raise additional funds sooner than currently planned. If either or both of Ritter or Qualigen hold less cash at the time of the Closing than the parties currently expect, the combined company will need to raise additional capital sooner than expected. Additional financing may not be available to the combined company when it needs it or may not be available on favorable terms. To the extent that the combined company raises additional capital by issuing equity securities, such an issuance may cause significant dilution to the combined company's stockholders' ownership and the terms of any new equity securities may have preferences over the combined company's common stock. Any debt financing the combined company enters into may involve covenants that restrict its operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of the combined company's assets, as well as prohibitions on its ability to create liens, pay dividends, redeem its stock or make investments. In addition, if the combined company raises additional funds through licensing, partnering or other strategic arrangements, it may be necessary to relinquish rights to some of the combined company's technologies or product candidates and proprietary rights, or grant licenses on terms that are not favorable to the combined company.

During the pendency of the merger, we may not be able to enter into a business combination with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect their respective businesses.

Covenants in the Merger Agreement impede our ability to make acquisitions, subject to certain exceptions relating to fiduciary duties, or to complete other transactions that would endanger the listing of our common stock on Nasdaq. As a result, if the merger is not completed, we may be at a disadvantage to our competitors during such period. In addition, while the Merger Agreement is in effect, we are generally prohibited from soliciting, initiating, encouraging or entering into certain extraordinary transactions, such as a merger, sale of assets, or other business combination with any third-party that would endanger the listing of our common stock on Nasdaq, subject to certain exceptions relating to fiduciary duties. Any such transactions could be favorable to our stockholders.

Certain provisions of the Merger Agreement may discourage third parties from submitting alternative takeover proposals to us, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.

The terms of the Merger Agreement prohibit us from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when our board of directors determines in good faith that an unsolicited alternative takeover proposal is or is reasonably likely to lead to a superior takeover proposal and that failure to cooperate with the proponent of the proposal would be reasonably likely to be inconsistent with our board of director's fiduciary duties. Any such transactions could be favorable to our stockholders.

If the conditions to the merger are not met, or the Merger Agreement is terminated pursuant to the conditions set forth in the Merger Agreement, the merger will not occur and it is likely that we will be involuntarily delisted from Nasdaq.

There can be no assurances that the necessary stockholder approvals will be obtained to complete the merger. Failure to obtain stockholder approval may result in a material delay in, or the abandonment of, the merger. Even if the merger is approved by Ritter stockholders and Qualigen stockholders, certain other specified conditions set forth in the Merger Agreement must be satisfied or waived to complete the merger. The Merger Agreement may also be terminated by the parties in certain circumstances, including, without limitation, by Qualigen if we fail to maintain our listing on Nasdaq. We cannot assure you that all of the conditions will be satisfied or waived, or that the Merger Agreement will not be terminated prior to the closing. If the conditions are not satisfied or waived, or the Merger Agreement is terminated, the merger will not occur or will be delayed, and we may lose some or all of the intended benefits of the merger. If the merger is not consummated, it is also likely that we will be involuntarily delisted from Nasdaq. See "*Risk Factors–Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock and the termination of the Merger Agreement by Qualigen*."

Litigation relating to the merger could require us to incur significant costs and suffer management distraction, and could delay or enjoin the merger.

We could be subject to demands or litigation related to the merger, whether or not the merger is consummated. Such actions may create uncertainty relating to the merger, or delay or enjoin the merger, result in substantial costs to us and divert management time and resources.

Risks Related to the Proposed Reverse Stock Split

The proposed reverse stock split may not increase the combined company's stock price over the long-term.

One of the proposals to be voted on at the special meeting to vote on the merger, is a proposal to approve a reverse stock split of our outstanding common stock immediately prior to the merger. One of the purposes of the proposed reverse stock split is to increase the per-share market price of our common stock in order to comply with the continued listing requirements of Nasdaq. It cannot be assured, however, that the proposed reverse stock split will accomplish this objective for any meaningful period of time. While it is expected that the reduction in the number of our outstanding shares will proportionally increase the market price of our common stock, it cannot be assured that the proposed reverse stock split will increase the market price of our common stock by a multiple of the proposed reverse stock split ratio, or result in any permanent or sustained increase in the market price of our common stock, which is dependent upon many factors, including the combined company's business and financial performance, general market conditions and prospects for future success. Thus, while the stock price of the combined company might meet the continued listing requirements of Nasdaq, it cannot be assured that it will continue to do so.

The proposed reverse stock split may decrease the liquidity of the combined company's common stock.

Although our board of directors believes that the anticipated increase in the market price of the combined company's common stock could encourage interest in its common stock and possibly promote greater liquidity for its stockholders, such liquidity could also be adversely affected by the reduced number of shares outstanding after the proposed reverse stock split. The reduction in the number of outstanding shares may lead to reduced trading and a smaller number of market makers for our common stock.

The proposed reverse stock split may lead to a decrease in the combined company's overall market capitalization.

Should the market price of the combined company's common stock decline after the proposed reverse stock split, the percentage decline may be greater, due to the smaller number of shares outstanding, than it would have been prior to the proposed reverse stock split. A reverse stock split may be viewed negatively by the market and, consequently, can lead to a decrease in the combined company's overall market capitalization. If the per share market price does not increase in proportion to the proposed reverse stock split ratio, then the value of the combined company, as measured by its stock capitalization, will be reduced. In some cases, the per-share stock price of companies that have effected reverse stock splits subsequently declined back to pre-reverse split levels, and accordingly, it cannot be assured that the total market value of the combined company's common stock will remain the same after the proposed reverse stock split is effected, or that the proposed reverse stock split will not have an adverse effect on the stock price of our common stock due to the reduced number of shares outstanding after the proposed reverse stock split.

Risks Related to Our Financial Condition and Our Need for Additional Financing, and Additional Risks Related to the Merger

There is no assurance that the merger will be completed in a timely manner or at all. If the merger is not completed, our business could suffer materially and our stock price could decline, and we will likely be involuntarily delisted from Nasdaq.

The closing of the merger is subject to the satisfaction or waiver of a number of closing conditions, as described above, including the required approvals by Ritter stockholders and Qualigen stockholders and other customary closing conditions. See the risk factors above titled, "*The issuance of our common stock to Qualigen stockholders pursuant to the Merger Agreement and the resulting change in control from the merger (pursuant to Nasdaq rules) along with certain other matters must be approved by our stockholders, and the Merger Agreement and transactions contemplated thereby must be approved by the Qualigen stockholders. Failure to obtain these approvals would prevent the closing of the merger.*" If the conditions are not satisfied or waived, the merger may be materially delayed or abandoned. If the merger is not consummated, our ongoing business may be adversely affected and, without realizing any of the benefits of having consummated the merger, we will be subject to a number of risks, including the following:

- we have incurred and expect to continue to incur significant expenses related to the merger even if the merger is not consummated;
- we could be obligated to pay Qualigen a termination fee of $100,000 under certain circumstances set forth in the Merger Agreement;

- the market price of our common stock may decline to the extent that the current market price reflects a market assumption that the merger will be completed; and

- matters relating to the merger have required and will continue to require substantial commitments of time and resources by our remaining management and employees, which could otherwise have been devoted to other opportunities that may have been beneficial to us.

We also could be subject to litigation related to any failure to consummate the merger or to perform our obligations under the Merger Agreement. If the merger is not completed, these risks may materialize and may adversely affect our business, financial condition and the market price of our common stock. If the merger is not consummated, it is also likely that we will be involuntarily delisted from Nasdaq. See "*Risk Factors–Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock and the termination of the Merger Agreement by Qualigen*."

If the merger is not completed, we may be unsuccessful in completing an alternative transaction on terms that are as favorable as the terms of the merger with Qualigen, or at all, and we may otherwise be unable to continue to operate our business. Our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

Our assets currently consist primarily of cash, cash equivalents and short-term investments, our RP-G28 assets, our listing on the Nasdaq Capital Market and the Merger Agreement with Qualigen. While we have entered into the Merger Agreement with Qualigen, the closing of the merger may be delayed or may not occur at all and there can be no assurance that the merger will deliver the anticipated benefits we expect or enhance stockholder value. If we are unable to consummate the merger, our board of directors may elect to pursue an alternative strategy, one of which may be a strategic transaction similar to the merger. If the merger is not consummated, it is likely that we will be involuntarily delisted from Nasdaq, which may make it more difficult for us to complete an alternative transaction. Attempting to complete an alternative transaction like the merger will be costly and time consuming, and we can make no assurances that such an alternative transaction would occur at all.

If the merger is not consummated, our board of directors may elect to continue our operations to determine if we can identify a path forward for RP-G28. We may seek to recommence the development and commercialization of RP-G28 as a prescription drug (which may require the filing of a new IND), or explore its potential development as an OTC product or dietary supplement for the consumer healthcare industry. However, our existing capital resources will not be adequate to enable us to conduct and complete any additional clinical trials that would be required to obtain the necessary regulatory approvals to commercialize RP-G28. We would need significant additional funding to initiate and complete any additional clinical trials of RP-G28 and to otherwise further the development of our RP-G28 program.

If the merger is not completed and we are unable to raise sufficient additional funds for the continued development of RP-G28, whether through potential collaborative, partnering or other strategic arrangements or otherwise, or if we otherwise determine to discontinue the development of our RP-G28 program, we will likely determine to cease operations.

If our board of directors pursues a dissolution and liquidation, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include severance obligations, regulatory and clinical obligations, and certain fees and expenses related to the merger. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, our stockholders could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

The issuance of shares of our common stock to Qualigen stockholders in the merger will substantially dilute the voting power of our current stockholders.

If the merger is completed, pre-merger Ritter securityholders are expected to own approximately 7.5% of the combined company, on a fully-diluted basis. Accordingly, the issuance of shares of our common stock to Qualigen stockholders in the merger will reduce significantly the relative voting power of each share of common stock held by our current stockholders. Consequently, our stockholders as a group will have significantly less influence over the management and policies of the combined company after the merger than prior to the merger. These estimates are based on the anticipated exchange ratio and are subject to adjustment as provided in the Merger Agreement.

Ritter stockholders may not receive any payment on the CVRs and the CVRs may otherwise expire valueless.

The right of our stockholders to receive any future payment for or derive any value from the CVRs will be contingent solely upon our ability to monetize all or any part of our current business or all or any part of our intellectual property or technology through a Legacy Monetization within the time periods specified in the CVR Agreement and the consideration received being greater than the amounts permitted to be retained or deducted by us (including the success bonus contemplated by the CVR Agreement) under the CVR Agreement. There is currently no third-party sale or transaction involving RP-G28 planned or contemplated and there is no guarantee that we will be able to find a buyer or strategic partner for these assets, particularly in light of our failed Liberatus Phase 3 clinical trial. If a Legacy Monetization is not achieved within the time periods specified in the CVR Agreement or the consideration received is not greater than the amounts permitted to be retained or deducted by us, no payments will be made under the CVR Agreement, and the CVRs will expire valueless. Qualigen has agreed to commit up to $350,000 to support our pursuit of a Legacy Monetization, subject to reductions.

Following the Effective Time, neither Ritter nor Qualigen will have any obligation to develop RP-G28, or to expend any effort or resources to divest or otherwise monetize RP-G28. If the up to $350,000 (or any such reduced amount) is insufficient to fund the expenses incurred in connection with a Legacy Monetization, neither Ritter nor Qualigen will have any obligation to provide further funding.

Furthermore, the CVRs will be unsecured obligations of the combined company and all payments under the CVRs, all other obligations under the CVR Agreement and the CVRs and any rights or claims relating thereto will be subordinated in right of payment to the prior payment in full of all current or future senior obligations of the combined company.

The tax treatment of the CVRs is uncertain.

The tax treatment of the CVRs is uncertain. There is no authority directly on point addressing the U.S. federal income tax treatment of contingent value rights with characteristics similar to the CVRs. Therefore, it is possible that the issuance of the CVRs may be treated as a distribution of equity with respect to our stock, as an "open transaction," or as a "debt instrument" for U.S. federal income tax purposes, and such questions are inherently factual in nature.

We have incurred losses since inception, and we anticipate that we will continue to incur losses for the foreseeable future.

Our net losses were $10.1 million for the year ended December 31, 2019. As of December 31, 2019, we had an accumulated deficit of $80.3 million. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect to continue to incur significant expenses and increased operating losses for the foreseeable future.

We have financed our operations primarily through the issuance and sale of common stock and warrants in public and private offerings, and have devoted substantially all of our financial resources and efforts on research and development, including clinical development of RP-G28. However, in September 2019 we announced that our Liberatus Phase 3 clinical trial of RP-G28 for LI failed to demonstrate statistical significance in its pre-specified primary and secondary endpoints. The failure of the Liberatus Phase 3 clinical trial to achieve its endpoints has significantly depressed our stock price and has severely harmed our ability to raise additional capital and to secure potential collaborative, partnering or other strategic arrangements for its RP-G28 assets, and consequently, our prospects to continue as a going concern have been severely diminished.

To become and remain profitable, we must develop and eventually commercialize a product with market potential, which would require us to raise additional capital. Currently, we have no ongoing collaborations for the development and commercialization of RP-G28 or any other product candidate and have limited sources of revenue. If the merger is not completed and we are unable to raise sufficient additional funds for the continued development of our RP-G28 program, whether through potential collaborative, partnering or other strategic arrangements or otherwise, or if we otherwise determine to discontinue the development of our RP-G28 program, we will likely determine to cease operations.

Even if we are able to raise additional funds to permit the continued development of RP-G28 or another product candidate, if we and/or any potential collaborators are unable to develop and commercialize RP-G28 or another product candidate, if development is further delayed or is eliminated, or if sales revenue from any product upon receiving marketing approval, if ever, is insufficient, we may never become profitable and it will not be successful.

We are substantially dependent on our remaining employees to facilitate the consummation of the merger.

As of the date of this Annual Report, we have only five full-time employees. Our ability to successfully complete the merger depends in large part on our ability to retain our remaining personnel. Despite our efforts to retain these employees, one or more may terminate their employment with us on short notice. The loss of the services of these employees could potentially harm our ability to consummate the merger, to run our day-to-day business operations, and to continue to fulfill our reporting obligations as a public company.

The pendency of the merger could have an adverse effect on the trading price of our common stock and our business, financial condition and prospects.

The pendency of the merger could disrupt our business in many ways, including:

- the attention of our remaining management and employees may be directed toward the completion of the merger and related matters and may be diverted from our day-to-day business operations; and
- third parties may seek to terminate or renegotiate their relationships with us as a result of the merger, whether pursuant to the terms of their existing agreements with us or otherwise.

The occurrence of these events or others resulting from the proposed merger could adversely affect the trading price of our common stock or harm its business, financial condition and prospects.

Risks Related to Regulatory Approval Status of RP-G28 and Ongoing Regulatory Requirements if the Merger is not Completed

Our business has been entirely dependent on the success of RP-G28, our only product candidate. The failure of RP-G28 to demonstrate statistical significance in its pre-specified primary and secondary endpoints in our Liberatus Phase 3 clinical trial has severely diminished our prospects to continue as a going concern. If the merger is not completed, we may seek to recommence the development and commercialization of RP-G28 as either a prescription drug (which may require the filing of a new IND), or explore its potential development as an OTC product or a dietary supplement for the consumer healthcare industry, which would, in any case, require significant additional funding. If we are unable to obtain funding for and to advance the development of RP-G28, we would likely be required to cease operations. Even if we are able to obtain funding for and to advance the development of RP-G28 (as either a prescription drug, OTC product or dietary supplement), we may never receive marketing approval for, or successfully commercialize, RP-G28 for any indication.

We currently have only one product candidate, RP-G28, previously in clinical development as a prescription drug, and our business has depended on RP-G28's successful clinical development, regulatory approval and commercialization. In September 2019, we announced that our Liberatus Phase 3 clinical trial of RP-G28 for lactose intolerance failed to demonstrate statistical significance in its primary and secondary endpoints.

The failure of the Liberatus trial to achieve its primary and secondary endpoints has significantly depressed our stock price and has severely harmed our ability to raise additional capital and to secure potential collaborative, partnering or other strategic arrangements for our RP-G28 assets, and consequently, our prospects to continue as a going concern have been severely diminished.

Following the Effective Time, neither Ritter nor Qualigen will have any obligation to continue the development of RP-G28, or to expend any funds or efforts with respect to RP-G28. Pursuant to the terms of the CVR Agreement, Qualigen has agreed to commit up to $350,000 (subject to possible reduction pursuant to the terms of the Merger Agreement) to support our continued pursuit of a Legacy Monetization. If the up to $350,000 (or any such reduced amount) is insufficient to fund the expenses incurred in connection with a Legacy Monetization, however, neither Ritter nor Qualigen will have any obligation to provide further funding.

Even if we were to obtain the additional funding necessary to advance the development of RP-G28 (as a prescription drug, OTC product or dietary supplement), including through a strategic partnership, the process for obtaining regulatory approval or completing the regulatory process necessary to commercialize RP-G28 could be extensive and lengthy. There can be no guarantee that we would ever obtain the regulatory approvals or the regulatory hurdles necessary to commercialize RP-G28 in these ways.

To commercialize RP-G28 as a prescription drug or OTC product, we will need to demonstrate to the FDA the safety and efficacy of RP-G28 for its intended use. Additional clinical testing is expensive, time consuming and uncertain as to outcome. OTC drugs must generally either receive premarket approval by the FDA through the NDA process or conform to a "monograph" for a particular drug category, as established by the FDA's OTC Drug Review. These monographs specify conditions whereby OTC drug ingredients are generally recognized as safe and effective, and not misbranded. Certain OTC drugs may remain on the market without an NDA approval until a monograph for its class of drugs is finalized as a regulation. However, once the FDA has made a final determination on the status of an OTC drug category, such products must either be the subject of an approved NDA or comply with the appropriate monograph for an OTC drug. No assurance can be given that RP-G28 may be sold as an OTC drug product under and NDA or under the FDA's OTC monograph product regulations. Of the large number of drugs in development in the United States, only a small percentage of drugs successfully complete the FDA regulatory process and are commercialized. Accordingly, even if we are able to complete development of RP-G28, we cannot assure you that RP-G28 will ever be commercialized.

If the merger is not completed, we may also seek to explore the development and commercialization of RP-G28 as a dietary supplement. A dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, soft gels, gel caps, liquids, or powders. Whatever their form may be, the Dietary Supplement Health and Education Act ("DSHEA") places dietary supplements in a special category under the general umbrella of "foods," not drugs, and requires that every supplement be labeled a dietary supplement. The DSHEA created a new regulatory framework for the safety and labeling of dietary supplements. Under DSHEA, a firm is responsible for determining that the dietary supplements it manufactures or distributes are safe and that any representations or claims made about them are substantiated by adequate evidence to show that they are not false or misleading. This means that dietary supplements do not need approval from the FDA before they are marketed. Except in the case of a new dietary ingredient, where pre-market review for safety data and other information is required by law, a firm does not have to provide the FDA with the evidence it relies on to substantiate safety or effectiveness before or after it markets its products.

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. In 2016, the FDA published an updated draft guidance, which is intended, among other things, to help manufacturers and distributors of dietary supplement products determine when they are required to file with the FDA a New Dietary Ingredient ("NDI"), notification with respect to a dietary supplement product. In this draft guidance, the FDA highlighted the necessity for marketers of dietary supplements to submit NDI notifications as an important preventive control to ensure that consumers are not exposed to potential unnecessary public health risks in the form of new ingredients with unknown safety profiles. Ritter cannot provide any assurance that if it decided to pursue RP-G28 as a dietary supplement, it would not be required to submit an NDI notification. If the FDA were to conclude that we should have filed an NDI notification, then we could be subject to enforcement actions by the FDA. Such enforcement actions could include product seizures and injunctive relief being granted against us, any of which would harm its business.

Additional or more stringent regulations of dietary supplements and other products have been considered from time to time. In recent years, there has been increased pressure in the United States and other markets to increase regulation of dietary supplements. New regulations, or new interpretations of those regulations, could impose additional restrictions, including requiring reformulation of some products to meet new standards, recalls or discontinuance of some products not able to be reformulated, additional record-keeping requirements, increased documentation of the properties of some products, additional or different labeling, additional scientific substantiation, additional adverse event reporting, or other new requirements.

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

If the merger is not completed and we elect to recommence the development and commercialization of RP-G28 as a prescription drug (which may require the filing of a new IND) or explore its potential development as an OTC product or a dietary supplement for the consumer healthcare industry, and we are able to obtain the necessary funding for such development, the detection of any undesirable side effects could delay or prevent marketing approval or commercialization. Alternatively, if we are able to identify and secure a Legacy Monetization for RP-G28, and undesirable side effects of RP-G28 are later identified, we could face seller liability.

There were no notable differences observed between placebo-treated subjects and RP-G28-treated subjects in the Phase 3 clinical trial. However, unforeseen side effects from RP-G28 could arise at any time during clinical development or, if approved, after RP-G28 has been marketed. Any undesirable or unacceptable side effects associated with RP-G28 could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, and could impact our ability to attract potential third-party collaborators, or could result in our facing seller liability in the event RP-G28 is sold to another party.

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

RP-G28, if approved (as either a prescription drug or OTC product) or launched as a dietary supplement, 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, 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 applicable current good manufacturing practice ("cGMPs"), whether governing drugs or dietary supplements. Accordingly, we and others with whom we works 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 its products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions by the FDA and must be consistent with the information in the product's approved label. Accordingly, we may not promote its approved products, if any, for indications or uses for which they are not approved. Similarly, the U.S. Federal Trade Commission (the "FTC") exercises jurisdiction over the advertising of OTC product and dietary supplements and has instituted numerous enforcement actions against OTC product and supplement companies for failure to have adequate substantiation for claims made in advertising or for the use of false or misleading advertising claims. Our failure to comply with applicable regulations could result in substantial monetary penalties, which could have a material adverse effect on our financial condition or results of operations.

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, or any product candidate we develop in the future, 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.

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 and FTC 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 and supplement 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.

Risks Related to Dependence on Third Parties

Any collaborative arrangements that we establish in the future may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. In addition, any future collaborative arrangements may place the development and commercialization of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

If the merger with Qualigen is not completed, we may continue to seek partnering, collaborative or similar strategic arrangements with third parties to develop and commercialize RP-G28 either as a prescription drug or OTC product or as a dietary supplement, but we may be unsuccessful in locating a third-party collaborator to develop and market RP-G28. If we are able to locate a third-party collaborator, the collaboration may not be successful or we may otherwise not realize the anticipated benefits from such collaboration.

Dependence on collaborative arrangements subjects us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our potential collaborators may devote to RP-G28;
- potential collaborations may experience financial difficulties or changes in business focus;
- we may be required to relinquish important rights such as marketing and distribution rights;
- should a collaborator fail to develop or commercialize RP-G28, we may not receive any future milestone payments and will not receive any royalties for RP-G28;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- under certain circumstances, a collaborator could move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which could delay the development and may increase the cost of developing RP-G28.

Any delay or disruption in the manufacture and supply of any product may negatively impact our operations.

We do not intend to manufacture any product that is offered for sale. We currently 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 if we decide to pursue the development of 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 or any other product candidate we may develop in the future.

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

- the possibility that we are unable to enter into a manufacturing agreement with third parties to manufacture RP-G28 or any other product candidate we may develop in the future;
- 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 a qualified replacement third-party manufacturer.

Any of these factors could cause the delay of approval or commercialization of RP-G28 or any other product candidate we may develop in the future (in the event the merger is not completed), or cause us to incur higher costs. Furthermore, if RP-G28 or another product candidate 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 or any other product candidate 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 or any other product candidate that is suitable for the late-stage regulatory review process and/or adequate to manufacture commercial quantities for such product candidate.

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

If the merger is not completed and we elect to continue the clinical development of RP-G28 (as either a prescription drug, OTC product or dietary supplement) we will continue to 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 contract research organizations (“CROs”) are on a study-by-study and project-by-project basis. Typically, we may terminate the agreements with notice and would be 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 its 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 its 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 its 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.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for RP-G28, it is less likely that it will be widely used.

In the event we are able to obtain the additional funding necessary to advance the clinical development of RP-G28, and RP-G28 is ultimately approved for sale by the applicable regulatory authorities, market acceptance and sales of RP-G28 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. 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.

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 would likely be lower than the prices it 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 its 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. If RP-G28 is ultimately approved for sale by the applicable regulatory authorities, we expect that it would experience pricing pressures in connection with the sale of RP-G28, 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. Although it is too early to determine the full effect of the ACA, the law appears likely to continue the 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. Congress and President Trump have 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 intentions. 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.

Risks Related to the Commercialization of RP-G28 or Any Other Product Candidate Developed by Us in the Future in the Event the Merger is not Completed

Any product approved for sale by the applicable regulatory authorities, or launched as an OTC product without the need for regulatory approval, may not achieve broad market acceptance among physicians, patients and healthcare payors, and as a result our revenues generated from sales of any such product may be limited.

The commercial success of any product we launch will depend upon its acceptance among the medical community, including physicians, health care payors and patients. The degree of market acceptance of a product will depend on a number of factors, including:

- limitations or warnings contained in our product candidates' labeling, including 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 or intended use for such product;
- 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 OTC products;
- the extent to which a product candidate is approved for inclusion on formularies of hospitals and managed care organizations;
- whether a product candidate 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 a product candidate or favorable publicity about competitive products;
- convenience and ease of administration of a product candidate; and
- potential product liability claims.

If RP-G28 or any other product candidate we develop is approved by the applicable regulatory authorities (or launched without the need for regulatory approval), 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 any product candidate may require significant resources and may never be successful.

The OTC drug business is subject to significant competitive pressures.

If the merger is not completed, we may continue to seek partnering, collaborative or similar strategic arrangements with third parties to develop and commercialize RP-G28 as an OTC product. The OTC healthcare product industry, however, is highly competitive. Many participants in this industry have substantially greater capital resources, technical staffs, facilities, marketing resources, product development, and distribution experience than we do. We believe that our ability to compete in the OTC healthcare product industry will depend on a number of factors, including product quality and price, availability, speed to market, consumer marketing, reliability, credit terms, brand name recognition, delivery time and post-sale service and support. However, our failure to appropriately and timely respond to consumer preferences and demand for new products could significantly harm its business, financial condition and results of operations. Furthermore, unfavorable publicity or consumer perception of products we develop and commercialize could have a material adverse effect on our business and operations. There can be no assurance that we would be able to compete successfully in this highly competitive OTC industry. If we are unable to compete effectively, our earnings would be significantly negatively impacted.

We have no internal sales, distribution and/or marketing capabilities and we would have to invest significant resources to develop those capabilities or enter into acceptable third-party sales and marketing arrangements in the event the merger is not completed and we decide to continue operations.

We have no internal sales, distribution and/or marketing capabilities at this time. To develop these capabilities, we would need to invest significant amounts of financial and management resources, some of which may need to be committed prior to any confirmation that a particular product candidate 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 the product candidate; 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. Its future revenues could depend heavily on the success of the efforts of third parties.

Risks Relating to Our Intellectual Property if the Merger is not Completed

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 products 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 its pending patent applications or with respect to any patent applications it files in the future, nor can we be sure that any of its existing patents or any patents that may be granted to it 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 or any other product candidate that may be approved by the FDA. Our inability to protect our patents, would also likely impact our ability to attract potential third-party collaborators.

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 our 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 its rights or permit us to gain or keep its 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 its 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 its pharmaceutical composition and method-of-use patents directed to RP-G28 and its use in treating lactose intolerance will have a limited impact on its ability to protect its 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. If we decide to pursue the continued development of RP-G28, including with a strategic partner, 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 its 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 lactose intolerance. 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 its product candidates or methods involving these candidates in the parent patent application. We could 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 its 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, its 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 its 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. Any of these factors could impact our ability to attract potential third-party collaborators.

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 it 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, methods of manufacture, or uses of RP-G28 (or any future product candidate), 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 its 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 Ritter, 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 its product candidates to market and may be precluded from manufacturing or selling its product candidates.

We cannot be certain that others have not filed patent applications for technology claimed in its 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 its operations or to attract potential third-party collaborators.

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. Furthermore, our inability to protect its patents, would also likely impact its ability to attract potential third-party collaborators.

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 competitors or potential competitors. We may be subject to claims that these employees, or that 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 were successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We have relied 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 have also relied 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 any trademarks in the future, 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 would be 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 Business and Strategy if the Merger is not Completed

If the merger is not completed and we decide to continue our operations and the development of RP-G28 as either a prescription drug, OTC product or dietary supplement, we will 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 lactose intolerance, the biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. If the merger is not completed and we decide to continue our operations and the development of RP-G28 as either a prescription drug, OTC product or dietary supplement, we would 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 would target 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 could compete with include microbiome-based development companies: Second Genome, Inc., Seres Health, Inc., Enterome SA, Vedanta Biosciences, Inc., and Rebiotix 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, which could render our products obsolete and noncompetitive.

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

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

If our competitors market products that are more effective, safer or less expensive, or that reach the market sooner than any of our product candidate approved for sale, 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.

If the merger is not completed and we are able to raise the additional funds necessary to pursue the continued development of RP-G28 (either as a prescription drug, OTC product or dietary supplement), we will need to expand our operations and increase the size of its company, and we may experience difficulties in managing growth.

If the merger is not completed and we are able to raise the additional funds necessary to pursue the continued development of RP-G28 (either as a prescription drug, OTC product or dietary supplement), we will need to increase its product development, scientific and administrative headcount to manage the development and commercialization of our product candidates. 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.

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

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 the merger is not completed and we decide to pursue the development of RP-G28 as either a prescription drug, OTC product or dietary supplement, we may face 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 its clinical trials, patients, health care providers or others using, administering or selling its 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 intends 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 it 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 ($2.0 million coverage), 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.

Risks Relating to Our Capital Stock

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

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 our common stock. 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 has been and may continue to be volatile, which could subject us to securities class action litigation and prevent our stockholders from being able to sell their shares at or above their purchase price.

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

- our ability to consummate the transactions contemplated by the Merger Agreement, including the merger;

- our ability to raise sufficient additional funds necessary for the continued development of RP-G28 (as a prescription drug, OTC product or dietary supplement), in the event we decide to continue development of RP-G28, whether through potential collaborative, partnering or other strategic arrangements or otherwise, and the terms and timing of any future collaborative, licensing or other strategic arrangements that we may establish;
- Our ability to realize any value from the sale of its RP-G28 assets, in the event we decide to sell or license RP-G28 to a third-party;
- our ability to maintain our listing on the Nasdaq Capital Market;
- results of clinical trials of our competitors' products;
- regulatory actions with respect to our products or Ritter's 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 its 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 us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause its share price or trading volume to decline.

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 approximately $8.0 million of our shares of common stock under our at-the-market ("ATM Agreement") sales agreement with A.G.P./Alliance Global Partners ("AGP"). The sale of a substantial number of shares of our common stock pursuant to the ATM Agreement, 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 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 (or, after the merger, the issuance of equity awards under the Ritter 2020 Plan) could result in significant dilution in the percentage ownership interest of our 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.

We are an "emerging growth company" and will be able to avail itself 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 Jumpstart Our Business Startups Act (the "JOBS Act"), and rely on 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 shareholder 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 (and the combined company following the merger) may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an emerging growth company until December 31, 2020, the last day of the fiscal year following the fifth anniversary of the date we completed our initial public offering, after which time the combined company will no longer be entitled to rely on the exemptions available to emerging growth companies.

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock and the termination of the Merger Agreement by Qualigen.

On August 19, 2019, we received a written notice from Nasdaq indicating that we were not in compliance with Nasdaq Listing Rule 5550(b)(1), as our stockholders' equity, as reported in our Quarterly Report on Form 10-Q for the period ended June 30, 2019, was below $2.5 million, which is the minimum stockholders' equity required for compliance with Rule 5550(b)(1). As of August 19, 2019, we also did not satisfy the conditions for the alternative market value of listed securities standard for continued listing or the net income standard for continued listing.

We were given until October 3, 2019 to submit a plan to regain compliance, which, if accepted by Nasdaq, could have resulted in us being granted an extension of up to 180 calendar days from the date of the original notice of noncompliance, or until February 15, 2020, to demonstrate compliance with Nasdaq Listing Rule 5550(b)(1).

On October 28, 2019, we received a second written notice from Nasdaq indicating that, because the closing bid price for 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 5550(a)(2) requires listed securities to maintain a minimum bid price of $1.00 per share (the "Minimum Bid Price Requirement"), 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. We were given until April 27, 2020, to regain compliance with the Minimum Bid Price Requirement. To regain compliance, the closing bid price of our common stock would need to meet or exceed $1.00 per share for a minimum of 10 consecutive business days during the 180-calendar day grace period.

On November 21, 2019, we received a letter from the Listing Qualifications Department of Nasdaq, notifying us that Nasdaq had determined to delist our common stock pursuant to Nasdaq's discretionary authority under Listing Rule 5101, based on our failure to comply with the above described continued listing requirements and its belief that we do not have any current operating business. The letter stated that, unless we appealed Nasdaq's determination and requested a hearing on the matter by the applicable deadline, trading of our common stock on the Nasdaq Capital Market would be suspended at the opening of business on December 3, 2019 and a Form 25-NSE would be filed with the SEC.

We appealed Nasdaq's determination and a hearing was held on January 16, 2020, at which we submitted our compliance plan to Nasdaq. The plan identified the Merger Agreement as a "change of control" transaction under Nasdaq Rule 5110(a) and indicated that upon filing the Registration Statement, we would file a Change of Control Application with Nasdaq via the Nasdaq Listing Center. The compliance plan also formally requested, on behalf of Ritter, and its proposed partner, Qualigen, that an exception through May 19, 2020 to complete the merger and provide evidence of compliance with all applicable requirements for Initial Listing on the Nasdaq Capital Market be made, which request has been granted by Nasdaq.

The terms of the Merger Agreement provide that the Merger Agreement may be terminated by Qualigen if we fail to maintain our listing on Nasdaq. If our common stock is delisted, we would expect our common stock to be traded in the OTC market, which could adversely affect the liquidity of our common stock. Additionally, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- a decreased ability to issue additional securities and a concomitant substantial impairment in our ability to obtain sufficient additional capital to fund its operations and to continue as a going concern;
- reduced liquidity for our stockholders; and
- potential loss of confidence by employees and potential future partners or collaborators; and loss of institutional investor interest and fewer business development opportunities.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of Ritter, 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 Certificate of Incorporation and our Bylaws may discourage, delay or prevent a merger, acquisition or other change in control 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 DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with Ritter 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 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 Certificate of Incorporation and our 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 Ritter 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 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 Certificate of Incorporation and our 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 our Certificate of Incorporation and 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 us.

Because the merger will result in an ownership change under Section 382 of the Code for Ritter, our pre-merger net operating loss carryforwards and certain other tax attributes will be subject to limitation or elimination. The net operating loss carryforwards and certain other tax attributes of Qualigen and of the combined company may also be subject to limitations as a result of ownership changes.

If a corporation undergoes an "ownership change" within the meaning of Section 382 of the Code, the corporation's net operating loss carryforwards and certain other tax attributes arising before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceed 50 percentage points by value over a rolling three-year period. Similar rules may apply under applicable state income tax laws. While we have not performed a detailed analysis of limitations on the use of our existing net operating loss carry forwards and certain other tax attributes arising before the ownership change, the merger will result in an ownership change for Ritter and, accordingly, our net operating loss carryforwards and certain other tax attributes will be subject to limitation and possibly elimination after the merger. The merger may, if part of a cumulative change in Qualigen's equity ownership by certain stockholders that exceeds 50 percentage points by value over a rolling three-year period, limit Qualigen's net operating loss carryforwards and certain other tax attributes. Additional ownership changes in the future could result in additional limitations on Ritter's, Qualigen's and the combined company's net operating loss carryforwards and certain other tax attributes. Consequently, even if the combined company achieves profitability, it may not be able to utilize a material portion of Ritter's, Qualigen's or the combined company's net operating loss carryforwards and certain other tax attributes, which could have a material adverse effect on cash flow and results of operations.

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 no rent for the first month of the term and paid 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 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 until November 2019 and increased 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 25, 2020, there were approximately 37 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

None

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

Since our inception, we have focused on the development of therapeutic products that modulate the gut microbiome to treat gastrointestinal diseases. Our only product candidate, RP-G28, is an orally administered, high purity GOS, for the treatment of 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.

We completed enrollment in our Phase 3 clinical trial of RP-G28 known as "Liberatus" in March 2019 and last patient visit in July 2019. In September 2019, we announced that our Phase 3 clinical trial of RP-G28 for LI failed to demonstrate statistical significance in its pre-specified primary and secondary endpoints. No further development efforts for RP-G28 are currently ongoing.

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 inactivated the IND for RP-G28 on February 21, 2020 as a result of our determination not to proceed with the clinical development of RP-G28 in light of the anticipated merger.

In October 2019, we announced that we had engaged AGP as financial advisor to explore and evaluate strategic alternatives to enhance shareholder value, which could include an acquisition, merger, reverse merger, other business combination, sale of assets, licensing or other strategic transaction.

On January 15, 2020, we entered into the Merger Agreement with Qualigen, pursuant to which a wholly-owned subsidiary of Ritter (the "Merger Sub") will merge with and into Qualigen, with Qualigen surviving as a wholly-owned subsidiary of Ritter.

If the merger is consummated, the combined company does not intend to continue the clinical development of RP-G28. Pursuant to the terms of the Merger Agreement, at the Effective Time, Ritter and John Beck, as the initial CVR Holders' representative and in his capacity as a consultant to Ritter, will enter into the CVR Agreement, pursuant to which, each stockholder of record as of immediately prior to the Effective Time (after giving effect to the exercise of any outstanding stock options or warrants and the conversion of any outstanding preferred stock, but not to be adjusted for any reverse split to be effected in connection with the merger) will receive one CVR for each share of our capital stock held by such stockholder, entitling the holder to receive the net proceeds, if any, from a Legacy Monetization that is entered into during the period beginning on the date the Merger Agreement was signed and ending on the third anniversary of the closing date of the Merger. Under the CVR Agreement, the combined company agreed to commit up to $350,000 (subject to reduction pursuant to the terms of the Merger Agreement) for certain expenses to be incurred by us in pursuing and closing any Legacy Monetization. The CVRs will not be transferable by the CVR Holders, except in certain limited circumstances, will not be certificated or evidenced by any instrument, will not accrue interest and will not be registered with the SEC or listed for trading on any exchange. The CVRs will terminate on the CVR Termination Date. No payments with respect to the CVRs will be payable in respect of any Legacy Monetization proceeds actually received after the CVR Termination Date by us. From and after the CVR Termination Date, any further proceeds received by us arising from any Legacy Monetization will be retained and will not be distributed to the CVR Holders.

We may not be successful in completing the merger. If the merger is not completed, we may seek to pursue the development and commercialization of RP-G28 as either a prescription drug, OTC product or dietary supplement for the consumer healthcare industry, which would, in any case, require significant additional funding. If we are unable to obtain funding for the development of RP-G28, whether through potential collaborative, partnering or other strategic arrangements or otherwise, we will likely be required to cease operations. See "*Risk Factors—Our business has been entirely dependent on the success of RP-G28, our only product candidate. The failure of RP-G28 to demonstrate statistical significance in its pre-specified primary and secondary endpoints in our Liberatus Phase 3 clinical trial has severely diminished our prospects to continue as a going concern. If the merger is not completed, we may seek to recommence the development and commercialization of RP-G28 as a prescription drug (which may require the filing of a new IND) or explore its potential development as an OTC product or a dietary supplement for the consumer healthcare industry, which would, in any case, require significant additional funding. If we are unable to obtain funding for and to advance the development of RP-G28, we would likely be required to cease operations. Even if we are able to obtain funding for and to advance the development of RP-G28 (as either a prescription drug or OTC product), we may never receive marketing approval for, or successfully commercialize, RP-G28 for any indication.*"

We have incurred net losses in each year since our inception, including net losses of approximately $10.1 million for the year ended December 31, 2019. We had an accumulated deficit of approximately $80.3 million as of December 31, 2019. 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.

Our operating expenses have decreased significantly since the completion of our Phase 3 clinical trial of RP-G28 and we have made additional operating expense reductions following the announcement of our Phase 3 clinical trial results, including reductions to executive and board compensation.

Any future development activities, clinical and pre-clinical testing, and commercialization of any product candidates, that have obtained the necessary regulatory approvals, will require significant financing.

Financial Overview

Revenue

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 product candidates, which we expect could take a number of years and is subject to significant uncertainty. Accordingly, we will need to raise additional capital to pursue any future development activities, clinical and pre-clinical testing and commercialization activities. 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, 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 its financial condition and its ability to develop product candidates.

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, 2019, we have incurred approximately $39.6 million in research and development expenses. Research and development expenses have been significantly reduced with the completion of our Phase 3 clinical trial of RP-G28 in early July 2019 and its decision to suspend development efforts of RP-G28 in September 2019.

We expect that its research and development expenses will increase in connection with any future development activities and clinical and pre-clinical testing.

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 facilities costs, salaries, benefits, and stock-based compensation for employees, professional fees for directors, fees for independent contractors, insurance and accounting and legal services.

Ritter expects that its general and administrative expenses will increase in connection with the proposed merger. These increases may relate to 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

The fair value of our financial instruments reflects the amounts that we estimate we 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). We disclose and recognize 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. Our 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.

We recognize 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, 2019.

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, 2019				
Assets:				
Money market fund	$ 1,552,115	$ —	$ —	$ 1,552,115
Total assets	$ 1,552,115	$ —	$ —	$ 1,552,115

	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

We use a market approach for determining the fair value of all its Level 1 money market funds and marketable securities. To value our money market funds, we value the funds at $1 stable net asset value, which is the market pricing convention for identical assets that we have the ability to access.

The investments were classified as available-for-sale debt securities. At December 31, 2019, the balance in our accumulated other comprehensive comprised primarily of temporary unrealized gains related to our available-for-sale debt securities. There were no realized gains or losses recognized on the sale or maturity of available-for-sale debt securities for the year ended December 31, 2019 and as a result, we did not reclassify any amounts out of accumulated other comprehensive loss for the period. We have no available-for-sale debt securities as of December 31, 2019.

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 exemptions and reduced reporting requirements, including without limitation, (i) not having to provide an auditor's attestation report on its system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) not having to comply 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 December 31, 2020.

Results of Operations

Comparison of the years ended December 31, 2019 and 2018

The following table summarizes the results of our operations for the years ended December 31, 2019 and 2018, together with the changes in those items in dollars and as a percentage:

	For the Years Ended December 31,		Dollar	Percentage
	2019	2018	Change	Change
Statements of Operations Data:				
Operating costs and expenses				
Research and development (a)	$ 6,126,972	$ 12,259,940	$ (6,132,968)	(50)%
Patent costs	146,281	204,396	(58,115)	(28)%
General and administrative	4,570,932	5,425,033	(854,101)	(16)%
Total operating costs and expenses	10,844,185	17,889,369	(7,045,184)	(39)%
Loss from operations	(10,844,185)	(17,889,369)	7,045,184	(39)%
Other income:				
Interest income	123,052	126,835	(3,783)	(3)%
Settlement of accounts payable (a)	588,114	893,823	(305,709)	(34)%
Total other income	711,166	1,020,658	(309,492)	(30)%
Net loss	**$ (10,133,019)**	**$ (16,868,711)**	**$ 6,735,692**	**(40)%**

(a) For comparative presentation purposes, settlement of accounts payable of $893,823 for the year ended December 31, 2018 was reclassified out of research and development and into settlement of accounts payable under other income.

Research and Development Expenses

Research and development expenses decreased by approximately $6.1 million, or 50%, for the year ended December 31, 2019 as compared to the year ended December 31, 2018. The primary reason for the decrease is the completion of our Phase 3 clinical trial in early July 2019.

Patent Costs

Patent costs were approximately $146,000 and $204,000 for the years ended December 31, 2019 and 2018, respectively, representing a decrease of approximately $58,000, or (28%). 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 patent applications in certain foreign countries was lower in 2019 than 2018.

General and Administrative Expenses

General and administrative expenses decreased by approximately $0.9 million, or 16%, for the year ended December 31, 2019 as compared to the year ended December 31, 2018. The decrease in general and administrative expenses was mainly due to a decrease in payroll and related expenses of approximately $0.6 million, a decrease in stock-based compensation expense of approximately $0.2 million, a decrease of approximately $0.2 million in state taxes, a decrease of approximately $0.2 million in business development expenses and a decrease of approximately $0.1 million in recruitment expenses, partially offset by an increase in professional fees of approximately $0.4 million during the year ended December 31, 2019.

Other Income

Other income decreased by approximately $0.3 million, or 34%, during the year ended December 31, 2019 as compared to the year ended December 31, 2018. The decrease was due to the smaller gain on settlement of accounts payable of approximately $0.6 million during the year ended December 31, 2019 as compared to approximately $0.9 million during the year ended December 31, 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, 2019, we had an accumulated deficit of approximately $80.3 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, 2019, we had net working capital of approximately $0.5 million and cash and cash equivalents of approximately $1.7 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 was amended and restated on March 29, 2019 and on July 23, 2019 (as amended and restated, the "Aspire Purchase Agreement"). The Aspire Purchase Agreement provided 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. As of December 31, 2019, we had not sold any shares of our common stock under this agreement. Subsequent to December 31, 2019 we sold approximately 1.8 million shares of our common stock under this agreement resulting in proceeds to us of approximately $0.5 million.

November 2018 Private Placement Financing

On November 5, 2018, we closed a 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 sold by us consisted of 6,000 shares of a newly designated class of our 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) and warrants to purchase an aggregate of 2,307,685 shares of our 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.

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 share 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).

At-the-Market Offering Agreement

On November 6, 2019, we entered into an ATM Agreement with AGP, pursuant to which we may offer and sell, from time to time through AGP, shares of our common stock (the "Placement Shares") having an aggregate offering price of up to $3,673,159 (which was subsequently increased to $8,030,917), subject to the terms and conditions of the ATM Agreement. Unless earlier terminated pursuant to the terms of the ATM Agreement, the ATM Agreement will automatically terminate upon the earlier to occur of (i) issuance and sale of all of the Placement Shares to or through AGP and (ii) August 1, 2022. As of December 31, 2019, we sold approximately 8.1 million shares of our common stock under the ATM Agreement resulting in net proceeds to us of approximately $1.4 million after commissions and expenses of approximately $50,000 . Subsequent to December 31, 2019 we sold approximately 16.8 million shares of our common stock under this agreement resulting in net proceeds to us of approximately $4.4 million after commissions and expenses of approximately $0.2 million.

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,	
	2019	**2018**
Net cash (used in) provided by:		
Operating activities	$ (14,516,690)	$ (13,332,927)
Investing activities	6,996,960	(6,970,999)
Financing activities	1,407,442	5,484,214
Net (decrease) increase in cash	**$ (6,112,288)**	**$ (14,819,712)**

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 $14.5 million during the year ended December 31, 2019 compared to $13.3 million during the year ended December 31, 2018. The increase in cash used in operating activities was driven primarily by the initiation in June 2018, of our Phase 3 clinical trial of RP-G28 and increasing activity in that trial through its completion in September 2019.

Investing Activities

Net cash provided by investing activities was approximately $7.0 million during the year ended December 31, 2019 as compared to net cash used in investing activities was approximately $7.0 during the year ended December 31, 2018. These receipt and expenditures were mostly related to our investment in marketable debt securities and for purchase of property and equipment used in our business.

Financing Activities

Net cash provided by financing activities was $1.4 million during the year ended December 31, 2019 as compared to approximately $5.5 million during the year ended December 31, 2018. Cash provided by financing activities in 2019 came from ATM Agreement and cash provided by financing activities in 2018 came from proceeds from the November 2018 private placement financing.

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 revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more product candidates, which we expects could take a number of years and is subject to significant uncertainty.

Contractual Obligations and Commitments

Master Services Agreement

In May 2018, Ritter entered into an Amended and Restated Master Services Agreement ("Service Agreement") with a CRO, pursuant to which the CRO agreed to perform certain services related to the management and execution of certain clinical trials involving RP-G28. The Services Agreement supersedes the Master Service Agreement, dated August 30, 2016, that Ritter 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. Ritter 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. Ritter 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 Ritter, terminate a task order if Ritter has materially defaulted on its obligations under the Services Agreement or any task order and has not cured such material default, as described in the Services Agreement.

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

Under the terms of the Supply Agreement with RSM on July 22, 2015, Ritter is required to pay RSM $400,000 within 10 days following FDA approval of an NDA for the first product owned or controlled by Ritter using Improved GOS as its active pharmaceutical ingredient.

Offer Letter Amendments

On October 15, 2019, Ritter entered into amendments to the respective employment offer letters of Andrew J. Ritter, its Chief Executive Officer, John W. Beck, its Chief Financial Officer, and Ira E. Ritter, its Chief Strategic Officer (the "Offer Letter Amendments"). Pursuant to the terms of the Offer Letter Amendments, each of Ritter's executive officers agreed to defer a portion of his annual base salary (the "Deferred Amounts"), as set forth below, until such time as the board of directors, in its sole discretion, decides to pay the Deferred Amounts (or any portion of the Deferred Amounts) to the executive officers, if ever.

Name of Executive Officer		Annual Deferred Amount
Andrew J. Ritter	$	70,200
John W. Beck	$	33,000
Ira E. Ritter	$	53,820

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 no rent for the first month of the term and paid 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 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 until November 2019 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 $117,000 and $118,000 for the years ended December 31, 2019 and 2018, respectively, and is recorded in general and administrative expenses in the accompanying statements of operations.

We determine if a contract contains a lease at inception. Our material operating lease relates to a single office space. Operating lease assets and liabilities are recognized at the lease commencement date. Operating lease liabilities represent the present value of lease payments not yet paid. Operating lease assets represent our right to use an underlying asset and are based upon the operating lease liabilities adjusted for prepayments or accrued lease payments, initial direct costs, lease incentives, and impairment of operating lease assets. To determine the present value of lease payments not yet paid, we estimate incremental secured borrowing rates corresponding to the maturities of the leases. As we have no outstanding debt or committed credit facilities, secured or otherwise, we estimate this rate based on prevailing financial market conditions, comparable company and credit analysis, and management judgment.

Our leases typically contain rent escalations over the lease term. We recognize expense for these leases on a straight-line basis over the lease term. Additionally, tenant incentives used to fund leasehold improvements are recognized when earned and reduce our right-of-use ("ROU") asset related to the lease. These are amortized through the ROU asset as reductions of expense over the lease term. Our lease agreement does not contain any material residual value guarantees or material restrictive covenants. We have no lease agreements with lease and non-lease components.

Related to the adoption of Topic 842, the Company's policy elections were as follows:

Separation of lease and non-lease components	While we do not currently have any lease agreement with lease and non-lease components, we elected this expedient to account for lease and non-lease components as separate components.
Short-term policy	We have elected the short-term lease recognition exemption for all applicable classes of underlying assets. Short-term disclosures include only those leases with a term greater than one month and 12 months or less, and expense is recognized on a straight-line basis over the lease term. Leases with an initial term of 12 months or less, that do not include an option to purchase the underlying asset that we are reasonably certain to exercise, are not recorded on the balance sheet.

Other information related to our leases is provided below.

		Year Ended December 31, 2019
Supplemental Cash Flows Information		
Cash paid for amounts included in the measurement of lease liability:		
Operating cash flows from operating lease	$	114,978
Operating lease asset obtained in exchange for lease obligation:		
Operating lease	$	198,319
Remaining lease term		
Operating lease		0.8 years
Discount rate		
Operating lease		6.0%

Future payments under non-cancelable extended operating leases having initial or remaining terms of one year or more are as follows for the remaining fiscal year and thereafter:

Future minimum lease payments year ending December 31,		
2020 (10 months)	$	103,254
Total future minimum lease payments, undiscounted		103,254
Less imputed interest		(2,783)
Present value of lease liabilities	$	100,471
Operating lease liabilities reported as of December 31, 2019:		
Operating lease liabilities-current	$	100,471
Operating lease liabilities-non-current		—
Total	$	100,471

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.

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, 2019. 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, 2019, 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, 2019, 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

None.

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 2020 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2019. 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 2020 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2019. 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 2020 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2019. 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 2020 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2019. 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 2020 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2019. 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:

(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**
2.1	Agreement and Plan of Merger, by and among Ritter Pharmaceuticals, Inc., RPG28 Merger Sub, Inc. and Qualigen Inc., dated January 15, 2020	8-K	001-37428	2.1	1/21/2020
2.2	Amendment No. 1 to Agreement and Plan of Merger by and among Ritter Pharmaceuticals, Inc., RPG28 Merger Sub, Inc. and Qualigen, Inc., dated February 1, 2020	8-K	001-37428	2.2	1/21/2020
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	Form of Common Stock Purchase Warrant	S-1	333-208818	4.7	12/31/2015
4.3	Form of Representative's Warrant Agreement	S-1/A	333-202924	4.7	5/8/2015
4.4	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
4.5	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
4.6	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
4.7	Description of Common Stock				
10.1+	Executive Compensation Plan	S-1	333-202924	10.3	5/8/2015

10.2+	2015 Equity Incentive Plan	S-8	333-207709	99.3	10/30/15
10.3+	Amendment to 2015 Equity Incentive Plan	8-K	001-37428	10.1	6/6/2016
10.4+	Second Amendment to 2015 Equity Incentive Plan	8-K	001-37428	10.1	6/6/2017
10.5+	Third Amendment to 2015 Equity Incentive Plan	8-K	001-37428	10.1	9/15/2017
10.6+	Form of Notice of Grant of Stock Option under the 2015 Equity Incentive Plan	S-8	333-207709	99.4	10/30/15
10.7+	Form of Performance Restricted Stock Unit Award Agreement	10-K	001-37428	10.10	4/1/2019
10.8+	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
10.9+	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
10.10+	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
10.11+	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
10.12+	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
10.13+	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
10.14	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

10.15	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
10.16	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
10.17	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
10.18	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
10.19	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
10.20+	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
10.21	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
10.22	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
10.23+	Amended and Restated Offer Letter, by and between Ritter Pharmaceuticals, Inc. and Andrew J. Ritter	10-Q	001-37428	10.5	8/14/2018
10.24+	Offer Letter, by and between Ritter Pharmaceuticals, Inc. and Ira E. Ritter	10-Q	001-37428	10.2	8/12/2015
10.25+	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
10.26+	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

10.27	Lease Agreement, dated July 9, 2015, between the Company and Century Park	10-Q	001-37428	10.1	11/10/2015
10.28+	Letter of Agreement, dated October 20, 2015 between Ritter Pharmaceuticals, Inc. and Chord Advisors, LLC	10-Q	001-37428	10.4	11/10/2015
10.29	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
10.30+	Offer Letter with John W. Beck, dated May 23, 2018	8-K	001-37428	10.1	5/29/2018
10.31	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
10.32	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
10.33	Form of Common Stock Purchase Warrant	10-Q	001-37428	10.4	11/9/2018
10.34	Amended and Restated Common Stock Purchase Agreement, by and between Ritter Pharmaceuticals, Inc. and Aspire Capital Fund, LLC, dated July 23, 2019	8-K	001-37428	10.1	7/24/2019
10.35	Amendment to Employment Salary Terms, by and between Ritter Pharmaceuticals, Inc. and Andrew Ritter dated October 15, 2019	8-K	001-37428	10.1	10/15/2019
10.36	Amendment to Employment Salary Terms, by and between Ritter Pharmaceuticals, Inc. and John Beck, dated October 15, 2019	8-K	001-37428	10.2	10/15/2019
10.37	Amendment to Employment Salary Terms, by and between Ritter Pharmaceuticals, Inc. and Ira Ritter, dated October 15, 2019	8-K	001-37428	10.3	10/15/2019
10.38	Sales Agreement, by and between Ritter Pharmaceuticals, Inc. and A.G.P./Alliance Global Partners	8-K	001-37428	10.1	11/7/2019
10.39	Form of Irrevocable Consent and Waiver of Restriction on Dilutive Issuances	10-Q	001-37428	10.5	11/14/2019
10.40	Form of Agreement to Exchange Warrants	8-K	001-37428	10.1	2/21/2020
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: March 31, 2020

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 March 31, 2020 in the capacities indicated.

Signature	Title	Date
/s/ Andrew J. Ritter Andrew J. Ritter	Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2020
/s/ John W. Beck John W. Beck	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 31, 2020
/s/ Ira E. Ritter Ira E. Ritter	Executive Chairman, Chief Strategic Officer and Director	March 31, 2020
/s/ Noah Doyle Noah Doyle	Director	March 31, 2020
/s/ Matthew W. Foehr Matthew W. Foehr	Director	March 31, 2020
/s/ Paul V. Maier Paul V. Maier	Director	March 31, 2020
/s/ William M. Merino William M. Merino	Director	March 31, 2020

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Ritter Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Ritter Pharmaceuticals, Inc. (the "Company") as of December 31, 2019 and 2018, and the related statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, 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 2 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 2 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 the Company's 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 audits 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.

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

Los Angeles, California
March 31, 2020

RITTER PHARMACEUTICALS, INC.
BALANCE SHEETS

	December 31, 2019	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 1,699,971	$ 7,812,259
Accrued interest receivable	771	54,456
Investment in marketable securities	—	6,988,780
Prepaid expenses and other current assets	509,519	421,522
Total current assets	2,210,261	15,277,017
Other assets		
Right-of-use assets	93,032	—
Other assets	478,075	22,725
Total other assets	571,107	22,725
Property and equipment, net	15,656	20,160
Total Assets	**$ 2,797,024**	**$ 15,319,902**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,417,317	$ 4,512,316
Accrued expenses	179,258	1,407,843
Lease liabilities	100,471	—
Other liabilities	—	13,359
Total current liabilities	1,697,046	5,933,518
Stockholders' equity		
Series A preferred stock, $0.001 par value; 9,500 shares authorized; 0 and 4,080 shares issued and outstanding as of December 31, 2019 and 2018, respectively	—	2,289,324
Series B preferred stock, $0.001 par value; 6,000 shares authorized; 1,850 and 5,608 shares issued and outstanding as of December 31, 2019 and 2018, respectively	1,288,956	3,906,931
Series C preferred stock, $0.001 par value; 1,880 shares authorized; 240 and 1,880 shares issued and outstanding as of December 31, 2019 and 2018, respectively	240,000	1,880,000
Common stock, $0.001 par value; 225,000,000 shares authorized; 19,108,331 and 6,036,562 shares issued and outstanding as of December 31, 2019 and 2018, respectively	19,108	6,037
Additional paid-in capital	79,885,078	71,505,160
Accumulated other comprehensive loss	—	(923)
Accumulated deficit	(80,333,164)	(70,200,145)
Total stockholders' equity	1,099,978	9,386,384
Total Liabilities and Stockholders' Equity	**$ 2,797,024**	**$ 15,319,902**

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,	
	2019	**2018**
Operating costs and expenses:		
Research and development (a)	$ 6,126,972	$ 12,259,940
Patent costs	146,281	204,396
General and administrative	4,570,932	5,425,033
Total operating costs and expenses	10,844,185	17,889,369
Operating loss	(10,844,185)	(17,889,369)
Other income:		
Interest income	123,052	126,835
Settlement of accounts payable (a)	588,114	893,823
Total other income	711,166	1,020,658
Net loss	**$ (10,133,019)**	**$ (16,868,711)**
Other comprehensive gain (loss):		
Unrealized gain (loss) on debt securities	923	(923)
Comprehensive loss	$ (10,132,096)	$ (16,869,634)
Net Loss	(10,133,019)	(16,868,711)
Deemed dividend of preferred stock	—	(2,537,844)
Net loss applicable to common stockholders	$ (10,133,019)	$ (19,406,555)
Net loss per common share – basic and diluted	$ (1.06)	$ (3.66)
Weighted average common shares outstanding – basic and diluted	9,570,061	5,304,667

(a) For comparative presentation purposes, settlement of accounts payable of $893,823 for the year ended December 31, 2018 was reclassified out of research and development and into settlement of accounts payable under other income.

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		Additional Paid-in Capital	Additional Accumulated Deficit	Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
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	—	—	—
Change in 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**
Shareholders fractional adjustment	—	—	—	—	—	—	(2)	—	—	—	—	—
Issuance of common shares from ATM Agreement	—	—	—	—	—	—	8,126,375	8,126	1,448,942	—	—	1,457,068
Stock issuance costs of ATM Agreement	—	—	—	—	—	—	—	—	(49,626)	—	—	(49,626)
Conversion of Series A preferred shares into common stock	(4,080)	(2,289,324)	—	—	—	—	1,020,000	1,020	2,288,304	—	—	—
Conversion of Series B preferred shares into common stock	—	—	(3,758)	(2,617,975)	—	—	2,890,396	2,890	2,615,085	—	—	—
Conversion of Series C preferred shares into common stock	—	—	—	—	(1,640)	(1,640,000)	1,000,000	1,000	1,639,000	—	—	—
Settlement of RSUs	—	—	—	—	—	—	35,000	35	(35)	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	438,248	—	—	438,248
Change in unrealized loss on available-for-sale securities	—	—	—	—	—	—	—	—	—	—	923	923
Net loss	—	—	—	—	—	—	—	—	—	(10,133,019)	—	(10,133,019)
Balance at December 31, 2019	**—**	**$ —**	**1,850**	**$ 1,288,956**	**240**	**$ 240,000**	**19,108,331**	**$ 19,108**	**$ 79,885,078**	**$ (80,333,164)**	**$ —**	**$ 1,099,978**

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

RITTER PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (10,133,019)	$ (16,868,711)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	6,093	5,721
Amortization of right-of-use assets	105,287	—
Stock-based compensation	438,248	645,823
Settlement of accounts payable	(588,114)	(893,823)
Amortization of discount on available-for-sale debt securities	(9,769)	(19,789)
Change in unrealized gain (loss) on investment in marketable debt securities	923	(923)
Changes in operating assets and liabilities:		
Accrued interest receivable	53,685	(54,456)
Prepaid expenses and other current assets	(87,997)	(254,122)
Other assets	(455,350)	(12,399)
Accounts payable	(2,506,885)	3,168,559
Accrued expenses	(1,228,585)	953,591
Lease liabilities	(97,848)	—
Other liabilities	(13,359)	(2,398)
Net cash and cash equivalents used in operating activities	**(14,516,690)**	**(13,332,927)**
Cash flows from investing activities		
Purchase of property and equipment	(1,589)	(2,008)
Purchase of investment in marketable securities	—	(6,968,991)
Sale of investments in marketable debt securities	6,998,549	—
Net cash and cash equivalents provided by (used in) investing activities	**6,996,960**	**(6,970,999)**
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 from ATM Agreement	1,457,068	—
Stock issuance costs of ATM Agreement	(49,626)	—
Payout to shareholders for fractional shares	—	(3,256)
Net cash and cash equivalents provided by financing activities	**1,407,442**	**5,484,214**
Net decrease in cash and cash equivalents	**(6,112,288)**	**(14,819,712)**
Cash and cash equivalents at beginning of year	**7,812,259**	**22,631,971**
Cash and cash equivalents at end of year	**$ 1,699,971**	**$ 7,812,259**
Supplemental disclosure of cash flow activities:		
Cash paid for taxes	$ 187,095	$ 2,233
Supplemental disclosure of non-cash investing and financing activities:		
Deemed dividend on preferred stock	$ —	$ 2,537,844
Conversion of preferred stock to common stock	$ 6,547,299	$ 2,057,794
Conversion of Series A preferred stock to Series C preferred stock	$ —	$ 1,880,000
Right-of-use assets obtained in exchange for lease liabilities	$ (198,319)	$ —
Lease liabilities arising from obtaining right-of-use assets	$ 100,471	$ —

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

NOTE 1 — ORGANIZATION AND PRINCIPAL ACTIVITIES

Since its inception, Ritter Pharmaceuticals, Inc. ("Ritter" or the "Company") has focused on the development of therapeutic products that modulate the gut microbiome to treat gastrointestinal diseases. The Company's only product candidate, RP-G28, is an orally administered, high purity galacto-oligosaccharide ("GOS"), 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.

Ritter was formed as a Nevada limited liability company on March 29, 2004 under the name Ritter Natural Sciences, LLC. Its 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.

In early 2008, the Company initiated a prescription drug development program by developing RP-G28, an improved, second-generation version of Lactagen, based on the belief that if it was successful in gaining approval from the U.S. Food and Drug Administration ("FDA"), it would 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 November 2010, Ritter was 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.

In November 2011, the Company completed a Phase 2a clinical trial of 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, the Company 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, the Company 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 its Phase 3 program. The Company reached general consensus with the FDA on certain elements of its Phase 3 program and clear guidance and recommendations on many necessary components of its Phase 3 program; including the clinical, non-clinical, and chemistry, manufacturing and controls ("CMC") requirements needed to support a new drug application ("NDA") submission.

In June 2018, the Company initiated the first pivotal Phase 3 clinical trial of RP-G28. Called "Liberatus", this study was to determine the efficacy, safety and tolerability of RP-G28 to treat LI when compared to placebo. The study was a multicenter, randomized, double-blind, placebo-controlled, parallel-group study conducted in the United States. Trial enrollment exceeded expectations, concluding with approximately 557 subjects randomized. More than 30 U.S. sites participated in the study. The protocol design included a 2-week screening period that included 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 consumed their normal diets including dairy products. The primary endpoint of the study was the mean change in LI symptom composite score 30-days post-treatment compared to baseline. Secondary endpoints were 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 utilized the prior validated symptom assessment measure and patient questionnaires to capture relevant outcomes. In addition, risk-based data review was used to monitor and assess potential protocol deviations and site quality indicators.

The Company completed enrollment of the Liberatus Phase 3 clinical trial of RP-G28 in March 2019 and last patient visit in July 2019. In September 2019, the Company announced that its Phase 3 clinical trial of RP-G28 for LI failed to demonstrate statistical significance in its pre-specified primary and secondary endpoints.

On October 7, 2019, the Company announced publicly that it had engaged AGP as a financial advisor to explore and evaluate potential strategic alternatives, as it continued to analyze the results of the trial to better understand the data and clinical outcome to assess a path forward for RP-G28. All further development efforts for RP-G28 have been suspended, until such time as the Company determines a path forward.

On January 15, 2020, Ritter entered into an Agreement and Plan of Merger (the "Merger Agreement") with Qualigen Inc. ("Qualigen"), pursuant to which a wholly owned Company Merger Sub will merge with and into Qualigen, with Qualigen surviving as a wholly owned subsidiary of Ritter Pharmaceuticals, Inc.

If the merger is consummated, the combined company does not intend to continue the clinical development of RP-G28. Pursuant to the terms of the Merger Agreement, at the Effective Time (as defined in the Merger Agreement), Ritter and John Beck, the Company's Chief Financial Officer, acting as the initial contingent value right ("CVR") holders' representative and in his capacity as a consultant to Ritter, will enter into a Contingent Value Rights Agreement (the "CVR Agreement"), pursuant to which, each stockholder of record as of immediately prior to the Effective Time (after giving effect to the exercise of any outstanding stock options or warrants and the conversion of any outstanding preferred stock, but not to be adjusted for any reverse split to be effected in connection with the merger) will receive one CVR for each share of capital stock held by such stockholder, entitling the holder to receive the net proceeds, if any, from any sale, license, transfer, spin-off or other monetizing event of all or any part of our current business or all or any part of our intellectual property or technology (a "Legacy Monetization") that is entered into during the period beginning on the date the Merger Agreement was signed and ending on the third anniversary of the closing date of the merger. Under the CVR Agreement, the combined company agreed to commit up to $350,000 (subject to reduction pursuant to the terms of the Merger Agreement) for certain expenses to be incurred by us in pursuing and closing any Legacy Monetization. The CVRs will not be transferable by the holders of CVRs ("CVR Holders"), except in certain limited circumstances, will not be certificated or evidenced by any instrument, will not accrue interest and will not be registered with the Securities and Exchange Commission (the "SEC") or listed for trading on any exchange. The CVRs will terminate on the tenth anniversary of the Effective Time (the "CVR Termination Date"). No payments with respect to the CVRs will be payable in respect of any Legacy Monetization proceeds actually received after the CVR Termination Date by us. From and after the CVR Termination Date, any further proceeds received by us arising from any Legacy Monetization will be retained by Ritter and will not be distributed to the CVR Holders.

The Company may not be successful in completing the merger. If the merger is not completed, Ritter may seek to pursue the development and commercialization of RP-G28 as either a prescription drug, OTC product or dietary supplement for the consumer healthcare industry, which would, in any case, require significant additional funding. If Ritter is unable to obtain funding for the development of RP-G28, whether through potential collaborative, partnering or other strategic arrangements or otherwise, it will likely be required to cease operations

The Company currently operates in one business segment focusing on the potential future 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 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 $10.1 million and $16.9 million for the years ended December 31, 2019 and 2018, respectively, and had net cash used in operating activities of approximately $14.5 million and $13.3 million, for the years ended December 31, 2019 and 2018, respectively. At December 31, 2019, the Company had working capital of approximately $0.5 million, an accumulated deficit of approximately $80.3 million, cash and cash equivalents of approximately $1.7 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. If the Plan of Merger is not successful, the Company may close down operations and operate as a shell company if the Company cannot raise the cash to continue operations. 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, 2019, cash and cash equivalents consisted of bank deposits, cash and investments in money market funds.

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 and comprehensive loss. The unrealized gains and losses on these securities are excluded from earnings and reported in other comprehensive loss 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, 2019 or 2018.

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, 2019.

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, 2019				
Assets:				
Money market fund	$ 1,552,115	$ —	$ —	$ 1,552,115
Total assets	$ 1,552,115	$ —	$ —	$ 1,552,115

	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 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 were classified as available-for-sale debt securities. At December 31, 2019, 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. Realized gains and losses are included in earnings The Company had no available-for-sale or held-to-maturity debt securities as of December 31, 2019.

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.

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, 2019 and 2018, comprehensive loss comprised of unrealized losses on investments in available-for-sale debt securities and held-to-maturity debt securities.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, 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 FASB also issued subsequent amendments to the initial guidance: ASU 2018-19, ASU 2019-04, and ASU 2019-05 (collectively, "Topic 326"). Topic 326 requires measurement and recognition of expected credit losses for financial assets held. The effective date and transition methodology for the amendments in Topic 326 are the same as in ASU 2016-13. The guidance is effective for public business entities that are SEC filers. The amendments in ASU No. 2016-13 are effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. For all other public business entities, the amendments in this ASU are effective for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company does not expect the adoption of this guidance will have a material impact 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 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 December 2019, the FASB issued ASU No. 2019-12, "*Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*" which is intended to simplify various aspects related to accounting for income taxes. The ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The ASU 2019-12 is effective for the Company beginning after December 15, 2021. The Company is evaluating the impact of the adoption of ASU 2019-12 on its financial statements, but does not expect such adoption to have a material impact.

Other accounting standard updates effective after December 31, 2019 are not expected to have a material impact on the Company's financial statements.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued 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.

The Company elected the available package of practical expedients , but not the hindsight practical expedient, and adopted this guidance as of January 1, 2019.

The standard had a material impact on the Company's balance sheets, but did not have an impact on its statements of operations and comprehensive loss. The most significant impact was the recognition of a ROU asset and lease liability for the Company's sole operating lease—the Company had no finance leases. Adoption of the standard did not require the Company to restate previously reported results as it elected 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 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 implemented by ASU No. 2018-07 are effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The Company adopted ASU 2018-07 on January 1, 2019 and it did not have a material effect on its results of operations, financial position or cash flows.

NOTE 4 — PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	Estimated Life	December 31, 2019	December 31, 2018
Computer equipment	5 years	$ 17,178	$ 15,589
Furniture and fixtures	7 years	19,158	19,158
Total property and equipment		36,336	34,747
Accumulated depreciation		(20,680)	(14,587)
Property and equipment, net		$ 15,656	$ 20,160

Depreciation expense of approximately $6,100 and $5,700 was recognized for each of the years ended December 31, 2019 and 2018, respectively, and is classified in general and administrative expense in the accompanying Statements of Operations and Comprehensive Loss.

NOTE 5 — COMMITMENTS AND CONTINGENCIES

Master Services Agreement

In May 2018, Ritter entered into an Amended and Restated Master Services Agreement ("Service Agreement") with a clinical research organization ("CRO"), pursuant to which the CRO agreed to perform certain services related to the management and execution of certain clinical trials involving RP-G28. The Services Agreement supersedes the Master Service Agreement, dated August 30, 2016, that Ritter 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. Ritter 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. Ritter 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 Ritter, terminate a task order if Ritter has materially defaulted on its obligations under the Services Agreement or any task order and has not cured such material default, as described in the Services Agreement.

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

Under the terms of the Supply Agreement with RSM on July 22, 2015, Ritter is required to pay RSM $400,000 within 10 days following FDA approval of an NDA for the first product owned or controlled by Ritter using Improved GOS as its active pharmaceutical ingredient.

Offer Letter Amendments

On October 15, 2019, Ritter entered into amendments to the respective employment offer letters of Andrew J. Ritter, its Chief Executive Officer, John W. Beck, its Chief Financial Officer, and Ira E. Ritter, its Chief Strategic Officer (the "Offer Letter Amendments"). Pursuant to the terms of the Offer Letter Amendments, each of Ritter's executive officers agreed to defer a portion of his annual base salary (the "Deferred Amounts"), as set forth below, until such time as the board of directors, in its sole discretion, decides to pay the Deferred Amounts (or any portion of the Deferred Amounts) to the executive officers, if ever.

Name of Executive Officer	Annual Deferred Amount
Andrew J. Ritter	$ 70,200
John W. Beck	$ 33,000
Ira E. Ritter	$ 53,820

Lease Agreement

On July 9, 2015, the Company entered into a lease with a California limited partnership, pursuant to which the Company leased approximately 2,780 square feet of office space in Los Angeles, California for its headquarters. The lease provides for a term of sixty-one (61) months, commencing on October 1, 2015. The Company paid no rent for the first month of the term and paid 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 the Company's proportionate share of any operating expenses, including real estate taxes. The Company has 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. Rent expense, recognized on a straight-line basis, was approximately $117,000 and $118,000 for the years ended December 31, 2019 and 2018, respectively, and is recorded in general and administrative expenses in the accompanying statements of operations and comprehensive loss.

Other information related to our leases is provided below.

	Year Ended December 31, 2019
Supplemental Cash Flows Information	
Cash paid for amounts included in the measurement of lease liability:	
Operating cash flows from operating lease	$ 114,978
Operating lease asset obtained in exchange for lease obligation:	
Operating lease	$ 198,319
Remaining lease term	
Operating lease	0.8 years
Discount rate	
Operating lease	6.0%

Future payments under non-cancelable extended operating leases having initial or remaining terms of one year or more are as follows for the remaining fiscal year and thereafter:

Future minimum lease payments year ending December 31,	
2020 (10 months)	$ 103,254
Total future minimum lease payments, undiscounted	103,254
Less imputed interest	(2,783)
Present value of lease liabilities	$ 100,471
Operating lease liabilities reported as of December 31, 2019:	
Operating lease liabilities-current	$ 100,471

Operating lease liabilities-non-current	—
Total	$ 100,471

The following table summarizes our lease obligations at December 31, 2019:

	LEASE COMMITMENTS
Years ended December 31,	**Operating Lease**
2020	$ 103,254
Total minimum lease payments	$ 103,254

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 of which are designated as preferred stock, consisting of (i) 9,500 shares that have been designated Series A convertible preferred stock, (ii) 6,000 shares that have been designated as Series B convertible preferred stock, and (iii) 1,880 shares that have been designated as Series C convertible preferred stock. Pursuant to the terms of the Certificate of Incorporation, the board of directors has the authority to issue preferred stock in one or more classes or series and to fix the designations, powers, preferences and rights, and the qualifications, limitations or restrictions thereof, including dividend rights, conversion right, voting rights, terms of redemption, liquidation preferences and the number of shares constituting any class or series, without further vote or action by the stockholders.

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, 2019, the Company had 19,108,331 shares of common stock, 0 shares of Series A convertible preferred stock, 1,850 shares of Series B convertible preferred stock and 240 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 and on July 23, 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 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 selected, it had 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 could not exceed $500,000, unless otherwise mutually agreed. In addition, on any date on which the Company submitted a Purchase Notice to Aspire Capital in an amount of at least 100,000 shares and its stock price was not less than $0.25 per share, the Company could 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 could be sold pursuant to Aspire Capital was 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 first 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 the Company's common stock immediately preceding the signing of the agreement. As of December 31, 2019, the Company has not sold any shares of common stock under this agreement. Subsequent to December 31, 2019 the Company sold approximately 1.8 million shares of common stock under this agreement resulting in proceeds of approximately $0.5 million.

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.

At-the-Market Offering Agreement

On November 6, 2019, the Company entered into an at the market sales agreement ("ATM Agreement") with AGP, pursuant to which it may offer and sell, from time to time through AGP, shares of its common stock (the "Placement Shares") having an aggregate offering price of up to $3,673,159 (which was subsequently increased to $8,030,917), subject to the terms and conditions of the ATM Agreement. Unless earlier terminated pursuant to the terms of the ATM Agreement, the ATM Agreement will automatically terminate upon the earlier to occur of (i) issuance and sale of all of the Placement Shares to or through AGP and (ii) August 1, 2022. As of December 31, 2019, the Company sold approximately 8.1 million shares of common stock under the ATM Agreement resulting net proceeds to of approximately $1.4 million after commissions and expenses of approximately $50,000. Subsequent to December 31, 2019 the Company sold approximately 16.8 million shares of common stock under this agreement resulting in net proceeds of approximately $4.4 million after commissions and expenses of approximately $0.2 million.

NOTE 7 — WARRANTS

Warrants to purchase an aggregate of 8,413,017 shares of the Company's common stock were outstanding at December 31, 2019. These warrants are all vested and exercisable, have exercise prices ranging from $0.15 to $93.00 per share, with a weighted average exercise price of $0.95, 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, 2019, the aggregate number of shares of common stock authorized for issuance under the 2015 Plan, as amended, was 2,750,000, and 1,737,615 shares were available for issuance as of December 31, 2019.

The following represents a summary of the options granted to employees and non-employees that are outstanding at December 31, 2019 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, 2018	673,885	$ 19.82	$ —	8.2
Options granted	698,750	0.62	—	8.6
Options forfeited	(207,991)	27.50	—	—
Outstanding at December 31, 2019	1,164,644	6.93	—	8.4
Exercisable at December 31, 2019	481,883	$ 20.54	$ —	7.8

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, 2019 was $0.62.

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,	
	2019	2018
Expected dividend yield	0.00%	0.00%
Expected stock-price volatility	46.33% - 69.38%	46.47% - 53.11%
Risk-free interest rate	1.47% - 2.60%	2.46% - 3.07%
Term of options	5 - 7	5 - 10
Stock price	$ 0.60 - $1.04	$ 1.85 - $3.40

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 $438,000 and $646,000 for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, there was approximately $254,000 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 1.4 years.

No stock options were exercised during the year ended December 31, 2019 and 2018.

NOTE 9 — 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 an 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 10 — INCOME TAXES

As of December 31, 2019, the Company has net operating loss carryforwards of approximately $63.5 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, 2019, the Company has Federal and state research and development credit carryforwards of approximately $3.2 million and $3.1 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, 2019. 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,	
	2019	**2018**
Statutory U.S. federal rate	21.0%	21.0%
State income tax, net of federal benefit	7.0%	7.0%
Meals & entertainment	(0.1)%	(0.1)%
Valuation allowance	(27.9)%	(27.9)%
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,	
	2019	2018
Deferred tax assets:		
Net operating loss carry forwards	$ 17,773,202	$ 15,108,073
Patent costs	423,747	382,812
Accrued Vacation	12,832	11,516
Research and development credit	5,241,066	4,314,813
Stock-based compensation	2,025,742	1,903,104
Other	10,200	8,495
Gross deferred tax assets	25,486,789	21,728,813
Valuation allowance	(25,486,789)	(21,728,813)
Net deferred tax assets	$ —	$ —

The Company did not record any accruals for income tax accounting uncertainties for the years ended December 31, 2019 and 2018.

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, 2019.

The Company does not have any unrecognized tax benefits that will significantly decrease or increase within 12 months of December 31, 2019.

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.

NOTE 11 — SUBSEQUENT EVENTS

On January 15, 2020, Ritter entered into an Agreement and Plan of Merger (the "Merger Agreement") with Qualigen Inc. ("Qualigen"), pursuant to which the Merger Sub will merge with and into Qualigen, with Qualigen surviving as a wholly owned subsidiary of Ritter. Upon closing, on a pro forma basis and based upon the number of shares of Ritter common stock expected to be issued in the merger, the pre-merger Ritter securityholders are expected to own approximately 7.5% of the combined company, on a fully diluted basis, and the pre-merger Qualigen securityholders are expected to own approximately 92.5% of the combined company, on a fully diluted basis. To consummate the merger, Ritter and Qualigen stockholders must adopt and approve the Merger Agreement and a series of Merger-related proposals. In addition to obtaining such stockholder approvals and appropriate regulatory approvals, each of the other closing conditions set forth in the Merger Agreement must be satisfied or waived.

Risks Related to COVID-19 Pandemic

The recent outbreak of COVID-19 originated in Wuhan, China, in December 2019 and has since spread to multiple countries, including the United States and several European countries. On March 11, 2020, the World Health Organization declared the outbreak a pandemic. The COVID-19 pandemic is affecting the United States and global economies and may affect the Company's operations and those of third parties on which the Company relies. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce the Company's ability to access capital, which could negatively impact the Company's short-term and long-term liquidity and the Company's and Qualigen's ability to complete the Plan of Merger on a timely basis or at all. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. The Company does not yet know the full extent of potential delays or impacts on its business, financing or other activities or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on the Company's liquidity, capital resources, operations and business and those of the third parties on which we rely.

Exhibit 4.7

RITTER PHARMACEUTICALS, INC.
DESCRIPTION OF COMMON STOCK

Ritter Pharmaceuticals, Inc. (the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") – common stock, par value $0.001 per share (the "Common Stock"). The Common Stock trades on The Nasdaq Capital Market under the trading symbol "RTTR."

The following summary description sets forth some of the general terms and provisions of the Common Stock. Because this is a summary description, it does not contain all of the information that may be important to you. For a more detailed description of the Common Stock, you should refer to the Company's Amended and Restated Certificate of Incorporation (the "Certificate") and the Amended and Restated Bylaws (the "Bylaws"), which are filed as exhibits to the Annual Report on Form 10-K to which this description is filed as an exhibit.

The Company's authorized capital stock consists of 240,000,000 shares, all with a par value of $0.001 per share, 225,000,000 of which are designated as Common Stock and 15,000,000 of which are designated as preferred stock, consisting of (i) 9,500 shares that have been designated Series A Convertible Preferred Stock, (ii) 6,000 shares that have been designated as Series B Convertible Preferred Stock, and (iii) 1,880 shares that have been designated as Series C Convertible Preferred Stock.

Common Stock

Pursuant to the terms of our Certificate, the holders of Common Stock are entitled to one vote per share on all matters to be voted upon by the stockholders, except on matters relating solely to terms of preferred stock. Subject to preferences that may be applicable to any outstanding preferred stock, the holders of Common Stock will be entitled to receive ratably such dividends, if any, as may be declared from time to time by the board of directors out of funds legally available therefor. In the event of our liquidation, dissolution or winding up, the holders of the Common Stock will be entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of preferred stock, if any, then outstanding. The holders of Common Stock will have no preemptive or conversion rights or other subscription rights. There will be no redemption or sinking fund provisions applicable to our common stock.

Anti-Takeover Effects of Delaware Law and Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

The provisions of Delaware law and the Company's Certificate and Bylaws, could discourage or make it more difficult to accomplish a proxy contest or other change in our management or the acquisition of control by a holder of a substantial amount of the Company's voting stock. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or in the Company's best interests. These provisions are intended to enhance the likelihood of continuity and stability in the composition of the Company's board of directors and in the policies formulated by the board of directors and to discourage certain types of transactions that may involve an actual or threatened change of control of the Company. These provisions are designed to reduce the Company's vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. Such provisions also may have the effect of preventing changes in the Company's management.

Delaware Statutory Business Combinations Provision. The Company is subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"). Section 203 prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. For purposes of Section 203, a "business combination" is defined broadly to include a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and, subject to certain exceptions, an "interested stockholder" is a person who, together with his or her affiliates and associates, owns, or within three years prior, did own, 15% or more of the corporation's voting stock.

Election and Removal of Directors. Except as may otherwise be provided by the DGCL, any director or the entire board of directors may be removed, with or without cause, at an annual meeting or a special meeting called for that purpose, by the affirmative vote of the majority of the votes cast by the shares of the Company's capital stock present in person or represented by proxy at such meeting and entitled to vote thereon, provided a quorum is present. Vacancies on the Company's board of directors resulting from the removal of directors and newly created directorships resulting from any increase in the number of directors may be filled solely by the affirmative vote of a majority of the remaining directors then in office (although less than a quorum) or by the sole remaining director. This system of electing and removing directors may discourage a third party from making a tender offer or otherwise attempting to obtain control of the Company, because it generally makes it more difficult for stockholders to replace a majority of the Company's directors. The Company's Certificate and Bylaws do not provide for cumulative voting in the election of directors.

Advance Notice Provisions for Stockholder Proposals and Stockholder Nominations of Directors. The Company's Bylaws provide that, for nominations to the board of directors or for other business to be properly brought by a stockholder before a meeting of stockholders, the stockholder must first have given timely notice of the proposal in writing to the Company's Secretary. For an annual meeting, a stockholder's notice generally must be delivered not less than 90 days or more than 120 days prior to the anniversary of the previous year's annual meeting.

Special Meetings of Stockholders. Special meetings of the stockholders may be called at any time only by the board of directors, the Chairman of the board of directors, the Chief Executive Officer or the President, subject to the rights of the holders of any series of preferred stock then outstanding.

Blank-Check Preferred Stock. The Company's 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 the board of directors does not approve.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Corporate Stock Transfer, Inc.

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 No. 333-236235 on Form S-4, Registration Statement Nos. 333-228501, and 333-232798 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 31, 2020, 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, 2019, included in this annual report on Form 10-K of Ritter Pharmaceuticals, Inc. for the year ended December 31, 2019.

/s/ Mayer Hoffman McCann P.C.

Los Angeles, California
March 31, 2020

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: March 31, 2020

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: March 31, 2020

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, 2019 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)
March 31, 2020

By: */s/ John W. Beck*
John W. Beck
Chief Financial Officer
(Principal Financial Officer)
March 31, 2020